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STUDY TITLE

Report

DHDPS

Repeated-dose 90-day oral toxicity study in Wistar animals
Administration by gavage

TEST FACILITY

BASF SE
Experimental Toxicology and Ecology
67056 Ludwigshafen, Germany

TEST FACILITY PROJECT IDENTIFICATION

Project No. 50C0066/05S019

PART II OF III
(TABLES SECTION, INDIVIDUAL VALUES)

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Study 50C0066/05S019

Individual Signs By Interval - Clinical Observation

Sex: **Male** - Phase: **In-life**

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	Day 92 [00:00 - 24:00]
0 / M 0 mg/kg bw/d	01	normal	NAD			1
		dead	sacrificed scheduled			1
	02	normal	NAD			1
		dead	sacrificed scheduled			1
	03	normal	NAD			1
		dead	sacrificed scheduled			1
	04	normal	NAD			1
		dead	sacrificed scheduled			1
	05	normal	NAD			1
		dead	sacrificed scheduled			1
	06	normal	NAD			1
		dead	sacrificed scheduled			1
	07	normal	NAD			1
		dead	sacrificed scheduled			1
	08	normal	NAD			1
		dead	sacrificed scheduled			1
	09	normal	NAD			1
		dead	sacrificed scheduled			1
	10	normal	NAD			1
		dead	sacrificed scheduled			1

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Individual Signs By Interval - Clinical Observation

Sex: **Male** - Phase: **In-life**

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	Day 92 [00:00 - 24:00]
1 / M 100 mg/kg bw/d	11	normal	NAD			1
		dead	sacrificed scheduled			1
	12	normal	NAD			1
		dead	sacrificed scheduled			1
	13	normal	NAD			1
		dead	sacrificed scheduled			1
	14	normal	NAD			1
		dead	sacrificed scheduled			1
	15	normal	NAD			1
		dead	sacrificed scheduled			1
	16	normal	NAD			1
		dead	sacrificed scheduled			1
	17	normal	NAD			1
		dead	sacrificed scheduled			1
	18	normal	NAD			1
		dead	sacrificed scheduled			1
	19	normal	NAD			1
		dead	sacrificed scheduled			1
	20	normal	NAD			1
		dead	sacrificed scheduled			1

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Study 50C0066/05S019

Individual Signs By Interval - Clinical Observation

Sex: **Male** - Phase: **In-life**

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	Day 92 [00:00 - 24:00]
2 / M 300 mg/kg bw/d	21...	feces	soft feces			1
		feces	discolored feces	Color: light brown		1
		dead	sacrificed scheduled			1
	22	feces	discolored feces	Color: light brown		1
		feces	soft feces			1
		dead	sacrificed scheduled			1
	23	feces	soft feces			1
		feces	discolored feces	Color: light brown		1
		dead	sacrificed scheduled			1
	24	feces	soft feces			1
		feces	discolored feces	Color: light brown		1
		dead	sacrificed scheduled			1
	25	feces	soft feces			1
		feces	discolored feces	Color: light brown		1
		dead	sacrificed scheduled			1
	26	feces	discolored feces	Color: light brown		1
		feces	soft feces			1
		dead	sacrificed scheduled			1
	27	feces	discolored feces	Color: light brown		1
		feces	soft feces			1
		dead	sacrificed scheduled			1
	28	feces	soft feces			1

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Study 50C0066/05S019

Individual Signs By Interval - Clinical Observation

Sex: **Male** - Phase: **In-life**

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	Day 92 [00:00 - 24:00]
2 / M 300 mg/kg bwd	...28	feces	discolored feces	Color: light brown		1
		dead	sacrificed scheduled			1
	29	feces	discolored feces	Color: light brown		1
		feces	soft feces			1
		dead	sacrificed scheduled			1
	30	feces	discolored feces	Color: light brown		1
		feces	soft feces			1
		dead	sacrificed scheduled			1

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Study 50C0066/05S019

Individual Signs By Interval - Clinical Observation

Sex: **Male** - Phase: **In-life**

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	Day 92 [00:00 - 24:00]
3 / M 1000/600 mg/kg bw/d	31	feces	soft feces			1
		feces	discolored feces	Color: light brown		1
		dead	sacrificed scheduled			1
		feces	soft feces			1
	32	feces	discolored feces	Color: light brown		1
		dead	sacrificed scheduled			1
		feces	soft feces			1
		feces	discolored feces	Color: light brown		1
	33	dead	sacrificed scheduled			1
		feces	soft feces			1
		feces	discolored feces	Color: light brown		1
		dead	sacrificed scheduled			1
3 / M 1000/600 mg/kg bw/d	34	feces	soft feces			1
		feces	discolored feces	Color: light brown		1
		dead	sacrificed scheduled			1
		feces	discolored feces	Color: light brown		1
	35	feces	soft feces			1
		dead	sacrificed scheduled			1
		feces	discolored feces	Color: light brown		1
		feces	soft feces			1
	36	dead	sacrificed scheduled			1
		feces	soft feces			1
		feces	discolored feces	Color: light brown		1
3 / M 1000/600 mg/kg bw/d	37	feces	discolored feces	Color: light brown		1
		dead	sacrificed scheduled			1
		feces	soft feces			1
		feces	discolored feces	Color: light brown		1
3 / M 1000/600 mg/kg bw/d	38	feces	discolored feces	Color: light brown		1
		feces	discolored feces	Color: light brown		1

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Individual Signs By Interval - Clinical Observation

Sex: **Male** - Phase: **In-life**

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	Day 92 [00:00 - 24:00]
3 / M 1000/600 mg/kg bw/d	...38	feces	soft feces			1
		dead	sacrificed scheduled			1
		feces	soft feces			1
	39	feces	discolored feces	Color: light brown		1
		dead	sacrificed scheduled			1
		feces	discolored feces	Color: light brown		1
	40	feces	soft feces			1
		dead	sacrificed scheduled			1
		feces	soft feces			1
		feces	discolored feces	Color: light brown		1
		dead	sacrificed scheduled			1
		feces	soft feces			1

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Study 50C0066/05S019

Individual Signs By Interval - Clinical Observation

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	Day 93 [00:00 - 24:00]
0 / F 0 mg/kg bw/d	41	normal	NAD			1
		dead	sacrificed scheduled			1
	42	normal	NAD			1
		dead	sacrificed scheduled			1
	43	normal	NAD			1
		dead	sacrificed scheduled			1
	44	normal	NAD			1
		dead	sacrificed scheduled			1
	45	normal	NAD			1
		dead	sacrificed scheduled			1
	46	normal	NAD			1
		dead	sacrificed scheduled			1
	47	normal	NAD			1
		dead	sacrificed scheduled			1
	48	normal	NAD			1
		dead	sacrificed scheduled			1
	49	normal	NAD			1
		dead	sacrificed scheduled			1
	50	normal	NAD			1
		dead	sacrificed scheduled			1

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Study 50C0066/05S019

Individual Signs By Interval - Clinical Observation

Sex: **Female** - Phase: **In-life**

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	Day 93 [00:00 - 24:00]
1 / F 100 mg/kg bw/d	51	normal	NAD			1
		dead	sacrificed scheduled			1
	52	normal	NAD			1
		dead	sacrificed scheduled			1
	53	normal	NAD			1
		dead	sacrificed scheduled			1
	54	normal	NAD			1
		dead	sacrificed scheduled			1
	55	normal	NAD			1
		dead	sacrificed scheduled			1
	56	normal	NAD			1
		dead	sacrificed scheduled			1
	57	normal	NAD			1
		dead	sacrificed scheduled			1
	58	normal	NAD			1
		dead	sacrificed scheduled			1
	59	normal	NAD			1
		dead	sacrificed scheduled			1
	60	normal	NAD			1
		dead	sacrificed scheduled			1

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Individual Signs By Interval - Clinical Observation

Sex: **Female** - Phase: **In-life**

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	Day 93 [00:00 - 24:00]
2 / F 300 mg/kg bw/d	61...	feces	discolored feces	Color: light brown		1
		feces	soft feces			1
		dead	sacrificed scheduled			1
	62	feces	discolored feces	Color: light brown		1
		feces	soft feces			1
		dead	sacrificed scheduled			1
	63	feces	soft feces			1
		feces	discolored feces	Color: light brown		1
		dead	sacrificed scheduled			1
	64	feces	soft feces			1
		feces	discolored feces	Color: light brown		1
		dead	sacrificed scheduled			1
	65	feces	discolored feces	Color: light brown		1
		feces	soft feces			1
		dead	sacrificed scheduled			1
	66	feces	soft feces			1
		feces	discolored feces	Color: light brown		1
		dead	sacrificed scheduled			1
	67	feces	soft feces			1
		feces	discolored feces	Color: light brown		1
		dead	sacrificed scheduled			1
	68	feces	soft feces			1

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Individual Signs By Interval - Clinical Observation

Sex: **Female** - Phase: **In-life**

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	Day
						93 [00:00 - 24:00]
	...68	feces	discolored feces	Color: light brown		1
		dead	sacrificed scheduled			1
		feces	soft feces			1
2 / F 300 mg/kg bwd	69	feces	discolored feces	Color: light brown		1
		dead	sacrificed scheduled			1
		feces	soft feces			1
	70	feces	discolored feces	Color: light brown		1
		dead	sacrificed scheduled			1

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Individual Signs By Interval - Clinical Observation

Sex: **Female** - Phase: **In-life**

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	Day 93 [00:00 - 24:00]
3 / F 1000 mg/kg bwd	71	feces	discolored feces	Color: light brown		1
		feces	soft feces			1
		dead	sacrificed scheduled			1
		feces	soft feces			1
	72	feces	discolored feces	Color: light brown		1
		dead	sacrificed scheduled			1
		feces	soft feces			1
		feces	discolored feces	Color: light brown		1
	73	dead	sacrificed scheduled			1
		feces	soft feces			1
		feces	discolored feces	Color: light brown		1
		dead	sacrificed scheduled			1
3 / F 1000 mg/kg bwd	74	feces	soft feces			1
		feces	discolored feces	Color: light brown		1
		dead	sacrificed scheduled			1
		feces	soft feces			1
	75	feces	discolored feces	Color: light brown		1
		dead	sacrificed scheduled			1
		feces	soft feces			1
		feces	discolored feces	Color: light brown		1
	76	dead	sacrificed scheduled			1
		feces	soft feces			1
		feces	discolored feces	Color: light brown		1
		dead	sacrificed scheduled			1
3 / F 1000 mg/kg bwd	77	feces	discolored feces	Color: light brown		1
		feces	soft feces			1
		dead	sacrificed scheduled			1
		feces	discolored feces	Color: light brown		1

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Individual Signs By Interval - Clinical Observation

Sex: **Female** - Phase: **In-life**

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	Day
3 / F 1000 mg/kg bw/d	...78	feces	soft feces			93 [00:00 - 24:00]
		dead	sacrificed scheduled			1
	79	feces	discolored feces	Color: light brown		1
		feces	soft feces			1
		dead	sacrificed scheduled			1
		feces	discolored feces	Color: light brown		1
80		feces	soft feces			1
		dead	sacrificed scheduled			1

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Individual Signs By Interval - Clinical Observation

Sex: **Male** - Phase: **In-life**

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	Day									
						0	7	14	21	28	35	42	49	56	63
0 / M 0 mg/kg bw/d	01	normal	NAD			1	1	1	1	1	1	1	1	1	1
	02	normal	NAD			1	1	1	1	1	1	1	1	1	1
	03	normal	NAD			1	1	1	1	1	1	1	1	1	1
	04	normal	NAD			1	1	1	1	1	1	1	1	1	1
	05	normal	NAD			1	1	1	1	1	1	1	1	1	1
	06	normal	NAD			1	1	1	1	1	1	1	1	1	1
	07	normal	NAD			1	1	1	1	1	1	1	1	1	1
	08	normal	NAD			1	1	1	1	1	1	1	1	1	1
	09	normal	NAD			1	1	1	1	1	1	1	1	1	1
	10	normal	NAD			1	1	1	1	1	1	1	1	1	1

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Individual Signs By Interval - Clinical Observation

Sex: **Male** - Phase: **In-life**

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	Day											
						0 [DCO]	7 [DCO]	14 [DCO]	21 [DCO]	28 [DCO]	35 [DCO]	42 [DCO]	49 [DCO]	56 [DCO]	63 [DCO]		
	11	normal	NAD			1	1	1	1	1	1	1	1	1	1		
		normal	NAD			1	1	1	1	1	1	1	1	1	1		
	12	mass	palpable through skin	Appearance: -, Directional terms: left, Size: < 1.5 cm, Location: axillary region													
		respiration	sounds														
1 / M		fur	piloerection														
100 mg/kg bw/d	13	normal	NAD			1	1	1	1	1	1	1	1	1	1		
	14	normal	NAD			1	1	1	1	1	1	1	1	1	1		
	15	normal	NAD			1	1	1	1	1	1	1	1	1	1		
	16	normal	NAD			1	1	1	1	1	1	1	1	1	1		
	17	normal	NAD			1	1	1	1	1	1	1	1	1	1		
	18	normal	NAD			1	1	1	1	1	1	1	1	1	1		
	19	normal	NAD			1	1	1	1	1	1	1	1	1	1		
	20	normal	NAD			1	1	1	1	1	1	1	1	1	1		

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Individual Signs By Interval - Clinical Observation

Sex: **Male** - Phase: **In-life**

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	Day										
						0 [DCO]	7 [DCO]	14 [DCO]	21 [DCO]	28 [DCO]	35 [DCO]	42 [DCO]	49 [DCO]	56 [DCO]	63 [DCO]	
21		normal	NAD			1	1	1	1	1	1	1	1	1	1	
		feces	soft feces													
		feces	discolored feces	Color: light brown												
22		normal	NAD			1	1	1	1	1	1	1	1	1	1	
		feces	discolored feces	Color: light brown												
		feces	soft feces													
23		normal	NAD			1	1	1	1	1	1	1	1	1	1	
		head	salivation	Grade: slight												
		feces	discolored feces	Color: light brown												
24		feces	soft feces													
		normal	NAD			1	1	1	1	1	1	1	1	1	1	
		feces	soft feces													
25		feces	discolored feces	Color: light brown												
		normal	NAD			1	1	1	1	1	1	1	1	1	1	
		head	salivation	Grade: slight												
26		feces	discolored feces	Color: light brown												
		feces	soft feces													
		normal	NAD			1	1	1	1	1	1	1	1	1	1	
27...		feces	discolored feces	Color: light brown												
		normal	NAD			1	1	1	1	1	1	1	1	1	1	
		feces	soft feces													

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Individual Signs By Interval - Clinical Observation

Sex: **Male** - Phase: **In-life**

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	Day									
						0	7	14	21	28	35	42	49	56	63
2 / M 300 mg/kg bwd	...27	feces	discolored feces		Color: light brown	1	1	1	1	1	1	1	1	1	1
		normal	NAD												
		respiration	sounds												
	28	feces	soft feces												
29		feces	discolored feces		Color: light brown	1	1	1	1	1	1	1	1	1	1
		normal	NAD												
		feces	discolored feces		Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces												
30		normal	NAD			1	1	1	1	1	1	1	1	1	1
		feces	soft feces												
		feces	discolored feces		Color: light brown										

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Individual Signs By Interval - Clinical Observation

Sex: **Male** - Phase: **In-life**

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	Day										
						0 [DCO]	7 [DCO]	14 [DCO]	21 [DCO]	28 [DCO]	35 [DCO]	42 [DCO]	49 [DCO]	56 [DCO]	63 [DCO]	
31		normal	NAD			1	1	1								
		feces	discolored feces	Color: light brown				1	1	1	1	1	1	1	1	
		feces	soft feces													
		normal	NAD			1	1	1								
		feces	discolored feces	Color: light brown				1	1	1	1	1	1	1	1	
32		feces	soft feces													
		normal	NAD			1	1	1								
		feces	discolored feces	Color: light brown				1	1	1	1	1	1	1	1	
		feces	soft feces													
		normal	NAD			1	1	1								
33		feces	discolored feces	Color: light brown				1	1	1	1	1	1	1	1	
		feces	soft feces													
		normal	NAD			1	1	1								
		feces	discolored feces	Color: light brown				1	1	1	1	1	1	1	1	
		feces	soft feces													
34		normal	NAD			1	1	1								
		feces	discolored feces	Color: light brown				1	1	1	1	1	1	1	1	
		feces	soft feces													
		normal	NAD			1	1	1								
		feces	discolored feces	Color: light brown				1	1	1	1	1	1	1	1	
35		feces	soft feces													
		normal	NAD			1	1	1								
		feces	discolored feces	Color: light brown				1	1	1	1	1	1	1	1	
		feces	soft feces													
		normal	NAD			1	1	1								
36		feces	discolored feces	Color: light brown				1	1	1	1	1	1	1	1	
		feces	soft feces													
		normal	NAD			1	1	1								
		feces	discolored feces	Color: light brown				1	1	1	1	1	1	1	1	
		feces	soft feces													
37		normal	NAD			1	1	1								
		feces	discolored feces	Color: light brown				1	1	1	1	1	1	1	1	
		feces	soft feces													
		normal	NAD			1	1	1								
		feces	discolored feces	Color: light brown				1	1	1	1	1	1	1	1	
38		feces	soft feces													
		normal	NAD			1	1	1								
		feces	discolored feces	Color: light brown				1	1	1	1	1	1	1	1	
		feces	soft feces													
		normal	NAD			1	1	1								

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Individual Signs By Interval - Clinical Observation

Sex: **Male** - Phase: **In-life**

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	Day									
						0	7	14	21	28	35	42	49	56	63
3 / M 1000/600 mg/kg bw/d	...38	feces	discolored feces	Color: light brown					1	1	1	1	1	1	1
		feces	soft feces												
		normal	NAD			1	1	1							
	39	feces	discolored feces	Color: light brown					1	1	1	1	1	1	1
		feces	soft feces												
		normal	NAD			1	1	1							
40		feces	discolored feces	Color: light brown					1	1	1	1	1	1	1
		feces	soft feces												

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Individual Signs By Interval - Clinical Observation

Sex: **Male** - Phase: **In-life**

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	Day			
						70 [DCO]	77 [DCO]	84 [DCO]	91 [DCO]
0 / M 0 mg/kg bw/d	01	normal	NAD			1	1	1	1
	02	normal	NAD			1	1	1	1
	03	normal	NAD			1	1	1	1
	04	normal	NAD			1	1	1	1
	05	normal	NAD			1	1	1	1
	06	normal	NAD			1	1	1	1
	07	normal	NAD			1	1	1	1
	08	normal	NAD			1	1	1	1
	09	normal	NAD			1	1	1	1
	10	normal	NAD			1	1	1	1

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Study 50C0066/05S019

Individual Signs By Interval - Clinical Observation

Sex: **Male** - Phase: **In-life**

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	Day			
						70 [DCO]	77 [DCO]	84 [DCO]	91 [DCO]
1 / M 100 mg/kg bw/d	11	normal	NAD			1	1	1	1
		normal	NAD			1	1		1
	12	mass	palpable through skin	Appearance: -, Directional terms: left, Size: < 1.5 cm, Location: axillary region				1	
		respiration	sounds						
		fur	piloerection						
	13	normal	NAD			1	1		1
	14	normal	NAD			1	1	1	1
	15	normal	NAD			1	1	1	1
	16	normal	NAD			1	1	1	1
	17	normal	NAD			1	1	1	1
	18	normal	NAD			1	1	1	1
	19	normal	NAD			1	1	1	1
	20	normal	NAD			1	1	1	1

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Study 50C0066/05S019

Individual Signs By Interval - Clinical Observation

Sex: **Male** - Phase: **In-life**

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	Day			
						70 [DCO]	77 [DCO]	84 [DCO]	91 [DCO]
21		normal	NAD			1	1	1	1
		feces	soft feces						
		feces	discolored feces	Color: light brown					1
		normal	NAD			1	1	1	1
		feces	discolored feces	Color: light brown					1
		feces	soft feces						1
		normal	NAD			1	1	1	1
		head	salivation	Grade: slight					
		feces	discolored feces	Color: light brown					1
		feces	soft feces						1
24	2 / M 300 mg/kg bwd	normal	NAD			1	1	1	1
		feces	soft feces						
		feces	discolored feces	Color: light brown					1
		normal	NAD			1	1	1	1
		head	salivation	Grade: slight					
		feces	discolored feces	Color: light brown					1
		feces	soft feces						1
		normal	NAD			1	1	1	1
		feces	soft feces						1
		feces	discolored feces	Color: light brown					1
27 ...		normal	NAD			1	1	1	1
		feces	soft feces						
		feces	discolored feces	Color: light brown					1
		normal	NAD			1	1	1	1
		head	salivation	Grade: slight					
		feces	discolored feces	Color: light brown					1
		feces	soft feces						1
		normal	NAD			1	1	1	1
		feces	soft feces						1
		feces	discolored feces	Color: light brown					1

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Study 50C0066/05S019

Individual Signs By Interval - Clinical Observation

Sex: **Male** - Phase: **In-life**

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	Day			
						70 [DCO]	77 [DCO]	84 [DCO]	91 [DCO]
	...27	feces	discolored feces	Color: light brown					1
		normal	NAD			1	1		
		respiration	sounds					1	
		feces	soft feces						1
2 / M 300 mg/kg bwd	28	feces	discolored feces	Color: light brown					1
		normal	NAD			1	1	1	
		feces	discolored feces	Color: light brown					1
		feces	soft feces						1
	29	normal	NAD			1	1	1	
		feces	discolored feces	Color: light brown					1
		feces	soft feces						1
		feces	soft feces						1
	30	normal	NAD			1	1	1	
		feces	discolored feces	Color: light brown					1
		feces	soft feces						1
		feces	soft feces						1

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Study 50C0066/05S019

Individual Signs By Interval - Clinical Observation

Sex: **Male** - Phase: **In-life**

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	Day			
						70 [DCO]	77 [DCO]	84 [DCO]	91 [DCO]
3 / M 1000/600 mg/kg bw/d	31	normal	NAD						
		feces	discolored feces	Color: light brown		1	1	1	1
		feces	soft feces					1	1
		normal	NAD						
	32	feces	discolored feces	Color: light brown		1	1	1	1
		feces	soft feces					1	1
		normal	NAD						
	33	feces	discolored feces	Color: light brown		1	1	1	1
		feces	soft feces					1	1
		normal	NAD						
3 / M 1000/600 mg/kg bw/d	34	feces	discolored feces	Color: light brown		1	1	1	1
		feces	soft feces					1	1
		normal	NAD						
	35	feces	discolored feces	Color: light brown		1	1	1	1
		feces	soft feces					1	1
		normal	NAD						
	36	feces	discolored feces	Color: light brown		1	1	1	1
		feces	soft feces					1	1
		normal	NAD						
	37	feces	discolored feces	Color: light brown		1	1	1	1
38		feces	soft feces					1	1
		normal	NAD						

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Individual Signs By Interval - Clinical Observation

Sex: **Male** - Phase: **In-life**

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	Day			
						70 [DCO]	77 [DCO]	84 [DCO]	91 [DCO]
3 / M 1000/600 mg/kg bw/d	...38	feces	discolored feces	Color: light brown		1	1	1	1
		feces	soft feces					1	1
		normal	NAD						
	39	feces	discolored feces	Color: light brown		1	1	1	1
		feces	soft feces					1	1
		normal	NAD						
40		feces	discolored feces	Color: light brown		1	1	1	1
		feces	soft feces					1	1

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Study 50C0066/05S019

Individual Signs By Interval - Clinical Observation

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	Day									
						0	7	14	21	28	35	42	49	56	63
O / F 0 mg/kg bw/d	41	normal	NAD			1	1	1	1	1	1	1	1	1	1
	42	normal	NAD			1	1	1	1	1	1	1	1	1	1
	43	normal	NAD			1	1	1	1	1	1	1	1	1	1
	44	normal	NAD			1	1	1	1	1	1	1	1	1	1
	45	normal	NAD			1	1	1	1	1	1	1	1	1	1
	46	normal	NAD			1	1	1	1	1	1	1	1	1	1
	47	normal	NAD			1	1	1	1	1	1	1	1	1	1
	48	normal	NAD			1	1	1	1	1	1	1	1	1	1
	49	normal	NAD			1	1	1	1	1	1	1	1	1	1
	50	normal	NAD			1	1	1	1	1	1	1	1	1	1

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Individual Signs By Interval - Clinical Observation

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	Day									
						0	7	14	21	28	35	42	49	56	63
1 / F 100 mg/kg bw/d	51	normal	NAD			1	1	1	1	1	1	1	1	1	1
	52	normal	NAD			1	1	1	1	1	1	1	1	1	1
	53	normal	NAD			1	1	1	1	1	1	1	1	1	1
	54	normal	NAD			1	1	1	1	1	1	1	1	1	1
	55	normal	NAD			1	1	1	1	1	1	1	1	1	1
	56	normal	NAD			1	1	1	1	1	1	1	1	1	1
	57	normal	NAD			1	1	1	1	1	1	1	1	1	1
	58	normal	NAD			1	1	1	1	1	1	1	1	1	1
	59	normal	NAD			1	1	1	1	1	1	1	1	1	1
	60	normal	NAD			1	1	1	1	1	1	1	1	1	1

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Study 50C0066/05S019

Individual Signs By Interval - Clinical Observation

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	Day											
						0	7	14	21	28	35	42	49	56	63		
	61	normal	NAD			1	1	1	1	1	1	1	1	1	1		
		feces	discolored feces	Color: light brown													
		feces	soft feces														
		normal	NAD			1	1	1	1	1	1	1	1	1	1		
		feces	soft feces														
	62	feces	discolored feces	Color: light brown													
		normal	NAD			1	1	1	1	1	1	1	1	1	1		
		head	salivation	Grade: slight													
		feces	discolored feces	Color: light brown													
		feces	soft feces														
2 / F 300 mg/kg bw/d	63	normal	NAD			1	1	1	1	1	1	1	1	1	1		
		head	salivation	Grade: slight													
		feces	discolored feces	Color: light brown													
		feces	soft feces														
		normal	NAD			1	1	1	1	1	1	1	1	1	1		
	64	head	salivation	Grade: slight													
		feces	soft feces														
		feces	discolored feces	Color: light brown													
		normal	NAD			1	1	1	1	1	1	1	1	1	1		
		head	salivation	Grade: slight													
	65	feces	discolored feces	Color: light brown													
		feces	soft feces														
		normal	NAD			1	1	1	1	1	1	1	1	1	1		
		feces	discolored feces	Color: light brown													
		feces	soft feces														
	66	normal	NAD			1	1	1	1	1	1	1	1	1	1		
		feces	discolored feces	Color: light brown													
		feces	soft feces														
		normal	NAD			1	1	1	1	1	1	1	1	1	1		
		feces	discolored feces	Color: light brown													
	67	feces	soft feces														
		normal	NAD			1	1	1	1	1	1	1	1	1	1		
		feces	discolored feces	Color: light brown													
		feces	soft feces														
		normal	NAD			1	1	1	1	1	1	1	1	1	1		

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Study 50C0066/05S019

Individual Signs By Interval - Clinical Observation

Sex: **Female** - Phase: **In-life**

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	Day									
						0	7	14	21	28	35	42	49	56	63
2 / F 300 mg/kg bwd	67	feces	discolored feces	Color: light brown											
		feces	soft feces												
		normal feces	NAD												
		feces	soft feces												
2 / F 300 mg/kg bwd	68	feces	discolored feces	Color: light brown											
		feces	soft feces												
		normal feces	NAD												
		feces	soft feces												
2 / F 300 mg/kg bwd	69	feces	discolored feces	Color: light brown											
		feces	soft feces												
		normal feces	NAD												
		feces	soft feces												
2 / F 300 mg/kg bwd	70	feces	discolored feces	Color: light brown											
		feces	soft feces												
		normal feces	NAD												
		feces	soft feces												

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Study 50C0066/05S019

Individual Signs By Interval - Clinical Observation

Sex: **Female** - Phase: **In-life**

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	Day										
						0	7	14	21	28	35	42	49	56	63	
						[DCO]	[DCO]	[DCO]	[DCO]	[DCO]	[DCO]	[DCO]	[DCO]	[DCO]	[DCO]	
3 / F 1000 mg/kg pow/d	71	normal	NAD			1	1	1		1	1	1	1	1	1	
		feces	discolored feces	Color: light brown												
		feces	soft feces													
	72	normal	NAD			1	1	1		1	1	1	1	1	1	
		feces	discolored feces	Color: light brown												
		feces	soft feces													
	73	normal	NAD			1	1	1		1	1	1	1	1	1	
		feces	discolored feces	Color: light brown												
		feces	soft feces													
	74	normal	NAD			1	1	1		1	1	1	1	1	1	
feces		discolored feces	Color: light brown													
feces		soft feces														
75	normal	NAD			1	1	1		1	1	1	1	1	1		
	feces	discolored feces	Color: light brown													
	feces	soft feces														
76	normal	NAD			1	1	1		1	1	1	1	1	1		
	feces	discolored feces	Color: light brown													
	feces	soft feces														
77	normal	NAD			1	1	1		1	1	1	1	1	1		
	feces	discolored feces	Color: light brown													
	feces	soft feces														
78	normal	NAD			1	1	1		1	1	1	1	1	1		
	feces	discolored feces	Color: light brown													
	feces	soft feces														

3 / F
1000 mg/kg
bw/d

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Individual Signs By Interval - Clinical Observation

Sex: **Female** - Phase: **In-life**

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	Day									
						0 [DCO]	7 [DCO]	14 [DCO]	21 [DCO]	28 [DCO]	35 [DCO]	42 [DCO]	49 [DCO]	56 [DCO]	63 [DCO]
3 / F 1000 mg/kg bowl/d	78	feces	discolored feces	Color: light brown				1	1	1	1	1	1	1	
		feces	soft feces												
	79	normal	NAD				1	1							
		feces	discolored feces	Color: light brown			1	1	1	1	1	1	1	1	
		head	salivation	Grade: moderate									1		
80	feces	soft feces													
	normal	NAD					1	1							
	feces	discolored feces	Color: light brown				1	1	1	1	1	1	1	1	
		feces	soft feces												

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Study 50C0066/05S019

Individual Signs By Interval - Clinical Observation

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	Day			
						70 [DCO]	77 [DCO]	84 [DCO]	91 [DCO]
O / F 0 mg/kg bw/d	41	normal	NAD			1	1	1	1
	42	normal	NAD			1	1	1	1
	43	normal	NAD			1	1	1	1
	44	normal	NAD			1	1	1	1
	45	normal	NAD			1	1	1	1
	46	normal	NAD			1	1	1	1
	47	normal	NAD			1	1	1	1
	48	normal	NAD			1	1	1	1
	49	normal	NAD			1	1	1	1
	50	normal	NAD			1	1	1	1

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Study 50C0066/05S019

Individual Signs By Interval - Clinical Observation

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	Day			
						70 [DCO]	77 [DCO]	84 [DCO]	91 [DCO]
1 / F 100 mg/kg bw/d	51	normal	NAD			1	1	1	1
	52	normal	NAD			1	1	1	1
	53	normal	NAD			1	1	1	1
	54	normal	NAD			1	1	1	1
	55	normal	NAD			1	1	1	1
	56	normal	NAD			1	1	1	1
	57	normal	NAD			1	1	1	1
	58	normal	NAD			1	1	1	1
	59	normal	NAD			1	1	1	1
	60	normal	NAD			1	1	1	1

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Study 50C0066/05S019

Individual Signs By Interval - Clinical Observation

Sex: **Female** - Phase: **In-life**

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	Day			
						70 [DCO]	77 [DCO]	84 [DCO]	91 [DCO]
	61	normal	NAD			1	1	1	
		feces	discolored feces	Color: light brown					1
		feces	soft feces						1
		normal	NAD			1	1	1	
		feces	soft feces						1
	62	feces	discolored feces	Color: light brown					1
		normal	NAD			1	1	1	
		head	salivation	Grade: slight					
		feces	discolored feces	Color: light brown					1
		feces	soft feces						1
2 / F 300 mg/kg bwd	63	normal	NAD			1	1	1	
		head	salivation	Grade: slight					
		feces	discolored feces	Color: light brown					1
		feces	soft feces						1
		normal	NAD			1	1	1	
	64	normal	NAD			1	1	1	
		head	salivation	Grade: slight					
		feces	soft feces						1
		feces	discolored feces	Color: light brown					1
		normal	NAD			1	1	1	
	65	normal	NAD			1	1	1	
		head	salivation	Grade: slight					
		feces	discolored feces	Color: light brown					1
		feces	soft feces						1
		normal	NAD			1	1	1	
	66	normal	NAD			1	1	1	
		feces	discolored feces	Color: light brown					1
		feces	soft feces						1
		normal	NAD			1	1	1	
		normal	NAD			1	1	1	

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Study 50C0066/05S019

Individual Signs By Interval - Clinical Observation

Sex: **Female** - Phase: **In-life**

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	Day			
						70 [DCO]	77 [DCO]	84 [DCO]	91 [DCO]
2 / F 300 mg/kg bw/d	..67	feces	discolored feces	Color: light brown					1
		feces	soft feces						1
	68	normal feces	NAD			1	1	1	1
		feces	soft feces						1
		feces	discolored feces	Color: light brown					1
	69	normal feces	NAD	Color: light brown		1	1	1	
		feces	discolored feces						1
		feces	soft feces						1
	70	normal feces	NAD			1	1	1	
		feces	soft feces						1
		feces	discolored feces	Color: light brown					1

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Study 50C0066/05S019

Individual Signs By Interval - Clinical Observation

Sex: **Female** - Phase: **In-life**

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	Day			
						70 [DCO]	77 [DCO]	84 [DCO]	91 [DCO]
3 / F 1000 mg/kg bw/d	71	normal	NAD						
		feces	discolored feces	Color: light brown		1	1	1	1
		feces	soft feces					1	1
	72	normal	NAD						
		feces	discolored feces	Color: light brown		1	1	1	1
		feces	soft feces					1	1
	73	normal	NAD						
		feces	discolored feces	Color: light brown		1	1	1	1
		feces	soft feces					1	1
	74	normal	NAD						
		feces	discolored feces	Color: light brown		1	1	1	1
		feces	soft feces					1	1
	75	normal	NAD						
		feces	discolored feces	Color: light brown		1	1	1	1
		feces	soft feces					1	1
	76	normal	NAD						
		feces	discolored feces	Color: light brown		1	1	1	1
		feces	soft feces					1	1
	77	normal	NAD						
		feces	discolored feces	Color: light brown		1	1	1	1
		feces	soft feces					1	1
	78	normal	NAD						
		feces	discolored feces	Color: light brown		1	1	1	1
		feces	soft feces					1	1

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Study 50C0066/05S019

Individual Signs By Interval - Clinical Observation

Sex: **Female** - Phase: **In-life**

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	Day			
						70 [DCO]	77 [DCO]	84 [DCO]	91 [DCO]
3 / F 1000 mg/kg bw/d	..78	feces	discolored feces	Color: light brown		1	1	1	1
		feces	soft feces						
	79	normal	NAD						
		feces	discolored feces	Color: light brown		1	1	1	1
		head	salivation	Grade: moderate					
80	normal	feces	soft feces					1	1
		normal	NAD						
		feces	discolored feces	Color: light brown		1	1	1	1
		feces	soft feces					1	1

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day							
					0	0	0	1	1	1	2	2
					[00:00-02:00]	[00:00-02:00]	[02:00-05:00]	[-01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[-01:00-00:00]	[00:00-02:00]
	01	normal	NAD		1	1	1	1	1	1	1	1
	02	normal	NAD		1	1	1	1	1	1	1	1
	03	normal	NAD		1	1	1	1	1	1	1	1
	04	normal	NAD		1	1	1	1	1	1	1	1
	05	normal	NAD		1	1	1	1	1	1	1	1
	06	normal	NAD		1	1	1	1	1	1	1	1
	07	normal	NAD		1	1	1	1	1	1	1	1
	08	normal	NAD		1	1	1	1	1	1	1	1
	09	normal	NAD		1	1	1	1	1	1	1	1
	10	normal	NAD		1	1	1	1	1	1	1	1

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					0	0	0	0	1	1	1	1	2	2
					[00:00-00:00]	[00:00-02:00]	[02:00-05:00]	[02:00-05:00]	[-01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[-01:00-00:00]	[00:00-02:00]	[02:00-05:00]
1 / M 100 mg/kg bw/d	11	normal	NAD		1	1	1	1	1	1	1	1	1	1
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		respiration	sounds											
		fur	piloerection											
	12	mass	palpable through skin	Size: < 1.5 cm, Appearance: -, Location: axillary region, Directional terms: left										
	13	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
	14	head	salivation	Grade: slight										
	15	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
	16	head	salivation	Grade: slight										
	17	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
	18	head	salivation	Grade: slight										
	19	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
	20	head	salivation	Grade: slight										

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					0	0	0	0	1	1	1	1	2	2
					[01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[01:00-00:00]	[00:00-02:00]	[01:00-00:00]	[02:00-05:00]
21		normal	NAD		1		1	1	1		1	1	1	1
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	22	normal	NAD		1		1	1	1		1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
23		normal	NAD		1		1	1	1		1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight										
	24	normal	NAD		1		1	1	1		1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
25		normal	NAD		1		1	1	1		1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		normal	NAD		1		1	1	1		1	1	1	1
		head	salivation	Grade: slight										
		feces	soft feces											

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					0	0	0	0	1	1	1	2	2	2
					[00:00-02:00]	[00:00-02:00]	[02:00-05:00]	[01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[01:00-00:00]	[00:00-02:00]	[00:00-02:00]	[02:00-05:00]
26		normal	NAD		1		1		1		1		1	
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
27		normal	NAD		1		1		1		1		1	
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
28		normal	NAD		1		1		1		1		1	
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
29		respiration	sounds											
		normal	NAD		1		1		1		1		1	
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
30		feces	soft feces											
		normal	NAD		1		1		1		1		1	
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

2 / M
300 mg/kg
bw/d

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					0	0	0	0	1	1	1	2	2	2
3 / M 1000/600 mg/kg bw/d	31	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	32	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	33	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	34	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	35	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day							
					0	0	0	1	1	1	2	2
3 / M 1000/600 mg/kg bw/d	36	normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown								
		feces	soft feces									
	37	normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown								
		feces	soft feces									
	38	normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown								
		feces	soft feces									
	39	normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate								
		feces	discolored feces	Grade: slight								
		feces	soft feces	Color: light brown								
	40	normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown								
		feces	soft feces									

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					3	3	3	3	4	4	4	4	5	5
					[01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[-01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[-01:00-00:00]	[00:00-02:00]	[01:00-00:00]	[02:00-05:00]
0 / M 0 mg/kg bw/d	01	normal	NAD		1	1	1	1	1	1	1	1	1	1
	02	normal	NAD		1	1	1	1	1	1	1	1	1	1
	03	normal	NAD		1	1	1	1	1	1	1	1	1	1
	04	normal	NAD		1	1	1	1	1	1	1	1	1	1
	05	normal	NAD		1	1	1	1	1	1	1	1	1	1
	06	normal	NAD		1	1	1	1	1	1	1	1	1	1
	07	normal	NAD		1	1	1	1	1	1	1	1	1	1
	08	normal	NAD		1	1	1	1	1	1	1	1	1	1
	09	normal	NAD		1	1	1	1	1	1	1	1	1	1
	10	normal	NAD		1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					3	3	3	3	4	4	4	4	5	5
					[00:00-00:00]	[00:00-02:00]	[02:00-05:00]	[02:00-05:00]	[-01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[-01:00-00:00]	[00:00-02:00]	[02:00-05:00]
1 / M 100 mg/kg bw/d	11	normal	NAD		1	1	1	1	1	1	1	1	1	1
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		respiration	sounds											
		fur	piloerection											
	12	mass	palpable through skin	Size: < 1.5 cm, Appearance: -, Location: axillary region, Directional terms: left										
	13	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	14	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	15	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	16	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	17	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	18	normal	NAD		1	1	1	1	1	1	1	1	1	1
	19	normal	NAD		1	1	1	1	1	1	1	1	1	1
	20	normal	NAD		1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					3	3	3	3	4	4	4	4	5	5
2 / M 300 mg/kg bw/d	21	normal	NAD		1	1	1	1	1	1	1	1	1	1
		feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	22	feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight										
24	23	feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
	25	feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					3	3	3	4	4	4	4	5	5	5
26		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
27		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
28	2 / M 300 mg/kg bw/d	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight										
		feces	soft feces	Color: light brown										
29		respiration	sounds											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
30		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					3	3	3	3	4	4	4	4	5	5
3 / M 1000/600 mg/kg bw/d	31	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	32	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	33	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	34	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	35	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					3	3	3	4	4	4	4	5	5	5
3 / M 1000/600 mg/kg bw/d	36	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	37	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	38	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	39	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight										
		feces	soft feces	Color: light brown										
	40	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day								
					6 [-01:00-00:00]	6 [00:00-02:00]	6 [02:00-05:00]	7 [-01:00-00:00]	7 [00:00-02:00]	7 [02:00-05:00]	8 [-01:00-00:00]	8 [00:00-02:00]	8 [02:00-05:00]
0 / M 0 mg/kg bw/d	01	normal	NAD		1	1	1		1	1	1	1	1
	02	normal	NAD		1	1	1		1	1	1	1	1
	03	normal	NAD		1	1	1		1	1	1	1	1
	04	normal	NAD		1	1	1		1	1	1	1	1
	05	normal	NAD		1	1	1		1	1	1	1	1
	06	normal	NAD		1	1	1		1	1	1	1	1
	07	normal	NAD		1	1	1		1	1	1	1	1
	08	normal	NAD		1	1	1		1	1	1	1	1
	09	normal	NAD		1	1	1		1	1	1	1	1
	10	normal	NAD		1	1	1		1	1	1	1	1

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day								
					6 [00:00-01:00]	6 [01:00-02:00]	6 [02:00-05:00]	7 [00:00-01:00]	7 [01:00-02:00]	7 [02:00-05:00]	8 [00:00-01:00]	8 [01:00-02:00]	8 [02:00-05:00]
1 / M 100 mg/kg pow/d	11	normal	NAD		1	1	1		1	1	1	1	1
		normal	NAD		1	1	1		1	1	1	1	1
		head	salivation	Grade: slight									
		respiration	sounds										
		fur	piloerection										
	12	mass	palpable through skin	Size: < 1.5 cm, Appearance: -, Location : axillary region, Directional terms: left									
	13	normal	NAD		1	1	1		1	1	1	1	1
		head	salivation	Grade: slight									
	14	normal	NAD		1	1	1		1	1	1	1	1
		head	salivation	Grade: slight									
15	normal	NAD		1	1	1		1	1	1	1	1	
	head	salivation	Grade: slight										
16	normal	NAD		1	1	1		1	1	1	1	1	
	head	salivation	Grade: slight										
17	normal	NAD		1	1	1		1	1	1	1	1	
	head	salivation	Grade: slight										
18	normal	NAD		1	1	1		1	1	1	1	1	
19	normal	NAD		1	1	1		1	1	1	1	1	
20	normal	NAD		1	1	1		1	1	1	1	1	

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day								
					6 [-01:00-00:00]	6 [00:00-02:00]	6 [02:00-05:00]	7 [-01:00-00:00]	7 [00:00-02:00]	7 [02:00-05:00]	8 [-01:00-00:00]	8 [00:00-02:00]	8 [02:00-05:00]
21		normal	NAD		1	1	1		1	1	1	1	1
		feces	discolored feces	Color: light brown									
		feces	soft feces										
		normal	NAD		1	1	1		1	1	1	1	
		head	salivation	Grade: slight									
		feces	discolored feces	Color: light brown									
22		feces	soft feces										
		normal	NAD		1	1	1		1	1	1	1	
		head	salivation	Grade: moderate									
		feces	discolored feces	Grade: slight									
		feces	soft feces	Color: light brown									
		normal	NAD		1	1	1		1	1	1	1	
23	2 / M 300 mg/kg bw/d	head	salivation	Grade: moderate									
		feces	discolored feces	Grade: slight									
		feces	soft feces	Color: light brown									
		normal	NAD		1	1	1		1	1	1	1	
		head	salivation	Grade: slight									
		feces	discolored feces	Color: light brown									
24		feces	soft feces										
		normal	NAD		1	1	1		1	1	1	1	
		head	salivation	Grade: slight									
		feces	discolored feces	Color: light brown									
		feces	soft feces										
		normal	NAD		1	1	1		1	1	1	1	
25		head	salivation	Grade: slight									
		feces	discolored feces	Color: light brown									
		feces	soft feces										
		normal	NAD		1	1	1		1	1	1	1	
		head	salivation	Grade: slight									
		feces	discolored feces	Color: light brown									

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day							
					6	6	6	7	7	7	8	8
26		normal	NAD		1	1	1		1	1	1	1
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown								
		feces	soft feces									
27		normal	NAD		1	1	1		1	1	1	1
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown								
		feces	soft feces									
28		normal	NAD		1	1	1		1	1	1	1
		head	salivation	Grade: moderate								
		feces	discolored feces	Grade: slight								
		feces	soft feces	Color: light brown								
29		respiration	sounds									
		normal	NAD		1	1	1		1	1	1	1
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown								
30		feces	soft feces									
		normal	NAD		1	1	1		1	1	1	1
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown								
		feces	soft feces									

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day							
					6	6	6	7	7	7	8	8
3 / M 1000/600 mg/kg bw/d	31	normal	NAD		1	1	1		1	1	1	1
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown								
		feces	soft feces									
	32	normal	NAD		1	1	1		1	1	1	1
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown								
		feces	soft feces									
	33	normal	NAD		1	1	1		1	1	1	1
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown								
		feces	soft feces									
	34	normal	NAD		1	1	1		1	1	1	1
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown								
		feces	soft feces									
	35	normal	NAD		1	1	1		1	1	1	1
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown								
		feces	soft feces									

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day								
					6 [-01:00-00:00]	6 [00:00-02:00]	6 [02:00-05:00]	7 [-01:00-00:00]	7 [00:00-02:00]	7 [02:00-05:00]	8 [-01:00-00:00]	8 [00:00-02:00]	8 [02:00-05:00]
36		normal	NAD		1	1	1		1	1	1	1	1
		head	salivation	Grade: slight									
		feces	discolored feces	Color: light brown									
		feces	soft feces										
37		normal	NAD		1	1	1		1	1	1	1	1
		head	salivation	Grade: slight									
		feces	discolored feces	Color: light brown									
		feces	soft feces										
38		normal	NAD		1	1	1		1	1	1	1	1
		head	salivation	Grade: slight									
		feces	discolored feces	Color: light brown									
		feces	soft feces										
39		normal	NAD		1	1	1		1	1	1	1	1
		head	salivation	Grade: moderate									
		feces	discolored feces	Grade: slight									
		feces	soft feces	Color: light brown									
40		normal	NAD		1	1	1		1	1	1	1	1
		head	salivation	Grade: slight									
		feces	discolored feces	Color: light brown									
		feces	soft feces										

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					9 [-01:00-00:00]	9 [00:00-02:00]	9 [02:00-05:00]	10 [-01:00-00:00]	10 [00:00-02:00]	10 [02:00-05:00]	11 [-01:00-00:00]	11 [00:00-02:00]	11 [02:00-05:00]	
0 / M 0 mg/kg bw/d	01	normal	NAD		1	1	1	1	1	1	1	1	1	
	02	normal	NAD		1	1	1	1	1	1	1	1	1	
	03	normal	NAD		1	1	1	1	1	1	1	1	1	
	04	normal	NAD		1	1	1	1	1	1	1	1	1	
	05	normal	NAD		1	1	1	1	1	1	1	1	1	
	06	normal	NAD		1	1	1	1	1	1	1	1	1	
	07	normal	NAD		1	1	1	1	1	1	1	1	1	
	08	normal	NAD		1	1	1	1	1	1	1	1	1	
	09	normal	NAD		1	1	1	1	1	1	1	1	1	
	10	normal	NAD		1	1	1	1	1	1	1	1	1	

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day										
					9	9	9	9	10	10	10	10	10	11	11
					[00:00-00:00]	[00:00-02:00]	[02:00-05:00]	[02:00-05:00]	[01:00-00:00]	[02:00-05:00]	[02:00-05:00]	[00:00-02:00]	[00:00-02:00]	[02:00-05:00]	[02:00-05:00]
1 / M 100 mg/kg bw/d	11	normal	NAD		1	1	1	1	1	1	1	1	1	1	1
		normal	NAD		1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight											
		respiration	sounds												
		fur	piloerection												
	12			Size: < 1.5 cm, Appearance: -, palpable through skin Location: axillary region, Directional terms: left											
		mass													
	13	normal	NAD		1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight											
	14	normal	NAD		1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight											
	15	normal	NAD		1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight											
	16	normal	NAD		1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight											
	17	normal	NAD		1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight											
	18	normal	NAD		1	1	1	1	1	1	1	1	1	1	1
	19	normal	NAD		1	1	1	1	1	1	1	1	1	1	1
	20	normal	NAD		1	1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day						
					9	9	9	10	10	10	11
21		normal	NAD		1	1	1	1	1	1	1
		feces	discolored feces	Color: light brown							
		feces	soft feces								
		normal	NAD		1	1	1	1	1	1	1
		head	salivation	Grade: slight							
		feces	discolored feces	Color: light brown							
22		feces	soft feces								
		normal	NAD		1	1	1	1	1	1	1
		head	salivation	Grade: moderate							
		feces	discolored feces	Color: light brown							
		feces	soft feces								
		normal	NAD		1	1	1	1	1	1	1
23		head	salivation	Grade: slight							
		feces	discolored feces	Color: light brown							
		feces	soft feces								
		normal	NAD		1	1	1	1	1	1	1
		head	salivation	Grade: slight							
		feces	discolored feces	Color: light brown							
24		feces	soft feces								
		normal	NAD		1	1	1	1	1	1	1
		head	salivation	Grade: slight							
		feces	discolored feces	Color: light brown							
		feces	soft feces								
		normal	NAD		1	1	1	1	1	1	1
25		head	salivation	Grade: slight							
		feces	discolored feces	Color: light brown							
		feces	soft feces								
		normal	NAD		1	1	1	1	1	1	1
		head	salivation	Grade: slight							
		feces	discolored feces	Color: light brown							

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day						
					9 [00:00-02:00]	9 [02:00-05:00]	10 [00:00-02:00]	10 [02:00-05:00]	11 [00:00-02:00]	11 [02:00-05:00]	
26		normal	NAD		1	1	1	1	1	1	
		head	salivation	Grade: slight							
		feces	discolored feces	Color: light brown							
		feces	soft feces								
27		normal	NAD		1	1	1	1	1	1	
		head	salivation	Grade: slight							
		feces	discolored feces	Color: light brown							
		feces	soft feces								
28		normal	NAD		1	1	1	1	1	1	
		head	salivation	Grade: moderate							
		feces	discolored feces	Grade: slight							
		feces	soft feces	Color: light brown							
29		normal	NAD		1	1	1	1	1	1	
		head	salivation	Grade: slight							
		feces	discolored feces	Color: light brown							
		feces	soft feces								
30		normal	NAD		1	1	1	1	1	1	
		head	salivation	Grade: slight							
		feces	discolored feces	Color: light brown							
		feces	soft feces								

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					9	9	9	10	10	10	11	11	11	11
	31	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	32	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
3 / M 1000/600 mg/kg bw/d	33	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	34	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	35	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day						
					9	9	9	10	10	11	11
3 / M 1000/600 mg/kg bw/d	36	normal	NAD		1	1	1	1	1	1	1
		head	salivation	Grade: slight							
		feces	discolored feces	Color: light brown							
		feces	soft feces								
	37	normal	NAD		1	1	1	1	1	1	1
		head	salivation	Grade: slight							
		feces	discolored feces	Color: light brown							
		feces	soft feces								
	38	normal	NAD		1	1	1	1	1	1	1
		head	salivation	Grade: slight							
		feces	discolored feces	Color: light brown							
		feces	soft feces								
	39	normal	NAD		1	1	1	1	1	1	1
		head	salivation	Grade: moderate							
		feces	discolored feces	Grade: slight							
		feces	soft feces	Color: light brown							
40		normal	NAD		1	1	1	1	1	1	1
		head	salivation	Grade: slight							
		feces	discolored feces	Color: light brown							
		feces	soft feces								

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day							
					12	12	12	13	13	13	14	14
	01	normal	NAD		1	1	1	1	1	1	1	1
	02	normal	NAD		1	1	1	1	1	1	1	1
	03	normal	NAD		1	1	1	1	1	1	1	1
	04	normal	NAD		1	1	1	1	1	1	1	1
	05	normal	NAD		1	1	1	1	1	1	1	1
0 / M	06	normal	NAD		1	1	1	1	1	1	1	1
0 mg/kg bw/d	07	normal	NAD		1	1	1	1	1	1	1	1
	08	normal	NAD		1	1	1	1	1	1	1	1
	09	normal	NAD		1	1	1	1	1	1	1	1
	10	normal	NAD		1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day							
					12	12	12	13	13	13	14	14
1 / M 100 mg/kg bw/d	11	normal	NAD		1	1	1	1	1	1	1	1
		normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		respiration	sounds									
		fur	piloerection									
	12	mass	palpable through skin	Size: < 1.5 cm, Appearance: -, Location: axillary region, Directional terms: left								
	13	normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		normal	NAD		1	1	1	1	1	1	1	1
	14	normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		normal	NAD		1	1	1	1	1	1	1	1
	15	normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		normal	NAD		1	1	1	1	1	1	1	1
	16	normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		normal	NAD		1	1	1	1	1	1	1	1
	17	normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		normal	NAD		1	1	1	1	1	1	1	1
	18	normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		normal	NAD		1	1	1	1	1	1	1	1
	19	normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		normal	NAD		1	1	1	1	1	1	1	1
	20	normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		normal	NAD		1	1	1	1	1	1	1	1
		normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		normal	NAD		1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					12	12	12	13	13	13	13	14	14	14
2 / M 300 mg/kg bw/d	21	normal	NAD		1	1	1	1	1	1	1	1	1	1
		feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	22	feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight										
24	23	feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
	25	feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day							
					12	12	12	13	13	13	14	14
	26	normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown								
		feces	soft feces									
	27	normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown								
		feces	soft feces									
2 / M 300 mg/kg bw/d		normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate								
		feces	discolored feces	Grade: slight								
		feces	soft feces	Color: light brown								
	28	respiration	sounds									
		normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown								
	29	normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown								
		feces	soft feces									
	30	normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown								
		feces	soft feces									

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					12	12	12	13	13	13	13	14	14	14
3 / M 1000/600 mg/kg bw/d	31	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	32	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	33	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	34	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	35	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					12	12	12	12	13	13	13	13	14	14
3 / M 1000/600 mg/kg bw/d	36	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	37	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	38	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	39	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight										
		feces	soft feces	Color: light brown										
	40	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day								
					15 [-01:00-00:00]	15 [00:00-02:00]	15 [02:00-05:00]	16 [-01:00-00:00]	16 [00:00-02:00]	16 [02:00-05:00]	17 [-01:00-00:00]	17 [00:00-02:00]	17 [02:00-05:00]
0 / M 0 mg/kg bw/d	01	normal	NAD		1	1	1	1	1	1	1	1	1
	02	normal	NAD		1	1	1	1	1	1	1	1	1
	03	normal	NAD		1	1	1	1	1	1	1	1	1
	04	normal	NAD		1	1	1	1	1	1	1	1	1
	05	normal	NAD		1	1	1	1	1	1	1	1	1
	06	normal	NAD		1	1	1	1	1	1	1	1	1
	07	normal	NAD		1	1	1	1	1	1	1	1	1
	08	normal	NAD		1	1	1	1	1	1	1	1	1
	09	normal	NAD		1	1	1	1	1	1	1	1	1
	10	normal	NAD		1	1	1	1	1	1	1	1	1

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					15	15	15	16	16	16	17	17	17	17
1 / M 100 mg/kg bw/d	11	normal	NAD		1	1	1	1	1	1	1	1	1	1
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		respiration	sounds											
		fur	piloerection											
	12	mass	palpable through skin	Size: < 1.5 cm, Appearance: -, Location: axillary region, Directional terms: left										
	13	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
	14	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
	15	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
	16	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
	17	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
	18	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
	19	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
	20	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day								
					15 [00:00-01:00]	15 [01:00-02:00]	15 [02:00-05:00]	16 [00:00-01:00]	16 [01:00-02:00]	16 [02:00-05:00]	17 [00:00-01:00]	17 [01:00-02:00]	17 [02:00-05:00]
21	normal	feces	NAD		1	1	1	1	1	1	1	1	1
		feces	discolored feces	Color: light brown									
		feces	soft feces										
	head	feces	NAD	1	1	1	1	1	1	1	1	1	
		feces	salivation	Grade: slight									
		feces	discolored feces	Color: light brown									
22	normal	feces	soft feces										
		feces	NAD	1	1	1	1	1	1	1	1	1	
		head	salivation	Grade: moderate									
	feces	feces	discolored feces	Grade: slight									
		feces	soft feces	Color: light brown									
		feces	soft feces										
23	normal	feces	NAD	1	1	1	1	1	1	1	1	1	1
		feces	salivation	Grade: moderate									
		feces	discolored feces	Grade: slight									
	feces	feces	discolored feces	Color: light brown									
		feces	soft feces										
		feces	soft feces										
24	normal	feces	NAD	1	1	1	1	1	1	1	1	1	1
		feces	salivation	Grade: slight									
		feces	discolored feces	Color: light brown									
	feces	feces	discolored feces	Color: light brown									
		feces	soft feces										
		feces	soft feces										
25	normal	feces	NAD	1	1	1	1	1	1	1	1	1	1
		feces	salivation	Grade: slight									
		feces	discolored feces	Color: light brown									
	feces	feces	discolored feces	Color: light brown									
		feces	soft feces										
		feces	soft feces										

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day								
					15 [01:00-00:00]	15 [00:00-02:00]	15 [02:00-05:00]	16 [01:00-00:00]	16 [00:00-02:00]	16 [02:00-05:00]	17 [01:00-00:00]	17 [00:00-02:00]	17 [02:00-05:00]
	26	normal	NAD		1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight									
		feces	discolored feces	Color: light brown									
		feces	soft feces										
	27	normal	NAD		1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight									
		feces	discolored feces	Color: light brown									
		feces	soft feces										
	28	normal	NAD		1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate									
		feces	discolored feces	Grade: slight									
		feces	soft feces	Color: light brown									
	29	respiration	sounds										
		normal	NAD		1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight									
		feces	discolored feces	Color: light brown									
	30	feces	soft feces										
		normal	NAD		1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight									
		feces	discolored feces	Color: light brown									
		feces	soft feces										

2 / M
300 mg/kg
bw/d

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					15 [-01:00-00:00]	15 [00:00-02:00]	15 [02:00-05:00]	16 [-01:00-00:00]	16 [00:00-02:00]	16 [02:00-05:00]	17 [-01:00-00:00]	17 [00:00-02:00]	17 [02:00-05:00]	
31		normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
32		normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
33		normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
34		normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
35		normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day								
					15 [-01:00-00:00]	15 [00:00-02:00]	15 [02:00-05:00]	16 [-01:00-00:00]	16 [00:00-02:00]	16 [02:00-05:00]	17 [-01:00-00:00]	17 [00:00-02:00]	17 [02:00-05:00]
36		normal	NAD										
		head	salivation	Grade: slight									
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1
		feces	soft feces										
37		normal	NAD										
		head	salivation	Grade: slight									
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1
		feces	soft feces										
38		normal	NAD										
		head	salivation	Grade: slight									
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1
		feces	soft feces										
39		normal	NAD										
		head	salivation	Grade: moderate									
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1
		feces	soft feces										
40		normal	NAD										
		head	salivation	Grade: slight									
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1
		feces	soft feces										

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day								
					18 [-01:00-00:00]	18 [00:00-02:00]	18 [02:00-05:00]	19 [-01:00-00:00]	19 [00:00-02:00]	19 [02:00-05:00]	20 [-01:00-00:00]	20 [00:00-02:00]	20 [02:00-05:00]
0 / M 0 mg/kg bw/d	01	normal	NAD		1	1	1	1	1	1	1	1	1
	02	normal	NAD		1	1	1	1	1	1	1	1	1
	03	normal	NAD		1	1	1	1	1	1	1	1	1
	04	normal	NAD		1	1	1	1	1	1	1	1	1
	05	normal	NAD		1	1	1	1	1	1	1	1	1
	06	normal	NAD		1	1	1	1	1	1	1	1	1
	07	normal	NAD		1	1	1	1	1	1	1	1	1
	08	normal	NAD		1	1	1	1	1	1	1	1	1
	09	normal	NAD		1	1	1	1	1	1	1	1	1
	10	normal	NAD		1	1	1	1	1	1	1	1	1

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					18	18	18	18	19	19	19	20	20	20
1 / M 100 mg/kg bw/d	11	normal	NAD		1	1	1	1	1	1	1	1	1	1
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		respiration	sounds											
		fur	piloerection											
	12	mass	palpable through skin	Size: < 1.5 cm, Appearance: -, Location: axillary region, Directional terms: left										
	13	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	14	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	15	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	16	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	17	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	18	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	19	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	20	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					18	18	18	19	19	19	20	20	20	20
2 / M 300 mg/kg bw/d	21	normal	NAD		1	1	1	1	1	1	1	1	1	1
		feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	22	feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight				1					1	
24	23	feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
	25	feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day							
					18 [00:00-02:00]	18 [02:00-05:00]	19 [00:00-02:00]	19 [02:00-05:00]	20 [00:00-02:00]	20 [02:00-05:00]	20 [00:00-02:00]	20 [02:00-05:00]
26		normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown								
		feces	soft feces									
27		normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown								
		feces	soft feces									
28		normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate								
		feces	discolored feces	Color: light brown								
		feces	soft feces									
29		respiration	normal									
		head	salivation	Grade: slight	1	1	1	1	1	1	1	1
		feces	discolored feces	Color: light brown								
		feces	soft feces									
30		normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown								
		feces	soft feces									

2 / M
300 mg/kg
bw/d

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day							
					18	18	18	19	19	19	20	20
3 / M 1000/600 mg/kg bw/d	31	normal	NAD									
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1
		feces	soft feces									
	32	normal	NAD									
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1
		feces	soft feces									
	33	normal	NAD									
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1
		feces	soft feces									
	34	normal	NAD									
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1
		feces	soft feces									
	35	normal	NAD									
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1
		feces	soft feces									

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day								
					18 [00:00-02:00]	18 [02:00-05:00]	19 [00:00-02:00]	19 [02:00-05:00]	19 [00:00-02:00]	19 [02:00-05:00]	20 [00:00-02:00]	20 [02:00-05:00]	
36		normal	NAD										
		head	salivation	Grade: slight									
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1
		feces	soft feces										
37		normal	NAD										
		head	salivation	Grade: slight									
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1
		feces	soft feces										
38		normal	NAD										
		head	salivation	Grade: slight									
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1
		feces	soft feces										
39		normal	NAD										
		head	salivation	Grade: moderate									
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1
		feces	soft feces										
40		normal	NAD										
		head	salivation	Grade: slight									
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1
		feces	soft feces										

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					21	21	21	22	22	22	23	23	23	23
					[01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[-01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[-01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[02:00-05:00]
0 / M 0 mg/kg bw/d	01	normal	NAD		1	1	1	1	1	1	1	1	1	1
	02	normal	NAD		1	1	1	1	1	1	1	1	1	1
	03	normal	NAD		1	1	1	1	1	1	1	1	1	1
	04	normal	NAD		1	1	1	1	1	1	1	1	1	1
	05	normal	NAD		1	1	1	1	1	1	1	1	1	1
	06	normal	NAD		1	1	1	1	1	1	1	1	1	1
	07	normal	NAD		1	1	1	1	1	1	1	1	1	1
	08	normal	NAD		1	1	1	1	1	1	1	1	1	1
	09	normal	NAD		1	1	1	1	1	1	1	1	1	1
	10	normal	NAD		1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					21	21	21	21	22	22	22	22	23	23
					[00:00-00:00]	[00:00-02:00]	[02:00-05:00]	[-01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[-01:00-00:00]	[00:00-02:00]	[00:00-02:00]	[02:00-05:00]
1 / M 100 mg/kg bw/d	11	normal	NAD		1	1	1	1	1	1	1	1	1	1
		normal	NAD		1	1	1	1	1	1	1	1	1	1
	12	head	salivation	Grade: slight										
		respiration	sounds											
		fur	piloerection											
		mass	palpable through skin	Size: < 1.5 cm, Appearance: -, Location: axillary region, Directional terms: left										
	13	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	14	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	15	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	16	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	17	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	18	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	19	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	20	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					21	21	21	21	22	22	22	22	23	23
					[00:00-02:00]	[02:00-05:00]	[01:00-00:00]	[00:00-02:00]	[01:00-00:00]	[02:00-05:00]	[01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[01:00-00:00]
2 / M 300 mg/kg bw/d	21	normal	NAD		1	1	1	1	1	1	1	1	1	1
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	22	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
	23	feces	discolored feces	Grade: slight	1			1						
	24	feces	soft feces	Color: light brown										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	25	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					21	21	21	22	22	22	23	23	23	23
					[00:00-00:00]	[00:00-02:00]	[02:00-05:00]	[01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[01:00-00:00]	[00:00-02:00]	[00:00-02:00]	[02:00-05:00]
26		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
27		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
28	2 / M 300 mg/kg bw/d	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight										
		feces	soft feces	Color: light brown										
29		respiration	sounds											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
30		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					21	21	21	21	22	22	22	23	23	23
					[00:00-00:00]	[00:00-02:00]	[02:00-05:00]	[02:00-05:00]	[01:00-00:00]	[02:00-05:00]	[02:00-05:00]	[01:00-00:00]	[00:00-02:00]	[02:00-05:00]
3 / M 1000/600 mg/kg bw/d	31	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	32	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	33	normal	NAD											
		head	salivation	Grade: slight	1	1	1	1	1	1	1	1	1	1
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	34	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	35	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					21	21	21	21	22	22	22	23	23	23
					[00:00-00:00]	[00:00-02:00]	[02:00-05:00]	[-01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[-01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[02:00-05:00]
3 / M 1000/600 mg/kg bw/d	36	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	37	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	38	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	39	normal	NAD											
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	40	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					24	24	24	25	25	25	26	26	26	26
					[01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[-01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[-01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[02:00-05:00]
0 / M 0 mg/kg bw/d	01	normal	NAD		1	1	1	1	1	1	1	1	1	1
	02	normal	NAD		1	1	1	1	1	1	1	1	1	1
	03	normal	NAD		1	1	1	1	1	1	1	1	1	1
	04	normal	NAD		1	1	1	1	1	1	1	1	1	1
	05	normal	NAD		1	1	1	1	1	1	1	1	1	1
	06	normal	NAD		1	1	1	1	1	1	1	1	1	1
	07	normal	NAD		1	1	1	1	1	1	1	1	1	1
	08	normal	NAD		1	1	1	1	1	1	1	1	1	1
	09	normal	NAD		1	1	1	1	1	1	1	1	1	1
	10	normal	NAD		1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day											
					24	24	24	25	25	25	25	26	26	26	26	26
					[01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[01:00-00:00]	[00:00-02:00]	[02:00-05:00]
1 / M 100 mg/kg bw/d	11	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
	12	head	salivation	Grade: slight												
		respiration	sounds													
		fur	piloerection													
		mass	palpable through skin	Size: < 1.5 cm, Appearance: -, Location: axillary region, Directional terms: left												
	13	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
		normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
		normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
		normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
	14	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
	15	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
	16	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
	17	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
	18	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
	19	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
	20	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					24	24	24	25	25	25	26	26	26	26
					[01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[-01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[-01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[02:00-05:00]
21		normal	NAD		1	1	1	1	1	1	1	1	1	1
		feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
22		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight										
		feces	soft feces	Color: light brown										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
23	2 / M 300 mg/kg bw/d	head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
24		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
25		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					24	24	24	25	25	25	25	26	26	26
	26	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	27	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
2 / M 300 mg/kg bw/d	28	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight										
		feces	soft feces	Color: light brown										
	29	respiration	sounds											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
	30	feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					24	24	24	25	25	25	26	26	26	26
					[00:00-00:00]	[00:00-02:00]	[02:00-05:00]	[01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[02:00-05:00]
3 / M 1000/600 mg/kg bw/d	31	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	32	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	33	normal	NAD											
		head	salivation	Grade: slight	1	1	1	1	1	1	1	1	1	1
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	34	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	35	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					24	24	24	25	25	25	26	26	26	26
3 / M 1000/600 mg/kg bw/d	36	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	37	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	38	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	39	normal	NAD											
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	40	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					27	27	27	28	28	28	28	29	29	29
0 / M 0 mg/kg bw/d	01	normal	NAD		1	1	1	1	1	1	1	1	1	1
	02	normal	NAD		1	1	1	1	1	1	1	1	1	1
	03	normal	NAD		1	1	1	1	1	1	1	1	1	1
	04	normal	NAD		1	1	1	1	1	1	1	1	1	1
	05	normal	NAD		1	1	1	1	1	1	1	1	1	1
	06	normal	NAD		1	1	1	1	1	1	1	1	1	1
	07	normal	NAD		1	1	1	1	1	1	1	1	1	1
	08	normal	NAD		1	1	1	1	1	1	1	1	1	1
	09	normal	NAD		1	1	1	1	1	1	1	1	1	1
	10	normal	NAD		1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day											
					27	27	27	27	28	28	28	28	28	29	29	29
1 / M 100 mg/kg bw/d	11	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
		respiration	sounds													
		fur	piloerection													
	12	mass	palpable through skin	Size: < 1.5 cm, Appearance: -, Location: axillary region, Directional terms: left												
	13	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
		normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
		normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
	14	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
		normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
		normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
	15	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
		normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
		normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
	16	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
		normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
		normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
	17	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
		normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
		normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
	18	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
		normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
		normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
	19	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
		normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
		normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
	20	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
		normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
		normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					27	27	27	28	28	28	28	29	29	29
2 / M 300 mg/kg bw/d	21	normal	NAD		1	1	1	1	1	1	1	1	1	1
		feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	22	feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight										
24	23	feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
	25	feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					27	27	27	28	28	28	28	29	29	29
	26	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	27	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
2 / M 300 mg/kg bw/d		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight								1		
		feces	soft feces	Color: light brown										
	28	respiration	sounds											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
	29	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	30	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					27	27	27	28	28	28	29	29	29	29
3 / M 1000/600 mg/kg bw/d	31	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	32	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	33	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	34	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	35	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					27	27	27	28	28	28	29	29	29	29
3 / M 1000/600 mg/kg bw/d	36	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	37	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	38	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	39	normal	NAD											
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	40	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					30	30	30	31	31	31	31	32	32	32
	01	normal	NAD		1	1	1	1	1	1	1	1	1	1
	02	normal	NAD		1	1	1	1	1	1	1	1	1	1
	03	normal	NAD		1	1	1	1	1	1	1	1	1	1
	04	normal	NAD		1	1	1	1	1	1	1	1	1	1
	05	normal	NAD		1	1	1	1	1	1	1	1	1	1
	06	normal	NAD		1	1	1	1	1	1	1	1	1	1
	07	normal	NAD		1	1	1	1	1	1	1	1	1	1
	08	normal	NAD		1	1	1	1	1	1	1	1	1	1
	09	normal	NAD		1	1	1	1	1	1	1	1	1	1
	10	normal	NAD		1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					30	30	30	31	31	31	31	32	32	32
1 / M 100 mg/kg bw/d	11	normal	NAD		1	1	1	1	1	1	1	1	1	1
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		respiration	sounds											
		fur	piloerection											
	12	mass	palpable through skin	Size: < 1.5 cm, Appearance: -, Location: axillary region, Directional terms: left										
	13	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
	14	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
	15	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
	16	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
	17	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
	18	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
	19	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
	20	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					30	30	30	31	31	31	31	32	32	32
2 / M 300 mg/kg bw/d	21	normal	NAD		1	1	1	1	1	1	1	1	1	1
		feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	22	feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight				1				1		
24	23	feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
	25	feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					30	30	30	31	31	31	31	32	32	32
	26	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	27	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown									1	
		feces	soft feces											
2 / M 300 mg/kg bw/d		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight				1						
		feces	soft feces	Color: light brown										
	28	respiration	sounds											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
	29	feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
	30	feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day											
					30	30	30	30	31	31	31	31	31	32	32	32
3 / M 1000/600 mg/kg bw/d	31	normal	NAD													
		head	salivation	Grade: slight												
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1	1	1
		feces	soft feces													
	32	normal	NAD													
		head	salivation	Grade: slight												
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1	1	1
		feces	soft feces													
	33	normal	NAD													
		head	salivation	Grade: slight												
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1	1	1
		feces	soft feces													
	34	normal	NAD													
		head	salivation	Grade: slight												
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1	1	1
		feces	soft feces													
	35	normal	NAD													
		head	salivation	Grade: slight												
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1	1	1
		feces	soft feces													

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					30	30	30	31	31	31	32	32	32	32
3 / M 1000/600 mg/kg bw/d	36	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	37	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	38	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	39	normal	NAD											
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	40	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					33	33	33	34	34	34	35	35	35	35
	01	normal	NAD		1	1	1	1	1	1	1	1	1	1
	02	normal	NAD		1	1	1	1	1	1	1	1	1	1
	03	normal	NAD		1	1	1	1	1	1	1	1	1	1
	04	normal	NAD		1	1	1	1	1	1	1	1	1	1
	05	normal	NAD		1	1	1	1	1	1	1	1	1	1
	06	normal	NAD		1	1	1	1	1	1	1	1	1	1
	07	normal	NAD		1	1	1	1	1	1	1	1	1	1
	08	normal	NAD		1	1	1	1	1	1	1	1	1	1
	09	normal	NAD		1	1	1	1	1	1	1	1	1	1
	10	normal	NAD		1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					33	33	33	34	34	34	35	35	35	35
					[00:00-00:00]	[00:00-02:00]	[02:00-05:00]	[01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[02:00-05:00]
1 / M 100 mg/kg bw/d	11	normal	NAD		1	1	1	1	1	1	1	1	1	1
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		respiration	sounds											
		fur	piloerection											
	12	mass	palpable through skin	Size: < 1.5 cm, Appearance: -, Location: axillary region, Directional terms: left										
	13	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	14	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	15	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	16	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	17	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	18	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	19	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	20	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					33	33	33	33	34	34	34	34	35	35
2 / M 300 mg/kg bw/d	21	normal	NAD		1	1	1	1	1	1	1	1	1	1
		feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	22	feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight					1				1	
24	23	feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
	25	feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					33	33	33	34	34	34	35	35	35	35
	26	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	27	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
2 / M 300 mg/kg bw/d		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight				1						
		feces	soft feces	Color: light brown										
	28	respiration	sounds											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
	29	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	30	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					33	33	33	34	34	34	35	35	35	35
3 / M 1000/600 mg/kg bw/d	31	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	32	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	33	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	34	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	35	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					33	33	33	34	34	34	35	35	35	35
3 / M 1000/600 mg/kg bw/d	36	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	37	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	38	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	39	normal	NAD											
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	40	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					36 [-01:00-00:00]	36 [00:00-02:00]	36 [02:00-05:00]	37 [-01:00-00:00]	37 [00:00-02:00]	37 [02:00-05:00]	38 [-01:00-00:00]	38 [00:00-02:00]	38 [02:00-05:00]	
0 / M 0 mg/kg bw/d	01	normal	NAD		1	1	1	1	1	1	1	1	1	1
	02	normal	NAD		1	1	1	1	1	1	1	1	1	1
	03	normal	NAD		1	1	1	1	1	1	1	1	1	1
	04	normal	NAD		1	1	1	1	1	1	1	1	1	1
	05	normal	NAD		1	1	1	1	1	1	1	1	1	1
	06	normal	NAD		1	1	1	1	1	1	1	1	1	1
	07	normal	NAD		1	1	1	1	1	1	1	1	1	1
	08	normal	NAD		1	1	1	1	1	1	1	1	1	1
	09	normal	NAD		1	1	1	1	1	1	1	1	1	1
	10	normal	NAD		1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day											
					36	36	36	37	37	37	37	37	37	38	38	38
1 / M 100 mg/kg bw/d	11	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
		respiration	sounds													
		fur	piloerection													
	12	mass	palpable through skin	Size: < 1.5 cm, Appearance: -, Location: axillary region, Directional terms: left												
	13	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
		normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
		normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
	14	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
		normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
		normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
	15	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
		normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
		normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
	16	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
		normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
		normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
	17	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
		normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
		normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
	18	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
		normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
		normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
	19	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
		normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
		normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
	20	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
		normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
		normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
		normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
		normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					36 [-01:00-00:00]	36 [00:00-02:00]	36 [02:00-05:00]	37 [-01:00-00:00]	37 [00:00-02:00]	37 [02:00-05:00]	38 [-01:00-00:00]	38 [00:00-02:00]	38 [02:00-05:00]	
21	normal feces	normal	NAD		1	1	1	1	1	1	1	1	1	
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	head feces	normal	NAD		1	1	1	1	1	1	1	1		
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
22	normal feces	normal	NAD		1	1	1	1	1	1	1	1		
		feces	soft feces											
		head	salivation	Grade: slight										
	head feces	normal	NAD		1	1	1	1	1	1	1	1		
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight										
23	normal feces	normal	NAD		1	1	1	1	1	1	1	1		
		feces	soft feces											
		head	salivation	Grade: moderate										
	head feces	normal	NAD		1	1	1	1	1	1	1	1		
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
24	normal feces	normal	NAD		1	1	1	1	1	1	1	1		
		feces	soft feces											
		head	salivation	Grade: slight										
	head feces	normal	NAD		1	1	1	1	1	1	1	1		
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
25	normal feces	normal	NAD		1	1	1	1	1	1	1	1		
		feces	soft feces											
		head	salivation	Grade: slight										
	head feces	normal	NAD		1	1	1	1	1	1	1	1		
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					36 [-01:00-00:00]	36 [00:00-02:00]	36 [02:00-05:00]	37 [-01:00-00:00]	37 [00:00-02:00]	37 [02:00-05:00]	38 [-01:00-00:00]	38 [00:00-02:00]	38 [02:00-05:00]	
	26	normal	NAD		1	1	1	1	1	1	1	1	1	
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	27	normal	NAD		1	1	1	1	1	1	1	1	1	
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	28	normal	NAD		1	1	1	1	1	1	1	1	1	
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight		1			1			1		
		feces	soft feces	Color: light brown										
	29	respiration	sounds											
		normal	NAD		1	1	1	1	1	1	1	1	1	
		head	salivation	Grade: slight					1					
		feces	discolored feces	Color: light brown										
	30	feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day								
					36 [-01:00-00:00]	36 [00:00-02:00]	36 [02:00-05:00]	37 [-01:00-00:00]	37 [00:00-02:00]	37 [02:00-05:00]	38 [-01:00-00:00]	38 [00:00-02:00]	38 [02:00-05:00]
3 / M 1000/600 mg/kg bw/d	31	normal	NAD										
		head	salivation	Grade: slight									
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	
		feces	soft feces										
	32	normal	NAD										
		head	salivation	Grade: slight									
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	
		feces	soft feces										
	33	normal	NAD										
		head	salivation	Grade: slight	1	1	1	1	1	1	1	1	
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	
		feces	soft feces										
	34	normal	NAD										
		head	salivation	Grade: slight									
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	
		feces	soft feces										
	35	normal	NAD										
		head	salivation	Grade: slight									
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	
		feces	soft feces										

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					36	36	36	37	37	37	37	38	38	38
3 / M 1000/600 mg/kg bw/d	36	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	37	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	38	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	39	normal	NAD											
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	40	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					39 [-01:00-00:00]	39 [00:00-02:00]	39 [02:00-05:00]	40 [-01:00-00:00]	40 [00:00-02:00]	40 [02:00-05:00]	41 [-01:00-00:00]	41 [00:00-02:00]	41 [02:00-05:00]	
0 / M 0 mg/kg bw/d	01	normal	NAD		1	1	1	1	1	1	1	1	1	1
	02	normal	NAD		1	1	1	1	1	1	1	1	1	1
	03	normal	NAD		1	1	1	1	1	1	1	1	1	1
	04	normal	NAD		1	1	1	1	1	1	1	1	1	1
	05	normal	NAD		1	1	1	1	1	1	1	1	1	1
	06	normal	NAD		1	1	1	1	1	1	1	1	1	1
	07	normal	NAD		1	1	1	1	1	1	1	1	1	1
	08	normal	NAD		1	1	1	1	1	1	1	1	1	1
	09	normal	NAD		1	1	1	1	1	1	1	1	1	1
	10	normal	NAD		1	1	1	1	1	1	1	1	1	1

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					39	39	39	40	40	40	41	41	41	41
					[00:00-00:00]	[00:00-02:00]	[02:00-05:00]	[01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[02:00-05:00]
1 / M 100 mg/kg bw/d	11	normal	NAD		1	1	1	1	1	1	1	1	1	1
		normal	NAD		1	1	1	1	1	1	1	1	1	1
	12	head	salivation	Grade: slight										
		respiration	sounds											
		fur	piloerection											
		mass	palpable through skin	Size: < 1.5 cm, Appearance: -, Location: axillary region, Directional terms: left										
	13	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	14	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	15	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	16	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	17	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	18	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	19	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	20	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					39	39	39	40	40	40	41	41	41	41
2 / M 300 mg/kg bw/d	21	normal	NAD		1	1	1	1	1	1	1	1	1	1
		feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	22	feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight			1	1	1	1	1	1	1	1
24	23	feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
	25	feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					39	39	39	40	40	40	41	41	41	41
					[01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[02:00-05:00]
26		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
27		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
28		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight					1				1	
		feces	soft feces	Color: light brown										
29		respiration	sounds											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
30		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day							
					39	39	39	40	40	40	41	41
					[01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[-01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[-01:00-00:00]	[00:00-02:00]
3 / M 1000/600 mg/kg bw/d	31	normal	NAD									
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1
		feces	soft feces									
	32	normal	NAD									
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1
		feces	soft feces									
	33	normal	NAD									
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1
		feces	soft feces									
	34	normal	NAD									
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1
		feces	soft feces									
	35	normal	NAD									
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1
		feces	soft feces									

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					39	39	39	40	40	40	41	41	41	41
3 / M 1000/600 mg/kg bw/d	36	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	37	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	38	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	39	normal	NAD											
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	40	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day							
					42	42	42	43	43	43	44	44
	01	normal	NAD		1	1	1	1	1	1	1	1
	02	normal	NAD		1	1	1	1	1	1	1	1
	03	normal	NAD		1	1	1	1	1	1	1	1
	04	normal	NAD		1	1	1	1	1	1	1	1
	05	normal	NAD		1	1	1	1	1	1	1	1
0 / M	06	normal	NAD		1	1	1	1	1	1	1	1
0 mg/kg bw/d	07	normal	NAD		1	1	1	1	1	1	1	1
	08	normal	NAD		1	1	1	1	1	1	1	1
	09	normal	NAD		1	1	1	1	1	1	1	1
	10	normal	NAD		1	1	1	1	1	1	1	1

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day							
					42	42	42	43	43	43	44	44
	11	normal	NAD		1	1	1	1	1	1	1	1
		normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		respiration	sounds									
		fur	piloerection									
	12	mass	palpable through skin	Size: < 1.5 cm, Appearance: -, Location: axillary region, Directional terms: left								
1 / M	13	normal	NAD		1	1	1	1	1	1	1	1
100 mg/kg		head	salivation	Grade: slight								
bw/d	14	normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
	15	normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
	16	normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
	17	normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
	18	normal	NAD		1	1	1	1	1	1	1	1
	19	normal	NAD		1	1	1	1	1	1	1	1
	20	normal	NAD		1	1	1	1	1	1	1	1

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					42	42	42	43	43	43	44	44	44	44
2 / M 300 mg/kg bw/d	21	normal	NAD		1	1	1	1	1	1	1	1	1	1
		feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
	22	head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD			1				1	1			1
	23	head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight	1	1		1				1		
		feces	soft feces	Color: light brown										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
24	head	salivation		Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
	head	salivation		Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
25	head	salivation		Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					42	42	42	43	43	43	43	44	44	44
	26	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	27	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
2 / M 300 mg/kg bw/d	28	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight				1						
		feces	soft feces	Color: light brown										
	29	respiration	sounds											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
	30	feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					42	42	42	43	43	43	44	44	44	44
3 / M 1000/600 mg/kg bw/d	31	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	32	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	33	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	34	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	35	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day							
					42	42	42	43	43	43	44	44
3 / M 1000/600 mg/kg bw/d	36	normal	NAD									
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1
		feces	soft feces									
	37	normal	NAD									
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1
		feces	soft feces									
	38	normal	NAD									
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1
		feces	soft feces									
	39	normal	NAD									
		head	salivation	Grade: moderate								
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1
		feces	soft feces									
40		normal	NAD									
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1
		feces	soft feces									

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					45	45	45	46	46	46	47	47	47	47
	01	normal	NAD		1	1	1	1	1	1	1	1	1	1
	02	normal	NAD		1	1	1	1	1	1	1	1	1	1
	03	normal	NAD		1	1	1	1	1	1	1	1	1	1
	04	normal	NAD		1	1	1	1	1	1	1	1	1	1
	05	normal	NAD		1	1	1	1	1	1	1	1	1	1
	06	normal	NAD		1	1	1	1	1	1	1	1	1	1
	07	normal	NAD		1	1	1	1	1	1	1	1	1	1
	08	normal	NAD		1	1	1	1	1	1	1	1	1	1
	09	normal	NAD		1	1	1	1	1	1	1	1	1	1
	10	normal	NAD		1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					45	45	45	46	46	46	47	47	47	47
					[01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[02:00-05:00]
1 / M 100 mg/kg bw/d	11	normal	NAD		1	1	1	1	1	1	1	1	1	1
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		respiration	sounds											
		fur	piloerection											
	12	mass	palpable through skin	Size: < 1.5 cm, Appearance: -, Location: axillary region, Directional terms: left										
	13	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	14	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	15	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	16	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	17	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	18	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	19	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	20	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					45	45	45	46	46	46	47	47	47	47
2 / M 300 mg/kg bw/d	21	normal	NAD		1	1	1	1	1	1	1	1	1	1
		feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	22	feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight										
24	23	feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
	25	feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					45	45	45	46	46	46	47	47	47	47
	26	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	27	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
2 / M 300 mg/kg bw/d		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight										
		feces	soft feces	Color: light brown										
	28	respiration	normal											
		head	salivation	Grade: slight	1	1	1	1	1	1	1	1	1	1
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	29	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	30	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					45	45	45	46	46	46	47	47	47	47
3 / M 1000/600 mg/kg bw/d	31	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	32	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	33	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	34	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	35	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					45	45	45	46	46	46	47	47	47	47
3 / M 1000/600 mg/kg bw/d	36	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	37	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	38	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	39	normal	NAD											
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	40	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					48	48	48	49	49	49	50	50	50	50
0 / M 0 mg/kg bw/d	01	normal	NAD		1	1	1	1	1	1	1	1	1	1
	02	normal	NAD		1	1	1	1	1	1	1	1	1	1
	03	normal	NAD		1	1	1	1	1	1	1	1	1	1
	04	normal	NAD		1	1	1	1	1	1	1	1	1	1
	05	normal	NAD		1	1	1	1	1	1	1	1	1	1
	06	normal	NAD		1	1	1	1	1	1	1	1	1	1
	07	normal	NAD		1	1	1	1	1	1	1	1	1	1
	08	normal	NAD		1	1	1	1	1	1	1	1	1	1
	09	normal	NAD		1	1	1	1	1	1	1	1	1	1
	10	normal	NAD		1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					48	48	48	48	49	49	49	50	50	50
1 / M 100 mg/kg bw/d	11	normal	NAD		1	1	1	1	1	1	1	1	1	1
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		respiration	sounds											
		fur	piloerection											
	12	mass	palpable through skin	Size: < 1.5 cm, Appearance: -, Location: axillary region, Directional terms: left										
	13	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
	14	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
	15	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
	16	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
	17	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
	18	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
	19	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
	20	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					48	48	48	49	49	49	50	50	50	50
2 / M 300 mg/kg bw/d	21	normal	NAD		1	1	1	1	1	1	1	1	1	1
		feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	22	feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD			1								1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight	1	1		1			1		1	
24	23	feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
	25	feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					48	48	48	48	49	49	49	50	50	50
	26	normal	NAD		1				1			1		
		head	salivation	Grade: slight		1								
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	27	normal	NAD		1				1			1		1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
2 / M 300 mg/kg bw/d	28	normal	NAD		1				1			1		1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight		1								
		feces	soft feces	Color: light brown										
	29	respiration	sounds											
		normal	NAD		1				1			1		1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
	30	feces	soft feces											
		normal	NAD		1				1			1		1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					48	48	48	49	49	49	50	50	50	50
3 / M 1000/600 mg/kg bw/d	31	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	32	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	33	normal	NAD											
		head	salivation	Grade: slight	1	1	1	1	1	1	1	1	1	1
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	34	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	35	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					48	48	48	49	49	49	50	50	50	50
3 / M 1000/600 mg/kg bw/d	36	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	37	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	38	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	39	normal	NAD											
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	40	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					51 [01:00-00:00]	51 [00:00-02:00]	51 [02:00-05:00]	52 [01:00-00:00]	52 [00:00-02:00]	52 [02:00-05:00]	53 [01:00-00:00]	53 [00:00-02:00]	53 [02:00-05:00]	
0 / M 0 mg/kg bw/d	01	normal	NAD		1	1	1	1	1	1	1	1	1	1
	02	normal	NAD		1	1	1	1	1	1	1	1	1	1
	03	normal	NAD		1	1	1	1	1	1	1	1	1	1
	04	normal	NAD		1	1	1	1	1	1	1	1	1	1
	05	normal	NAD		1	1	1	1	1	1	1	1	1	1
	06	normal	NAD		1	1	1	1	1	1	1	1	1	1
	07	normal	NAD		1	1	1	1	1	1	1	1	1	1
	08	normal	NAD		1	1	1	1	1	1	1	1	1	1
	09	normal	NAD		1	1	1	1	1	1	1	1	1	1
	10	normal	NAD		1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day							
					51 [00:00-00:00]	51 [02:00-05:00]	52 [00:00-00:00]	52 [01:00-00:00]	52 [02:00-05:00]	53 [00:00-02:00]	53 [01:00-00:00]	53 [02:00-05:00]
	11	normal	NAD		1	1	1	1	1	1	1	1
		normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		respiration	sounds									
	12	fur	piloerection									
		mass	palpable through skin	Size: < 1.5 cm, Appearance: -, Location : axillary region, Directional terms: left								
1 / M 100 mg/kg bw/d	13	normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
	14	normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
	15	normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
	16	normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
	17	normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
	18	normal	NAD		1	1	1	1	1	1	1	1
	19	normal	NAD		1	1	1	1	1	1	1	1
20	normal	NAD		1	1	1	1	1	1	1	1	

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					51	51	51	51	52	52	52	53	53	53
2 / M 300 mg/kg bw/d	21	normal	NAD		1	1	1	1	1	1	1	1	1	1
		feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
	22	head	salivation	Grade: slight		1								
		feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD			1								1
	23	head	salivation	Grade: moderate									1	
		feces	discolored feces	Grade: slight	1	1		1	1	1				
		feces	soft feces	Color: light brown										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
24	head	salivation	Grade: slight											
		feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
	head	salivation	Grade: slight											
		feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
25	head	salivation	Grade: slight											
		feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					51 [-01:00-00:00]	51 [00:00-02:00]	51 [02:00-05:00]	52 [-01:00-00:00]	52 [00:00-02:00]	52 [02:00-05:00]	53 [-01:00-00:00]	53 [00:00-02:00]	53 [02:00-05:00]	
	26	normal	NAD		1	1	1	1		1		1	1	
		head	salivation	Grade: slight				1						
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	27	normal	NAD		1	1	1	1	1	1	1	1	1	
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	28	normal	NAD		1	1	1	1		1	1	1	1	
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight		1		1						
		feces	soft feces	Color: light brown										
	29	respiration	sounds											
		normal	NAD		1	1	1	1	1	1	1	1	1	
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
	30	feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					51 [-01:00-00:00]	51 [00:00-02:00]	51 [02:00-05:00]	52 [-01:00-00:00]	52 [00:00-02:00]	52 [02:00-05:00]	53 [-01:00-00:00]	53 [00:00-02:00]	53 [02:00-05:00]	
	31	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	32	normal	NAD											
		head	salivation	Grade: slight		1								
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
3 / M 1000/600 mg/kg bw/d	33	normal	NAD											
		head	salivation	Grade: slight					1				1	
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	34	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	35	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					51	51	51	52	52	52	53	53	53	53
3 / M 1000/600 mg/kg bw/d	36	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	37	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	38	normal	NAD											
		head	salivation	Grade: slight	1	1	1	1	1	1	1	1	1	1
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	39	normal	NAD											
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight										
		feces	soft feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
40		normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					54 [-01:00-00:00]	54 [00:00-02:00]	54 [02:00-05:00]	55 [-01:00-00:00]	55 [00:00-02:00]	55 [02:00-05:00]	56 [-01:00-00:00]	56 [00:00-02:00]	56 [02:00-05:00]	
0 / M 0 mg/kg bw/d	01	normal	NAD		1	1	1	1	1	1	1	1	1	
	02	normal	NAD		1	1	1	1	1	1	1	1	1	
	03	normal	NAD		1	1	1	1	1	1	1	1	1	
	04	normal	NAD		1	1	1	1	1	1	1	1	1	
	05	normal	NAD		1	1	1	1	1	1	1	1	1	
	06	normal	NAD		1	1	1	1	1	1	1	1	1	
	07	normal	NAD		1	1	1	1	1	1	1	1	1	
	08	normal	NAD		1	1	1	1	1	1	1	1	1	
	09	normal	NAD		1	1	1	1	1	1	1	1	1	
	10	normal	NAD		1	1	1	1	1	1	1	1	1	

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					54 [-01:00-00:00]	54 [00:00-02:00]	54 [02:00-05:00]	55 [-01:00-00:00]	55 [00:00-02:00]	55 [02:00-05:00]	56 [-01:00-00:00]	56 [00:00-02:00]	56 [02:00-05:00]	
1 / M 100 mg/kg b.w/d	11	normal	NAD		1	1	1	1	1	1	1	1	1	1
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		respiration	sounds											
		fur	piloerection											
	12	mass	palpable through skin	Size: < 1.5 cm, Appearance: -, Location : axillary region, Directional terms: left										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
13	normal	NAD		1	1	1	1	1	1	1	1	1	1	
	head	salivation	Grade: slight											
14	normal	NAD		1	1	1	1	1	1	1	1	1	1	
	head	salivation	Grade: slight											
15	normal	NAD		1	1	1	1	1	1	1	1	1	1	
	head	salivation	Grade: slight											
16	normal	NAD		1	1	1	1	1	1	1	1	1	1	
	head	salivation	Grade: slight											
17	normal	NAD		1	1	1	1	1	1	1	1	1	1	
	head	salivation	Grade: slight											
18	normal	NAD		1	1	1	1	1	1	1	1	1	1	
	head	salivation	Grade: slight											
19	normal	NAD		1	1	1	1	1	1	1	1	1	1	
	head	salivation	Grade: slight											
20	normal	NAD		1	1	1	1	1	1	1	1	1	1	
	head	salivation	Grade: slight											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					54	54	54	55	55	55	56	56	56	56
21		normal	NAD		1	1	1	1	1	1	1	1	1	1
		feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
22		feces	soft feces											
		normal	NAD			1	1	1	1	1				1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight	1	1			1		1		1	
		feces	soft feces	Color: light brown										
		normal	NAD											
23	2 / M 300 mg/kg bw/d	head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
24		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
25		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					54 [00:00-02:00]	54 [02:00-05:00]	55 [00:00-02:00]	55 [02:00-05:00]	56 [00:00-02:00]	56 [02:00-05:00]	56 [00:00-02:00]	56 [02:00-05:00]	56 [00:00-02:00]	56 [02:00-05:00]
26		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight			1							
		feces	discolored feces	Color: light brown										
		feces	soft feces											
27		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
28		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
29		respiration	normal		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
30		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					54	54	54	55	55	55	56	56	56	56
3 / M 1000/600 mg/kg bw/d	31	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	32	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	33	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	34	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	35	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					54	54	54	55	55	55	56	56	56	56
3 / M 1000/600 mg/kg bw/d	36	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	37	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	38	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	39	normal	NAD											
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	40	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					57 [-01:00-00:00]	57 [00:00-02:00]	57 [02:00-05:00]	58 [-01:00-00:00]	58 [00:00-02:00]	58 [02:00-05:00]	59 [-01:00-00:00]	59 [00:00-02:00]	59 [02:00-05:00]	
0 / M 0 mg/kg bw/d	01	normal	NAD		1	1	1	1	1	1	1	1	1	1
	02	normal	NAD		1	1	1	1	1	1	1	1	1	1
	03	normal	NAD		1	1	1	1	1	1	1	1	1	1
	04	normal	NAD		1	1	1	1	1	1	1	1	1	1
	05	normal	NAD		1	1	1	1	1	1	1	1	1	1
	06	normal	NAD		1	1	1	1	1	1	1	1	1	1
	07	normal	NAD		1	1	1	1	1	1	1	1	1	1
	08	normal	NAD		1	1	1	1	1	1	1	1	1	1
	09	normal	NAD		1	1	1	1	1	1	1	1	1	1
	10	normal	NAD		1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					57 [00:00-02:00]	57 [02:00-05:00]	57 [01:00-00:00]	58 [00:00-02:00]	58 [02:00-05:00]	58 [01:00-00:00]	59 [00:00-02:00]	59 [02:00-05:00]		
1 / M 100 mg/kg bw/d	11	normal	NAD		1	1	1	1	1	1	1	1		
		normal	NAD		1	1	1	1	1	1	1	1		
		head respiration	salivation	Grade: slight										
		fur	piloerection											
	12	mass	palpable through skin	Size: < 1.5 cm, Appearance: -, Location : axillary region, Directional terms: left										
		normal	NAD		1	1	1	1	1	1	1	1		
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1		
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1		
13	head	salivation	Grade: slight											
14	normal	NAD		1	1	1	1	1	1	1	1			
15	normal	NAD		1	1	1	1	1	1	1	1			
16	normal	NAD		1	1	1	1	1	1	1	1			
17	normal	NAD		1	1	1	1	1	1	1	1			
18	normal	NAD		1	1	1	1	1	1	1	1			
19	normal	NAD		1	1	1	1	1	1	1	1			
20	normal	NAD		1	1	1	1	1	1	1	1			

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					57	57	57	58	58	58	58	59	59	59
2 / M 300 mg/kg bw/d	21	normal	NAD		1	1	1	1	1	1	1	1	1	1
		feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
	22	head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD			1						1	1	1
	23	head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight	1	1		1			1			
		feces	soft feces	Color: light brown										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
24	head	salivation	Grade: slight											
		feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
	head	salivation	Grade: slight											
		feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
25	head	salivation	Grade: slight											
		feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					57 [00:00-02:00]	57 [02:00-05:00]	57 [01:00-00:00]	58 [00:00-02:00]	58 [02:00-05:00]	58 [01:00-00:00]	59 [00:00-02:00]	59 [02:00-05:00]	59 [01:00-00:00]	59 [00:00-02:00]
26		normal	NAD		1									
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
27		normal	NAD		1									
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
28		normal	NAD		1									
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
29		respiration	normal											
		head	salivation	Grade: slight	1									
		feces	discolored feces	Color: light brown										
		feces	soft feces											
30		normal	NAD		1									
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					57	57	57	58	58	58	59	59	59	59
3 / M 1000/600 mg/kg bw/d	31	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	32	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	33	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	34	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	35	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					57 [00:00-02:00]	57 [02:00-05:00]	58 [00:00-02:00]	58 [02:00-05:00]	59 [00:00-02:00]	59 [02:00-05:00]				
36	normal	NAD												
	head	salivation	Grade: slight											
	feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1			
	feces	soft feces												
37	normal	NAD												
	head	salivation	Grade: slight											
	feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1			
	feces	soft feces												
38	normal	NAD												
	head	salivation	Grade: slight											
	feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1			
	feces	soft feces												
39	normal	NAD												
	head	salivation	Grade: moderate											
	feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1			
	feces	soft feces												
40	normal	NAD												
	head	salivation	Grade: slight											
	feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1			
	feces	soft feces												

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					60	60	60	61	61	61	62	62	62	62
	01	normal	NAD		1	1	1	1	1	1	1	1	1	1
	02	normal	NAD		1	1	1	1	1	1	1	1	1	1
	03	normal	NAD		1	1	1	1	1	1	1	1	1	1
	04	normal	NAD		1	1	1	1	1	1	1	1	1	1
	05	normal	NAD		1	1	1	1	1	1	1	1	1	1
	06	normal	NAD		1	1	1	1	1	1	1	1	1	1
	07	normal	NAD		1	1	1	1	1	1	1	1	1	1
	08	normal	NAD		1	1	1	1	1	1	1	1	1	1
	09	normal	NAD		1	1	1	1	1	1	1	1	1	1
	10	normal	NAD		1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day											
					60	60	60	61	61	61	62	62	62	62	62	62
	11	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
		respiration	sounds													
		fur	piloerection													
	12	mass	palpable through skin	Size: < 1.5 cm, Appearance: -, Location: axillary region, Directional terms: left												
1 / M	13	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
100 mg/kg		head	salivation	Grade: slight												
bw/d	14	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
	15	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
	16	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
	17	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
	18	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
	19	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
	20	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day											
					60	60	60	60	61	61	61	61	61	62	62	62
2 / M 300 mg/kg bw/d	21	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		feces	discolored feces	Color: light brown												
		feces	soft feces													
		normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
	22	feces	discolored feces	Color: light brown												
		feces	soft feces													
		normal	NAD			1										1
		head	salivation	Grade: moderate												
		feces	discolored feces	Grade: slight	1	1		1	1					1		
24	23	feces	discolored feces	Color: light brown												
		feces	soft feces													
		normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
		feces	discolored feces	Color: light brown												
	24	feces	soft feces													
		normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
		feces	discolored feces	Color: light brown												
		feces	soft feces													
25	25	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
		feces	discolored feces	Color: light brown												
		feces	soft feces													
		normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					60	60	60	61	61	61	62	62	62	62
26		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
27		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
28	2 / M 300 mg/kg bw/d	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight				1				1		
		feces	soft feces	Color: light brown										
29		respiration	sounds											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
30		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					60	60	60	61	61	61	62	62	62	62
3 / M 1000/600 mg/kg bw/d	31	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	32	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	33	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	34	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	35	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					60	60	60	61	61	61	62	62	62	62
3 / M 1000/600 mg/kg bw/d	36	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	37	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	38	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	39	normal	NAD											
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	40	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					63 [-01:00-00:00]	63 [00:00-02:00]	63 [02:00-05:00]	64 [-01:00-00:00]	64 [00:00-02:00]	64 [02:00-05:00]	65 [-01:00-00:00]	65 [00:00-02:00]	65 [02:00-05:00]	
0 / M 0 mg/kg bw/d	01	normal	NAD		1	1	1	1	1	1	1	1	1	1
	02	normal	NAD		1	1	1	1	1	1	1	1	1	1
	03	normal	NAD		1	1	1	1	1	1	1	1	1	1
	04	normal	NAD		1	1	1	1	1	1	1	1	1	1
	05	normal	NAD		1	1	1	1	1	1	1	1	1	1
	06	normal	NAD		1	1	1	1	1	1	1	1	1	1
	07	normal	NAD		1	1	1	1	1	1	1	1	1	1
	08	normal	NAD		1	1	1	1	1	1	1	1	1	1
	09	normal	NAD		1	1	1	1	1	1	1	1	1	1
	10	normal	NAD		1	1	1	1	1	1	1	1	1	1

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					63	63	63	64	64	64	65	65	65	65
	11	normal	NAD		1	1	1	1	1	1	1	1	1	1
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		respiration	sounds											
		fur	piloerection											
	12	mass	palpable through skin	Size: < 1.5 cm, Appearance: -, Location: axillary region, Directional terms: left										
1 / M	13	normal	NAD		1	1	1	1	1	1	1	1	1	1
100 mg/kg		head	salivation	Grade: slight										
bw/d	14	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	15	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	16	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	17	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	18	normal	NAD		1	1	1	1	1	1	1	1	1	1
	19	normal	NAD		1	1	1	1	1	1	1	1	1	1
	20	normal	NAD		1	1	1	1	1	1	1	1	1	1

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					63	63	63	64	64	64	65	65	65	65
2 / M 300 mg/kg bw/d	21	normal	NAD		1	1	1	1	1	1	1	1	1	1
		feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	22	feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD			1				1				1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight	1	1		1	1		1	1		
24	23	feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
	25	feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					63 [-01:00-00:00]	63 [00:00-02:00]	63 [02:00-05:00]	64 [-01:00-00:00]	64 [00:00-02:00]	64 [02:00-05:00]	65 [-01:00-00:00]	65 [00:00-02:00]	65 [02:00-05:00]	
	26	normal	NAD		1	1	1	1	1	1	1	1	1	
		head	salivation	Grade: slight								1		
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	27	normal	NAD		1	1	1	1	1	1	1	1	1	
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	28	normal	NAD		1	1	1	1	1	1	1	1	1	
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight		1			1			1		
		feces	soft feces	Color: light brown										
	29	respiration	sounds											
		normal	NAD		1	1	1	1	1	1	1	1	1	
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
	30	feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					63	63	63	64	64	64	65	65	65	65
3 / M 1000/600 mg/kg bw/d	31	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	32	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	33	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	34	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	35	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					63	63	63	64	64	64	65	65	65	65
3 / M 1000/600 mg/kg bw/d	36	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	37	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	38	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	39	normal	NAD											
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	40	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					66 [-01:00-00:00]	66 [00:00-02:00]	66 [02:00-05:00]	67 [-01:00-00:00]	67 [00:00-02:00]	67 [02:00-05:00]	68 [-01:00-00:00]	68 [00:00-02:00]	68 [02:00-05:00]	
0 / M 0 mg/kg bw/d	01	normal	NAD		1	1	1	1	1	1	1	1	1	1
	02	normal	NAD		1	1	1	1	1	1	1	1	1	1
	03	normal	NAD		1	1	1	1	1	1	1	1	1	1
	04	normal	NAD		1	1	1	1	1	1	1	1	1	1
	05	normal	NAD		1	1	1	1	1	1	1	1	1	1
	06	normal	NAD		1	1	1	1	1	1	1	1	1	1
	07	normal	NAD		1	1	1	1	1	1	1	1	1	1
	08	normal	NAD		1	1	1	1	1	1	1	1	1	1
	09	normal	NAD		1	1	1	1	1	1	1	1	1	1
	10	normal	NAD		1	1	1	1	1	1	1	1	1	1

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day							
					66 [00:00-00:00]	66 [00:00-02:00]	66 [02:00-05:00]	67 [00:00-02:00]	67 [01:00-00:00]	67 [02:00-05:00]	68 [00:00-02:00]	68 [02:00-05:00]
1 / M 100 mg/kg bw/d	11	normal	NAD		1	1	1	1	1	1	1	1
		normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		respiration	sounds									
		fur	piloerection									
	12	mass	palpable through skin	Size: < 1.5 cm, Appearance: -, Location: axillary region, Directional terms: left								
		normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
	13	normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		normal	NAD		1	1	1	1	1	1	1	1
	14	normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		normal	NAD		1	1	1	1	1	1	1	1
	15	normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		normal	NAD		1	1	1	1	1	1	1	1
	16	normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		normal	NAD		1	1	1	1	1	1	1	1
	17	normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		normal	NAD		1	1	1	1	1	1	1	1
	18	normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		normal	NAD		1	1	1	1	1	1	1	1
	19	normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		normal	NAD		1	1	1	1	1	1	1	1
	20	normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		normal	NAD		1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					66	66	66	67	67	67	67	68	68	68
21		normal	NAD		1	1	1	1	1	1	1	1	1	1
		feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
22		feces	soft feces											
		normal	NAD											
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD											
23		head	salivation	Grade: slight	1	1	1	1	1	1	1	1	1	1
		feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
24		feces	soft feces											
		normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
25		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day											
					66	66	66	66	67	67	67	67	68	68	68	68
26		normal	NAD		1				1				1			
		head	salivation	Grade: slight		1			1					1		
		feces	discolored feces	Color: light brown												
		feces	soft feces													
27		normal	NAD		1				1				1			
		head	salivation	Grade: slight												
		feces	discolored feces	Color: light brown												
		feces	soft feces													
28	2 / M 300 mg/kg bw/d	normal	NAD		1				1				1			
		head	salivation	Grade: moderate												
		feces	discolored feces	Grade: slight					1					1		
		feces	soft feces	Color: light brown												
29		respiration	sounds													
		normal	NAD		1				1				1			
		head	salivation	Grade: slight												
		feces	discolored feces	Color: light brown												
30		feces	soft feces													
		normal	NAD		1				1				1			
		head	salivation	Grade: slight												
		feces	discolored feces	Color: light brown												
		feces	soft feces													

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					66	66	66	67	67	67	68	68	68	68
3 / M 1000/600 mg/kg bw/d	31	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	32	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	33	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	34	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	35	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					66	66	66	66	67	67	67	67	68	68
3 / M 1000/600 mg/kg bw/d	36	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	37	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	38	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	39	normal	NAD											
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	40	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					69 [-01:00-00:00]	69 [00:00-02:00]	69 [02:00-05:00]	70 [-01:00-00:00]	70 [00:00-02:00]	70 [02:00-05:00]	71 [-01:00-00:00]	71 [00:00-02:00]	71 [02:00-05:00]	
0 / M 0 mg/kg bw/d	01	normal	NAD		1	1	1	1	1	1	1	1	1	
	02	normal	NAD		1	1	1	1	1	1	1	1	1	
	03	normal	NAD		1	1	1	1	1	1	1	1	1	
	04	normal	NAD		1	1	1	1	1	1	1	1	1	
	05	normal	NAD		1	1	1	1	1	1	1	1	1	
	06	normal	NAD		1	1	1	1	1	1	1	1	1	
	07	normal	NAD		1	1	1	1	1	1	1	1	1	
	08	normal	NAD		1	1	1	1	1	1	1	1	1	
	09	normal	NAD		1	1	1	1	1	1	1	1	1	
	10	normal	NAD		1	1	1	1	1	1	1	1	1	

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					69	69	69	70	70	70	70	71	71	71
					[01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[01:00-00:00]
1 / M 100 mg/kg bw/d	11	normal	NAD		1	1	1	1	1	1	1	1	1	1
		normal	NAD		1	1	1	1	1	1	1	1	1	1
	12	head	salivation	Grade: slight										
		respiration	sounds											
		fur	piloerection											
		mass	palpable through skin	Size: < 1.5 cm, Appearance: -, Location: axillary region, Directional terms: left										
	13	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	14	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	15	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	16	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	17	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	18	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	19	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	20	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					69	69	69	70	70	70	70	71	71	71
2 / M 300 mg/kg bw/d	21	normal	NAD		1	1	1	1	1	1	1	1	1	1
		feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	22	feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD			1				1				1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight	1	1	1	1	1	1	1	1	1	1
24	23	feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
	25	feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					69	69	69	70	70	70	71	71	71	71
26		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
27		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
28	2 / M 300 mg/kg bw/d	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight	1	1	1	1	1	1	1	1	1	1
		feces	soft feces	Color: light brown										
29		respiration	sounds											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
30		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day						
					69	69	69	70	70	70	71
3 / M 1000/600 mg/kg bw/d	31	normal	NAD								
		head	salivation	Grade: slight							
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1
		feces	soft feces								
	32	normal	NAD								
		head	salivation	Grade: slight							
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1
		feces	soft feces								
	33	normal	NAD								
		head	salivation	Grade: slight							
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1
		feces	soft feces								
	34	normal	NAD								
		head	salivation	Grade: slight							
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1
		feces	soft feces								
	35	normal	NAD								
		head	salivation	Grade: slight							
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1
		feces	soft feces								

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					69	69	69	70	70	70	70	71	71	71
3 / M 1000/600 mg/kg bw/d	36	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	37	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	38	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	39	normal	NAD											
		head	salivation	Grade: moderate	1									
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	40	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					72	72	72	73	73	73	74	74	74	74
	01	normal	NAD		1	1	1	1	1	1	1	1	1	1
	02	normal	NAD		1	1	1	1	1	1	1	1	1	1
	03	normal	NAD		1	1	1	1	1	1	1	1	1	1
	04	normal	NAD		1	1	1	1	1	1	1	1	1	1
	05	normal	NAD		1	1	1	1	1	1	1	1	1	1
	06	normal	NAD		1	1	1	1	1	1	1	1	1	1
	07	normal	NAD		1	1	1	1	1	1	1	1	1	1
	08	normal	NAD		1	1	1	1	1	1	1	1	1	1
	09	normal	NAD		1	1	1	1	1	1	1	1	1	1
	10	normal	NAD		1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day								
					72 [-01:00-00:00]	72 [00:00-02:00]	72 [02:00-05:00]	73 [-01:00-00:00]	73 [00:00-02:00]	73 [02:00-05:00]	74 [-01:00-00:00]	74 [00:00-02:00]	74 [02:00-05:00]
	11	normal	NAD		1	1	1	1	1	1	1	1	1
		normal	NAD		1	1	1	1	1	1	1	1	1
		head respiration	salivation sounds	Grade: slight									
		fur	piloerection										
	12	mass	palpable through skin	Size: < 1.5 cm, Appearance: -, Location: axillary region, Directional terms: left									
1 / M 100 mg/kg bw/d	13	normal	NAD		1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight									
	14	normal	NAD		1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight									
	15	normal	NAD		1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight									
	16	normal	NAD		1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight									
	17	normal	NAD		1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight									
	18	normal	NAD		1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight									
	19	normal	NAD		1	1	1	1	1	1	1	1	1
	20	normal	NAD		1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					72	72	72	73	73	73	74	74	74	74
2 / M 300 mg/kg bw/d	21	normal	NAD		1	1	1	1	1	1	1	1	1	1
		feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight		1								
	22	feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD			1				1				1
		head	salivation	Grade: moderate		1								
		feces	discolored feces	Grade: slight	1		1	1			1		1	
24	23	feces	soft feces	Color: light brown										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	25	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight		1				1			1	
		feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day							
					72	72	72	73	73	73	74	74
26		normal	NAD		1			1		1		
		head	salivation	Grade: slight		1			1			1
		feces	discolored feces	Color: light brown								
		feces	soft feces									
27		normal	NAD		1			1		1		
		head	salivation	Grade: slight								1
		feces	discolored feces	Color: light brown								
		feces	soft feces									
28	2 / M 300 mg/kg bw/d	normal	NAD		1			1		1		
		head	salivation	Grade: moderate					1			1
		feces	discolored feces	Color: light brown								
		feces	soft feces									
29		respiration	normal									
		head	salivation	Grade: slight	1			1		1		1
		feces	discolored feces	Color: light brown								
		feces	soft feces									
30		normal	NAD		1			1		1		
		head	salivation	Grade: slight					1			1
		feces	discolored feces	Color: light brown								
		feces	soft feces									

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					72	72	72	73	73	73	74	74	74	74
3 / M 1000/600 mg/kg bw/d	31	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	32	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	33	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	34	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	35	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					72	72	72	73	73	73	74	74	74	74
3 / M 1000/600 mg/kg bw/d	36	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	37	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	38	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	39	normal	NAD											
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	40	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					75 [-01:00-00:00]	75 [00:00-02:00]	75 [02:00-05:00]	76 [-01:00-00:00]	76 [00:00-02:00]	76 [02:00-05:00]	77 [-01:00-00:00]	77 [00:00-02:00]	77 [02:00-05:00]	
0 / M 0 mg/kg bw/d	01	normal	NAD		1	1	1	1	1	1	1	1	1	1
	02	normal	NAD		1	1	1	1	1	1	1	1	1	1
	03	normal	NAD		1	1	1	1	1	1	1	1	1	1
	04	normal	NAD		1	1	1	1	1	1	1	1	1	1
	05	normal	NAD		1	1	1	1	1	1	1	1	1	1
	06	normal	NAD		1	1	1	1	1	1	1	1	1	1
	07	normal	NAD		1	1	1	1	1	1	1	1	1	1
	08	normal	NAD		1	1	1	1	1	1	1	1	1	1
	09	normal	NAD		1	1	1	1	1	1	1	1	1	1
	10	normal	NAD		1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					75 [-01:00-00:00]	75 [00:00-02:00]	75 [02:00-05:00]	76 [-01:00-00:00]	76 [00:00-02:00]	76 [02:00-05:00]	77 [-01:00-00:00]	77 [00:00-02:00]	77 [02:00-05:00]	
1 / M 100 mg/kg bw/d	11	normal	NAD		1	1	1	1	1	1	1	1	1	1
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		respiration	sounds											
		fur	piloerection											
	12	mass	palpable through skin	Size: < 1.5 cm, Appearance: -, Location : axillary region, Directional terms: left										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	14	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	15	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	16	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	17	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	18	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	19	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	20	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					75	75	75	76	76	76	77	77	77	77
	21	normal feces	NAD		1	1	1	1	1	1	1	1	1	1
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	22	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
2 / M	23	feces	discolored feces	Grade: slight										
300 mg/kg		feces	soft feces	Color: light brown										
bw/d		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	25	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					75	75	75	76	76	76	77	77	77	77
	26	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	27	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
2 / M 300 mg/kg bw/d	28	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight										
		feces	soft feces	Color: light brown										
	29	respiration	sounds											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
	30	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					75	75	75	76	76	76	77	77	77	77
3 / M 1000/600 mg/kg bw/d	31	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	32	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	33	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	34	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	35	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					75	75	75	76	76	76	77	77	77	77
3 / M 1000/600 mg/kg bw/d	36	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	37	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	38	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	39	normal	NAD											
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	40	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					78	78	78	79	79	79	80	80	80	80
	01	normal	NAD		1	1	1	1	1	1	1	1	1	1
	02	normal	NAD		1	1	1	1	1	1	1	1	1	1
	03	normal	NAD		1	1	1	1	1	1	1	1	1	1
	04	normal	NAD		1	1	1	1	1	1	1	1	1	1
	05	normal	NAD		1	1	1	1	1	1	1	1	1	1
	06	normal	NAD		1	1	1	1	1	1	1	1	1	1
	07	normal	NAD		1	1	1	1	1	1	1	1	1	1
	08	normal	NAD		1	1	1	1	1	1	1	1	1	1
	09	normal	NAD		1	1	1	1	1	1	1	1	1	1
	10	normal	NAD		1	1	1	1	1	1	1	1	1	1

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					78	78	78	78	79	79	79	80	80	80
					[01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[01:00-00:00]
1 / M 100 mg/kg bw/d	11	normal	NAD		1	1	1	1	1	1	1	1	1	1
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		respiration	sounds											
		fur	piloerection											
	12	mass	palpable through skin	Size: < 1.5 cm, Appearance: -, Location: axillary region, Directional terms: left										
	13	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	14	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	15	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	16	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	17	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	18	normal	NAD		1	1	1	1	1	1	1	1	1	1
	19	normal	NAD		1	1	1	1	1	1	1	1	1	1
	20	normal	NAD		1	1	1	1	1	1	1	1	1	1

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					78	78	78	79	79	79	80	80	80	80
2 / M 300 mg/kg bw/d	21	normal	NAD		1	1	1	1	1	1	1	1	1	1
		feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
	22	head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
	23	head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight										
		feces	soft feces	Color: light brown										
		normal	NAD		1	1	1	1	1	1	1	1	1	1
24	head	salivation	Grade: slight											
		feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
	feces	salivation	Grade: slight											
		feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
25	head	salivation	Grade: slight											
		feces	discolored feces	Color: light brown										
	feces	salivation	Grade: slight											
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					78	78	78	79	79	79	80	80	80	80
		normal	NAD		1	1	1	1	1	1	1	1	1	1
	26	head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
	27	head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
		respiration	sounds											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
	28	head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
		respiration	sounds											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
	29	head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
	30	head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day							
					78	78	78	79	79	79	80	80
3 / M 1000/600 mg/kg bw/d	31	normal	NAD									
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1
		feces	soft feces									
	32	normal	NAD									
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1
		feces	soft feces									
	33	normal	NAD									
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1
		feces	soft feces									
	34	normal	NAD									
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1
		feces	soft feces									
	35	normal	NAD									
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1
		feces	soft feces									

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day							
					78	78	78	79	79	79	80	80
3 / M 1000/600 mg/kg bw/d	36	normal	NAD									
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1
		feces	soft feces									
	37	normal	NAD									
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1
		feces	soft feces									
	38	normal	NAD									
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1
		feces	soft feces									
	39	normal	NAD									
		head	salivation	Grade: moderate								
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1
		feces	soft feces									
40		normal	NAD									
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1
		feces	soft feces									

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					81 [-01:00-00:00]	81 [00:00-02:00]	81 [02:00-05:00]	82 [-01:00-00:00]	82 [00:00-02:00]	82 [02:00-05:00]	83 [-01:00-00:00]	83 [00:00-02:00]	83 [02:00-05:00]	
0 / M 0 mg/kg bw/d	01	normal	NAD		1	1	1	1	1	1	1	1	1	1
	02	normal	NAD		1	1	1	1	1	1	1	1	1	1
	03	normal	NAD		1	1	1	1	1	1	1	1	1	1
	04	normal	NAD		1	1	1	1	1	1	1	1	1	1
	05	normal	NAD		1	1	1	1	1	1	1	1	1	1
	06	normal	NAD		1	1	1	1	1	1	1	1	1	1
	07	normal	NAD		1	1	1	1	1	1	1	1	1	1
	08	normal	NAD		1	1	1	1	1	1	1	1	1	1
	09	normal	NAD		1	1	1	1	1	1	1	1	1	1
	10	normal	NAD		1	1	1	1	1	1	1	1	1	1

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					81 [00:00-02:00]	81 [02:00-05:00]	82 [00:00-02:00]	82 [02:00-05:00]	83 [00:00-02:00]	83 [02:00-05:00]	83 [00:00-02:00]	83 [02:00-05:00]	83 [00:00-02:00]	83 [02:00-05:00]
1 / M 100 mg/kg bw/d	11	normal	NAD		1	1	1	1	1	1	1	1	1	1
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		respiration	sounds		1				1		1		1	1
		fur	piloerection											1
	12	mass	palpable through skin	Size: < 1.5 cm, Appearance: -, Location: axillary region, Directional terms: left					1		1		1	1
	13	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	14	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	15	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	16	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	17	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	18	normal	NAD		1	1	1	1	1	1	1	1	1	1
	19	normal	NAD		1	1	1	1	1	1	1	1	1	1
	20	normal	NAD		1	1	1	1	1	1	1	1	1	1

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					81	81	81	81	82	82	82	83	83	83
2 / M 300 mg/kg bw/d	21	normal	NAD		1	1	1	1	1	1	1	1	1	1
		feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	22	feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight								1		
24	23	feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
	25	feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					81 [-01:00-00:00]	81 [00:00-02:00]	81 [02:00-05:00]	82 [-01:00-00:00]	82 [00:00-02:00]	82 [02:00-05:00]	83 [-01:00-00:00]	83 [00:00-02:00]	83 [02:00-05:00]	
	26	normal	NAD		1	1	1	1	1	1				1
		head	salivation	Grade: slight									1	
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	27	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	28	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight	1				1					
		feces	soft feces	Color: light brown										
	29	respiration	sounds											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
	30	feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					81 [-01:00-00:00]	81 [00:00-02:00]	81 [02:00-05:00]	82 [-01:00-00:00]	82 [00:00-02:00]	82 [02:00-05:00]	83 [-01:00-00:00]	83 [00:00-02:00]	83 [02:00-05:00]	
31		normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces									1	1	
32		normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces									1	1	
33		normal	NAD											
		head	salivation	Grade: slight					1					
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces									1	1	
34		normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces									1	1	
35		normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces									1	1	

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day							
					81 [00:00-02:00]	81 [02:00-05:00]	82 [00:00-02:00]	82 [02:00-05:00]	83 [00:00-02:00]	83 [02:00-05:00]	83 [00:00-02:00]	83 [02:00-05:00]
36		normal	NAD									
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1
		feces	soft feces								1	1
37		normal	NAD									
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1
		feces	soft feces								1	1
38		normal	NAD									
		head	salivation	Grade: slight							1	
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1
		feces	soft feces								1	1
39		normal	NAD									
		head	salivation	Grade: moderate								
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1
		feces	soft feces								1	1
40		normal	NAD									
		head	salivation	Grade: slight							1	
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1
		feces	soft feces								1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					84 [-01:00-00:00]	84 [00:00-02:00]	84 [02:00-05:00]	85 [-01:00-00:00]	85 [00:00-02:00]	85 [02:00-05:00]	86 [-01:00-00:00]	86 [00:00-02:00]	86 [02:00-05:00]	
0 / M 0 mg/kg bw/d	01	normal	NAD		1	1	1	1	1	1	1	1	1	1
	02	normal	NAD		1	1	1	1	1	1	1	1	1	1
	03	normal	NAD		1	1	1	1	1	1	1	1	1	1
	04	normal	NAD		1	1	1	1	1	1	1	1	1	1
	05	normal	NAD		1	1	1	1	1	1	1	1	1	1
	06	normal	NAD		1	1	1	1	1	1	1	1	1	1
	07	normal	NAD		1	1	1	1	1	1	1	1	1	1
	08	normal	NAD		1	1	1	1	1	1	1	1	1	1
	09	normal	NAD		1	1	1	1	1	1	1	1	1	1
	10	normal	NAD		1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					84	84	84	85	85	85	86	86	86	86
	11	normal	NAD		1	1	1	1	1	1	1	1	1	1
		normal	NAD											
		head	salivation	Grade: slight	1	1	1	1	1	1				
		respiration	sounds		1	1	1	1	1	1				
		fur	piloerection		1	1	1	1	1	1				
	12			Size: < 1.5 cm, Appearance: -, palpable through skin Location: axillary region, Directional terms: left	1	1	1	1	1	1	1	1	1	1
1 / M	13	normal	NAD		1	1	1	1	1	1	1	1	1	1
100 mg/kg		head	salivation	Grade: slight	1	1	1	1	1	1				
bw/d	14	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight	1	1	1	1	1	1				
	15	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight	1	1	1	1	1	1				
	16	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight	1	1	1	1	1	1				
	17	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight	1	1	1	1	1	1				
	18	normal	NAD		1	1	1	1	1	1	1	1	1	1
	19	normal	NAD		1	1	1	1	1	1	1	1	1	1
	20	normal	NAD		1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					84 [-01:00-00:00]	84 [00:00-02:00]	84 [02:00-05:00]	85 [-01:00-00:00]	85 [00:00-02:00]	85 [02:00-05:00]	86 [-01:00-00:00]	86 [00:00-02:00]	86 [02:00-05:00]	
21		normal	NAD		1	1	1	1	1	1	1	1	1	1
		feces	discolored feces	Color: light brown										
		feces	soft feces		1	1	1	1	1	1	1	1	1	
		normal	NAD		1									
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown		1	1	1	1	1	1	1	1	
22		feces	soft feces		1	1	1	1	1	1	1	1	1	
		normal	NAD		1									
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown		1	1	1	1	1	1	1		
		feces	soft feces			1	1	1	1	1	1	1		
		normal	NAD		1									
23	2 / M 300 mg/kg pow/d	head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown		1	1	1	1	1	1	1	1	
		feces	soft feces		1	1	1	1	1	1	1	1		
		normal	NAD		1									
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown		1	1	1	1	1	1	1		
24		normal	NAD		1									
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown		1	1	1	1	1	1	1		
		feces	soft feces		1	1	1	1	1	1	1	1		
		normal	NAD		1									
		head	salivation	Grade: slight										
25		feces	discolored feces	Color: light brown		1	1	1	1	1	1	1	1	
		feces	soft feces		1	1	1	1	1	1	1	1		
		normal	NAD		1									
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown		1	1	1	1	1	1	1		
		feces	soft feces		1	1	1	1	1	1	1	1		

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					84 [00:00-00:00]	84 [00:00-02:00]	84 [02:00-05:00]	85 [00:00-02:00]	85 [02:00-05:00]	85 [00:00-02:00]	85 [02:00-05:00]	86 [00:00-02:00]	86 [02:00-05:00]	86 [00:00-02:00]
26		normal	NAD		1									
		head	salivation	Grade: slight		1						1		
		feces	discolored feces	Color: light brown		1	1	1	1	1	1	1	1	1
		feces	soft feces			1	1	1	1	1	1	1	1	1
27		normal	NAD		1									
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown		1	1	1	1	1	1	1	1	1
		feces	soft feces			1	1	1	1	1	1	1	1	1
28		normal	NAD											
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown		1	1	1	1	1	1	1	1	1
		feces	soft feces			1	1	1	1	1	1	1	1	1
29		normal	NAD		1									
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown		1	1	1	1	1	1	1	1	1
		feces	soft feces			1	1	1	1	1	1	1	1	1
30		normal	NAD		1									
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown		1	1	1	1	1	1	1	1	1
		feces	soft feces			1	1	1	1	1	1	1	1	1

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					84	84	84	85	85	85	86	86	86	86
3 / M 1000/600 mg/kg bw/d	31	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1
	32	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1
	33	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1
	34	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1
	35	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					84 [00:00-02:00]	84 [02:00-05:00]	85 [01:00-00:00]	85 [00:00-02:00]	85 [02:00-05:00]	86 [01:00-00:00]	86 [00:00-02:00]	86 [02:00-05:00]		
36		normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	
		feces	soft feces		1	1	1	1	1	1	1	1	1	
37		normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	
		feces	soft feces		1	1	1	1	1	1	1	1	1	
38		normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	
		feces	soft feces		1	1	1	1	1	1	1	1	1	
39		normal	NAD											
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight										
		feces	soft feces	Color: light brown	1	1	1	1	1	1	1	1	1	
40		normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	
		feces	soft feces		1	1	1	1	1	1	1	1	1	

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					87 [-01:00-00:00]	87 [00:00-02:00]	87 [02:00-05:00]	88 [-01:00-00:00]	88 [00:00-02:00]	88 [02:00-05:00]	89 [-01:00-00:00]	89 [00:00-02:00]	89 [02:00-05:00]	
0 / M 0 mg/kg bw/d	01	normal	NAD		1	1	1	1	1	1	1	1	1	1
	02	normal	NAD		1	1	1	1	1	1	1	1	1	1
	03	normal	NAD		1	1	1	1	1	1	1	1	1	1
	04	normal	NAD		1	1	1	1	1	1	1	1	1	1
	05	normal	NAD		1	1	1	1	1	1	1	1	1	1
	06	normal	NAD		1	1	1	1	1	1	1	1	1	1
	07	normal	NAD		1	1	1	1	1	1	1	1	1	1
	08	normal	NAD		1	1	1	1	1	1	1	1	1	1
	09	normal	NAD		1	1	1	1	1	1	1	1	1	1
	10	normal	NAD		1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					87	87	87	88	88	88	89	89	89	89
	11	normal	NAD		1	1	1	1	1	1	1	1	1	1
		normal	NAD											
		head	salivation	Grade: slight										
		respiration	sounds											
		fur	piloerection											
	12	mass	palpable through skin	Size: < 1.5 cm, Appearance: -, Location: axillary region, Directional terms: left	1	1	1							
1 / M	13	normal	NAD		1	1	1	1	1	1	1	1	1	1
100 mg/kg		head	salivation	Grade: slight										
bw/d	14	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	15	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	16	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	17	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	18	normal	NAD		1	1	1	1	1	1	1	1	1	1
	19	normal	NAD		1	1	1	1	1	1	1	1	1	1
	20	normal	NAD		1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					87 [00:00-02:00]	87 [02:00-05:00]	87 [01:00-00:00]	88 [00:00-02:00]	88 [02:00-05:00]	89 [01:00-00:00]	89 [00:00-02:00]	89 [02:00-05:00]		
2 / M 300 mg/kg bw/d	21	normal	NAD											
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1		
		feces	soft feces		1	1	1	1	1	1	1	1		
		normal	NAD											
		head	salivation	Grade: slight										
	22	feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1		
		feces	soft feces		1	1	1	1	1	1	1	1		
		normal	NAD											
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight	1	1	1	1	1	1	1	1		
24	23	feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1		
		feces	soft feces		1	1	1	1	1	1	1	1		
		normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1		
	25	feces	soft feces		1	1	1	1	1	1	1	1		
		normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1		
		feces	soft feces		1	1	1	1	1	1	1	1		

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day											
					87	87	87	88	88	88	89	89	89	89	89	89
	26	normal	NAD													
		head	salivation	Grade: slight												
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1	1	1
	27	normal	NAD													
		head	salivation	Grade: slight												
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1	1	1
2 / M 300 mg/kg bw/d		normal	NAD													
		head	salivation	Grade: moderate												
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1	1	1
	29	respiration	normal		1	1	1									
		head	salivation	Grade: slight												
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1	1	1
	30	normal	NAD													
		head	salivation	Grade: slight												
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					87	87	87	88	88	88	89	89	89	89
3 / M 1000/600 mg/kg bw/d	31	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1
	32	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1
	33	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1
	34	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1
	35	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					87 [01:00-00:00]	87 [00:00-02:00]	87 [02:00-05:00]	88 [01:00-00:00]	88 [00:00-02:00]	88 [02:00-05:00]	89 [01:00-00:00]	89 [00:00-02:00]	89 [02:00-05:00]	
36	normal	NAD												
	head	salivation	Grade: slight											
	feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1	1
	feces	soft feces		1	1	1	1	1	1	1	1	1	1	1
	normal	NAD												
	head	salivation	Grade: slight											
37	feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1	1
	feces	soft feces		1	1	1	1	1	1	1	1	1	1	1
	normal	NAD												
	head	salivation	Grade: slight											
	feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1	1
	feces	soft feces		1	1	1	1	1	1	1	1	1	1	1
38	normal	NAD												
	head	salivation	Grade: slight											
	feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1	1
	feces	soft feces		1	1	1	1	1	1	1	1	1	1	1
	normal	NAD												
	head	salivation	Grade: moderate											
39	feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1	1
	feces	soft feces		1	1	1	1	1	1	1	1	1	1	1
	normal	NAD												
	head	salivation	Grade: slight											
	feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1	1
	feces	soft feces		1	1	1	1	1	1	1	1	1	1	1
40	normal	NAD												
	head	salivation	Grade: slight											
	feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1	1
	feces	soft feces		1	1	1	1	1	1	1	1	1	1	1
	normal	NAD												
	head	salivation	Grade: slight											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day				
					90 [-01:00-00:00]	90 [00:00-02:00]	90 [02:00-05:00]	91 [01:00-00:00]	91 [00:00-02:00]
0 / M 0 mg/kg bw/d	01	normal	NAD		1	1	1	1	1
	02	normal	NAD		1	1	1	1	1
	03	normal	NAD		1	1	1	1	1
	04	normal	NAD		1	1	1	1	1
	05	normal	NAD		1	1	1	1	1
	06	normal	NAD		1	1	1	1	1
	07	normal	NAD		1	1	1	1	1
	08	normal	NAD		1	1	1	1	1
	09	normal	NAD		1	1	1	1	1
	10	normal	NAD		1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day					
					90 [-01:00-00:00]	90 [00:00-02:00]	90 [02:00-05:00]	91 [-01:00-00:00]	91 [00:00-02:00]	91 [02:00-05:00]
1 / M 100 mg/kg bw/d	11	normal	NAD		1	1	1	1	1	1
		normal	NAD		1	1	1	1	1	1
		head	salivation	Grade: slight						
		respiration	sounds							
		fur	pileorection							
	12	mass	palpable through skin	Size: < 1.5 cm, Appearance: -, Location: axillary region, Directional terms: left						
	13	normal	NAD		1	1	1	1	1	1
		head	salivation	Grade: slight		1			1	
	14	normal	NAD		1	1	1	1	1	1
		head	salivation	Grade: slight						
	15	normal	NAD		1	1	1	1	1	1
		head	salivation	Grade: slight						
	16	normal	NAD		1	1	1	1	1	1
		head	salivation	Grade: slight						
	17	normal	NAD		1	1	1	1	1	1
		head	salivation	Grade: slight		1				
	18	normal	NAD		1	1	1	1	1	1
	19	normal	NAD		1	1	1	1	1	1
	20	normal	NAD		1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day						
					90 [-01:00-00:00]	90 [00:00-02:00]	90 [02:00-05:00]	91 [-01:00-00:00]	91 [00:00-02:00]	91 [02:00-05:00]	
2 / M 300 mg/kg bowl/d	21	normal	NAD								
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	
		feces	soft feces		1	1	1	1	1	1	
		normal	NAD								
	22	head	salivation	Grade: slight							
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1
		normal	NAD								
	23	head	salivation	Grade: moderate		1			1		
		feces	discolored feces	Grade: slight	1	1	1	1	1	1	1
		feces	soft feces	Color: light brown	1	1	1	1	1	1	1
		normal	NAD								
24	head	salivation	Grade: slight								
	feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	
	feces	soft feces		1	1	1	1	1	1	1	
	normal	NAD									
25	head	salivation	Grade: slight						1		
	feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	
	feces	soft feces		1	1	1	1	1	1	1	
	normal	NAD									

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day					
					90 [-01:00-00:00]	90 [00:00-02:00]	90 [02:00-05:00]	91 [-01:00-00:00]	91 [00:00-02:00]	91 [02:00-05:00]
2 / M 300 mg/kg bwd	26	normal	NAD							
		head	salivation	Grade: slight						
		feces	discolored feces	Color: light brown	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1
		normal	NAD							
		head	salivation	Grade: slight						
	27	feces	discolored feces	Color: light brown	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1
		normal	NAD							
		head	salivation	Grade: moderate						
		feces	discolored feces	Grade: slight						
		feces	soft feces	Color: light brown	1	1	1	1	1	1
28	respiration	sounds								
	normal	NAD								
	head	salivation	Grade: slight							
	feces	discolored feces	Color: light brown	1	1	1	1	1	1	
	feces	soft feces		1	1	1	1	1	1	
	feces	soft feces		1	1	1	1	1	1	
29	normal	NAD								
	head	salivation	Grade: slight							
	feces	discolored feces	Color: light brown	1	1	1	1	1	1	
	feces	soft feces		1	1	1	1	1	1	
	normal	NAD								
	head	salivation	Grade: slight							
30	feces	discolored feces	Color: light brown	1	1	1	1	1	1	
	feces	soft feces		1	1	1	1	1	1	
	normal	NAD								
	head	salivation	Grade: slight							
	feces	discolored feces	Color: light brown	1	1	1	1	1	1	
	feces	soft feces		1	1	1	1	1	1	

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day				
					90 [-01:00-00:00]	90 [00:00-02:00]	90 [02:00-05:00]	91 [01:00-00:00]	91 [00:00-02:00]
3 / M 1000/600 mg/kg bw/d	31	normal	NAD						
		head	salivation	Grade: slight					
		feces	discolored feces	Color: light brown	1	1	1	1	1
		feces	soft feces		1	1	1	1	1
		normal	NAD						
		head	salivation	Grade: slight					
	32	feces	discolored feces	Color: light brown	1	1	1	1	1
		feces	soft feces		1	1	1	1	1
		normal	NAD						
		head	salivation	Grade: slight					
		feces	discolored feces	Color: light brown	1	1	1	1	1
		feces	soft feces		1	1	1	1	1
3 / M 1000/600 mg/kg bw/d	33	normal	NAD						
		head	salivation	Grade: slight					
		feces	discolored feces	Color: light brown	1	1	1	1	1
		feces	soft feces		1	1	1	1	1
		normal	NAD						
		head	salivation	Grade: slight					
	34	feces	discolored feces	Color: light brown	1	1	1	1	1
		feces	soft feces		1	1	1	1	1
		normal	NAD						
		head	salivation	Grade: slight					
		feces	discolored feces	Color: light brown	1	1	1	1	1
		feces	soft feces		1	1	1	1	1
35	35	normal	NAD						
		head	salivation	Grade: slight					
		feces	discolored feces	Color: light brown	1	1	1	1	1
		feces	soft feces		1	1	1	1	1
		normal	NAD						
		head	salivation	Grade: slight					

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day				
					90 [-01:00-00:00]	90 [00:00-02:00]	90 [02:00-05:00]	91 [-01:00-00:00]	91 [00:00-02:00]
3 / M 1000/600 mg/kg bw/d	36	normal	NAD						
		head	salivation	Grade: slight					
		feces	discolored feces	Color: light brown	1	1	1	1	1
		feces	soft feces		1	1	1	1	1
	37	normal	NAD						
		head	salivation	Grade: slight					
		feces	discolored feces	Color: light brown	1	1	1	1	1
		feces	soft feces		1	1	1	1	1
	38	normal	NAD						
		head	salivation	Grade: slight					
		feces	discolored feces	Color: light brown	1	1	1	1	1
		feces	soft feces		1	1	1	1	1
	39	normal	NAD						
		head	salivation	Grade: moderate					
		feces	discolored feces	Grade: slight					
		feces	soft feces	Color: light brown	1	1	1	1	1
	40	normal	NAD						
		head	salivation	Grade: slight					
		feces	discolored feces	Color: light brown	1	1	1	1	1
		feces	soft feces		1	1	1	1	1
		normal	NAD						
		head	salivation	Grade: slight					
		feces	discolored feces	Color: light brown	1	1	1	1	1
		feces	soft feces		1	1	1	1	1

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					0	0	0	0	1	1	1	1	2	2
					[00:00-02:00]	[00:00-02:00]	[02:00-05:00]	[02:00-05:00]	[-01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[-01:00-00:00]	[00:00-02:00]	[02:00-05:00]
0 / F 0 mg/kg bw/d	41	normal	NAD		1	1	1	1	1	1	1	1	1	1
	42	normal	NAD		1	1	1	1	1	1	1	1	1	1
	43	normal	NAD		1	1	1	1	1	1	1	1	1	1
	44	normal	NAD		1	1	1	1	1	1	1	1	1	1
	45	normal	NAD		1	1	1	1	1	1	1	1	1	1
	46	normal	NAD		1	1	1	1	1	1	1	1	1	1
	47	normal	NAD		1	1	1	1	1	1	1	1	1	1
	48	normal	NAD		1	1	1	1	1	1	1	1	1	1
	49	normal	NAD		1	1	1	1	1	1	1	1	1	1
	50	normal	NAD		1	1	1	1	1	1	1	1	1	1

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					0	0	0	0	1	1	1	1	2	2
					[00:00-02:00]	[00:00-02:00]	[02:00-05:00]	[01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[01:00-00:00]	[00:00-02:00]	[00:00-02:00]	[02:00-05:00]
1 / F 100 mg/kg bwd	51	normal head	NAD	Grade: slight	1	1	1	1	1	1	1	1	1	1
	52	normal head	NAD	Grade: slight	1	1	1	1	1	1	1	1	1	1
	53	normal head	NAD	Grade: slight	1	1	1	1	1	1	1	1	1	1
	54	normal	NAD		1	1	1	1	1	1	1	1	1	1
	55	normal	NAD		1	1	1	1	1	1	1	1	1	1
	56	normal	NAD		1	1	1	1	1	1	1	1	1	1
	57	normal head	NAD	Grade: slight	1	1	1	1	1	1	1	1	1	1
	58	normal	NAD		1	1	1	1	1	1	1	1	1	1
	59	normal	NAD		1	1	1	1	1	1	1	1	1	1
	60	normal	NAD		1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					0	0	0	0	1	1	1	2	2	2
2 / F 300 mg/kg bw/d	61	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	62	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	63	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	64	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	65	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					0	0	0	0	1	1	1	1	2	2
					[00:00-01:00]	[00:00-02:00]	[02:00-05:00]	[02:00-05:00]	[-01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[02:00-05:00]	[00:00-02:00]	[02:00-05:00]
66		normal	NAD		1		1		1	1	1		1	1
		head	salivation	Grade: moderate										
				Grade: slight										
		feces	discolored feces	Color: light brown										
67		feces	soft feces											
		normal	NAD		1		1		1	1	1		1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
68		feces	soft feces											
		normal	NAD		1		1		1	1	1		1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight										
69		feces	soft feces	Color: light brown										
		normal	NAD		1		1		1	1	1		1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
70		feces	soft feces											
		normal	NAD		1		1		1	1	1		1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
2 / F 300 mg/kg bw/d		feces	soft feces											
		normal	NAD		1		1		1	1	1		1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					0	0	0	0	1	1	1	2	2	2
					[00:00-02:00]	[00:00-02:00]	[02:00-05:00]	[01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[01:00-00:00]	[00:00-02:00]	[00:00-02:00]	[02:00-05:00]
3 / F 1000 mg/kg bw/d	71	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	72	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight										
		feces	soft feces	Color: light brown										
	73	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	74	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	75	normal	NAD		1	1	1	1	1	1	1	1	1	1
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					0	0	0	0	1	1	1	2	2	2
					[00:00-02:00]	[00:00-02:00]	[02:00-05:00]	[02:00-05:00]	[-01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[-01:00-00:00]	[00:00-02:00]	[02:00-05:00]
3 / F 1000 mg/kg bw/d	76	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	77	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	78	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	79	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight										
		feces	soft feces	Color: light brown										
	80	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					3	3	3	3	4	4	4	4	5	5
					[01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[-01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[-01:00-00:00]	[00:00-02:00]	[01:00-00:00]	[02:00-05:00]
0 / F 0 mg/kg bw/d	41	normal	NAD		1	1	1	1	1	1	1	1	1	1
	42	normal	NAD		1	1	1	1	1	1	1	1	1	1
	43	normal	NAD		1	1	1	1	1	1	1	1	1	1
	44	normal	NAD		1	1	1	1	1	1	1	1	1	1
	45	normal	NAD		1	1	1	1	1	1	1	1	1	1
	46	normal	NAD		1	1	1	1	1	1	1	1	1	1
	47	normal	NAD		1	1	1	1	1	1	1	1	1	1
	48	normal	NAD		1	1	1	1	1	1	1	1	1	1
	49	normal	NAD		1	1	1	1	1	1	1	1	1	1
	50	normal	NAD		1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					3	3	3	3	4	4	4	4	5	5
					[01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[02:00-05:00]	[01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[02:00-05:00]	[01:00-00:00]	[00:00-02:00]
1 / F 100 mg/kg bwd	51	normal head	NAD salivation	Grade: slight	1	1	1	1	1	1	1	1	1	1
	52	normal head	NAD salivation	Grade: slight	1	1	1	1	1	1	1	1	1	1
	53	normal head	NAD salivation	Grade: slight	1	1	1	1	1	1	1	1	1	1
	54	normal	NAD		1	1	1	1	1	1	1	1	1	1
	55	normal	NAD		1	1	1	1	1	1	1	1	1	1
	56	normal	NAD		1	1	1	1	1	1	1	1	1	1
	57	normal head	NAD salivation	Grade: slight	1	1	1	1	1	1	1	1	1	1
	58	normal	NAD		1	1	1	1	1	1	1	1	1	1
	59	normal	NAD		1	1	1	1	1	1	1	1	1	1
	60	normal	NAD		1	1	1	1	1	1	1	1	1	1

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					3	3	3	3	4	4	4	4	5	5
61		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
62		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
63		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
64		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
65		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

2 / F
300 mg/kg
bw/d

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					3	3	3	3	4	4	4	4	5	5
66		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight										
		feces	soft feces	Color: light brown										
67		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
68		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight										
		feces	soft feces	Color: light brown										
69		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
70		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					3	3	3	3	4	4	4	4	5	5
3 / F 1000 mg/kg bw/d	71	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	72	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight										
		feces	soft feces	Color: light brown										
	73	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	74	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	75	normal	NAD		1	1	1	1	1	1	1	1	1	1
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					3	3	3	3	4	4	4	4	5	5
3 / F 1000 mg/kg bw/d	76	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
	77	feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	78	feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
	79	head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight										
		feces	soft feces	Color: light brown										
80		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day								
					6 [-01:00-00:00]	6 [00:00-02:00]	6 [02:00-05:00]	7 [-01:00-00:00]	7 [00:00-02:00]	7 [02:00-05:00]	8 [-01:00-00:00]	8 [00:00-02:00]	8 [02:00-05:00]
0 / F 0 mg/kg bw/d	41	normal	NAD		1	1	1		1	1	1	1	1
	42	normal	NAD		1	1	1		1	1	1	1	1
	43	normal	NAD		1	1	1		1	1	1	1	1
	44	normal	NAD		1	1	1		1	1	1	1	1
	45	normal	NAD		1	1	1		1	1	1	1	1
	46	normal	NAD		1	1	1		1	1	1	1	1
	47	normal	NAD		1	1	1		1	1	1	1	1
	48	normal	NAD		1	1	1		1	1	1	1	1
	49	normal	NAD		1	1	1		1	1	1	1	1
	50	normal	NAD		1	1	1		1	1	1	1	1

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day								
					6 [-01:00-00:00]	6 [00:00-02:00]	6 [02:00-05:00]	7 [-01:00-00:00]	7 [00:00-02:00]	7 [02:00-05:00]	8 [-01:00-00:00]	8 [00:00-02:00]	8 [02:00-05:00]
1 / F 100 mg/kg bwd	51	normal head	NAD salivation	Grade: slight	1	1	1		1	1	1	1	1
	52	normal head	NAD salivation	Grade: slight	1	1	1		1	1	1	1	1
	53	normal head	NAD salivation	Grade: slight	1	1	1		1	1	1	1	1
	54	normal	NAD		1	1	1		1	1	1	1	1
	55	normal	NAD		1	1	1		1	1	1	1	1
	56	normal	NAD		1	1	1		1	1	1	1	1
	57	normal head	NAD salivation	Grade: slight	1	1	1		1	1	1	1	1
	58	normal	NAD		1	1	1		1	1	1	1	1
	59	normal	NAD		1	1	1		1	1	1	1	1
	60	normal	NAD		1	1	1		1	1	1	1	1

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day							
					6	6	6	7	7	7	8	8
61		normal	NAD		1	1	1		1	1	1	1
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown								
		feces	soft feces									
62		normal	NAD		1	1	1		1	1	1	1
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown								
		feces	soft feces									
63		normal	NAD		1	1	1		1	1	1	1
		head	salivation	Grade: moderate								
		feces	discolored feces	Color: light brown								
		feces	soft feces									
64		normal	NAD		1	1	1		1	1	1	1
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown								
		feces	soft feces									
65		normal	NAD		1	1	1		1	1	1	1
		head	salivation	Grade: moderate								
		feces	discolored feces	Color: light brown								
		feces	soft feces									

2 / F
300 mg/kg
bw/d

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day							
					6	6	6	7	7	7	8	8
66		normal	NAD		1	1	1			1	1	1
		head	salivation	Grade: moderate								
		feces	discolored feces	Grade: slight								
		feces	soft feces	Color: light brown								
67		normal	NAD		1	1	1			1	1	1
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown								
		feces	soft feces									
68	2 / F 300 mg/kg bw/d	normal	NAD		1	1	1			1	1	1
		head	salivation	Grade: moderate								
		feces	discolored feces	Grade: slight								
		feces	soft feces	Color: light brown								
69		normal	NAD		1	1	1			1	1	1
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown								
		feces	soft feces									
70		normal	NAD		1	1	1			1	1	1
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown								
		feces	soft feces									

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day							
					6	6	6	7	7	7	8	8
3 / F 1000 mg/kg bw/d	71	normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown								
		feces	soft feces									
	72	normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate								
		feces	discolored feces	Grade: slight								
		feces	soft feces	Color: light brown								
	73	normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown								
		feces	soft feces									
	74	normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown								
		feces	soft feces									
	75	normal	NAD		1	1	1	1	1	1	1	1
		feces	discolored feces	Color: light brown								
		feces	soft feces									

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day								
					6 [-01:00-00:00]	6 [00:00-02:00]	6 [02:00-05:00]	7 [-01:00-00:00]	7 [00:00-02:00]	7 [02:00-05:00]	8 [-01:00-00:00]	8 [00:00-02:00]	8 [02:00-05:00]
3 / F 1000 mg/kg b.w/d	76	normal	NAD		1	1	1		1	1	1	1	1
		head	salivation	Grade: slight									
		feces	discolored feces	Color: light brown									
	77	feces	soft feces										
		normal	NAD		1	1	1		1	1	1	1	1
		head	salivation	Grade: slight									
	78	feces	discolored feces	Color: light brown									
		feces	soft feces										
		normal	NAD		1	1	1		1	1	1	1	1
	79	head	salivation	Grade: moderate									
		feces	discolored feces	Grade: slight									
		feces	soft feces	Color: light brown									
80	normal	NAD		1	1	1		1	1	1	1	1	
	head	salivation	Grade: slight										
	feces	discolored feces	Color: light brown										

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day								
					9 [01:00-00:00]	9 [00:00-02:00]	9 [02:00-05:00]	10 [01:00-00:00]	10 [00:00-02:00]	10 [02:00-05:00]	11 [01:00-00:00]	11 [00:00-02:00]	11 [02:00-05:00]
0 / F 0 mg/kg bw/d	41	normal	NAD		1	1	1	1	1	1	1	1	1
	42	normal	NAD		1	1	1	1	1	1	1	1	1
	43	normal	NAD		1	1	1	1	1	1	1	1	1
	44	normal	NAD		1	1	1	1	1	1	1	1	1
	45	normal	NAD		1	1	1	1	1	1	1	1	1
	46	normal	NAD		1	1	1	1	1	1	1	1	1
	47	normal	NAD		1	1	1	1	1	1	1	1	1
	48	normal	NAD		1	1	1	1	1	1	1	1	1
	49	normal	NAD		1	1	1	1	1	1	1	1	1
	50	normal	NAD		1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day						
					9	9	9	10	10	10	11
1 / F 100 mg/kg bwd	51	normal head	NAD		1	1	1	1	1	1	1
		head	salivation	Grade: slight							
	52	normal head	NAD		1	1	1	1	1	1	1
		head	salivation	Grade: slight							
	53	normal head	NAD		1	1	1	1	1	1	1
		head	salivation	Grade: slight							
	54	normal	NAD		1	1	1	1	1	1	1
	55	normal	NAD		1	1	1	1	1	1	1
	56	normal	NAD		1	1	1	1	1	1	1
	57	normal head	NAD		1	1	1	1	1	1	1
		head	salivation	Grade: slight							
	58	normal	NAD		1	1	1	1	1	1	1
	59	normal	NAD		1	1	1	1	1	1	1
	60	normal	NAD		1	1	1	1	1	1	1

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day						
					9	9	9	10	10	10	11
61		normal	NAD		1	1	1	1	1	1	1
		head	salivation	Grade: slight							
		feces	discolored feces	Color: light brown							
		feces	soft feces								
62		normal	NAD		1	1	1	1	1	1	1
		head	salivation	Grade: slight							
		feces	discolored feces	Color: light brown							
		feces	soft feces								
63		normal	NAD		1	1	1	1	1	1	1
		head	salivation	Grade: moderate							
		feces	discolored feces	Color: light brown							
		feces	soft feces								
64		normal	NAD		1	1	1	1	1	1	1
		head	salivation	Grade: slight							
		feces	discolored feces	Color: light brown							
		feces	soft feces								
65		normal	NAD		1	1	1	1	1	1	1
		head	salivation	Grade: moderate							
		feces	discolored feces	Color: light brown							
		feces	soft feces								

2 / F
300 mg/kg
bw/d

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day							
					9	9	9	10	10	10	11	11
66		normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate								
		feces	discolored feces	Grade: slight								
		feces	soft feces	Color: light brown								
67		normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown								
		feces	soft feces									
68	2 / F 300 mg/kg bw/d	normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate								
		feces	discolored feces	Grade: slight								
		feces	soft feces	Color: light brown								
69		normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown								
		feces	soft feces									
70		normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown								
		feces	soft feces									

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day						
					9	9	9	10	10	11	11
3 / F 1000 mg/kg bw/d	71	normal	NAD		1	1	1	1	1	1	1
		head	salivation	Grade: slight							
		feces	discolored feces	Color: light brown							
		feces	soft feces								
	72	normal	NAD		1	1	1	1	1	1	1
		head	salivation	Grade: moderate							
		feces	discolored feces	Grade: slight							
		feces	soft feces	Color: light brown							
	73	normal	NAD		1	1	1	1	1	1	1
		head	salivation	Grade: slight							
		feces	discolored feces	Color: light brown							
		feces	soft feces								
	74	normal	NAD		1	1	1	1	1	1	1
		head	salivation	Grade: slight							
		feces	discolored feces	Color: light brown							
		feces	soft feces								
	75	normal	NAD		1	1	1	1	1	1	1
		feces	discolored feces	Color: light brown							
		feces	soft feces								

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day						
					9	9	9	10	10	11	11
3 / F 1000 mg/kg bw/d	76	normal	NAD		1	1	1	1	1	1	1
		head	salivation	Grade: slight							
		feces	discolored feces	Color: light brown							
	77	feces	soft feces								
		normal	NAD		1	1	1	1	1	1	1
		head	salivation	Grade: slight							
	78	feces	discolored feces	Color: light brown							
		feces	soft feces								
		normal	NAD		1	1	1	1	1	1	1
	79	head	salivation	Grade: moderate							
		feces	discolored feces	Grade: slight							
		feces	soft feces	Color: light brown							
80		normal	NAD		1	1	1	1	1	1	1
		head	salivation	Grade: slight							
		feces	discolored feces	Color: light brown							
		feces	soft feces								

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day							
					12	12	12	13	13	13	14	14
	41	normal	NAD		1	1	1	1	1	1	1	1
	42	normal	NAD		1	1	1	1	1	1	1	1
	43	normal	NAD		1	1	1	1	1	1	1	1
	44	normal	NAD		1	1	1	1	1	1	1	1
	45	normal	NAD		1	1	1	1	1	1	1	1
	46	normal	NAD		1	1	1	1	1	1	1	1
	47	normal	NAD		1	1	1	1	1	1	1	1
	48	normal	NAD		1	1	1	1	1	1	1	1
	49	normal	NAD		1	1	1	1	1	1	1	1
	50	normal	NAD		1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day								
					12 [-01:00-00:00]	12 [00:00-02:00]	12 [02:00-05:00]	13 [-01:00-00:00]	13 [00:00-02:00]	13 [02:00-05:00]	14 [-01:00-00:00]	14 [00:00-02:00]	14 [02:00-05:00]
1 / F 100 mg/kg bwd	51	normal head	NAD salivation	Grade: slight	1	1	1	1	1	1	1	1	1
	52	normal head	NAD salivation	Grade: slight	1	1	1	1	1	1	1	1	1
	53	normal head	NAD salivation	Grade: slight	1	1	1	1	1	1	1	1	1
	54	normal	NAD		1	1	1	1	1	1	1	1	1
	55	normal	NAD		1	1	1	1	1	1	1	1	1
	56	normal	NAD		1	1	1	1	1	1	1	1	1
	57	normal head	NAD salivation	Grade: slight	1	1	1	1	1	1	1	1	1
	58	normal	NAD		1	1	1	1	1	1	1	1	1
	59	normal	NAD		1	1	1	1	1	1	1	1	1
	60	normal	NAD		1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day							
					12	12	12	13	13	13	14	14
2 / F 300 mg/kg bw/d	61	normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown								
		feces	soft feces									
	62	normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown								
		feces	soft feces									
	63	normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate								
		feces	discolored feces	Color: light brown								
		feces	soft feces									
	64	normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown								
		feces	soft feces									
	65	normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate								
		feces	discolored feces	Color: light brown								
		feces	soft feces									

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					12	12	12	13	13	13	13	14	14	14
66		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight										
		feces	soft feces	Color: light brown										
67		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
68	2 / F 300 mg/kg bw/d	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight										
		feces	soft feces	Color: light brown										
69		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
70		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day							
					12	12	12	13	13	13	14	14
3 / F 1000 mg/kg bw/d	71	normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown								
		feces	soft feces									
	72	normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate								
		feces	discolored feces	Grade: slight								
		feces	soft feces	Color: light brown								
	73	normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown								
		feces	soft feces									
	74	normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown								
		feces	soft feces									
	75	normal	NAD		1	1	1	1	1	1	1	1
		feces	discolored feces	Color: light brown								
		feces	soft feces									

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					12	12	12	12	13	13	13	13	14	14
3 / F 1000 mg/kg bw/d	76	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
	77	feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	78	feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal	NAD		1	1	1	1	1	1	1	1	1	1
	79	head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight										
		feces	soft feces	Color: light brown										
80		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day								
					15 [01:00-00:00]	15 [00:00-02:00]	15 [02:00-05:00]	16 [01:00-00:00]	16 [00:00-02:00]	16 [02:00-05:00]	17 [01:00-00:00]	17 [00:00-02:00]	17 [02:00-05:00]
0 / F 0 mg/kg bw/d	41	normal	NAD		1	1	1	1	1	1	1	1	1
	42	normal	NAD		1	1	1	1	1	1	1	1	1
	43	normal	NAD		1	1	1	1	1	1	1	1	1
	44	normal	NAD		1	1	1	1	1	1	1	1	1
	45	normal	NAD		1	1	1	1	1	1	1	1	1
	46	normal	NAD		1	1	1	1	1	1	1	1	1
	47	normal	NAD		1	1	1	1	1	1	1	1	1
	48	normal	NAD		1	1	1	1	1	1	1	1	1
	49	normal	NAD		1	1	1	1	1	1	1	1	1
	50	normal	NAD		1	1	1	1	1	1	1	1	1

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day											
					15 [00:00-01:00]	15 [01:00-02:00]	15 [02:00-05:00]	16 [00:00-01:00]	16 [01:00-02:00]	16 [02:00-05:00]	17 [00:00-01:00]	17 [01:00-02:00]	17 [02:00-05:00]			
1 / F 100 mg/kg bwd	51	normal head	NAD salivation	Grade: slight	1											
	52	normal head	NAD salivation	Grade: slight	1	1	1									
	53	normal head	NAD salivation	Grade: slight	1											
	54	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
	55	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
	56	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
	57	normal head	NAD salivation	Grade: slight	1	1	1	1	1	1	1	1	1	1	1	1
	58	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
	59	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
	60	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					15 [01:00-00:00]	15 [00:00-02:00]	15 [02:00-05:00]	16 [01:00-00:00]	16 [00:00-02:00]	16 [02:00-05:00]	17 [01:00-00:00]	17 [00:00-02:00]	17 [02:00-05:00]	
	61	normal	NAD		1	1	1	1	1	1		1	1	
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	62	normal	NAD		1	1	1	1	1	1	1	1	1	
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	63	normal	NAD		1	1	1	1	1	1	1	1	1	
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	64	normal	NAD		1	1	1	1	1	1	1	1	1	
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	65	normal	NAD		1	1	1	1	1	1	1	1	1	
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

2 / F
300 mg/kg
bw/d

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					15	15	15	16	16	16	17	17	17	17
66		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight										
		feces	soft feces	Color: light brown										
67		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
68	2 / F 300 mg/kg bw/d	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight										
		feces	soft feces	Color: light brown										
69		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
70		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day								
					15 [-01:00-00:00]	15 [00:00-02:00]	15 [02:00-05:00]	16 [-01:00-00:00]	16 [00:00-02:00]	16 [02:00-05:00]	17 [-01:00-00:00]	17 [00:00-02:00]	17 [02:00-05:00]
3 / F 1000 mg/kg pow/d	71	normal	NAD										
		head	salivation	Grade: slight									
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	
		feces	soft feces										
	72	normal	NAD										
		head	salivation	Grade: moderate									
		feces	discolored feces	Grade: slight									
		feces	soft feces	Color: light brown	1	1	1	1	1	1	1	1	
	73	normal	NAD										
		head	salivation	Grade: slight		1						1	
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	
		feces	soft feces										
74	normal	NAD											
	head	salivation	Grade: slight								1		
	feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1		
	feces	soft feces											
75	normal	NAD											
	feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	
	feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day								
					15 [01:00-00:00]	15 [00:00-02:00]	15 [02:00-05:00]	16 [01:00-00:00]	16 [00:00-02:00]	16 [02:00-05:00]	17 [01:00-00:00]	17 [00:00-02:00]	17 [02:00-05:00]
	76	normal	NAD										
		head	salivation	Grade: slight									
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1
		feces	soft feces										
	77	normal	NAD										
		head	salivation	Grade: slight									
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1
		feces	soft feces										
3 / F 1000 mg/kg bowl/d	78	normal	NAD										
		head	salivation	Grade: slight									
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1
		feces	soft feces										
	79	normal	NAD										
		head	salivation	Grade: moderate									
		feces	discolored feces	Grade: slight									
		feces	soft feces	Color: light brown	1	1	1	1	1	1	1	1	1
	80	normal	NAD										
		head	salivation	Grade: slight									
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1
		feces	soft feces										

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day								
					18 [01:00-00:00]	18 [00:00-02:00]	18 [02:00-05:00]	19 [01:00-00:00]	19 [00:00-02:00]	19 [02:00-05:00]	20 [01:00-00:00]	20 [00:00-02:00]	20 [02:00-05:00]
0 / F 0 mg/kg bw/d	41	normal	NAD		1	1	1	1	1	1	1	1	1
	42	normal	NAD		1	1	1	1	1	1	1	1	1
	43	normal	NAD		1	1	1	1	1	1	1	1	1
	44	normal	NAD		1	1	1	1	1	1	1	1	1
	45	normal	NAD		1	1	1	1	1	1	1	1	1
	46	normal	NAD		1	1	1	1	1	1	1	1	1
	47	normal	NAD		1	1	1	1	1	1	1	1	1
	48	normal	NAD		1	1	1	1	1	1	1	1	1
	49	normal	NAD		1	1	1	1	1	1	1	1	1
	50	normal	NAD		1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					18	18	18	18	19	19	19	20	20	20
1 / F 100 mg/kg bwd	51	normal head	NAD salivation	Grade: slight	1	1	1	1	1	1	1	1	1	1
	52	normal head	NAD salivation	Grade: slight	1	1	1	1	1	1	1	1	1	1
	53	normal head	NAD salivation	Grade: slight	1	1	1	1	1	1	1	1	1	1
	54	normal	NAD		1	1	1	1	1	1	1	1	1	1
	55	normal	NAD		1	1	1	1	1	1	1	1	1	1
	56	normal	NAD		1	1	1	1	1	1	1	1	1	1
	57	normal head	NAD salivation	Grade: slight	1	1	1	1	1	1	1	1	1	1
	58	normal	NAD		1	1	1	1	1	1	1	1	1	1
	59	normal	NAD		1	1	1	1	1	1	1	1	1	1
	60	normal	NAD		1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day							
					18	18	18	19	19	19	20	20
2 / F 300 mg/kg bw/d	61	normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown								
		feces	soft feces									
	62	normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown								
		feces	soft feces									
	63	normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate								
		feces	discolored feces	Color: light brown								
		feces	soft feces									
	64	normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown								
		feces	soft feces									
	65	normal	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate								
		feces	discolored feces	Color: light brown								
		feces	soft feces									

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					18	18	18	19	19	19	20	20	20	20
66		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight								1		
		feces	soft feces	Color: light brown										
67		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
68	2 / F 300 mg/kg bw/d	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight										
		feces	soft feces	Color: light brown										
69		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
70		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day						
					18 [00:00-02:00]	18 [02:00-05:00]	19 [00:00-02:00]	19 [02:00-05:00]	20 [00:00-02:00]	20 [02:00-05:00]	20 [02:00-05:00]
3 / F 1000 mg/kg bw/d	71	normal	NAD								
		head	salivation	Grade: slight							
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1
		feces	soft feces								
	72	normal	NAD								
		head	salivation	Grade: moderate							
		feces	discolored feces	Grade: slight							
		feces	soft feces	Color: light brown	1	1	1	1	1	1	1
	73	normal	NAD								
		head	salivation	Grade: slight	1	1	1	1	1	1	1
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1
		feces	soft feces								
	74	normal	NAD								
		head	salivation	Grade: slight							
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1
		feces	soft feces								
	75	normal	NAD								
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1
		feces	soft feces								

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day							
					18	18	18	19	19	19	20	20
3 / F 1000 mg/kg bw/d	76	normal	NAD									
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1
		feces	soft feces									
	77	normal	NAD									
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1
		feces	soft feces									
	78	normal	NAD									
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1
		feces	soft feces									
	79	normal	NAD									
		head	salivation	Grade: moderate								
		feces	discolored feces	Grade: slight	1	1	1	1	1	1	1	1
		feces	soft feces	Color: light brown	1	1	1	1	1	1	1	1
80		normal	NAD									
		head	salivation	Grade: slight	1	1	1	1	1	1	1	1
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1
		feces	soft feces									

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					21 [-01:00-00:00]	21 [00:00-02:00]	21 [02:00-05:00]	22 [-01:00-00:00]	22 [00:00-02:00]	22 [02:00-05:00]	23 [-01:00-00:00]	23 [00:00-02:00]	23 [02:00-05:00]	
0 / F 0 mg/kg bw/d	41	normal	NAD		1	1	1	1	1	1	1	1	1	1
	42	normal	NAD		1	1	1	1	1	1	1	1	1	1
	43	normal	NAD		1	1	1	1	1	1	1	1	1	1
	44	normal	NAD		1	1	1	1	1	1	1	1	1	1
	45	normal	NAD		1	1	1	1	1	1	1	1	1	1
	46	normal	NAD		1	1	1	1	1	1	1	1	1	1
	47	normal	NAD		1	1	1	1	1	1	1	1	1	1
	48	normal	NAD		1	1	1	1	1	1	1	1	1	1
	49	normal	NAD		1	1	1	1	1	1	1	1	1	1
	50	normal	NAD		1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day											
					21	21	21	21	22	22	22	22	22	23	23	23
1 / F 100 mg/kg bwd	51	normal head	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
	52	normal head	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
	53	normal head	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
	54	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
	55	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
	56	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
	57	normal head	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
	58	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
	59	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
	60	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					21	21	21	21	22	22	22	23	23	23
2 / F 300 mg/kg bw/d	61	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	62	normal	NAD		1				1	1	1	1	1	1
		head	salivation	Grade: slight		1								
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	63	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	64	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	65	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown		1						1		
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					21	21	21	22	22	22	23	23	23	23
66		normal	NAD		1			1		1				1
		head	salivation	Grade: moderate					1				1	
		feces	discolored feces	Grade: slight	1									
		feces	soft feces	Color: light brown										
67		normal	NAD		1			1		1			1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
68	2 / F 300 mg/kg bw/d	normal	NAD		1			1		1			1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight	1				1					
		feces	soft feces	Color: light brown										
69		normal	NAD		1			1		1			1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
70		normal	NAD		1			1		1			1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					21	21	21	22	22	22	23	23	23	23
					[01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[02:00-05:00]
3 / F 1000 mg/kg bw/d	71	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	72	normal	NAD											
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight										
		feces	soft feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
	73	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	74	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	75	normal	NAD											
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					21	21	21	21	22	22	22	23	23	23
					[01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[01:00-00:00]
3 / F 1000 mg/kg bw/d	76	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	77	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	78	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	79	normal	NAD											
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight	1	1	1	1	1	1	1	1	1	1
		feces	soft feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
80		normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					24	24	24	25	25	25	26	26	26	26
					[01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[-01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[-01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[02:00-05:00]
0 / F 0 mg/kg bw/d	41	normal	NAD		1	1	1	1	1	1	1	1	1	1
	42	normal	NAD		1	1	1	1	1	1	1	1	1	1
	43	normal	NAD		1	1	1	1	1	1	1	1	1	1
	44	normal	NAD		1	1	1	1	1	1	1	1	1	1
	45	normal	NAD		1	1	1	1	1	1	1	1	1	1
	46	normal	NAD		1	1	1	1	1	1	1	1	1	1
	47	normal	NAD		1	1	1	1	1	1	1	1	1	1
	48	normal	NAD		1	1	1	1	1	1	1	1	1	1
	49	normal	NAD		1	1	1	1	1	1	1	1	1	1
	50	normal	NAD		1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					24	24	24	25	25	25	25	26	26	26
					[01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[-01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[-01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[02:00-05:00]
1 / F 100 mg/kg bwd	51	normal head	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	52	normal head	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	53	normal head	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	54	normal	NAD		1	1	1	1	1	1	1	1	1	1
	55	normal	NAD		1	1	1	1	1	1	1	1	1	1
	56	normal	NAD		1	1	1	1	1	1	1	1	1	1
	57	normal head	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	58	normal	NAD		1	1	1	1	1	1	1	1	1	1
	59	normal	NAD		1	1	1	1	1	1	1	1	1	1
	60	normal	NAD		1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					24	24	24	25	25	25	25	26	26	26
2 / F 300 mg/kg bw/d	61	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	62	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	63	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	64	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	65	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					24	24	24	25	25	25	26	26	26	26
66		normal	NAD		1			1			1			1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight		1			1				1	
		feces	soft feces	Color: light brown										
67		normal	NAD		1			1			1			1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
68	2 / F 300 mg/kg bw/d	normal	NAD		1			1			1			1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight		1			1				1	
		feces	soft feces	Color: light brown										
69		normal	NAD		1			1			1			1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
70		normal	NAD		1			1			1			1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					24	24	24	25	25	25	26	26	26	26
3 / F 1000 mg/kg bw/d	71	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	72	normal	NAD											
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight										
		feces	soft feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
	73	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	74	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	75	normal	NAD											
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					24	24	24	25	25	25	26	26	26	26
					[01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[-01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[-01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[02:00-05:00]
3 / F 1000 mg/kg bw/d	76	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	77	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	78	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	79	normal	NAD											
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight	1	1	1	1	1	1	1	1	1	1
		feces	soft feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
80		normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					27	27	27	28	28	28	28	29	29	29
	41	normal	NAD		1	1	1	1	1	1	1	1	1	1
	42	normal	NAD		1	1	1	1	1	1	1	1	1	1
	43	normal	NAD		1	1	1	1	1	1	1	1	1	1
	44	normal	NAD		1	1	1	1	1	1	1	1	1	1
	45	normal	NAD		1	1	1	1	1	1	1	1	1	1
	46	normal	NAD		1	1	1	1	1	1	1	1	1	1
	47	normal	NAD		1	1	1	1	1	1	1	1	1	1
	48	normal	NAD		1	1	1	1	1	1	1	1	1	1
	49	normal	NAD		1	1	1	1	1	1	1	1	1	1
	50	normal	NAD		1	1	1	1	1	1	1	1	1	1

O / F

0 mg/kg bw/d

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					27	27	27	28	28	28	29	29	29	29
1 / F 100 mg/kg bwd	51	normal head	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	52	normal head	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	53	normal head	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	54	normal	NAD		1	1	1	1	1	1	1	1	1	1
	55	normal	NAD		1	1	1	1	1	1	1	1	1	1
	56	normal	NAD		1	1	1	1	1	1	1	1	1	1
	57	normal head	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	58	normal	NAD		1	1	1	1	1	1	1	1	1	1
	59	normal	NAD		1	1	1	1	1	1	1	1	1	1
	60	normal	NAD		1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day											
					27	27	27	27	28	28	28	28	28	29	29	29
2 / F 300 mg/kg bw/d	61	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
		feces	discolored feces	Color: light brown												
		feces	soft feces													
	62	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
		feces	discolored feces	Color: light brown												
		feces	soft feces													
	63	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate												
		feces	discolored feces	Color: light brown												
		feces	soft feces													
	64	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
		feces	discolored feces	Color: light brown												
		feces	soft feces													
	65	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate												
		feces	discolored feces	Color: light brown												
		feces	soft feces													

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					27	27	27	28	28	28	28	29	29	29
66		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight										
		feces	soft feces	Color: light brown										
67		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
68	2 / F 300 mg/kg bw/d	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight										
		feces	soft feces	Color: light brown										
69		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
70		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					27	27	27	28	28	28	29	29	29	29
3 / F 1000 mg/kg bw/d	71	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	72	normal	NAD											
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight										
		feces	soft feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
	73	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	74	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	75	normal	NAD											
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					27	27	27	28	28	28	29	29	29	29
3 / F 1000 mg/kg bw/d	76	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	77	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	78	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	79	normal	NAD											
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight										
		feces	soft feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
80		normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day							
					30	30	30	31	31	31	32	32
					[01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[-01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[-01:00-00:00]	[00:00-02:00]
	41	normal	NAD		1	1	1	1	1	1	1	1
	42	normal	NAD		1	1	1	1	1	1	1	1
	43	normal	NAD		1	1	1	1	1	1	1	1
	44	normal	NAD		1	1	1	1	1	1	1	1
	45	normal	NAD		1	1	1	1	1	1	1	1
	46	normal	NAD		1	1	1	1	1	1	1	1
	47	normal	NAD		1	1	1	1	1	1	1	1
	48	normal	NAD		1	1	1	1	1	1	1	1
	49	normal	NAD		1	1	1	1	1	1	1	1
	50	normal	NAD		1	1	1	1	1	1	1	1

0 / F

0 mg/kg bw/d

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					30	30	30	31	31	31	31	32	32	32
1 / F 100 mg/kg bwd	51	normal head	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	52	normal head	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	53	normal head	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	54	normal	NAD		1	1	1	1	1	1	1	1	1	1
	55	normal	NAD		1	1	1	1	1	1	1	1	1	1
	56	normal	NAD		1	1	1	1	1	1	1	1	1	1
	57	normal head	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	58	normal	NAD		1	1	1	1	1	1	1	1	1	1
	59	normal	NAD		1	1	1	1	1	1	1	1	1	1
	60	normal	NAD		1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day											
					30	30	30	30	31	31	31	31	31	32	32	32
2 / F 300 mg/kg bw/d	61	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
		feces	discolored feces	Color: light brown												
		feces	soft feces													
	62	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
		feces	discolored feces	Color: light brown												
		feces	soft feces													
	63	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate												
		feces	discolored feces	Color: light brown												
		feces	soft feces													
	64	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
		feces	discolored feces	Color: light brown												
		feces	soft feces													
	65	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate												
		feces	discolored feces	Color: light brown												
		feces	soft feces													

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					30	30	30	31	31	31	31	32	32	32
66		normal	NAD		1		1	1	1	1	1	1		1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight		1						1		
		feces	soft feces	Color: light brown										
67		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight					1					
		feces	discolored feces	Color: light brown										
		feces	soft feces											
68	2 / F 300 mg/kg bw/d	normal	NAD		1	1	1	1	1	1	1	1		1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight		1			1			1		
		feces	soft feces	Color: light brown										
69		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
70		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					30	30	30	31	31	31	32	32	32	32
3 / F 1000 mg/kg bw/d	71	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	72	normal	NAD											
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight									1	
		feces	soft feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
	73	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	74	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	75	normal	NAD											
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					30	30	30	31	31	31	32	32	32	32
3 / F 1000 mg/kg bw/d	76	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	77	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	78	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	79	normal	NAD											
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight	1	1	1	1	1	1	1	1	1	1
		feces	soft feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
80		normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					33	33	33	34	34	34	34	35	35	35
					[01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[-01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[-01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[02:00-05:00]
0 / F 0 mg/kg bw/d	41	normal	NAD		1	1	1	1	1	1	1	1	1	1
	42	normal	NAD		1	1	1	1	1	1	1	1	1	1
	43	normal	NAD		1	1	1	1	1	1	1	1	1	1
	44	normal	NAD		1	1	1	1	1	1	1	1	1	1
	45	normal	NAD		1	1	1	1	1	1	1	1	1	1
	46	normal	NAD		1	1	1	1	1	1	1	1	1	1
	47	normal	NAD		1	1	1	1	1	1	1	1	1	1
	48	normal	NAD		1	1	1	1	1	1	1	1	1	1
	49	normal	NAD		1	1	1	1	1	1	1	1	1	1
	50	normal	NAD		1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					33	33	33	33	34	34	34	34	35	35
1 / F 100 mg/kg bw/d	51	normal head	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	52	normal head	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	53	normal head	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	54	normal	NAD		1	1	1	1	1	1	1	1	1	1
	55	normal	NAD		1	1	1	1	1	1	1	1	1	1
	56	normal	NAD		1	1	1	1	1	1	1	1	1	1
	57	normal head	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	58	normal	NAD		1	1	1	1	1	1	1	1	1	1
	59	normal	NAD		1	1	1	1	1	1	1	1	1	1
	60	normal	NAD		1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					33	33	33	34	34	34	34	35	35	35
2 / F 300 mg/kg bw/d	61	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	62	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	63	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	64	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	65	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					33	33	33	34	34	34	35	35	35	35
66		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight										
		feces	soft feces	Color: light brown										
67		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
68	2 / F 300 mg/kg bw/d	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight				1				1		
		feces	soft feces	Color: light brown										
69		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
70		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					33	33	33	34	34	34	35	35	35	35
		normal	NAD											
	71	head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
		normal	NAD											
		head	salivation	Grade: moderate										
	72			Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
		normal	NAD											
3 / F		head	salivation	Grade: slight										
1000 mg/kg	73			Color: light brown	1	1	1	1	1	1	1	1	1	1
bw/d		feces	discolored feces											
		feces	soft feces											
		normal	NAD											
		head	salivation	Grade: slight										
	74			Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	discolored feces											
		feces	soft feces											
		normal	NAD											
	75			Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	discolored feces											
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					33	33	33	34	34	34	35	35	35	35
					[01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[02:00-05:00]
3 / F 1000 mg/kg bw/d	76	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
	77	feces	soft feces											
		normal	NAD											
		head	salivation	Grade: slight										
	78	feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
		normal	NAD											
	79	head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
80	79	normal	NAD											
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
	80	feces	soft feces											
		normal	NAD											
		head	salivation	Grade: slight										
80	80	feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
		normal	NAD											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day								
					36 [-01:00-00:00]	36 [00:00-02:00]	36 [02:00-05:00]	37 [-01:00-00:00]	37 [00:00-02:00]	37 [02:00-05:00]	38 [-01:00-00:00]	38 [00:00-02:00]	38 [02:00-05:00]
0 / F 0 mg/kg bw/d	41	normal	NAD		1	1	1	1	1	1	1	1	1
	42	normal	NAD		1	1	1	1	1	1	1	1	1
	43	normal	NAD		1	1	1	1	1	1	1	1	1
	44	normal	NAD		1	1	1	1	1	1	1	1	1
	45	normal	NAD		1	1	1	1	1	1	1	1	1
	46	normal	NAD		1	1	1	1	1	1	1	1	1
	47	normal	NAD		1	1	1	1	1	1	1	1	1
	48	normal	NAD		1	1	1	1	1	1	1	1	1
	49	normal	NAD		1	1	1	1	1	1	1	1	1
	50	normal	NAD		1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day											
					36 [00:00-00:00]	36 [00:00-02:00]	36 [02:00-05:00]	37 [00:00-00:00]	37 [00:00-02:00]	37 [02:00-05:00]	38 [00:00-00:00]	38 [00:00-02:00]	38 [02:00-05:00]			
1 / F 100 mg/kg bwd	51	normal head	NAD	salivation	Grade: slight	1	1	1	1	1	1	1	1	1		
	52	normal head	NAD	salivation	Grade: slight	1	1	1	1	1	1	1	1	1		
	53	normal head	NAD	salivation	Grade: slight	1	1	1	1	1	1	1	1	1		
	54	normal	NAD			1	1	1	1	1	1	1	1	1		
	55	normal	NAD			1	1	1	1	1	1	1	1	1		
	56	normal	NAD			1	1	1	1	1	1	1	1	1		
	57	normal head	NAD	salivation	Grade: slight	1	1	1	1	1	1	1	1	1		
	58	normal	NAD			1	1	1	1	1	1	1	1	1		
	59	normal	NAD			1	1	1	1	1	1	1	1	1		
	60	normal	NAD			1	1	1	1	1	1	1	1	1		

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					36	36	36	37	37	37	37	38	38	38
2 / F 300 mg/kg bw/d	61	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	62	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	63	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	64	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	65	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					36 [-01:00-00:00]	36 [00:00-02:00]	36 [02:00-05:00]	37 [-01:00-00:00]	37 [00:00-02:00]	37 [02:00-05:00]	38 [-01:00-00:00]	38 [00:00-02:00]	38 [02:00-05:00]	
	66	normal head	NAD salivation	Grade: moderate	1	1	1	1		1		1		1
		feces	discolored feces	Grade: slight					1			1		
		feces	soft feces	Color: light brown										
		normal head	NAD salivation	Grade: slight	1	1	1	1	1	1	1	1	1	1
	67	feces	discolored feces	Color: light brown										
		feces	soft feces											
		normal head	NAD salivation	Grade: moderate	1	1	1	1	1	1	1	1	1	1
		feces	discolored feces	Grade: slight								1		
	68	feces	soft feces	Color: light brown										
		normal head	NAD salivation	Grade: moderate	1	1	1	1	1	1	1	1	1	1
		feces	discolored feces	Grade: slight								1		
		feces	soft feces	Color: light brown										
	69	normal head	NAD salivation	Grade: slight	1	1	1	1	1	1	1	1	1	1
		feces	discolored feces	Grade: slight										
		feces	soft feces	Color: light brown										
		normal head	NAD salivation	Grade: moderate	1	1	1	1	1	1	1	1	1	1
	70	feces	discolored feces	Grade: slight										
		feces	soft feces	Color: light brown										
		normal head	NAD salivation	Grade: slight	1	1	1	1	1	1	1	1	1	1
		feces	discolored feces	Color: light brown										

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					36	36	36	37	37	37	37	38	38	38
3 / F 1000 mg/kg bw/d	71	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	72	normal	NAD											
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight										
		feces	soft feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
	73	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	74	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	75	normal	NAD											
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					36 [01:00-00:00]	36 [00:00-02:00]	36 [02:00-05:00]	37 [01:00-00:00]	37 [00:00-02:00]	37 [02:00-05:00]	38 [01:00-00:00]	38 [00:00-02:00]	38 [02:00-05:00]	
3 / F 1000 mg/kg bowl/d	76	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	
		feces	soft feces											
	77	normal	NAD											
		head	salivation	Grade: slight					1					
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	
		feces	soft feces											
	78	normal	NAD											
		head	salivation	Grade: slight					1					
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	
		feces	soft feces											
	79	normal	NAD											
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight		1							1	
		feces	soft feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
80	normal	NAD												
	head	salivation	Grade: slight					1						
	feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1	
	feces	soft feces												

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day							
					39	39	39	40	40	40	41	41
	41	normal	NAD		1	1	1	1	1	1	1	1
	42	normal	NAD		1	1	1	1	1	1	1	1
	43	normal	NAD		1	1	1	1	1	1	1	1
	44	normal	NAD		1	1	1	1	1	1	1	1
	45	normal	NAD		1	1	1	1	1	1	1	1
	46	normal	NAD		1	1	1	1	1	1	1	1
	47	normal	NAD		1	1	1	1	1	1	1	1
	48	normal	NAD		1	1	1	1	1	1	1	1
	49	normal	NAD		1	1	1	1	1	1	1	1
	50	normal	NAD		1	1	1	1	1	1	1	1

O / F

0 mg/kg bw/d

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					39	39	39	40	40	40	41	41	41	41
1 / F 100 mg/kg bwd	51	normal head	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	52	normal head	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	53	normal head	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	54	normal	NAD		1	1	1	1	1	1	1	1	1	1
	55	normal	NAD		1	1	1	1	1	1	1	1	1	1
	56	normal	NAD		1	1	1	1	1	1	1	1	1	1
	57	normal head	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	58	normal	NAD		1	1	1	1	1	1	1	1	1	1
	59	normal	NAD		1	1	1	1	1	1	1	1	1	1
	60	normal	NAD		1	1	1	1	1	1	1	1	1	1

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					39	39	39	40	40	40	41	41	41	41
2 / F 300 mg/kg bw/d	61	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	62	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	63	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	64	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	65	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					39	39	39	40	40	40	41	41	41	41
66		normal	NAD		1									
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight		1			1					
		feces	soft feces	Color: light brown										
67		normal	NAD		1									
		head	salivation	Grade: slight		1								
		feces	discolored feces	Color: light brown										
		feces	soft feces											
68		normal	NAD		1									
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight		1			1					
		feces	soft feces	Color: light brown										
69		normal	NAD		1									
		head	salivation	Grade: slight		1								
		feces	discolored feces	Color: light brown										
		feces	soft feces											
70		normal	NAD		1									
		head	salivation	Grade: slight		1								
		feces	discolored feces	Color: light brown										
		feces	soft feces											

2 / F
300 mg/kg
bw/d

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day							
					39	39	39	40	40	40	41	41
3 / F 1000 mg/kg bw/d	71	normal	NAD									
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1
		feces	soft feces									
	72	normal	NAD									
		head	salivation	Grade: moderate								
		feces	discolored feces	Grade: slight								
		feces	soft feces	Color: light brown	1	1	1	1	1	1	1	1
	73	normal	NAD									
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1
		feces	soft feces									
	74	normal	NAD									
		head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1
		feces	soft feces									
	75	normal	NAD									
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1
		feces	soft feces									

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					39	39	39	40	40	40	41	41	41	41
		normal	NAD											
	76	head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
		normal	NAD											
	77	head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
		normal	NAD											
3 / F	78	head	salivation	Grade: slight	1	1	1	1	1	1	1	1	1	1
1000 mg/kg		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
bw/d		feces	soft feces											
		normal	NAD											
	79	head	salivation	Grade: moderate										
				Grade: slight	1	1	1	1	1	1	1	1	1	1
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
		normal	NAD											
	80	head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day							
					42	42	42	43	43	43	44	44
	41	normal	NAD		1	1	1	1	1	1	1	1
	42	normal	NAD		1	1	1	1	1	1	1	1
	43	normal	NAD		1	1	1	1	1	1	1	1
	44	normal	NAD		1	1	1	1	1	1	1	1
	45	normal	NAD		1	1	1	1	1	1	1	1
	46	normal	NAD		1	1	1	1	1	1	1	1
	47	normal	NAD		1	1	1	1	1	1	1	1
	48	normal	NAD		1	1	1	1	1	1	1	1
	49	normal	NAD		1	1	1	1	1	1	1	1
	50	normal	NAD		1	1	1	1	1	1	1	1

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day							
					42	42	42	43	43	43	44	44
1 / F 100 mg/kg bwd	51	normal head	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
	52	normal head	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
	53	normal head	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
	54	normal	NAD		1	1	1	1	1	1	1	1
	55	normal	NAD		1	1	1	1	1	1	1	1
	56	normal	NAD		1	1	1	1	1	1	1	1
	57	normal head	NAD		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight								
	58	normal	NAD		1	1	1	1	1	1	1	1
	59	normal	NAD		1	1	1	1	1	1	1	1
	60	normal	NAD		1	1	1	1	1	1	1	1

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					42	42	42	43	43	43	44	44	44	44
2 / F 300 mg/kg bw/d	61	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	62	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	63	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	64	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	65	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					42	42	42	43	43	43	44	44	44	44
66		normal	NAD		1		1		1		1		1	
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight		1			1			1		
		feces	soft feces	Color: light brown										
67		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
68	2 / F 300 mg/kg bw/d	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight				1						
		feces	soft feces	Color: light brown										
69		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
70		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day							
					42	42	42	43	43	43	44	44
		normal	NAD									
	71	head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1
		feces	soft feces									
		normal	NAD									
		head	salivation	Grade: moderate								
	72			Grade: slight								
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1
		feces	soft feces									
		normal	NAD									
3 / F		head	salivation	Grade: slight								
1000 mg/kg	73			Color: light brown	1	1	1	1	1	1	1	1
bw/d		feces	discolored feces									
		feces	soft feces									
		normal	NAD									
		head	salivation	Grade: slight								
	74			Color: light brown	1	1	1	1	1	1	1	1
		feces	discolored feces									
		feces	soft feces									
		normal	NAD									
	75			Color: light brown	1	1	1	1	1	1	1	1
		feces	discolored feces									
		feces	soft feces									

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day							
					42	42	42	43	43	43	44	44
		normal	NAD									
	76	head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1
		feces	soft feces									
		normal	NAD									
	77	head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1
		feces	soft feces									
		normal	NAD									
3 / F	78	head	salivation	Grade: slight								
1000 mg/kg		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1
bw/d		feces	soft feces									
		normal	NAD									
	79	head	salivation	Grade: moderate								
				Grade: slight								
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1
		feces	soft feces									
		normal	NAD									
	80	head	salivation	Grade: slight								
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1
		feces	soft feces									

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					45 [-01:00-00:00]	45 [00:00-02:00]	45 [02:00-05:00]	46 [-01:00-00:00]	46 [00:00-02:00]	46 [02:00-05:00]	47 [-01:00-00:00]	47 [00:00-02:00]	47 [02:00-05:00]	
0 / F 0 mg/kg bw/d	41	normal	NAD		1	1	1	1	1	1	1	1	1	1
	42	normal	NAD		1	1	1	1	1	1	1	1	1	1
	43	normal	NAD		1	1	1	1	1	1	1	1	1	1
	44	normal	NAD		1	1	1	1	1	1	1	1	1	1
	45	normal	NAD		1	1	1	1	1	1	1	1	1	1
	46	normal	NAD		1	1	1	1	1	1	1	1	1	1
	47	normal	NAD		1	1	1	1	1	1	1	1	1	1
	48	normal	NAD		1	1	1	1	1	1	1	1	1	1
	49	normal	NAD		1	1	1	1	1	1	1	1	1	1
	50	normal	NAD		1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					45 [01:00-00:00]	45 [00:00-02:00]	45 [02:00-05:00]	46 [01:00-00:00]	46 [00:00-02:00]	46 [02:00-05:00]	47 [01:00-00:00]	47 [00:00-02:00]	47 [02:00-05:00]	
1 / F 100 mg/kg bwd	51	normal head	NAD salivation											
		normal head	NAD salivation	Grade: slight	1	1	1	1	1	1	1	1	1	1
	52	normal head	NAD salivation	Grade: slight										
		normal head	NAD salivation	Grade: slight	1	1	1	1	1	1	1	1	1	1
	53	normal head	NAD salivation	Grade: slight										
		normal head	NAD salivation	Grade: slight	1	1	1	1	1	1	1	1	1	1
	54	normal	NAD		1	1	1	1	1	1	1	1	1	1
		normal	NAD		1	1	1	1	1	1	1	1	1	1
	55	normal	NAD		1	1	1	1	1	1	1	1	1	1
		normal	NAD		1	1	1	1	1	1	1	1	1	1
56	normal	NAD		1	1	1	1	1	1	1	1	1	1	
	normal head	NAD salivation	Grade: slight											
57	normal head	NAD salivation	Grade: slight	1	1	1	1	1	1	1	1	1	1	
	normal	NAD		1	1	1	1	1	1	1	1	1	1	
58	normal	NAD		1	1	1	1	1	1	1	1	1	1	
	normal	NAD		1	1	1	1	1	1	1	1	1	1	
59	normal	NAD		1	1	1	1	1	1	1	1	1	1	
	normal	NAD		1	1	1	1	1	1	1	1	1	1	
60	normal	NAD		1	1	1	1	1	1	1	1	1	1	

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					45	45	45	46	46	46	47	47	47	47
	61	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	62	normal	NAD		1			1	1	1	1	1	1	1
		head	salivation	Grade: slight		1								
		feces	discolored feces	Color: light brown										
		feces	soft feces											
2 / F 300 mg/kg bw/d	63	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight										
		feces	soft feces	Color: light brown										
	64	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	65	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight	1									
		feces	soft feces	Color: light brown										

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					45	45	45	46	46	46	47	47	47	47
66		normal	NAD		1		1		1		1			1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight	1				1			1		
		feces	soft feces	Color: light brown										
67		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
68	2 / F 300 mg/kg bw/d	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight	1							1		
		feces	soft feces	Color: light brown										
69		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
70		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					45	45	45	46	46	46	47	47	47	47
3 / F 1000 mg/kg bw/d	71	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	72	normal	NAD											
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight										
		feces	soft feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
	73	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	74	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	75	normal	NAD											
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					45	45	45	46	46	46	47	47	47	47
					[01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[02:00-05:00]
3 / F 1000 mg/kg bw/d	76	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	77	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	78	normal	NAD											
		head	salivation	Grade: slight	1	1	1	1	1	1	1	1	1	1
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	79	normal	NAD											
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight	1	1	1	1	1	1	1	1	1	1
		feces	soft feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
80		normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					48	48	48	49	49	49	50	50	50	50
					[01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[-01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[-01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[02:00-05:00]
0 / F 0 mg/kg bw/d	41	normal	NAD		1	1	1	1	1	1	1	1	1	1
	42	normal	NAD		1	1	1	1	1	1	1	1	1	1
	43	normal	NAD		1	1	1	1	1	1	1	1	1	1
	44	normal	NAD		1	1	1	1	1	1	1	1	1	1
	45	normal	NAD		1	1	1	1	1	1	1	1	1	1
	46	normal	NAD		1	1	1	1	1	1	1	1	1	1
	47	normal	NAD		1	1	1	1	1	1	1	1	1	1
	48	normal	NAD		1	1	1	1	1	1	1	1	1	1
	49	normal	NAD		1	1	1	1	1	1	1	1	1	1
	50	normal	NAD		1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					48	48	48	49	49	49	49	50	50	50
1 / F 100 mg/kg bwd	51	normal head	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	52	normal head	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	53	normal head	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	54	normal	NAD		1	1	1	1	1	1	1	1	1	1
	55	normal	NAD		1	1	1	1	1	1	1	1	1	1
	56	normal	NAD		1	1	1	1	1	1	1	1	1	1
	57	normal head	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	58	normal	NAD		1	1	1	1	1	1	1	1	1	1
	59	normal	NAD		1	1	1	1	1	1	1	1	1	1
	60	normal	NAD		1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					48	48	48	49	49	49	50	50	50	50
2 / F 300 mg/kg bw/d	61	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	62	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight					1					
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	63	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	64	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	65	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					48	48	48	49	49	49	50	50	50	50
66		normal	NAD		1			1			1			1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight		1						1		
		feces	soft feces	Color: light brown										
67		normal	NAD		1			1			1			1
		head	salivation	Grade: slight		1								
		feces	discolored feces	Color: light brown										
		feces	soft feces											
68	2 / F 300 mg/kg bw/d	normal	NAD		1			1			1			1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight		1						1		
		feces	soft feces	Color: light brown										
69		normal	NAD		1			1			1			1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
70		normal	NAD		1			1			1			1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					48	48	48	49	49	49	50	50	50	50
3 / F 1000 mg/kg bw/d	71	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	72	normal	NAD											
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight										
		feces	soft feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
	73	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	74	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	75	normal	NAD											
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					48	48	48	49	49	49	50	50	50	50
3 / F 1000 mg/kg bw/d	76	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	77	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	78	normal	NAD											
		head	salivation	Grade: slight	1	1	1	1	1	1	1	1	1	1
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	79	normal	NAD											
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight				1	1	1	1	1	1	1
		feces	soft feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
80		normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					51 [-01:00-00:00]	51 [00:00-02:00]	51 [02:00-05:00]	52 [-01:00-00:00]	52 [00:00-02:00]	52 [02:00-05:00]	53 [-01:00-00:00]	53 [00:00-02:00]	53 [02:00-05:00]	
0 / F 0 mg/kg bw/d	41	normal	NAD		1	1	1	1	1	1	1	1	1	
	42	normal	NAD		1	1	1	1	1	1	1	1	1	
	43	normal	NAD		1	1	1	1	1	1	1	1	1	
	44	normal	NAD		1	1	1	1	1	1	1	1	1	
	45	normal	NAD		1	1	1	1	1	1	1	1	1	
	46	normal	NAD		1	1	1	1	1	1	1	1	1	
	47	normal	NAD		1	1	1	1	1	1	1	1	1	
	48	normal	NAD		1	1	1	1	1	1	1	1	1	
	49	normal	NAD		1	1	1	1	1	1	1	1	1	
	50	normal	NAD		1	1	1	1	1	1	1	1	1	

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					51 [-01:00-00:00]	51 [00:00-02:00]	51 [02:00-05:00]	52 [-01:00-00:00]	52 [00:00-02:00]	52 [02:00-05:00]	53 [-01:00-00:00]	53 [00:00-02:00]	53 [02:00-05:00]	
1 / F 100 mg/kg bwd	51	normal head	NAD salivation	Grade: slight	1	1	1	1	1	1	1	1	1	1
	52	normal head	NAD salivation	Grade: slight	1	1	1	1	1	1	1	1	1	1
	53	normal head	NAD salivation	Grade: slight	1	1	1	1	1	1	1	1	1	1
	54	normal	NAD		1	1	1	1	1	1	1	1	1	1
	55	normal	NAD		1	1	1	1	1	1	1	1	1	1
	56	normal	NAD		1	1	1	1	1	1	1	1	1	1
	57	normal head	NAD salivation	Grade: slight	1	1	1	1	1	1	1	1	1	1
	58	normal	NAD		1	1	1	1	1	1	1	1	1	1
	59	normal	NAD		1	1	1	1	1	1	1	1	1	1
	60	normal	NAD		1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					51	51	51	51	52	52	52	53	53	53
2 / F 300 mg/kg bw/d	61	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	62	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	63	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	64	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	65	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown									1	
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					51 [-01:00-00:00]	51 [00:00-02:00]	51 [02:00-05:00]	52 [-01:00-00:00]	52 [00:00-02:00]	52 [02:00-05:00]	53 [-01:00-00:00]	53 [00:00-02:00]	53 [02:00-05:00]	
	66	normal	NAD		1			1		1				
		head	salivation	Grade: moderate					1					
		feces	discolored feces	Grade: slight		1								
		feces	soft feces	Color: light brown										
	67	normal	NAD		1			1		1				
		head	salivation	Grade: slight						1		1		1
		feces	discolored feces	Color: light brown										
		feces	soft feces											
2 / F 300 mg/kg bw/d	68	normal	NAD		1			1		1				1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight									1	
		feces	soft feces	Color: light brown										
	69	normal	NAD		1			1		1				1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	70	normal	NAD		1			1		1				1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					51 [-01:00-00:00]	51 [00:00-02:00]	51 [02:00-05:00]	52 [-01:00-00:00]	52 [00:00-02:00]	52 [02:00-05:00]	53 [-01:00-00:00]	53 [00:00-02:00]	53 [02:00-05:00]	
3 / F 1000 mg/kg pow/d	71	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	
		feces	soft feces											
	72	normal	NAD											
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight	1	1	1	1	1	1	1	1	1	
		feces	soft feces	Color: light brown	1	1	1	1	1	1	1	1	1	
	73	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	
		feces	soft feces											
74	normal	NAD												
	head	salivation	Grade: slight											
	feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1		
	feces	soft feces												
75	normal	NAD												
	feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1	
	feces	soft feces												

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					51	51	51	52	52	52	53	53	53	53
					[01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[-01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[-01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[02:00-05:00]
3 / F 1000 mg/kg bw/d	76	normal	NAD											
		head	salivation	Grade: slight					1				1	
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	77	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	78	normal	NAD											
		head	salivation	Grade: slight	1	1	1	1	1	1	1	1	1	1
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	79	normal	NAD											
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight	1	1	1	1	1	1	1	1	1	1
		feces	soft feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
	80	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					54 [-01:00-00:00]	54 [00:00-02:00]	54 [02:00-05:00]	55 [-01:00-00:00]	55 [00:00-02:00]	55 [02:00-05:00]	56 [-01:00-00:00]	56 [00:00-02:00]	56 [02:00-05:00]	
0 / F 0 mg/kg bw/d	41	normal	NAD		1	1	1	1	1	1	1	1	1	1
	42	normal	NAD		1	1	1	1	1	1	1	1	1	1
	43	normal	NAD		1	1	1	1	1	1	1	1	1	1
	44	normal	NAD		1	1	1	1	1	1	1	1	1	1
	45	normal	NAD		1	1	1	1	1	1	1	1	1	1
	46	normal	NAD		1	1	1	1	1	1	1	1	1	1
	47	normal	NAD		1	1	1	1	1	1	1	1	1	1
	48	normal	NAD		1	1	1	1	1	1	1	1	1	1
	49	normal	NAD		1	1	1	1	1	1	1	1	1	1
	50	normal	NAD		1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					54 [-01:00-00:00]	54 [00:00-02:00]	54 [02:00-05:00]	55 [-01:00-00:00]	55 [00:00-02:00]	55 [02:00-05:00]	56 [-01:00-00:00]	56 [00:00-02:00]	56 [02:00-05:00]	
1 / F 100 mg/kg bwd	51	normal head	NAD salivation	Grade: slight	1									
	52	normal head	NAD salivation	Grade: slight	1	1	1	1	1	1	1	1	1	1
	53	normal head	NAD salivation	Grade: slight	1									
	54	normal	NAD		1	1	1	1	1	1	1	1	1	1
	55	normal	NAD		1	1	1	1	1	1	1	1	1	1
	56	normal	NAD		1	1	1	1	1	1	1	1	1	1
	57	normal head	NAD salivation	Grade: slight	1	1	1	1	1	1	1	1	1	1
	58	normal	NAD		1	1	1	1	1	1	1	1	1	1
	59	normal	NAD		1	1	1	1	1	1	1	1	1	1
	60	normal	NAD		1	1	1	1	1	1	1	1	1	1

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					54	54	54	55	55	55	56	56	56	56
61		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
62		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
63		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown							1			
		feces	soft feces											
64		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown							1			
		feces	soft feces											
65		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown							1			
		feces	soft feces											

2 / F
300 mg/kg
bw/d

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					54	54	54	55	55	55	56	56	56	56
66		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate					1					
		feces	discolored feces	Grade: slight										
		feces	soft feces	Color: light brown										
67		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
68	2 / F 300 mg/kg bw/d	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight				1						
		feces	soft feces	Color: light brown										
69		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
70		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					54	54	54	55	55	55	56	56	56	56
3 / F 1000 mg/kg bw/d	71	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	72	normal	NAD											
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight										
		feces	soft feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
	73	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	74	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	75	normal	NAD											
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day										
					54	54	54	55	55	55	56	56	56	56	56
3 / F 1000 mg/kg bw/d	76	normal	NAD												
		head	salivation	Grade: slight											
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1	1
		feces	soft feces												
	77	normal	NAD												
		head	salivation	Grade: slight											
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1	1
		feces	soft feces												
	78	normal	NAD												
		head	salivation	Grade: slight											
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1	1
		feces	soft feces												
	79	normal	NAD												
		head	salivation	Grade: moderate											
		feces	discolored feces	Grade: slight	1	1	1	1	1	1	1	1	1	1	1
		feces	soft feces	Color: light brown	1	1	1	1	1	1	1	1	1	1	1
	80	normal	NAD												
		head	salivation	Grade: slight											
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1	1
		feces	soft feces												

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					57 [01:00-00:00]	57 [00:00-02:00]	57 [02:00-05:00]	58 [01:00-00:00]	58 [00:00-02:00]	58 [02:00-05:00]	59 [01:00-00:00]	59 [00:00-02:00]	59 [02:00-05:00]	
0 / F 0 mg/kg bw/d	41	normal	NAD		1	1	1	1	1	1	1	1	1	1
	42	normal	NAD		1	1	1	1	1	1	1	1	1	1
	43	normal	NAD		1	1	1	1	1	1	1	1	1	1
	44	normal	NAD		1	1	1	1	1	1	1	1	1	1
	45	normal	NAD		1	1	1	1	1	1	1	1	1	1
	46	normal	NAD		1	1	1	1	1	1	1	1	1	1
	47	normal	NAD		1	1	1	1	1	1	1	1	1	1
	48	normal	NAD		1	1	1	1	1	1	1	1	1	1
	49	normal	NAD		1	1	1	1	1	1	1	1	1	1
	50	normal	NAD		1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					57 [01:00-00:00]	57 [00:00-02:00]	57 [02:00-05:00]	58 [01:00-00:00]	58 [00:00-02:00]	58 [02:00-05:00]	59 [01:00-00:00]	59 [00:00-02:00]	59 [02:00-05:00]	
1 / F 100 mg/kg bwd	51	normal head	NAD salivation	Grade: slight	1	1	1	1	1	1	1	1	1	1
	52	normal head	NAD salivation	Grade: slight	1	1	1	1	1	1	1	1	1	1
	53	normal head	NAD salivation	Grade: slight	1	1	1	1	1	1	1	1	1	1
	54	normal	NAD		1	1	1	1	1	1	1	1	1	1
	55	normal	NAD		1	1	1	1	1	1	1	1	1	1
	56	normal	NAD		1	1	1	1	1	1	1	1	1	1
	57	normal head	NAD salivation	Grade: slight	1	1	1	1	1	1	1	1	1	1
	58	normal	NAD		1	1	1	1	1	1	1	1	1	1
	59	normal	NAD		1	1	1	1	1	1	1	1	1	1
	60	normal	NAD		1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					57	57	57	58	58	58	59	59	59	59
	61	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	62	normal	NAD		1		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight		1								
		feces	discolored feces	Color: light brown										
		feces	soft feces											
2 / F 300 mg/kg bw/d	63	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	64	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	65	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown		1					1	1	1	1
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					57 [00:00-02:00]	57 [02:00-05:00]	57 [01:00-00:00]	58 [00:00-02:00]	58 [02:00-05:00]	58 [01:00-00:00]	59 [00:00-02:00]	59 [02:00-05:00]	59 [01:00-00:00]	59 [02:00-05:00]
66		normal	NAD		1									
		head	salivation	Grade: moderate		1								
		feces	discolored feces	Grade: slight				1					1	
		feces	soft feces	Color: light brown										
67		normal	NAD		1									
		head	salivation	Grade: slight		1		1			1		1	
		feces	discolored feces	Color: light brown										
		feces	soft feces											
68		normal	NAD		1									
		head	salivation	Grade: moderate		1		1			1		1	
		feces	discolored feces	Grade: slight		1							1	
		feces	soft feces	Color: light brown										
69		normal	NAD		1									
		head	salivation	Grade: slight		1		1			1		1	
		feces	discolored feces	Color: light brown										
		feces	soft feces											
70		normal	NAD		1									
		head	salivation	Grade: slight		1		1			1		1	
		feces	discolored feces	Color: light brown										
		feces	soft feces											

2 / F
300 mg/kg
bw/d

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					57	57	57	58	58	58	59	59	59	59
3 / F 1000 mg/kg bw/d	71	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	72	normal	NAD											
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight										
		feces	soft feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
	73	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	74	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	75	normal	NAD											
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					57	57	57	58	58	58	59	59	59	59
3 / F 1000 mg/kg bw/d	76	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	77	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	78	normal	NAD											
		head	salivation	Grade: slight	1	1	1	1	1	1	1	1	1	1
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	79	normal	NAD											
		head	salivation	Grade: moderate	1	1	1	1	1	1	1	1	1	1
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	80	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					60	60	60	61	61	61	62	62	62	62
	41	normal	NAD		1	1	1	1	1	1	1	1	1	1
	42	normal	NAD		1	1	1	1	1	1	1	1	1	1
	43	normal	NAD		1	1	1	1	1	1	1	1	1	1
	44	normal	NAD		1	1	1	1	1	1	1	1	1	1
	45	normal	NAD		1	1	1	1	1	1	1	1	1	1
	46	normal	NAD		1	1	1	1	1	1	1	1	1	1
	47	normal	NAD		1	1	1	1	1	1	1	1	1	1
	48	normal	NAD		1	1	1	1	1	1	1	1	1	1
	49	normal	NAD		1	1	1	1	1	1	1	1	1	1
	50	normal	NAD		1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day											
					60	60	60	60	61	61	61	61	61	62	62	62
1 / F 100 mg/kg bwd	51	normal head	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
	52	normal head	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
	53	normal head	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
	54	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
	55	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
	56	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
	57	normal head	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
	58	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
	59	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
	60	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day											
					60	60	60	60	61	61	61	61	61	61	62	62
2 / F 300 mg/kg bw/d	61	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
		feces	discolored feces	Color: light brown												
		feces	soft feces													
	62	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
		feces	discolored feces	Color: light brown												
		feces	soft feces													
	63	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate												
		feces	discolored feces	Color: light brown												
		feces	soft feces													
	64	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
		feces	discolored feces	Color: light brown												
		feces	soft feces													
	65	normal	NAD													
		head	salivation	Grade: moderate												
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1	1	1
		feces	soft feces													

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					60	60	60	61	61	61	62	62	62	62
66		normal head	NAD		1		1				1			1
		salivation		Grade: moderate										
		feces	discolored feces	Grade: slight	1	1						1		
		feces	soft feces	Color: light brown										
67		normal head	NAD		1	1	1	1	1	1	1	1	1	1
		salivation		Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
68	2 / F 300 mg/kg bw/d	normal head	NAD		1	1	1	1	1	1	1	1	1	1
		salivation		Grade: moderate										
		feces	discolored feces	Grade: slight	1	1								
		feces	soft feces	Color: light brown										
69		normal head	NAD		1	1	1	1	1	1	1	1	1	1
		salivation		Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
70		normal head	NAD		1	1	1	1	1	1	1	1	1	1
		salivation		Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					60	60	60	61	61	61	62	62	62	62
3 / F 1000 mg/kg bw/d	71	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	72	normal	NAD											
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight										
		feces	soft feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
	73	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	74	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	75	normal	NAD											
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day											
					60	60	60	61	61	61	62	62	62	62	62	62
3 / F 1000 mg/kg bw/d	76	normal	NAD													
		head	salivation	Grade: slight												
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1	1	1
		feces	soft feces													
	77	normal	NAD													
		head	salivation	Grade: slight												
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1	1	1
		feces	soft feces													
	78	normal	NAD													
		head	salivation	Grade: slight	1	1	1	1	1	1	1	1	1	1	1	1
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1	1	1
		feces	soft feces													
	79	normal	NAD													
		head	salivation	Grade: moderate												
		feces	discolored feces	Grade: slight	1	1	1	1	1	1	1	1	1	1	1	1
		feces	soft feces	Color: light brown	1	1	1	1	1	1	1	1	1	1	1	1
	80	normal	NAD													
		head	salivation	Grade: slight												
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1	1	1
		feces	soft feces													

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					63 [-01:00-00:00]	63 [00:00-02:00]	63 [02:00-05:00]	64 [-01:00-00:00]	64 [00:00-02:00]	64 [02:00-05:00]	65 [-01:00-00:00]	65 [00:00-02:00]	65 [02:00-05:00]	
0 / F 0 mg/kg bw/d	41	normal	NAD		1	1	1	1	1	1	1	1	1	1
	42	normal	NAD		1	1	1	1	1	1	1	1	1	1
	43	normal	NAD		1	1	1	1	1	1	1	1	1	1
	44	normal	NAD		1	1	1	1	1	1	1	1	1	1
	45	normal	NAD		1	1	1	1	1	1	1	1	1	1
	46	normal	NAD		1	1	1	1	1	1	1	1	1	1
	47	normal	NAD		1	1	1	1	1	1	1	1	1	1
	48	normal	NAD		1	1	1	1	1	1	1	1	1	1
	49	normal	NAD		1	1	1	1	1	1	1	1	1	1
	50	normal	NAD		1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					63 [00:00-01:00]	63 [01:00-02:00]	63 [02:00-05:00]	64 [00:00-01:00]	64 [01:00-02:00]	64 [02:00-05:00]	65 [00:00-01:00]	65 [01:00-02:00]	65 [02:00-05:00]	
1 / F 100 mg/kg bwd	51	normal head	NAD salivation											
	52	normal head	NAD salivation	Grade: slight	1	1	1	1	1	1	1	1	1	1
	53	normal head	NAD salivation	Grade: slight	1	1	1	1	1	1	1	1	1	1
	54	normal	NAD		1	1	1	1	1	1	1	1	1	1
	55	normal	NAD		1	1	1	1	1	1	1	1	1	1
56	normal	NAD		1	1	1	1	1	1	1	1	1	1	
57	normal head	NAD salivation	Grade: slight	1	1	1	1	1	1	1	1	1	1	1
58	normal	NAD		1	1	1	1	1	1	1	1	1	1	1
59	normal	NAD		1	1	1	1	1	1	1	1	1	1	1
60	normal	NAD		1	1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					63	63	63	64	64	64	65	65	65	65
2 / F 300 mg/kg bw/d	61	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	62	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	63	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	64	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	65	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					63 [-01:00-00:00]	63 [00:00-02:00]	63 [02:00-05:00]	64 [-01:00-00:00]	64 [00:00-02:00]	64 [02:00-05:00]	65 [-01:00-00:00]	65 [00:00-02:00]	65 [02:00-05:00]	
	66	normal	NAD		1		1		1		1			1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight		1							1	
		feces	soft feces	Color: light brown										
	67	normal	NAD		1		1		1		1		1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
2 / F 300 mg/kg bw/d	68	normal	NAD		1		1		1		1		1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight									1	
		feces	soft feces	Color: light brown										
	69	normal	NAD		1		1		1		1		1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	70	normal	NAD		1		1		1		1		1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					63	63	63	64	64	64	65	65	65	65
3 / F 1000 mg/kg bw/d	71	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	72	normal	NAD											
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight										
		feces	soft feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
	73	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	74	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	75	normal	NAD											
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					63	63	63	64	64	64	65	65	65	65
3 / F 1000 mg/kg bw/d	76	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	77	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	78	normal	NAD											
		head	salivation	Grade: slight	1	1	1	1	1	1	1	1	1	1
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	79	normal	NAD											
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight	1	1	1	1	1	1	1	1	1	1
		feces	soft feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
80		normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day								
					66 [-01:00-00:00]	66 [00:00-02:00]	66 [02:00-05:00]	67 [-01:00-00:00]	67 [00:00-02:00]	67 [02:00-05:00]	68 [-01:00-00:00]	68 [00:00-02:00]	68 [02:00-05:00]
0 / F 0 mg/kg bw/d	41	normal	NAD		1	1	1	1	1	1	1	1	1
	42	normal	NAD		1	1	1	1	1	1	1	1	1
	43	normal	NAD		1	1	1	1	1	1	1	1	1
	44	normal	NAD		1	1	1	1	1	1	1	1	1
	45	normal	NAD		1	1	1	1	1	1	1	1	1
	46	normal	NAD		1	1	1	1	1	1	1	1	1
	47	normal	NAD		1	1	1	1	1	1	1	1	1
	48	normal	NAD		1	1	1	1	1	1	1	1	1
	49	normal	NAD		1	1	1	1	1	1	1	1	1
	50	normal	NAD		1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day								
					66 [01:00-00:00]	66 [00:00-02:00]	66 [02:00-05:00]	67 [01:00-00:00]	67 [00:00-02:00]	67 [02:00-05:00]	68 [01:00-00:00]	68 [00:00-02:00]	68 [02:00-05:00]
1 / F 100 mg/kg bwd	51	normal head	NAD salivation	Grade: slight	1	1	1	1	1	1	1	1	1
	52	normal head	NAD salivation	Grade: slight	1	1	1	1	1	1	1	1	1
	53	normal head	NAD salivation	Grade: slight	1	1	1	1	1	1	1	1	1
	54	normal	NAD		1	1	1	1	1	1	1	1	1
	55	normal	NAD		1	1	1	1	1	1	1	1	1
	56	normal	NAD		1	1	1	1	1	1	1	1	1
	57	normal head	NAD salivation	Grade: slight	1	1	1	1	1	1	1	1	1
	58	normal	NAD		1	1	1	1	1	1	1	1	1
	59	normal	NAD		1	1	1	1	1	1	1	1	1
	60	normal	NAD		1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day											
					66	66	66	66	67	67	67	67	67	68	68	68
2 / F 300 mg/kg bw/d	61	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
		feces	discolored feces	Color: light brown												
		feces	soft feces													
	62	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
		feces	discolored feces	Color: light brown												
		feces	soft feces													
	63	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate												
		feces	discolored feces	Color: light brown												
		feces	soft feces													
	64	normal	NAD		1	1	1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight												
		feces	discolored feces	Color: light brown												
		feces	soft feces													
	65	normal	NAD													
		head	salivation	Grade: moderate												
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1	1	1
		feces	soft feces													

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					66	66	66	66	67	67	67	67	68	68
	66	normal head	NAD		1				1				1	
		salivation		Grade: moderate										
		feces	discolored feces	Grade: slight		1							1	
		feces	soft feces	Color: light brown										
	67	normal head	NAD		1				1				1	
		salivation		Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
2 / F 300 mg/kg bw/d	68	normal head	NAD		1				1				1	
		salivation		Grade: moderate										
		feces	discolored feces	Grade: slight									1	
		feces	soft feces	Color: light brown										
	69	normal head	NAD		1				1				1	
		salivation		Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	70	normal head	NAD		1				1				1	
		salivation		Grade: slight										
		feces	discolored feces	Color: light brown									1	
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					66	66	66	66	67	67	67	67	68	68
3 / F 1000 mg/kg bw/d	71	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	72	normal	NAD											
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight										
		feces	soft feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
	73	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	74	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	75	normal	NAD											
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					66	66	66	67	67	67	67	68	68	68
3 / F 1000 mg/kg bw/d	76	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	77	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	78	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	79	normal	NAD											
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight	1	1	1	1	1	1	1	1	1	1
		feces	soft feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
80		normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					69 [-01:00-00:00]	69 [00:00-02:00]	69 [02:00-05:00]	70 [-01:00-00:00]	70 [00:00-02:00]	70 [02:00-05:00]	71 [-01:00-00:00]	71 [00:00-02:00]	71 [02:00-05:00]	
0 / F 0 mg/kg bw/d	41	normal	NAD		1	1	1	1	1	1	1	1	1	1
	42	normal	NAD		1	1	1	1	1	1	1	1	1	1
	43	normal	NAD		1	1	1	1	1	1	1	1	1	1
	44	normal	NAD		1	1	1	1	1	1	1	1	1	1
	45	normal	NAD		1	1	1	1	1	1	1	1	1	1
	46	normal	NAD		1	1	1	1	1	1	1	1	1	1
	47	normal	NAD		1	1	1	1	1	1	1	1	1	1
	48	normal	NAD		1	1	1	1	1	1	1	1	1	1
	49	normal	NAD		1	1	1	1	1	1	1	1	1	1
	50	normal	NAD		1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					69	69	69	70	70	70	70	71	71	71
1 / F 100 mg/kg bwd	51	normal head	NAD	Grade: slight	1	1	1	1	1	1	1	1	1	1
	52	normal head	NAD	Grade: slight	1	1	1	1	1	1	1	1	1	1
	53	normal head	NAD	Grade: slight	1	1	1	1	1	1	1	1	1	1
	54	normal	NAD		1	1	1	1	1	1	1	1	1	1
	55	normal	NAD		1	1	1	1	1	1	1	1	1	1
	56	normal	NAD		1	1	1	1	1	1	1	1	1	1
	57	normal head	NAD	Grade: slight	1	1	1	1	1	1	1	1	1	1
	58	normal	NAD		1	1	1	1	1	1	1	1	1	1
	59	normal	NAD		1	1	1	1	1	1	1	1	1	1
	60	normal	NAD		1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					69	69	69	70	70	70	70	71	71	71
2 / F 300 mg/kg bw/d	61	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	62	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	63	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	64	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	65	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					69	69	69	70	70	70	71	71	71	71
	66	normal	NAD		1		1			1				1
		head	salivation	Grade: moderate					1					
		feces	discolored feces	Grade: slight		1						1		
		feces	soft feces	Color: light brown										
	67	normal	NAD		1		1		1		1		1	1
		head	salivation	Grade: slight		1								
		feces	discolored feces	Color: light brown										
		feces	soft feces											
2 / F 300 mg/kg bw/d	68	normal	NAD		1		1		1		1		1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight		1			1					
		feces	soft feces	Color: light brown										
	69	normal	NAD		1		1		1		1		1	1
		head	salivation	Grade: slight		1								
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	70	normal	NAD		1		1		1		1		1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					69	69	69	70	70	70	71	71	71	71
3 / F 1000 mg/kg bw/d	71	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	72	normal	NAD											
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight										
		feces	soft feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
	73	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	74	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	75	normal	NAD											
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					69	69	69	70	70	70	70	71	71	71
3 / F 1000 mg/kg bw/d	76	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
	77	feces	soft feces											
		normal	NAD											
		head	salivation	Grade: slight										
	78	feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
		normal	NAD											
	79	head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
80	79	normal	NAD											
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
	80	feces	soft feces											
		normal	NAD											
		head	salivation	Grade: slight										
80	80	feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
		normal	NAD											

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day							
					72	72	72	73	73	73	74	74
	41	normal	NAD		1	1	1	1	1	1	1	1
	42	normal	NAD		1	1	1	1	1	1	1	1
	43	normal	NAD		1	1	1	1	1	1	1	1
	44	normal	NAD		1	1	1	1	1	1	1	1
	45	normal	NAD		1	1	1	1	1	1	1	1
	46	normal	NAD		1	1	1	1	1	1	1	1
	47	normal	NAD		1	1	1	1	1	1	1	1
	48	normal	NAD		1	1	1	1	1	1	1	1
	49	normal	NAD		1	1	1	1	1	1	1	1
	50	normal	NAD		1	1	1	1	1	1	1	1

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					72	72	72	73	73	73	74	74	74	74
1 / F 100 mg/kg bwd	51	normal head	NAD	Grade: slight	1	1	1	1	1	1	1	1	1	1
	52	normal head	NAD	Grade: slight	1	1	1	1	1	1	1	1	1	1
	53	normal head	NAD	Grade: slight	1	1	1	1	1	1	1	1	1	1
	54	normal	NAD		1	1	1	1	1	1	1	1	1	1
	55	normal	NAD		1	1	1	1	1	1	1	1	1	1
	56	normal	NAD		1	1	1	1	1	1	1	1	1	1
	57	normal head	NAD	Grade: slight	1	1	1	1	1	1	1	1	1	1
	58	normal	NAD		1	1	1	1	1	1	1	1	1	1
	59	normal	NAD		1	1	1	1	1	1	1	1	1	1
	60	normal	NAD		1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					72	72	72	73	73	73	74	74	74	74
2 / F 300 mg/kg bw/d	61	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	62	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	63	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	64	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	65	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					72	72	72	73	73	73	74	74	74	74
66		normal	NAD		1			1			1			1
		head	salivation	Grade: moderate		1			1				1	
		feces	discolored feces	Grade: slight										
		feces	soft feces	Color: light brown										
67		normal	NAD		1			1			1		1	1
		head	salivation	Grade: slight		1			1					
		feces	discolored feces	Color: light brown										
		feces	soft feces											
68	2 / F 300 mg/kg bw/d	normal	NAD		1			1			1			1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight		1			1				1	
		feces	soft feces	Color: light brown										
69		normal	NAD		1			1			1		1	1
		head	salivation	Grade: slight		1			1					
		feces	discolored feces	Color: light brown										
		feces	soft feces											
70		normal	NAD		1			1			1		1	1
		head	salivation	Grade: slight		1			1					
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					72	72	72	73	73	73	74	74	74	74
3 / F 1000 mg/kg bw/d	71	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	72	normal	NAD											
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight										
		feces	soft feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
	73	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	74	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	75	normal	NAD											
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					72	72	72	73	73	73	74	74	74	74
3 / F 1000 mg/kg bw/d	76	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	77	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	78	normal	NAD											
		head	salivation	Grade: slight	1	1	1	1	1	1	1	1	1	1
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	79	normal	NAD											
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight	1	1	1	1	1	1	1	1	1	1
		feces	soft feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
	80	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					75 [-01:00-00:00]	75 [00:00-02:00]	75 [02:00-05:00]	76 [-01:00-00:00]	76 [00:00-02:00]	76 [02:00-05:00]	77 [-01:00-00:00]	77 [00:00-02:00]	77 [02:00-05:00]	
0 / F 0 mg/kg bw/d	41	normal	NAD		1	1	1	1	1	1	1	1	1	
	42	normal	NAD		1	1	1	1	1	1	1	1	1	
	43	normal	NAD		1	1	1	1	1	1	1	1	1	
	44	normal	NAD		1	1	1	1	1	1	1	1	1	
	45	normal	NAD		1	1	1	1	1	1	1	1	1	
	46	normal	NAD		1	1	1	1	1	1	1	1	1	
	47	normal	NAD		1	1	1	1	1	1	1	1	1	
	48	normal	NAD		1	1	1	1	1	1	1	1	1	
	49	normal	NAD		1	1	1	1	1	1	1	1	1	
	50	normal	NAD		1	1	1	1	1	1	1	1	1	

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					75 [-01:00-00:00]	75 [00:00-02:00]	75 [02:00-05:00]	76 [-01:00-00:00]	76 [00:00-02:00]	76 [02:00-05:00]	77 [-01:00-00:00]	77 [00:00-02:00]	77 [02:00-05:00]	
1 / F 100 mg/kg bwd	51	normal head	NAD salivation	Grade: slight	1	1	1	1	1	1	1	1	1	
	52	normal head	NAD salivation	Grade: slight	1	1	1	1	1	1	1	1	1	
	53	normal head	NAD salivation	Grade: slight	1	1	1	1	1	1	1	1	1	
	54	normal	NAD		1	1	1	1	1	1	1	1	1	
	55	normal	NAD		1	1	1	1	1	1	1	1	1	
	56	normal	NAD		1	1	1	1	1	1	1	1	1	
	57	normal head	NAD salivation	Grade: slight	1	1	1	1	1	1	1	1	1	
	58	normal	NAD		1	1	1	1	1	1	1	1	1	
	59	normal	NAD		1	1	1	1	1	1	1	1	1	
	60	normal	NAD		1	1	1	1	1	1	1	1	1	

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					75	75	75	76	76	76	77	77	77	77
2 / F 300 mg/kg bw/d	61	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	62	normal	NAD		1		1	1	1	1	1	1	1	1
		head	salivation	Grade: slight		1						1		
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	63	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight										
		feces	soft feces	Color: light brown										
	64	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	65	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight		1			1					
		feces	soft feces	Color: light brown										

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					75	75	75	76	76	76	77	77	77	77
	66	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight								1		
		feces	soft feces	Color: light brown										
	67	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown								1		
		feces	soft feces											
2 / F 300 mg/kg bw/d	68	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight								1		
		feces	soft feces	Color: light brown										
	69	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	70	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					75	75	75	76	76	76	77	77	77	77
3 / F 1000 mg/kg bw/d	71	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	72	normal	NAD											
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight										
		feces	soft feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
	73	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	74	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	75	normal	NAD											
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					75	75	75	76	76	76	77	77	77	77
3 / F 1000 mg/kg bw/d	76	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	77	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	78	normal	NAD											
		head	salivation	Grade: slight	1	1	1	1	1	1	1	1	1	1
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	79	normal	NAD											
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight	1	1	1	1	1	1	1	1	1	1
		feces	soft feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
	80	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					78 [01:00-00:00]	78 [00:00-02:00]	78 [02:00-05:00]	79 [01:00-00:00]	79 [00:00-02:00]	79 [02:00-05:00]	80 [01:00-00:00]	80 [00:00-02:00]	80 [02:00-05:00]	
0 / F 0 mg/kg bw/d	41	normal	NAD		1	1	1	1	1	1	1	1	1	1
	42	normal	NAD		1	1	1	1	1	1	1	1	1	1
	43	normal	NAD		1	1	1	1	1	1	1	1	1	1
	44	normal	NAD		1	1	1	1	1	1	1	1	1	1
	45	normal	NAD		1	1	1	1	1	1	1	1	1	1
	46	normal	NAD		1	1	1	1	1	1	1	1	1	1
	47	normal	NAD		1	1	1	1	1	1	1	1	1	1
	48	normal	NAD		1	1	1	1	1	1	1	1	1	1
	49	normal	NAD		1	1	1	1	1	1	1	1	1	1
	50	normal	NAD		1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					78	78	78	79	79	79	80	80	80	80
1 / F 100 mg/kg bwd	51	normal head	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	52	normal head	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	53	normal head	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	54	normal	NAD		1	1	1	1	1	1	1	1	1	1
	55	normal	NAD		1	1	1	1	1	1	1	1	1	1
	56	normal	NAD		1	1	1	1	1	1	1	1	1	1
	57	normal head	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	58	normal	NAD		1	1	1	1	1	1	1	1	1	1
	59	normal	NAD		1	1	1	1	1	1	1	1	1	1
	60	normal	NAD		1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					78	78	78	79	79	79	80	80	80	80
2 / F 300 mg/kg bw/d	61	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	62	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	63	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	64	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	65	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					78	78	78	79	79	79	80	80	80	80
66		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight				1				1		
		feces	soft feces	Color: light brown										
67		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
68	2 / F 300 mg/kg bw/d	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight								1		
		feces	soft feces	Color: light brown										
69		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
70		normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					78	78	78	79	79	79	80	80	80	80
3 / F 1000 mg/kg bw/d	71	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	72	normal	NAD											
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight										
		feces	soft feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
	73	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	74	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	75	normal	NAD											
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					78	78	78	79	79	79	80	80	80	80
3 / F 1000 mg/kg bw/d	76	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	77	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	78	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
	79	normal	NAD											
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight	1	1	1	1	1	1	1	1	1	1
		feces	soft feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
	80	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					81 [-01:00-00:00]	81 [00:00-02:00]	81 [02:00-05:00]	82 [-01:00-00:00]	82 [00:00-02:00]	82 [02:00-05:00]	83 [-01:00-00:00]	83 [00:00-02:00]	83 [02:00-05:00]	
0 / F 0 mg/kg bw/d	41	normal	NAD		1	1	1	1	1	1	1	1	1	1
	42	normal	NAD		1	1	1	1	1	1	1	1	1	1
	43	normal	NAD		1	1	1	1	1	1	1	1	1	1
	44	normal	NAD		1	1	1	1	1	1	1	1	1	1
	45	normal	NAD		1	1	1	1	1	1	1	1	1	1
	46	normal	NAD		1	1	1	1	1	1	1	1	1	1
	47	normal	NAD		1	1	1	1	1	1	1	1	1	1
	48	normal	NAD		1	1	1	1	1	1	1	1	1	1
	49	normal	NAD		1	1	1	1	1	1	1	1	1	1
	50	normal	NAD		1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day								
					81 [-01:00-00:00]	81 [00:00-02:00]	81 [02:00-05:00]	82 [-01:00-00:00]	82 [00:00-02:00]	82 [02:00-05:00]	83 [-01:00-00:00]	83 [00:00-02:00]	83 [02:00-05:00]
1 / F 100 mg/kg bwd	51	normal head	NAD salivation	Grade: slight	1	1	1	1	1	1	1	1	1
	52	normal head	NAD salivation	Grade: slight	1	1	1	1	1	1	1	1	1
	53	normal head	NAD salivation	Grade: slight	1	1	1	1	1	1	1	1	1
	54	normal	NAD		1	1	1	1	1	1	1	1	1
	55	normal	NAD		1	1	1	1	1	1	1	1	1
	56	normal	NAD		1	1	1	1	1	1	1	1	1
	57	normal head	NAD salivation	Grade: slight	1	1	1	1	1	1	1	1	1
	58	normal	NAD		1	1	1	1	1	1	1	1	1
	59	normal	NAD		1	1	1	1	1	1	1	1	1
	60	normal	NAD		1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					81	81	81	81	82	82	82	83	83	83
2 / F 300 mg/kg bw/d	61	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	62	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight					1					
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	63	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	64	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown										
		feces	soft feces											
	65	normal	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown	1				1					
		feces	soft feces											

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					81 [-01:00-00:00]	81 [00:00-02:00]	81 [02:00-05:00]	82 [-01:00-00:00]	82 [00:00-02:00]	82 [02:00-05:00]	83 [-01:00-00:00]	83 [00:00-02:00]	83 [02:00-05:00]	
	66	normal head	NAD salivation		1		1			1				1
		feces	discolored feces	Grade: moderate		1						1		
		feces	soft feces	Color: light brown										
		normal head	NAD salivation	Grade: slight		1	1	1	1	1	1	1	1	1
	67	feces	discolored feces	Grade: slight										
		feces	soft feces	Color: light brown										
		normal head	NAD salivation	Grade: moderate		1	1	1	1	1	1	1	1	1
		feces	discolored feces	Grade: slight										
2 / F 300 mg/kg bw/d	68	feces	soft feces	Color: light brown										
		normal head	NAD salivation	Grade: slight		1	1	1	1	1	1	1	1	
		feces	discolored feces	Grade: moderate										
		feces	soft feces	Color: light brown										
	69	normal head	NAD salivation	Grade: slight		1	1	1	1	1	1	1	1	1
		feces	discolored feces	Grade: slight										
		feces	soft feces	Color: light brown										
		normal head	NAD salivation	Grade: moderate		1	1	1	1	1	1	1	1	
	70	feces	discolored feces	Grade: slight										
		feces	soft feces	Color: light brown										
		normal head	NAD salivation	Grade: slight		1	1	1	1	1	1	1	1	
		feces	discolored feces	Grade: moderate										

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day								
					81 [-01:00-00:00]	81 [00:00-02:00]	81 [02:00-05:00]	82 [-01:00-00:00]	82 [00:00-02:00]	82 [02:00-05:00]	83 [-01:00-00:00]	83 [00:00-02:00]	83 [02:00-05:00]
3 / F 1000 mg/kg pow/d	71	normal	NAD										
		head	salivation	Grade: slight									
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1
		feces	soft feces									1	1
	72	normal	NAD										
		head	salivation	Grade: moderate									
		feces	discolored feces	Grade: slight								1	
		feces	soft feces	Color: light brown	1	1	1	1	1	1	1	1	1
	73	normal	NAD										
		head	salivation	Grade: slight									
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1
		feces	soft feces									1	1
74	normal	NAD											
	head	salivation	Grade: slight										
	feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	
	feces	soft feces									1	1	
75	normal	NAD											
	feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	
	feces	soft feces										1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					81	81	81	82	82	82	83	83	83	83
					[01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[-01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[-01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[02:00-05:00]
3 / F 1000 mg/kg bw/d	76	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
	77	feces	soft feces											
		normal	NAD											
		head	salivation	Grade: slight										
	78	feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
		normal	NAD											
	79	head	salivation	Grade: slight	1	1	1	1	1	1	1	1	1	1
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces											
80		normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					84 [-01:00-00:00]	84 [00:00-02:00]	84 [02:00-05:00]	85 [-01:00-00:00]	85 [00:00-02:00]	85 [02:00-05:00]	86 [-01:00-00:00]	86 [00:00-02:00]	86 [02:00-05:00]	
0 / F 0 mg/kg bw/d	41	normal	NAD		1	1	1	1	1	1	1	1	1	1
	42	normal	NAD		1	1	1	1	1	1	1	1	1	1
	43	normal	NAD		1	1	1	1	1	1	1	1	1	1
	44	normal	NAD		1	1	1	1	1	1	1	1	1	1
	45	normal	NAD		1	1	1	1	1	1	1	1	1	1
	46	normal	NAD		1	1	1	1	1	1	1	1	1	1
	47	normal	NAD		1	1	1	1	1	1	1	1	1	1
	48	normal	NAD		1	1	1	1	1	1	1	1	1	1
	49	normal	NAD		1	1	1	1	1	1	1	1	1	1
	50	normal	NAD		1	1	1	1	1	1	1	1	1	1

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					84 [01:00-00:00]	84 [00:00-02:00]	84 [02:00-05:00]	85 [01:00-00:00]	85 [00:00-02:00]	85 [02:00-05:00]	86 [01:00-00:00]	86 [00:00-02:00]	86 [02:00-05:00]	
1 / F 100 mg/kg bwd	51	normal head	NAD salivation	Grade: slight	1				1	1	1	1	1	1
	52	normal head	NAD salivation	Grade: slight	1	1	1	1	1	1	1	1	1	1
	53	normal head	NAD salivation	Grade: slight	1	1	1	1	1	1	1	1	1	1
	54	normal	NAD		1	1	1	1	1	1	1	1	1	1
	55	normal	NAD		1	1	1	1	1	1	1	1	1	1
	56	normal	NAD		1	1	1	1	1	1	1	1	1	1
	57	normal head	NAD salivation	Grade: slight	1	1	1	1	1	1	1	1	1	1
	58	normal	NAD		1	1	1	1	1	1	1	1	1	1
	59	normal	NAD		1	1	1	1	1	1	1	1	1	1
	60	normal	NAD		1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					84	84	84	85	85	85	86	86	86	86
		normal	NAD		1	1	1							
	61	head	salivation	Grade: slight									1	
		feces	discolored feces	Color: light brown				1	1	1	1	1	1	1
		feces	soft feces					1	1	1	1	1	1	1
		normal	NAD		1		1							
	62	head	salivation	Grade: slight		1								
		feces	discolored feces	Color: light brown				1	1	1	1	1	1	1
		feces	soft feces					1	1	1	1	1	1	1
		normal	NAD		1	1	1							
	63	head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown				1	1	1	1	1	1	1
		feces	soft feces					1	1	1	1	1	1	1
		normal	NAD		1	1	1							
	64	head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown				1	1	1	1	1	1	1
		feces	soft feces					1	1	1	1	1	1	1
		normal	NAD		1	1	1							
	65	head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown				1	1	1	1	1	1	1
		feces	soft feces					1	1	1	1	1	1	1

2 / F
300 mg/kg
bw/d

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					84	84	84	85	85	85	86	86	86	86
		normal	NAD		1									
		head	salivation	Grade: moderate										
	66			Grade: slight										
		feces	discolored feces	Color: light brown				1	1	1	1	1	1	1
		feces	soft feces					1	1	1	1	1	1	1
		normal	NAD		1									
		head	salivation	Grade: slight										
	67			Color: light brown				1	1	1	1	1	1	1
		feces	discolored feces					1	1	1	1	1	1	1
		feces	soft feces					1	1	1	1	1	1	1
		normal	NAD		1									
		head	salivation	Grade: moderate										
	68			Grade: slight				1	1	1	1	1	1	1
		feces	discolored feces	Color: light brown				1	1	1	1	1	1	1
		feces	soft feces					1	1	1	1	1	1	1
		normal	NAD		1									
		head	salivation	Grade: slight										
	69			Color: light brown				1	1	1	1	1	1	1
		feces	discolored feces					1	1	1	1	1	1	1
		feces	soft feces					1	1	1	1	1	1	1
		normal	NAD		1									
		head	salivation	Grade: slight										
	70			Color: light brown				1	1	1	1	1	1	1
		feces	discolored feces					1	1	1	1	1	1	1
		feces	soft feces					1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					84	84	84	85	85	85	86	86	86	86
3 / F 1000 mg/kg bw/d	71	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1
	72	normal	NAD											
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight										
		feces	soft feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
	73	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1
	74	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1
	75	normal	NAD											
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					84	84	84	85	85	85	86	86	86	86
					[01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[-01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[-01:00-00:00]	[00:00-02:00]	[02:00-05:00]	[02:00-05:00]
3 / F 1000 mg/kg bw/d	76	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
	77	feces	soft feces		1	1	1	1	1	1	1	1	1	1
		normal	NAD											
		head	salivation	Grade: slight										
	78	feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1
		normal	NAD											
	79	head	salivation	Grade: moderate					1				1	
		feces	discolored feces	Grade: slight	1	1	1	1						
		feces	soft feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
80		normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					87 [-01:00-00:00]	87 [00:00-02:00]	87 [02:00-05:00]	88 [-01:00-00:00]	88 [00:00-02:00]	88 [02:00-05:00]	89 [-01:00-00:00]	89 [00:00-02:00]	89 [02:00-05:00]	
0 / F 0 mg/kg bw/d	41	normal	NAD		1	1	1	1	1	1	1	1	1	1
	42	normal	NAD		1	1	1	1	1	1	1	1	1	1
	43	normal	NAD		1	1	1	1	1	1	1	1	1	1
	44	normal	NAD		1	1	1	1	1	1	1	1	1	1
	45	normal	NAD		1	1	1	1	1	1	1	1	1	1
	46	normal	NAD		1	1	1	1	1	1	1	1	1	1
	47	normal	NAD		1	1	1	1	1	1	1	1	1	1
	48	normal	NAD		1	1	1	1	1	1	1	1	1	1
	49	normal	NAD		1	1	1	1	1	1	1	1	1	1
	50	normal	NAD		1	1	1	1	1	1	1	1	1	1

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					87	87	87	88	88	88	89	89	89	89
1 / F 100 mg/kg bwd	51	normal head	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight									1	
	52	normal head	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	53	normal head	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight										
	54	normal	NAD		1	1	1	1	1	1	1	1	1	1
	55	normal	NAD		1	1	1	1	1	1	1	1	1	1
	56	normal	NAD		1	1	1	1	1	1	1	1	1	1
	57	normal head	NAD		1	1	1	1	1	1	1	1	1	1
		head	salivation	Grade: slight									1	
	58	normal	NAD		1	1	1	1	1	1	1	1	1	1
	59	normal	NAD		1	1	1	1	1	1	1	1	1	1
	60	normal	NAD		1	1	1	1	1	1	1	1	1	1

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					87	87	87	88	88	88	89	89	89	89
2 / F 300 mg/kg bw/d	61	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1
		normal	NAD											
		head	salivation	Grade: slight										
	62	feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1
		normal	NAD											
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1
2 / F 300 mg/kg bw/d	63	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1
		normal	NAD											
		head	salivation	Grade: slight										
	64	feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1
		normal	NAD											
		head	salivation	Grade: moderate										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1
2 / F 300 mg/kg bw/d	65	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1
		normal	NAD											
		head	salivation	Grade: moderate										

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					87	87	87	88	88	88	89	89	89	89
		normal	NAD											
		head	salivation	Grade: moderate										
	66			Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1
		normal	NAD											
		head	salivation	Grade: slight										
	67			Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	discolored feces		1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1
		normal	NAD											
		head	salivation	Grade: moderate										
	68			Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1
		normal	NAD											
		head	salivation	Grade: slight										
	69			Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	discolored feces		1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1
		normal	NAD											
		head	salivation	Grade: slight										
	70			Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	discolored feces		1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1

2 / F
300 mg/kg
bw/d

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					87	87	87	88	88	88	89	89	89	89
3 / F 1000 mg/kg bw/d	71	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1
	72	normal	NAD											
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight	1	1	1	1	1	1	1	1	1	1
		feces	soft feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
	73	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1
	74	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1
	75	normal	NAD											
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					87	87	87	88	88	88	89	89	89	89
		normal	NAD											
	76	head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1
		normal	NAD											
	77	head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1
		normal	NAD											
	78	head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1
		normal	NAD											
		head	salivation	Grade: moderate										
	79			Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1
		normal	NAD											
		head	salivation	Grade: slight										
	80			Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1

3 / F
1000 mg/kg
bw/d

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day								
					90 [-01:00-00:00]	90 [00:00-02:00]	90 [02:00-05:00]	91 [-01:00-00:00]	91 [00:00-02:00]	91 [02:00-05:00]	92 [-01:00-00:00]	92 [00:00-02:00]	92 [02:00-05:00]
0 / F 0 mg/kg bw/d	41	normal	NAD		1	1	1	1	1	1	1	1	1
	42	normal	NAD		1	1	1	1	1	1	1	1	1
	43	normal	NAD		1	1	1	1	1	1	1	1	1
	44	normal	NAD		1	1	1	1	1	1	1	1	1
	45	normal	NAD		1	1	1	1	1	1	1	1	1
	46	normal	NAD		1	1	1	1	1	1	1	1	1
	47	normal	NAD		1	1	1	1	1	1	1	1	1
	48	normal	NAD		1	1	1	1	1	1	1	1	1
	49	normal	NAD		1	1	1	1	1	1	1	1	1
	50	normal	NAD		1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day										
					90 [00:00-01:00]	90 [01:00-02:00]	90 [02:00-05:00]	91 [00:00-01:00]	91 [01:00-02:00]	91 [02:00-05:00]	92 [00:00-01:00]	92 [01:00-02:00]	92 [02:00-05:00]		
1 / F 100 mg/kg bwd	51	normal head	NAD salivation	Grade: slight	1										
	52	normal head	NAD salivation	Grade: slight	1										
	53	normal head	NAD salivation	Grade: slight	1										
	54	normal	NAD		1										
	55	normal	NAD		1										
	56	normal	NAD		1										
	57	normal head	NAD salivation	Grade: slight	1										
	58	normal	NAD		1										
	59	normal	NAD		1										
	60	normal	NAD		1										

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day											
					90	90	90	90	91	91	91	91	91	92	92	92
2 / F 300 mg/kg bw/d	61	normal	NAD													
		head	salivation	Grade: slight												
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1	1	1
		normal	NAD													
		head	salivation	Grade: slight												
	62	feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1	1	1
		normal	NAD													
		head	salivation	Grade: moderate												
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1	1	1
2 / F 300 mg/kg bw/d	63	normal	NAD													
		head	salivation	Grade: slight												
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1	1	1
		normal	NAD													
		head	salivation	Grade: slight												
	64	feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1	1	1
		normal	NAD													
		head	salivation	Grade: moderate												
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1	1	1
2 / F 300 mg/kg bw/d	65	normal	NAD													
		head	salivation	Grade: slight												
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1	1	1
		normal	NAD													
		head	salivation	Grade: moderate												

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day											
					90	90	90	90	91	91	91	91	91	91	92	92
2 / F 300 mg/kg bw/d	66	normal head	NAD													
		head	salivation	Grade: moderate												
				Grade: slight												
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1	1	1
		normal head	NAD													
	67	head	salivation	Grade: slight												
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1	1	1
		normal head	NAD													
		head	salivation	Grade: moderate												
				Grade: slight												
2 / F 300 mg/kg bw/d	68	feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1	1	1
		normal head	NAD													
		head	salivation	Grade: slight												
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1	1	1
	69	normal head	NAD													
		head	salivation	Grade: slight												
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1	1	1
		normal head	NAD													
		head	salivation	Grade: slight												
2 / F 300 mg/kg bw/d	70	feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1	1	1
		normal head	NAD													
		head	salivation	Grade: slight												
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1	1	1

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Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					90	90	90	91	91	91	92	92	92	92
3 / F 1000 mg/kg bw/d	71	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1
	72	normal	NAD											
		head	salivation	Grade: moderate										
		feces	discolored feces	Grade: slight										
		feces	soft feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
	73	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1
	74	normal	NAD											
		head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1
75		normal	NAD											
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1

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Study 50C0066/05S019

Individual Signs Pre- and/or Post-Dosing - Dosing subschedule: [00:00-00:00] - In-life

Sex: Female - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Day									
					90	90	90	91	91	91	92	92	92	92
		normal	NAD											
	76	head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1
		normal	NAD											
	77	head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1
		normal	NAD											
	78	head	salivation	Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1
		normal	NAD											
		head	salivation	Grade: moderate										
	79			Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1
		normal	NAD											
		head	salivation	Grade: slight										
	80			Grade: slight										
		feces	discolored feces	Color: light brown	1	1	1	1	1	1	1	1	1	1
		feces	soft feces		1	1	1	1	1	1	1	1	1	1

3 / F
1000 mg/kg
bw/d

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Study 50C0066/05S019

Individual Food Consumption Per Animal And Day [g/Day]

Sex: **Male** - Phase: **In-life**

Group	Cage	Animals	d 3 -> 7	d 10 -> 14	d 17 -> 21	d 24 -> 28	d 31 -> 35	d 38 -> 42	d 45 -> 49	d 52 -> 56	d 59 -> 63	d 66 -> 70
0 / M	01	04, 01, 02, 03, 05	18.5	21.5	22.4	23.8	23.2	25.3	20.6	20.5	22.7	22.8
0 mg/kg bw/d	02	08, 09, 07, 10, 06	18.5	21.7	24.6	22.4	21.9	21.8	20.8	20.9	22.1	22.2

d = day

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Study 50C0066/05S019

Individual Food Consumption Per Animal And Day [g/Day]

Sex: **Male** - Phase: **In-life**

Group	Cage	Animals	d 3 -> 7	d 10 -> 14	d 17 -> 21	d 24 -> 28	d 31 -> 35	d 38 -> 42	d 45 -> 49	d 52 -> 56	d 59 -> 63	d 66 -> 70
1 / M	03	13, 11, 12, 14, 15	18.4	21.3	22.0	23.0	24.4	28.1	27.6SP	22.2	25.3	23.5
100 mg/kg bw/d	04	17, 18, 16, 19, 20	17.1	19.9	21.5	22.4	23.0	25.8	21.0	23.0	20.7	20.9

d = day; SP = Spill

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Study 50C0066/05S019

Individual Food Consumption Per Animal And Day [g/Day]

Sex: **Male** - Phase: **In-life**

Group	Cage	Animals	d 3 -> 7	d 10 -> 14	d 17 -> 21	d 24 -> 28	d 31 -> 35	d 38 -> 42	d 45 -> 49	d 52 -> 56	d 59 -> 63	d 66 -> 70
2 / M	05	21, 22, 25, 24, 23	17.7	23.7	25.1	26.8	26.0	23.5	20.0	22.3	23.4	22.5
300 mg/kg bw/d	06	26, 28, 29, 27, 30	19.0	21.6	23.6	24.9	23.7	22.3	20.1	20.5	20.5	23.1

d = day

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Study 50C0066/05S019

Individual Food Consumption Per Animal And Day [g/Day]

Sex: **Male** - Phase: **In-life**

Group	Cage	Animals	d 3 -> 7	d 10 -> 14	d 17 -> 21	d 24 -> 28	d 31 -> 35	d 38 -> 42	d 45 -> 49	d 52 -> 56	d 59 -> 63	d 66 -> 70
3 / M	07	31, 33, 32, 34, 35	15.2	17.4	21.2	18.8	21.6	19.6	20.5	20.6	16.8	20.8
1000/600 mg/kg bw/d 08		36, 39, 37, 38, 40	15.1	21.3	21.9	20.6	19.9	20.1	18.8	19.1	19.8	17.6

d = day

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Study 50C0066/05S019

Individual Food Consumption Per Animal And Day [g/Day]

Sex: **Male** - Phase: **In-life**

Group	Cage	Animals	d 73 -> 77	d 80 -> 84	d 87 -> 91
0 / M	01	04, 01, 02, 03, 05	21.9	21.5	22.9
0 mg/kg bw/d	02	08, 09, 07, 10, 06	20.3	20.8	21.4

d = day

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Study 50C0066/05S019

Individual Food Consumption Per Animal And Day [g/Day]

Sex: **Male** - Phase: **In-life**

Group	Cage	Animals	d 73 -> 77	d 80 -> 84	d 87 -> 91
1 / M	03	13, 11, 12, 14, 15	20.7	22.5	21.5
100 mg/kg bw/d	04	17, 18, 16, 19, 20	19.8	21.9	20.3

d = day

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Study 50C0066/05S019

Individual Food Consumption Per Animal And Day [g/Day]

Sex: **Male** - Phase: **In-life**

Group	Cage	Animals	d 73 -> 77	d 80 -> 84	d 87 -> 91
2 / M	05	21, 22, 25, 24, 23	23.3	22.6	21.2
300 mg/kg bw/d	06	26, 28, 29, 27, 30	20.8	19.6	21.9

d = day

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Study 50C0066/05S019

Individual Food Consumption Per Animal And Day [g/Day]

Sex: **Male** - Phase: **In-life**

Group	Cage	Animals	d 73 -> 77	d 80 -> 84	d 87 -> 91
3 / M	07	31, 33, 32, 34, 35	28.7	25.8	25.8
1000/600 mg/kg bw/d 08		36, 39, 37, 38, 40	20.3	19.6	20.0

d = day

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Study 50C0066/05S019

Individual Food Consumption Per Animal And Day [g/Day]

Sex: Female - Phase: In-life

Group	Cage	Animals	d 3 -> 7	d 10 -> 14	d 17 -> 21	d 24 -> 28	d 31 -> 35	d 38 -> 42	d 45 -> 49	d 52 -> 56	d 59 -> 63	d 66 -> 70
0 / F	09	45, 44, 42, 43, 41	12.8	14.4	14.8	16.5	15.1	15.8	14.8	17.1	16.9	17.8
0 mg/kg bw/d	10	47, 48, 50, 49, 46	13.1	14.9	15.1	16.2	15.3	15.4	14.5	15.3	15.7	16.2

d = day

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Study 50C0066/05S019

Individual Food Consumption Per Animal And Day [g/Day]

Sex: Female - Phase: In-life

Group	Cage	Animals	d 3 -> 7	d 10 -> 14	d 17 -> 21	d 24 -> 28	d 31 -> 35	d 38 -> 42	d 45 -> 49	d 52 -> 56	d 59 -> 63	d 66 -> 70
1 / F	11	55, 51, 54, 52, 53	13.0	13.9	14.4	15.3	14.7	14.8	13.6	13.4	14.6	15.1
100 mg/kg bw/d	12	58, 59, 56, 57, 60	12.6	14.1	14.4	14.6	14.5	14.7	13.2	13.6	14.3	15.1

d = day

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Study 50C0066/05S019

Individual Food Consumption Per Animal And Day [g/Day]

Sex: Female - Phase: In-life

Group	Cage	Animals	d 3 -> 7	d 10 -> 14	d 17 -> 21	d 24 -> 28	d 31 -> 35	d 38 -> 42	d 45 -> 49	d 52 -> 56	d 59 -> 63	d 66 -> 70
2 / F	13	61, 63, 64, 65, 62	12.6	14.0	15.0	15.1	15.6	15.1	20.1	14.2	13.6	14.5
300 mg/kg bw/d	14	66, 67, 69, 70, 68	12.6	15.0	15.1	16.2	14.2	14.9	13.6	14.0	17.0	15.2

d = day

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Study 50C0066/05S019

Individual Food Consumption Per Animal And Day [g/Day]

Sex: Female - Phase: In-life

Group	Cage	Animals	d 3 -> 7	d 10 -> 14	d 17 -> 21	d 24 -> 28	d 31 -> 35	d 38 -> 42	d 45 -> 49	d 52 -> 56	d 59 -> 63	d 66 -> 70
3 / F	15	73, 71, 72, 75, 74	10.6	19.1	15.3	15.9	15.0	15.8	15.2	29.3	13.2	19.6
1000 mg/kg bw/d	16	78, 76, 77, 80, 79	12.1	25.8	14.6	16.5	16.0	15.5	14.9	15.3	18.9	16.2

d = day

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Study 50C0066/05S019

Individual Food Consumption Per Animal And Day [g/Day]

Sex: Female - Phase: In-life

Group	Cage	Animals	d 73 -> 77	d 80 -> 84	d 87 -> 91
0 / F	09	45, 44, 42, 43, 41	16.9	16.4	15.3
0 mg/kg bw/d	10	47, 48, 50, 49, 46	15.5	15.0	14.9

d = day

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Study 50C0066/05S019

Individual Food Consumption Per Animal And Day [g/Day]

Sex: Female - Phase: In-life

Group	Cage	Animals	d 73 -> 77	d 80 -> 84	d 87 -> 91
1 / F	11	55, 51, 54, 52, 53	15.9	14.6	13.6
100 mg/kg bw/d	12	58, 59, 56, 57, 60	13.8	14.3	14.0

d = day

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Study 50C0066/05S019

Individual Food Consumption Per Animal And Day [g/Day]

Sex: Female - Phase: In-life

Group	Cage	Animals	d 73 -> 77	d 80 -> 84	d 87 -> 91
2 / F	13	61, 63, 64, 65, 62	15.6	15.0	14.5
300 mg/kg bw/d	14	66, 67, 69, 70, 68	14.7	14.8	14.6

d = day

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Individual Food Consumption Per Animal And Day [g/Day]

Sex: Female - Phase: In-life

Group	Cage	Animals	d 73 -> 77	d 80 -> 84	d 87 -> 91
3 / F	15	73, 71, 72, 75, 74	14.5	16.3	15.7
1000 mg/kg bw/d	16	78, 76, 77, 80, 79	22.0	17.2	15.2

d = day

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Study 50C0066/05S019

Individual Body Weights - BW / Body Weights [g]

Sex: Male - Phase: In-life

Dose Group	Animal Number	day 0	day 7	day 14	day 21	day 28	day 35	day 42	day 49	day 56	day 63
0 / M 0 mg/kg bw/d	01	164.0	213.5	261.0	302.5	331.3	354.7	379.3	374.0	397.3	411.9
	02	152.5	196.6	233.3	259.7	287.1	299.6	313.3	314.6	325.8	333.5
	03	158.9	200.7	244.6	281.9	316.0	340.8	356.1	369.0	376.9	388.9
	04	171.9	224.3	273.6	316.7	353.3	380.0	404.2	412.3	427.3	451.6
	05	149.2	191.7	233.7	269.1	301.1	327.2	344.8	353.1	369.8	387.6
	06	162.7	205.1	247.6	283.8	305.7	327.0	341.6	343.5	369.0	377.2
	07	156.3	197.7	240.1	272.2	294.6	310.8	327.8	332.1	349.3	365.8
	08	156.7	197.9	241.5	273.8	299.1	315.6	334.4	346.1	362.3	373.1
	09	155.9	200.6	239.7	280.7	303.9	324.4	339.4	357.4	374.7	393.2
	10	156.1	204.5	262.0	292.9	325.3	350.0	373.3	387.6	398.5	411.6

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Individual Body Weights - BW / Body Weights [g]

Sex: Male - Phase: In-life

Dose Group	Animal Number	day 0	day 7	day 14	day 21	day 28	day 35	day 42	day 49	day 56	day 63
1 / M 100 mg/kg bw/d	11	159.2	199.4	239.0	270.8	298.3	323.1	338.3	345.1	359.6	364.1
	12	163.6	211.6	263.7	304.8	337.4	367.4	380.5	397.8	408.0	420.3
	13	160.8	196.3	234.8	260.5	282.8	301.6	307.9	321.2	328.0	335.8
	14	167.3	216.7	265.4	302.2	332.4	364.4	383.9	401.6	418.8	426.9
	15	153.9	197.8	244.5	284.6	317.1	343.8	362.5	376.2	386.7	396.1
	16	157.7	189.6	220.9	243.3	261.1	280.4	290.0	289.1	299.5	310.2
	17	153.2	197.3	245.1	288.4	318.8	340.3	354.0	370.6	382.1	395.2
	18	144.9	184.8	221.4	247.2	266.3	285.8	298.2	308.8	317.2	330.9
	19	150.6	203.0	247.6	283.0	312.6	337.4	362.1	376.7	392.5	399.8
	20	159.9	202.9	246.0	282.7	314.8	342.0	360.5	370.8	385.9	398.5

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Individual Body Weights - BW / Body Weights [g]

Sex: Male - Phase: In-life

Dose Group	Animal Number	day 0	day 7	day 14	day 21	day 28	day 35	day 42	day 49	day 56	day 63
2 / M 300 mg/kg bw/d	21	160.2	204.4	249.4	280.5	297.5	307.7	329.5	335.2	345.9	350.1
	22	156.4	197.3	246.1	279.2	311.4	327.3	344.5	347.4	355.8	366.9
	23	158.9	202.6	246.4	276.1	305.4	319.1	334.4	346.4	352.9	362.7
	24	161.9	202.8	240.5	265.0	274.5	278.5	289.8	297.4	308.4	316.4
	25	158.9	182.5	225.2	264.8	294.7	310.6	327.2	340.5	345.5	353.5
	26	153.3	197.4	236.4	274.8	302.4	322.1	333.7	332.9	344.3	355.6
	27	150.2	183.0	220.2	255.8	278.4	295.0	304.6	320.6	325.3	337.5
	28	158.7	207.5	256.2	292.8	320.0	334.5	349.0	350.3	380.6	391.8
	29	169.8	209.3	253.0	287.1	310.0	326.6	340.1	369.3	356.9	363.6
	30	152.9	193.3	282.3	264.9	286.6	300.5	307.2	324.8	337.2	348.3

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Study 50C0066/05S019

Individual Body Weights - BW / Body Weights [g]

Sex: Male - Phase: In-life

Dose Group	Animal Number	day 0	day 7	day 14	day 21	day 28	day 35	day 42	day 49	day 56	day 63
3 / M 1000/600 mg/kg bw/d	31	151.0	181.6	209.4	232.1	243.5	252.0	261.5	259.1	269.6	273.9
	32	165.5	205.1	239.0	264.3	282.3	294.1	300.5	304.0	307.4	321.9
	33	155.5	184.4	218.7	248.2	261.9	282.2	297.2	298.7	307.6	310.5
	34	152.4	179.6	209.8	241.7	257.7	278.3	293.9	306.0	296.4	290.6
	35	159.6	193.5	224.9	258.0	266.6	289.5	297.7	304.9	311.5	314.3
	36	157.3	181.7	208.5	238.7	251.9	266.0	280.4	292.1	297.3	299.3
	37	159.5	188.1	220.7	237.9	247.0	248.1	251.2	254.4	256.6	264.2
	38	169.6	207.9	257.0	294.4	306.3	324.4	347.5	368.0	376.9	394.7
	39	157.9	193.6	235.6	266.7	290.9	300.7	308.2	322.6	324.0	336.2
	40	154.1	183.6	221.9	255.8	268.3	285.7	305.1	310.3	315.2	318.0

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Study 50C0066/05S019

Individual Body Weights - BW / Body Weights [g]

Sex: Male - Phase: In-life

Dose Group	Animal Number	day 70	day 77	day 84	day 91
0 / M 0 mg/kg bw/d	01	422.3	434.9	439.7	444.3
	02	340.4	352.4	364.0	361.8
	03	394.8	407.3	414.1	415.3
	04	457.4	463.3	476.2	475.4
	05	395.8	410.5	414.6	421.3
	06	385.9	393.9	394.2	400.0
	07	372.2	384.0	388.9	395.8
	08	378.4	383.8	389.1	397.9
	09	402.1	405.3	412.3	415.3
	10	417.1	428.2	441.0	444.3

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Study 50C0066/05S019

Individual Body Weights - BW / Body Weights [g]

Sex: Male - Phase: In-life

Dose Group	Animal Number	day 70	day 77	day 84	day 91
1 / M 100 mg/kg bw/d	11	372.1	364.9	381.8	383.7
	12	436.6	423.0	416.5	421.2
	13	342.1	350.5	350.2	352.1
	14	444.9	450.5	463.5	470.1
	15	412.9	418.0	427.6	429.2
	16	310.5	316.8	319.7	327.1
	17	407.4	407.3	413.3	419.3
	18	335.4	341.1	346.4	346.4
	19	400.3	410.8	417.5	415.9
	20	413.2	423.4	431.2	442.3

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Study 50C0066/05S019

Individual Body Weights - BW / Body Weights [g]

Sex: Male - Phase: In-life

Dose Group	Animal Number	day 70	day 77	day 84	day 91
2 / M 300 mg/kg bw/d	21	356.4	367.3	372.5	374.0
	22	376.9	392.3	403.3	404.5
	23	369.1	372.9	374.1	381.9
	24	316.3	323.4	328.8	329.6
	25	358.3	372.2	379.8	379.1
	26	362.8	362.2	373.6	377.7
	27	349.1	359.2	365.8	362.2
	28	407.4	410.2	394.0	408.0
	29	368.7	369.8	372.9	382.0
	30	358.4	361.8	373.1	374.1

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Study 50C0066/05S019

Individual Body Weights - BW / Body Weights [g]

Sex: **Male** - Phase: **In-life**

Dose Group	Animal Number	day 70	day 77	day 84	day 91
3 / M 1000/600 mg/kg bw/d	31	279.0	282.1	286.5	287.6
	32	330.5	341.5	345.1	349.1
	33	320.2	333.7	339.9	346.8
	34	303.5	313.0	318.8	317.6
	35	315.1	330.0	335.7	340.1
	36	300.5	311.8	314.1	316.8
	37	266.4	263.0	270.2	272.9
	38	398.1	411.8	424.6	424.2
	39	346.3	354.5	360.1	357.3
	40	318.0	324.3	332.0	334.2

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Study 50C0066/05S019

Individual Body Weights - BW / Body Weights [g]

Sex: Female - Phase: In-life

Dose Group	Animal Number	day 0	day 7	day 14	day 21	day 28	day 35	day 42	day 49	day 56	day 63
0 / F 0 mg/kg bw/d	41	126.8	138.4	160.9	171.0	178.8	183.6	193.8	200.9	204.5	207.9
	42	120.3	136.5	152.5	160.4	178.8	189.8	193.8	195.4	203.7	211.9
	43	119.3	131.8	140.1	162.4	170.4	177.2	178.6	193.9	194.5	203.5
	44	121.7	148.5	169.4	188.1	197.0	215.1	224.3	230.8	230.8	246.7
	45	123.3	138.5	166.9	181.9	195.6	196.5	213.6	219.1	220.4	230.0
	46	126.2	153.7	176.4	196.3	204.1	224.8	235.3	242.8	241.9	255.3
	47	125.3	149.4	170.3	189.0	195.4	213.1	221.7	225.7	222.8	232.0
	48	133.9	149.2	162.0	178.0	190.0	196.1	196.1	207.4	213.3	217.0
	49	122.9	134.6	155.1	169.6	180.3	182.8	196.1	203.6	206.2	208.0
	50	141.7	156.0	175.5	204.1	219.4	232.1	230.3	248.7	255.1	259.8

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Study 50C0066/05S019

Individual Body Weights - BW / Body Weights [g]

Sex: Female - Phase: In-life

Dose Group	Animal Number	day 0	day 7	day 14	day 21	day 28	day 35	day 42	day 49	day 56	day 63
1 / F 100 mg/kg bw/d	51	118.5	144.3	164.8	179.4	185.6	204.1	210.5	215.4	217.8	230.9
	52	131.0	152.8	166.1	179.6	188.4	195.0	195.3	204.6	210.3	214.5
	53	132.0	152.1	170.3	184.9	197.4	205.8	216.0	219.0	225.5	234.3
	54	133.5	154.3	168.9	178.2	196.3	205.4	192.0	207.2	224.1	227.0
	55	120.5	140.3	153.0	165.1	172.7	183.2	209.5	197.0	195.3	206.7
	56	115.5	131.1	143.1	162.4	170.4	176.6	179.6	188.0	192.9	196.1
	57	132.9	149.5	167.2	187.8	201.9	210.9	221.5	228.4	231.5	231.7
	58	125.0	144.3	160.3	166.7	182.7	196.4	200.7	197.7	208.4	221.3
	59	127.2	142.2	157.7	177.8	189.5	198.4	199.4	209.5	215.6	218.4
	60	134.4	159.4	179.8	189.8	197.9	213.9	222.6	226.7	226.7	241.2

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Study 50C0066/05S019

Individual Body Weights - BW / Body Weights [g]

Sex: Female - Phase: In-life

Dose Group	Animal Number	day 0	day 7	day 14	day 21	day 28	day 35	day 42	day 49	day 56	day 63
2 / F 300 mg/kg bw/d	61	132.1	146.6	158.0	179.5	191.6	200.4	200.4	208.3	215.6	218.5
	62	134.6	154.3	168.6	177.6	202.4	208.8	217.6	222.0	233.8	238.3
	63	121.1	139.2	160.5	177.2	188.9	197.7	210.0	214.8	219.5	224.7
	64	121.1	141.6	164.1	173.6	185.8	197.2	204.5	216.7	215.8	220.3
	65	122.3	139.8	157.3	166.1	177.2	191.5	199.2	202.7	212.8	211.2
	66	121.4	135.8	153.9	160.8	178.3	185.6	188.8	185.5	195.1	203.8
	67	135.1	151.2	168.3	179.3	197.7	207.4	215.9	218.4	227.0	226.6
	68	134.2	155.0	179.0	192.0	203.7	208.6	216.8	223.0	223.9	218.2
	69	123.9	141.3	160.7	167.6	182.0	186.6	190.7	191.0	196.2	200.3
	70	113.7	135.4	163.9	163.8	168.1	180.2	184.6	189.1	185.4	199.0

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Study 50C0066/05S019

Individual Body Weights - BW / Body Weights [g]

Sex: Female - Phase: In-life

Dose Group	Animal Number	day 0	day 7	day 14	day 21	day 28	day 35	day 42	day 49	day 56	day 63
3 / F 1000 mg/kg bw/d	71	136.3	144.6	163.0	181.9	192.1	197.3	202.7	207.3	209.8	209.3
	72	119.7	133.8	152.7	170.1	179.7	185.6	195.8	198.6	202.8	211.0
	73	118.2	133.2	151.1	168.1	177.6	181.0	189.3	194.1	198.4	201.0
	74	135.6	153.7	173.9	188.3	199.7	209.0	222.1	228.0	228.1	226.8
	75	126.6	139.8	159.2	170.9	185.9	189.6	194.7	201.1	205.0	205.6
	76	117.6	137.6	159.0	173.4	183.5	193.4	203.8	204.5	208.6	221.8
	77	119.4	138.2	159.7	175.5	186.8	195.1	207.9	210.8	214.5	213.9
	78	127.6	148.8	171.9	178.5	201.6	207.9	210.2	209.7	223.4	231.8
	79	137.2	156.0	177.2	195.6	211.3	220.3	227.0	236.0	242.4	247.3
	80	128.5	141.1	160.9	166.5	175.8	194.4	198.5	196.9	202.3	205.6

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Study 50C0066/05S019

Individual Body Weights - BW / Body Weights [g]

Sex: Female - Phase: In-life

Dose Group	Animal Number	day 70	day 77	day 84	day 91
0 / F 0 mg/kg bw/d	41	216.3	219.8	219.3	214.7
	42	214.5	211.5	218.9	224.7
	43	200.5	207.1	210.8	211.1
	44	255.3	258.5	250.3	264.9
	45	229.5	238.4	239.0	231.3
	46	262.8	267.4	264.5	267.7
	47	235.2	240.9	233.9	240.5
	48	216.8	222.8	227.1	223.5
	49	217.3	222.8	224.9	220.3
	50	254.1	265.8	272.3	273.9

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Study 50C0066/05S019

Individual Body Weights - BW / Body Weights [g]

Sex: Female - Phase: In-life

Dose Group	Animal Number	day 70	day 77	day 84	day 91
1 / F 100 mg/kg bw/d	51	232.6	238.0	234.9	235.4
	52	213.8	220.0	224.4	226.6
	53	238.3	245.1	243.0	243.8
	54	226.2	228.9	234.2	239.0
	55	212.9	217.6	212.7	219.2
	56	192.3	202.8	203.5	201.5
	57	237.9	242.6	243.8	240.4
	58	221.4	215.7	226.9	232.3
	59	214.9	228.9	230.7	226.6
	60	247.5	243.5	247.0	252.1

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Study 50C0066/05S019

Individual Body Weights - BW / Body Weights [g]

Sex: Female - Phase: In-life

Dose Group	Animal Number	day 70	day 77	day 84	day 91
2 / F 300 mg/kg bw/d	61	215.8	226.5	226.5	222.5
	62	246.3	246.4	243.2	248.3
	63	227.2	234.1	234.7	231.3
	64	222.1	227.5	227.7	228.1
	65	217.9	213.2	224.2	226.6
	66	205.7	201.7	206.7	207.3
	67	232.1	231.0	240.5	239.4
	68	232.1	237.1	239.9	235.8
	69	205.7	203.8	207.0	205.2
	70	201.3	199.7	198.7	205.5

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Study 50C0066/05S019

Individual Body Weights - BW / Body Weights [g]

Sex: Female - Phase: In-life

Dose Group	Animal Number	day 70	day 77	day 84	day 91
3 / F 1000 mg/kg bw/d	71	211.5	214.8	211.4	215.0
	72	211.6	210.2	206.0	214.5
	73	199.8	199.1	206.6	204.1
	74	230.7	234.3	239.3	237.4
	75	206.5	207.7	213.5	206.6
	76	222.8	222.7	225.4	228.1
	77	224.9	228.5	228.4	221.2
	78	230.2	227.0	235.7	234.2
	79	247.8	255.8	252.5	252.4
	80	202.9	207.4	210.3	211.8

[illegible]

Table IIA - 442

FUNCTIONAL OBSERVATIONAL BATTERY

Project No. 50C0066/05S019

test group 0
male animals

open field observations

Individual values
week 12

	Rank	Animal No.	1	2	3	4	5	6	7	8	9	10
behavior when removed from cage	(0-4)	0	0	0	0	0	0	0	0	0	0	0
fur	(0-5)	0	0	0	0	0	0	0	0	0	0	0
skin	(0-7)	0	0	0	0	0	0	0	0	0	0	0
salivation	(0-3)	0	0	0	0	0	0	0	0	0	0	0
nose discharge	(0-2)	0	0	0	0	0	0	0	0	0	0	0
lacrimation	(0-3)	0	0	0	0	0	0	0	0	0	0	0
eyes/pupil size	(0-7)	0	0	0	0	0	0	0	0	0	0	0
posture	(0-7)	1	1	1	1	1	1	1	1	1	1	1
palpebral closure	(0-3)	0	0	0	0	0	0	0	0	0	0	0
respiration	(0-4)	0	0	0	0	0	0	0	0	0	0	0
tremors	(0-3)	0	0	0	0	0	0	0	0	0	0	0
convulsions	(0-3)	0	0	0	0	0	0	0	0	0	0	0
abnormal movements/stereotypics	(0-4)	0	0	0	0	0	0	0	0	0	0	0
impairment of gait	(0-7)	1	1	1	1	1	1	1	1	1	1	1
activity/arousal level	(0-4)	0	0	0	0	0	0	0	0	0	0	0
feces	(0-6)	0	0	0	0	0	0	0	0	0	0	0
urine	(0-3)	1	1	1	1	1	1	0	1	1	1	0

Table IIA - 443

Project No. 50C0066/05S019		FUNCTIONAL OBSERVATIONAL BATTERY										Table IIA -			
test group 0 male animals	sensorimotor tests/reflexes	Rank	Animal No.		Individual values										week 12
			1	2	3	4	5	6	7	8	9	10			
	approach response	(0-3)	0	1	0	1	1	1	1	1	0	0	0	1	
	touch response	(0-4)	1	0	0	0	1	0	1	0	0	0	0	0	
	vision	(0-1)	0	0	0	0	0	0	0	0	0	0	0	0	
	pupillary reflex	(0-3)	0	0	0	0	0	0	0	0	0	0	0	0	
	pinna reflex	(0-1)	0	0	0	0	0	0	0	0	0	0	0	0	
	audition	(0-3)	0	0	0	0	0	0	0	0	0	0	0	0	
	coordination of movements	(0-3)	0	0	0	0	0	0	0	0	0	0	0	0	
	behavior during handling	(0-3)	0	0	0	0	0	0	0	0	0	0	0	0	
	vocalization	(0-3)	0	0	0	0	0	0	0	0	0	0	0	0	
	pain perception	(0-3)	0	0	0	0	0	0	0	0	0	0	0	0	
other findings			0	0	0	0	0	0	0	0	0	0	0	0	

Table IIA - 444

Project No. 50C0066/05S019		FUNCTIONAL OBSERVATIONAL BATTERY												Individual values				week 12			
test group 1	male animals	home cage observation	Rank	Animal No.								12	13	14	15	16	17	18	19	20	
				11	10	9	8	7	6	5	4										
		posture	(0-7)	1	1	1	1	1	1	1	1	1	1	0	1	0	0	0	0		
		tremors	(0-3)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
		convulsions	(0-3)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
		abnormal movements	(0-4)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
		impairment of gait	(0-7)	0	0	0	1	1	1	1	1	1	0	1	1	0	0	0	0		
		other findings		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		

Table IIA - 445

FUNCTIONAL OBSERVATIONAL BATTERY

Project No. 50C0066/05S019

test group 1
male animals

open field observations

	Rank	Animal No.	11	12	13	14	15	16	17	18	19	20
behavior when removed from cage	(0-4)	0	0	0	0	0	0	0	0	0	0	0
fur	(0-5)	0	0	0	0	0	0	0	0	0	0	0
skin	(0-7)	0	0	0	0	0	0	0	0	0	0	0
salivation	(0-3)	0	0	0	0	0	0	0	0	0	0	0
nose discharge	(0-2)	0	0	0	0	0	0	0	0	0	0	0
lacrimation	(0-3)	0	0	0	0	0	0	0	0	0	0	0
eyes/pupil size	(0-7)	0	0	0	0	0	0	0	0	0	0	0
posture	(0-7)	1	1	1	1	1	1	1	1	1	1	1
palpebral closure	(0-3)	0	0	0	0	0	0	0	0	0	0	0
respiration	(0-4)	0	0	0	0	0	0	0	0	0	0	0
tremors	(0-3)	0	0	0	0	0	0	0	0	0	0	0
convulsions	(0-3)	0	0	0	0	0	0	0	0	0	0	0
abnormal movements/stereotypics	(0-4)	0	0	0	0	0	0	0	0	0	0	0
impairment of gait	(0-7)	1	1	1	1	1	1	1	1	1	1	1
activity/arousal level	(0-4)	0	0	0	0	0	0	0	0	0	0	0
feces	(0-6)	0	0	0	0	0	0	0	0	0	0	0
urine	(0-3)	0	0	1	1	1	1	0	1	1	0	1

Table IIA - 446

Project No. 50C0066/05S019		FUNCTIONAL OBSERVATIONAL BATTERY												Individual values				week 12				Table IIA -	
		Animal No.																					
		Rank	11	12	13	14	15	16	17	18	19	20											
test group 1 male animals	Sensorimotor tests/reflexes																						
		approach response	(0-3)	0	0	1	1	1	0	1	0	1	0	0	1	0	0	0	0	0	1		
		touch response	(0-4)	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0		
		vision	(0-1)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
		pupillary reflex	(0-3)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
		pinna reflex	(0-1)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
		audition	(0-3)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
		coordination of movements	(0-3)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
		behavior during handling	(0-3)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
		vocalization	(0-3)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
		pain perception	(0-3)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
		other findings		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		

Table IIA - 447

Project No. 50C0066/05S019		FUNCTIONAL OBSERVATIONAL BATTERY												Table IIA -	
test group 2 male animals		Individual values												week 12	
Home cage observation		Rank	Animal No.		21	22	23	24	25	26	27	28	29	30	
posture		(0-7)	0	0	0	0	1	0	1	0	0	0	0	0	
tremors		(0-3)	0	0	0	0	0	0	0	0	0	0	0	0	
convulsions		(0-3)	0	0	0	0	0	0	0	0	0	0	0	0	
abnormal movements		(0-4)	0	0	0	0	0	0	0	0	0	0	0	0	
impairment of gait		(0-7)	0	0	0	0	0	0	1	0	0	0	0	0	
other findings			0	0	0	0	0	0	0	0	0	0	0	0	

Table IIA - 448

FUNCTIONAL OBSERVATIONAL BATTERY

Project No. 50C0066/05S019

test group 2
male animals

Open field observations

Individual values
week 12

	Rank	Animal No.	21	22	23	24	25	26	27	28	29	30
behavior when removed from cage	(0-4)	0	0	0	0	0	0	0	0	0	0	0
fur	(0-5)	0	0	0	0	0	0	0	0	0	0	0
skin	(0-7)	0	0	0	0	0	0	0	0	0	0	0
salivation	(0-3)	0	0	0	0	0	0	0	0	0	0	0
nose discharge	(0-2)	0	0	0	0	0	0	0	0	0	0	0
lacrimation	(0-3)	0	0	0	0	0	0	0	0	0	0	0
eyes/pupil size	(0-7)	0	0	0	0	0	0	0	0	0	0	0
posture	(0-7)	1	1	1	1	1	1	1	1	1	1	1
palpebral closure	(0-3)	0	0	0	0	0	0	0	0	0	0	0
respiration	(0-4)	0	0	0	0	0	0	0	0	0	0	0
tremors	(0-3)	0	0	0	0	0	0	0	0	0	0	0
convulsions	(0-3)	0	0	0	0	0	0	0	0	0	0	0
abnormal movements/stereotypics	(0-4)	0	0	0	0	0	0	0	0	0	0	0
impairment of gait	(0-7)	1	1	1	1	1	1	1	1	1	1	1
activity/arousal level	(0-4)	0	0	0	0	0	0	0	0	0	0	0
feces	(0-6)	0	0	0	0	0	2*/4	0	0	2*/4	0	0
urine	(0-3)	1	0	0	0	0	0	0	1	0	1	1

*= light brown

Table IIA - 449

FUNCTIONAL OBSERVATIONAL BATTERY

Project No. 50C0066/05S019

test group 2
male animals

Sensorimotor tests/reflexes

	Rank	Animal No.	21	22	23	24	25	26	27	28	29	30
approach response	(0-3)	1	0	0	0	1	1	0	1	0	1	1
touch response	(0-4)	0	0	0	0	1	0	1	0	0	0	1
vision	(0-1)	0	0	0	0	0	0	0	0	0	0	0
pupillary reflex	(0-3)	0	0	0	0	0	0	0	0	0	0	0
pinna reflex	(0-1)	0	0	0	0	0	0	0	0	0	0	0
audition	(0-3)	0	0	0	0	0	0	0	0	0	0	0
coordination of movements	(0-3)	0	0	0	0	0	0	0	0	0	0	0
behavior during handling	(0-3)	0	0	0	0	0	0	0	0	0	0	0
vocalization	(0-3)	0	0	0	0	0	0	0	0	0	0	0
pain perception	(0-3)	0	0	0	0	0	0	0	0	0	0	0
other findings		0	0	0	0	0	0	0	0	0	0	0

Table IIA - 450

FUNCTIONAL OBSERVATIONAL BATTERY

Project No. 50C0066/05S019

test group 3
male animals

Home cage observation

	Rank	Animal No.	31	32	33	34	35	36	37	38	39	40
posture	(0-7)	0	1	1	1	1	1	0	0	1	0	1
tremors	(0-3)	0	0	0	0	0	0	0	0	0	0	0
convulsions	(0-3)	0	0	0	0	0	0	0	0	0	0	0
abnormal movements	(0-4)	0	0	0	1	1	0	0	0	0	0	0
impairment of gait	(0-7)	0	0	0	0	0	0	0	0	0	0	1
other findings		0	0	0	0	0	0	0	0	0	0	0

Table IIA - 451

Project No. 50C0066/05S019		FUNCTIONAL OBSERVATIONAL BATTERY												Table IIA -	
		Individual values												week 12	
test group 3 male animals	Open field observations	Rank	Animal No.		32	33	34	35	36	37	38	39	40		
			31												
behavior when removed from cage fur skin salivation nose discharge lacrimation eyes/pupil size posture palpebral closure respiration tremors convulsions abnormal movements/stereotypics impairment of gait activity/arousal level feces urine		(0-4)	0	0	0	0	0	0	0	0	0	0	0		
		(0-5)	0	0	0	0	0	0	0	0	0	0	0		
		(0-7)	0	0	0	0	0	0	0	0	0	0	0		
		(0-3)	0	0	0	0	0	0	0	0	0	0	0		
		(0-2)	0	0	0	0	0	0	0	0	0	0	0		
		(0-3)	0	0	0	0	0	0	0	0	0	0	0		
		(0-7)	0	0	0	0	0	0	0	0	0	0	0		
		(0-7)	1	1	1	1	1	1	1	1	1	1	1		
		(0-3)	0	0	0	0	0	0	0	0	0	0	0		
		(0-4)	0	0	0	0	0	0	0	0	0	0	0		
		(0-3)	0	0	0	0	0	0	0	0	0	0	0		
		(0-3)	0	0	0	0	0	0	0	0	0	0	0		
		(0-4)	0	0	0	0	0	0	0	0	0	0	0		
		(0-7)	1	1	1	1	1	1	1	1	1	1	1		
		(0-4)	0	0	0	0	0	0	0	0	0	0	0		
	(0-6)	0	0	0	0	0	0	0	0	0	0	0			
	(0-3)	0	1	1	1	0	1	1	0	1	1	0			

Table IIA - 452

		FUNCTIONAL OBSERVATIONAL BATTERY												week 12	
		Rank	Animal No.	31	32	33	34	35	36	37	38	39	40		
Project No. 50C0066/05S019															
test group 3															
male animals															
Sensorimotor tests/reflexes															
approach response		(0-3)	0	0	0	1	0	0	1	0	0	0	1		
touch response		(0-4)	0	0	0	0	0	0	0	0	0	0	0		
vision		(0-1)	0	0	0	0	0	0	0	0	0	0	0		
pupillary reflex		(0-3)	0	0	0	0	0	0	0	0	0	0	0		
pinna reflex		(0-1)	0	0	0	0	0	0	0	0	0	0	0		
audition		(0-3)	0	0	0	0	0	0	0	0	0	0	0		
coordination of movements		(0-3)	0	0	0	0	0	0	0	0	0	0	0		
behavior during handling		(0-3)	0	0	0	0	0	0	0	0	0	0	0		
vocalization		(0-3)	0	0	0	0	0	0	0	0	0	0	0		
pain perception		(0-3)	0	0	0	0	0	0	0	0	0	0	0		
other findings			0	0	0	0	0	0	0	0	0	0	0		

Table IIA - 453

Project No. 50C0066/05S019		FUNCTIONAL OBSERVATIONAL BATTERY												Table IIA -	
		Individual values												week 12	
test group 0 female animals															
home cage observation		Rank	Animal No.												
		41	42	43	44	45	46	47	48	49	50				
posture	(0-7)	0	1	1	1	1	1	0	1	1	0	1	0		
tremors	(0-3)	0	0	0	0	0	0	0	0	0	0	0	0		
convulsions	(0-3)	0	0	0	0	0	0	0	0	0	0	0	0		
abnormal movements	(0-4)	0	0	0	0	0	0	0	0	0	0	0	0		
impairment of gait	(0-7)	0	0	1	1	0	0	0	0	0	1	0	0		
other findings		0	0	0	0	0	0	0	0	0	0	0	0		

Table IIA - 454

FUNCTIONAL OBSERVATIONAL BATTERY

Project No. 50C0066/05S019

test group 0
female animals

open field observations

Individual values
week 12

	Rank	Animal No.	41	42	43	44	45	46	47	48	49	50
behavior when removed from cage	(0-4)	0	0	0	0	0	0	0	0	0	0	0
fur	(0-5)	0	0	0	0	0	0	0	0	0	0	0
skin	(0-7)	0	0	0	0	0	0	0	0	0	0	0
salivation	(0-3)	0	0	0	0	0	0	0	0	0	0	0
nose discharge	(0-2)	0	0	0	0	0	0	0	0	0	0	0
lacrimation	(0-3)	0	0	0	0	0	0	0	0	0	0	0
eyes/pupil size	(0-7)	0	0	0	0	0	0	0	0	0	0	0
posture	(0-7)	1	1	1	1	1	1	1	1	1	1	1
palpebral closure	(0-3)	0	0	0	0	0	0	0	0	0	0	0
respiration	(0-4)	0	0	0	0	0	0	0	0	0	0	0
tremors	(0-3)	0	0	0	0	0	0	0	0	0	0	0
convulsions	(0-3)	0	0	0	0	0	0	0	0	0	0	0
abnormal movements/stereotypics	(0-4)	0	0	0	0	0	0	0	0	0	0	0
impairment of gait	(0-7)	1	1	1	1	1	1	1	1	1	1	1
activity/arousal level	(0-4)	0	0	0	0	0	0	0	0	0	0	0
feces	(0-6)	0	0	0	0	0	0	0	0	0	0	0
urine	(0-3)	0	0	0	0	0	0	0	0	0	0	0

Table IIA - 455

FUNCTIONAL OBSERVATIONAL BATTERY

Project No. 50C0066/05S019

test group 0
female animals

sensorimotor tests/reflexes

Individual values
week 12

	Rank	Animal No.	41	42	43	44	45	46	47	48	49	50
approach response	(0-3)	0	0	0	0	1	1	0	1	1	1	0
touch response	(0-4)	0	0	0	0	0	0	0	1	0	0	0
vision	(0-1)	0	0	0	0	0	0	0	0	0	0	0
pupillary reflex	(0-3)	0	0	0	0	0	0	0	0	0	0	0
pinna reflex	(0-1)	0	0	0	0	0	0	0	0	0	0	0
audition	(0-3)	0	0	0	0	0	0	0	0	0	0	0
coordination of movements	(0-3)	0	0	0	0	0	0	0	0	0	0	0
behavior during handling	(0-3)	0	0	0	0	0	0	0	0	0	0	0
vocalization	(0-3)	0	0	0	0	0	0	0	0	0	0	0
pain perception	(0-3)	0	0	0	0	0	0	0	0	0	0	0
other findings		0	0	0	0	0	0	0	0	0	0	0

Table IIA - 456

FUNCTIONAL OBSERVATIONAL BATTERY

Project No. 50C0066/05S019

test group 1
female animals

home cage observation

Individual values
week 12

	Rank	Animal No.	51	52	53	54	55	56	57	58	59	60
posture	(0-7)	1	0	1	1	1	0	0	1	1	1	1
tremors	(0-3)	0	0	0	0	0	0	0	0	0	0	0
convulsions	(0-3)	0	0	0	0	0	0	0	0	0	0	0
abnormal movements	(0-4)	0	0	0	0	0	0	0	0	0	0	0
impairment of gait	(0-7)	0	0	0	1	0	0	0	1	1	0	0
other findings		0	0	0	0	0	0	0	0	0	0	0

Table IIA - 457

		FUNCTIONAL OBSERVATIONAL BATTERY											
		Individual values											
		week 12											
		51	52	53	54	55	56	57	58	59	60		
		Rank	Animal No.										
Project No. 50C0066/05S019													
test group 1													
female animals													
open field observations													
behavior when removed from cage		(0-4)	0	0	0	0	0	0	0	0	0		
fur		(0-5)	0	0	0	0	0	0	0	0	0		
skin		(0-7)	0	0	0	0	0	0	0	0	0		
salivation		(0-3)	0	0	0	0	0	0	0	0	0		
nose discharge		(0-2)	0	0	0	0	0	0	0	0	0		
lacrimation		(0-3)	0	0	0	0	0	0	0	0	0		
eyes/pupil size		(0-7)	0	0	0	0	0	0	0	0	0		
posture		(0-7)	1	1	1	1	1	1	1	1	1		
palpebral closure		(0-3)	0	0	0	0	0	0	0	0	0		
respiration		(0-4)	0	0	0	0	0	0	0	0	0		
tremors		(0-3)	0	0	0	0	0	0	0	0	0		
convulsions		(0-3)	0	0	0	0	0	0	0	0	0		
abnormal movements/stereotypics		(0-4)	0	0	0	0	0	0	0	0	0		
impairment of gait		(0-7)	1	1	1	1	1	1	1	1	1		
activity/arousal level		(0-4)	0	0	0	0	0	0	0	0	0		
feces		(0-6)	0	0	0	0	0	0	0	0	0		
urine		(0-3)	0	0	1	0	0	0	0	0	0		

Table IIA - 458

Project No. 50C0066/05S019		FUNCTIONAL OBSERVATIONAL BATTERY											
		Individual values											
test group 1 female animals		week 12											
Sensorimotor tests/reflexes		Rank	Animal No.	51	52	53	54	55	56	57	58	59	60
approach response		(0-3)	0	0	0	0	1	0	0	0	1	0	0
touch response		(0-4)	0	0	0	1	1	0	0	0	1	1	0
vision		(0-1)	0	0	0	0	0	0	0	0	0	0	0
pupillary reflex		(0-3)	0	0	0	0	0	0	0	0	0	0	0
pinna reflex		(0-1)	0	0	0	0	0	0	0	0	0	0	0
audition		(0-3)	0	0	0	0	0	0	0	0	0	0	0
coordination of movements		(0-3)	0	0	0	0	0	0	0	0	0	0	0
behavior during handling		(0-3)	0	0	0	0	0	0	0	0	0	0	0
vocalization		(0-3)	0	0	0	0	0	0	0	0	0	0	0
pain perception		(0-3)	0	0	0	0	0	0	0	0	0	0	0
other findings			0	0	0	0	0	0	0	0	0	0	0

Table IIA - 459

Project No. 50C0066/05S019		FUNCTIONAL OBSERVATIONAL BATTERY												Table IIA -	
test group 2 female animals	Home cage observation	Rank	Animal No.				Individual values							week 12	
			61	62	63	64	65	66	67	68	69	70			
	posture	(0-7)	0	1	1	1	1	1	1	1	0	1	1		
	tremors	(0-3)	0	0	0	0	0	0	0	0	0	0	0		
	convulsions	(0-3)	0	0	0	0	0	0	0	0	0	0	0		
	abnormal movements	(0-4)	0	0	0	0	0	0	0	0	0	0	0		
	impairment of gait	(0-7)	0	0	1	0	1	1	0	0	0	1	0		
	other findings		0	0	0	0	0	0	0	0	0	0	0		

Table IIA - 460

Project No. 50C0066/05S019 test group 2 female animals		FUNCTIONAL OBSERVATIONAL BATTERY												Table IIA -						
		Open field observations	Rank	Animal No.		Individual values												week 12		
				61	62	63	64	65	66	67	68	69	70	68	69	70				
behavior when removed from cage		(0-4)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
fur		(0-5)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
skin		(0-7)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
salivation		(0-3)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
nose discharge		(0-2)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
lacrimation		(0-3)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
eyes/pupil size		(0-7)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
posture		(0-7)	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
palpebral closure		(0-3)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
respiration		(0-4)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
tremors		(0-3)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
convulsions		(0-3)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
abnormal movements/stereotypics		(0-4)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
impairment of gait		(0-7)	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
activity/arousal level		(0-4)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
feces		(0-6)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
urine		(0-3)	1	1	1	1	0	1	0	1	0	1	0	1	0	1	0	1	0	

Table IIA - 461

Project No. 50C0066/05S019 test group 2 female animals		FUNCTIONAL OBSERVATIONAL BATTERY												Table IIA -	
		Individual values													
		Rank	Animal No.										week 12		
Sensorimotor tests/reflexes			61	62	63	64	65	66	67	68	69	70			
approach response	(0-3)	0	0	0	1	1	1	0	0	1	0	0			
touch response	(0-4)	1	0	0	1	1	0	0	0	0	1	0			
vision	(0-1)	0	0	0	0	0	0	0	0	0	0	0			
pupillary reflex	(0-3)	0	0	0	0	0	0	0	0	0	0	0			
pinna reflex	(0-1)	0	0	0	0	0	0	0	0	0	0	0			
audition	(0-3)	0	0	0	0	0	0	0	0	0	0	0			
coordination of movements	(0-3)	0	0	0	0	0	0	0	0	0	0	0			
behavior during handling	(0-3)	0	0	0	0	0	0	0	0	0	0	0			
vocalization	(0-3)	0	0	0	0	0	0	0	0	0	0	0			
pain perception	(0-3)	0	0	0	0	0	0	0	0	0	0	0			
other findings		0	0	0	0	0	0	0	0	0	0	0			

Table IIA - 462

Project No. 50C0066/05S019		FUNCTIONAL OBSERVATIONAL BATTERY												Table IIA -				
test group 3 female animals	Home cage observation	Rank	Animal No.		Individual values												week 12	
			71	72	73	74	75	76	77	78	79	80	79	80				
	posture	(0-7)	1	0	1	1	1	0	1	1	1	1	1	1	1			
	tremors	(0-3)	0	0	0	0	0	0	0	0	0	0	0	0	0			
	convulsions	(0-3)	0	0	0	0	0	0	0	0	0	0	0	0	0			
	abnormal movements	(0-4)	0	0	0	0	0	0	0	0	0	0	0	0	0			
	impairment of gait	(0-7)	1	0	0	0	1	0	0	0	0	0	1	0	0			
	other findings		0	0	0	0	0	0	0	0	0	0	0	0	0			

Table IIA - 463

Project No. 50C0066/05S019 test group 3 female animals		FUNCTIONAL OBSERVATIONAL BATTERY												Table IIA -					
		Open field observations	Rank	Animal No.		Individual values												week 12	
				71	72	73	74	75	76	77	78	79	80	78	79	80			
behavior when removed from cage		(0-4)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
fur		(0-5)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
skin		(0-7)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
salivation		(0-3)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
nose discharge		(0-2)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
lacrimation		(0-3)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
eyes/pupil size		(0-7)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
posture		(0-7)	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
palpebral closure		(0-3)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
respiration		(0-4)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
tremors		(0-3)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
convulsions		(0-3)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
abnormal movements/stereotypics		(0-4)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
impairment of gait		(0-7)	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
activity/arousal level		(0-4)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
feces		(0-6)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
urine		(0-3)	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	

Table IIA - 464

Project No. 50C0066/05S019 test group 3 female animals		FUNCTIONAL OBSERVATIONAL BATTERY												Table IIA -		
		Individual values														
		Rank	Animal No.	71	72	73	74	75	76	77	78	79	80			
Sensorimotor tests/reflexes																
approach response		(0-3)	0	0	0	0	1	0	0	0	0	1	0	0	0	0
touch response		(0-4)	0	0	0	0	0	0	0	0	0	0	0	0	0	0
vision		(0-1)	0	0	0	0	0	0	0	0	0	0	0	0	0	0
pupillary reflex		(0-3)	0	0	0	0	0	0	0	0	0	0	0	0	0	0
pinna reflex		(0-1)	0	0	0	0	0	0	0	0	0	0	0	0	0	0
audition		(0-3)	0	0	0	0	0	0	0	0	0	0	0	0	0	0
coordination of movements		(0-3)	0	0	0	0	0	0	0	0	0	0	0	0	0	0
behavior during handling		(0-3)	0	0	0	0	0	0	0	0	0	0	0	0	0	0
vocalization		(0-3)	0	0	0	0	0	0	0	0	0	0	0	0	0	0
pain perception		(0-3)	0	0	0	0	0	0	0	0	0	0	0	0	0	0
other findings			0	0	0	0	0	0	0	0	0	0	0	0	0	0

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Study 50C0066/05S019

Individual Functional Observation Battery

Sex: **Male** - Phase: **In-life**

Dose Group	Animal Number	Feces [N] week 12	Rearing [N] week 12	GSF 1 [Newton] week 12	GSF 2 [Newton] week 12	GS H 1 [Newton] week 12	GS H 2 [Newton] week 12	FST 1 [cm] week 12	FST 2 [cm] week 12
0 / M 0 mg/kg bw/d	01	0	8	17.3	18.0	10.2	10.7	12.4	12.2
	02	0	9	17.7	16.5	9.9	10.6	14.4	14.5
	03	0	5	16.7	16.3	10.1	9.7	11.7	12.6
	04	0	5	14.1	14.2	10.3	9.6	12.2	12.0
	05	0	4	16.8	16.2	10.6	10.6	14.0	13.2
	06	0	11	12.5	11.9	7.2	6.4	9.5	9.4
	07	0	6	18.3	18.8	11.9	11.4	14.5	14.0
	08	0	3	14.5	15.6	10.0	10.5	13.8	13.2
	09	0	5	14.9	14.4	12.9	12.3	12.5	13.4
	10	0	8	19.4	19.2	12.7	12.1	12.2	13.0

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Study 50C0066/05S019

Individual Functional Observation Battery

Sex: **Male** - Phase: **In-life**

Dose Group	Animal Number	Feces [N] week 12	Rearing [N] week 12	GSF 1 [Newton] week 12	GSF 2 [Newton] week 12	GS H 1 [Newton] week 12	GS H 2 [Newton] week 12	FST 1 [cm] week 12	FST 2 [cm] week 12
1 / M 100 mg/kg bw/d	11	0	7	14.5	15.1	8.8	8.9	12.9	13.6
	12	0	2	14.4	13.8	10.5	11.3	12.1	12.2
	13	0	2	15.5	14.3	11.5	11.3	15.7	15.7
	14	0	5	18.2	16.4	13.3	12.5	14.5	15.1
	15	0	6	15.3	15.0	10.0	11.1	12.5	11.3
	16	0	3	11.3	12.2	7.8	8.5	10.0	9.7
	17	0	6	16.5	17.4	11.0	11.3	11.8	12.5
	18	0	7	18.4	18.2	9.7	9.2	9.0	9.8
	19	0	3	15.5	14.8	10.1	9.4	12.5	12.5
	20	0	4	17.5	17.8	10.0	10.0	16.9	17.1

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Study 50C0066/05S019

Individual Functional Observation Battery

Sex: **Male** - Phase: **In-life**

Dose Group	Animal Number	Feces [N] week 12	Rearing [N] week 12	GSF 1 [Newton] week 12	GSF 2 [Newton] week 12	GS H 1 [Newton] week 12	GS H 2 [Newton] week 12	FST 1 [cm] week 12	FST 2 [cm] week 12
2 / M 300 mg/kg bw/d	21	0	5	16.4	16.7	9.6	9.3	16.0	16.8
	22	0	11	16.2	17.0	10.0	11.5	16.9	16.0
	23	0	13	17.1	16.8	10.7	11.1	11.5	11.9
	24	0	5	14.6	15.6	10.8	10.9	12.8	13.5
	25	3	2	13.9	14.8	9.3	8.6	13.7	14.3
	26	0	3	14.3	13.6	8.9	8.6	12.3	13.2
	27	0	7	16.3	16.7	9.8	10.1	11.8	11.6
	28	2	3	11.2	12.6	10.3	11.1	14.2	14.8
	29	0	6	17.5	16.7	11.9	12.3	14.4	14.8
	30	0	9	15.0	15.0	7.6	6.9	12.2	12.4

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Study 50C0066/05S019

Individual Functional Observation Battery

Sex: **Male** - Phase: **In-life**

Dose Group	Animal Number	Feces [N] week 12	Rearing [N] week 12	GSF 1 [Newton] week 12	GSF 2 [Newton] week 12	GS H 1 [Newton] week 12	GS H 2 [Newton] week 12	FST 1 [cm] week 12	FST 2 [cm] week 12
3 / M 1000/600 mg/kg bw/d	31	0	6	12.7	12.0	9.5	10.7	7.9	7.9
	32	0	5	14.0	13.5	11.0	10.7	12.5	13.5
	33	0	4	13.0	13.4	10.0	10.5	13.4	13.0
	34	0	5	12.0	12.5	9.8	8.6	8.6	9.4
	35	0	6	15.5	14.6	9.9	10.0	15.0	15.7
	36	0	12	14.5	13.5	10.0	9.4	12.4	11.7
	37	0	8	13.2	13.9	10.1	9.8	9.2	10.5
	38	0	6	15.5	15.1	10.9	11.8	11.6	11.2
	39	0	5	9.1	10.5	7.5	6.5	13.6	13.8
	40	0	7	11.8	12.0	9.1	9.0	11.4	12.4

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Study 50C0066/05S019

Individual Functional Observation Battery

Sex: Female - Phase: In-life

Dose Group	Animal Number	Feces [N] week 12	Rearing [N] week 12	GSF 1 [Newton] week 12	GSF 2 [Newton] week 12	GS H 1 [Newton] week 12	GS H 2 [Newton] week 12	FST 1 [cm] week 12	FST 2 [cm] week 12
0 / F 0 mg/kg bw/d	41	0	10	10.0	10.8	9.2	8.5	9.6	9.5
	42	0	15	15.6	15.9	11.0	10.4	9.6	10.9
	43	0	12	12.7	11.5	8.7	9.7	13.7	13.5
	44	0	7	13.3	12.3	7.2	7.0	9.2	8.9
	45	0	10	14.4	12.9	8.1	8.5	11.5	10.8
	46	0	15	9.8	10.3	7.7	7.7	10.4	9.5
	47	0	13	10.4	10.3	5.8	6.8	9.4	9.1
	48	0	8	13.0	12.1	10.7	10.7	10.2	9.1
	49	0	12	10.4	10.6	8.9	9.2	10.2	9.1
	50	0	5	8.9	7.6	9.0	10.3	8.7	8.9

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Study 50C0066/05S019

Individual Functional Observation Battery

Sex: Female - Phase: In-life

Dose Group	Animal Number	Feces [N] week 12	Rearing [N] week 12	GSF 1 [Newton] week 12	GSF 2 [Newton] week 12	GS H 1 [Newton] week 12	GS H 2 [Newton] week 12	FST 1 [cm] week 12	FST 2 [cm] week 12
1 / F 100 mg/kg bw/d	51	0	2	13.2	13.0	7.7	8.2	10.5	10.0
	52	0	5	9.5	10.0	6.3	7.0	13.8	12.5
	53	0	5	13.3	13.3	7.3	6.8	10.8	11.7
	54	0	10	13.2	13.2	7.0	7.3	9.9	10.2
	55	0	14	13.7	12.8	7.9	8.2	11.5	11.5
	56	0	12	10.4	11.5	5.6	6.8	8.8	9.4
	57	0	12	10.5	10.5	7.8	8.7	8.7	9.5
	58	0	20	13.0	13.7	5.9	5.8	10.2	9.9
	59	0	20	10.9	11.8	7.7	6.8	9.0	9.8
	60	0	13	12.7	11.8	10.3	9.2	12.0	11.7

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Study 50C0066/05S019

Individual Functional Observation Battery

Sex: Female - Phase: In-life

Dose Group	Animal Number	Feces [N] week 12	Rearing [N] week 12	GSF 1 [Newton] week 12	GSF 2 [Newton] week 12	GS H 1 [Newton] week 12	GS H 2 [Newton] week 12	FST 1 [cm] week 12	FST 2 [cm] week 12
2 / F 300 mg/kg bw/d	61	0	6	11.9	12.4	7.1	8.0	9.2	8.9
	62	0	8	14.3	15.0	8.8	9.5	11.6	10.9
	63	0	11	14.8	13.9	9.0	8.6	12.6	11.5
	64	0	8	10.7	11.5	7.7	6.7	11.8	11.7
	65	0	10	11.4	12.3	8.2	9.3	12.0	12.6
	66	0	21	9.2	8.7	6.7	7.1	10.4	11.2
	67	0	16	13.5	14.0	8.9	9.0	13.3	13.8
	68	0	9	9.3	8.8	6.6	7.2	9.2	9.3
	69	0	16	12.8	13.3	8.2	7.7	11.2	12.5
	70	0	8	11.4	11.2	7.0	7.3	8.3	8.0

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Study 50C0066/05S019

Individual Functional Observation Battery

Sex: Female - Phase: In-life

Dose Group	Animal Number	Feces [N] week 12	Rearing [N] week 12	GSF 1 [Newton] week 12	GSF 2 [Newton] week 12	GS H 1 [Newton] week 12	GS H 2 [Newton] week 12	FST 1 [cm] week 12	FST 2 [cm] week 12
3 / F 1000 mg/kg bw/d	71	0	2	13.8	12.6	5.8	6.3	12.4	11.0
	72	0	13	11.8	11.2	9.1	9.2	10.7	9.5
	73	0	11	10.2	9.9	6.5	7.1	11.0	10.3
	74	0	16	13.4	14.4	8.8	7.8	11.9	12.0
	75	0	7	14.3	14.4	8.7	9.2	9.5	10.5
	76	0	15	12.7	12.7	9.2	8.8	7.7	7.6
	77	0	16	8.6	8.6	8.7	9.3	11.6	12.7
	78	0	6	12.1	13.3	8.0	7.9	12.3	11.1
	79	0	9	12.4	11.5	7.8	8.3	10.9	10.5
	80	0	10	11.2	10.2	6.1	6.5	10.2	10.7

Table IIA-473

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BASF
Project Number 50C0066/05S019

INDIVIDUAL DATA LISTING WITH MEANS MOTOR ACTIVITY WEEK 12

M A L E S

Animal No.	Interv. 1 Beam Interr.	Interv. 2 Beam Interr.	Interv. 3 Beam Interr.	Interv. 4 Beam Interr.	Interv. 5 Beam Interr.	Interv. 6 Beam Interr.	Interv. 7 Beam Interr.	Interv. 8 Beam Interr.
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0 / M

1	812	503	601	218	214	137	301	268
2	492	493	112	1	10	11	77	0
3	614	414	229	279	108	12	7	56
4	907	418	444	291	145	1	0	0
5	664	471	278	229	316	4	12	17
6	613	717	473	442	283	425	228	111
7	787	592	262	218	116	0	40	88
8	991	642	757	384	333	185	89	0
9	1595	637	467	258	96	1	1	0
10	793	533	439	372	217	48	44	21
M	826.8	542.0	406.2	269.2	183.8	82.4	79.9	56.1
SD	308.4	101.6	190.6	121.6	106.1	136.8	103.5	84.5
N	10	10	10	10	10	10	10	10

1 / M

11	1138	431	145	21	9	31	29	12
12	606	451	381	226	118	107	26	31
13	721	507	394	312	232	11	51	55
14	675	393	296	342	41	79	3	14
15	968	515	187	409	69	30	15	2
16	1036	399	281	209	95	93	14	32
17	1373	783	159	3	1	0	4	3
18	751	792	181	63	101	103	0	22
19	982	645	423	137	83	1	4	105
20	640	550	374	255	231	124	3	0
M	889.0	546.6	282.1	197.7	98.0	57.9	14.9	27.6
SD	251.2	147.7	107.5	138.9	80.1	48.1	16.2	32.1
N	10	10	10	10	10	10	10	10

Table IIA-474

PRINT DATE 19NOV13

BASF
Project Number 50C0066/05S019
INDIVIDUAL DATA LISTING WITH MEANS
MOTOR ACTIVITY WEEK 12

M A L E S

Animal No.	Interv. 1 Beam Interr.	Interv. 2 Beam Interr.	Interv. 3 Beam Interr.	Interv. 4 Beam Interr.	Interv. 5 Beam Interr.	Interv. 6 Beam Interr.	Interv. 7 Beam Interr.	Interv. 8 Beam Interr.
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2 / M

21	719	392	516	185	194	61	2	8
22	800	558	334	112	4	21	35	6
23	1027	497	357	258	78	284	87	0
24	1146	500	284	195	154	27	187	34
25	787	489	169	267	155	34	39	12
26	909	506	312	176	343	152	17	35
27	705	455	382	228	51	8	136	15
28	477	471	261	109	41	16	9	3
29	1075	758	483	400	273	130	34	174
30	1172	509	366	189	253	37	5	2
M	881.7	513.5	346.4	211.9	154.6	77.0	55.1	28.9
SD	223.7	96.0	101.8	84.5	112.0	87.6	62.3	52.5
N	10	10	10	10	10	10	10	10

3 / M

31	681	478	385	103	8	28	8	15
32	1257	645	350	92	4	22	0	23
33	1670	489	389	265	13	60	40	0
34	683	665	542	294	105	20	6	29
35	634	382	321	200	26	109	51	112
36	699	326	355	170	184	63	28	16
37	717	605	213	63	0	13	0	46
38	1023	549	441	441	261	213	84	148
39	509	484	341	64	45	19	9	14
40	811	373	242	207	111	1	4	13
M	868.4	499.6	347.9	189.9	75.7	54.8	23.0	41.6
SD	353.7	116.8	88.8	119.9	88.8	64.1	27.8	48.8
N	10	10	10	10	10	10	10	10

Table IIA-475
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BASF
Project Number 50C0066/05S019
INDIVIDUAL DATA LISTING WITH MEANS
MOTOR ACTIVITY WEEK 12

M A L E S

Animal No. Interv. 9 Beam Interr. Interv. 10 Beam Interr. Interv. 11 Beam Interr. Interv. 12 Beam Interr.

0 / M

1	91	94	0	0	0	0
2	1	5	9	7	0	7
3	6	10	27	0	0	0
4	1	0	11	1	1	1
5	0	42	5	1	1	1
6	285	33	2	5	5	5
7	63	21	28	18	18	18
8	3	4	6	2	2	2
9	0	0	8	0	0	0
10	22	45	12	3	3	3
M	47.2	25.4	10.8	3.7	3.7	3.7
SD	89.3	29.5	9.6	5.5	5.5	5.5
N	10	10	10	10	10	10

1 / M

11	63	34	0	0	0	0
12	54	2	8	44	44	44
13	7	20	1	2	2	2
14	1	12	10	5	5	5
15	0	11	2	7	7	7
16	1	182	9	16	16	16
17	4	3	32	5	5	5
18	31	2	73	2	2	2
19	11	14	7	0	0	0
20	2	14	0	8	8	8
M	17.4	29.4	14.2	8.9	8.9	8.9
SD	23.6	54.5	22.7	13.2	13.2	13.2
N	10	10	10	10	10	10

Table IIA-476

PRINT DATE 19NOV13

BASF
Project Number 50C0066/05S019
INDIVIDUAL DATA LISTING WITH MEANS
MOTOR ACTIVITY WEEK 12

M A L E S

Animal No.	Interv. 9 Beam Interr.	Interv. 10 Beam Interr.	Interv. 11 Beam Interr.	Interv. 12 Beam Interr.
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2 / M

21	12	5	4	16
22	11	154	1	0
23	0	13	9	94
24	26	13	24	17
25	8	4	2	16
26	38	1	0	26
27	5	0	1	9
28	9	1	4	4
29	309	318	158	72
30	48	18	5	60

M	56.6	52.7	20.8	31.4
SD	94.6	104.2	48.7	32.2
N	10	10	10	10

3 / M

31	87	61	23	23
32	10	9	7	8
33	0	9	1	0
34	21	6	7	0
35	18	1	25	11
36	0	21	26	51
37	33	27	1	33
38	70	17	4	8
39	16	8	33	180
40	9	25	14	8

M	26.4	18.4	14.1	32.2
SD	29.4	17.3	11.8	54.3
N	10	10	10	10

Table IIA-477

PRINT DATE 19NOV13

BASF
Project Number 50C0066/05S019
INDIVIDUAL DATA LISTING WITH MEANS
MOTOR ACTIVITY WEEK 12

Animal No.	Interv. 1		Interv. 2		Interv. 3		Interv. 4		Interv. 5		Interv. 6		Interv. 7		Interv. 8	
	Beam	Interr.	Beam	Interr.	Beam	Interr.	Beam	Interr.	Beam	Interr.	Beam	Interr.	Beam	Interr.	Beam	Interr.
41	1251		487		409		73		3		2		22		261	
42	1245		1020		699		217		35		17		2		21	
43	1348		759		729		68		0		16		21		2	
44	2100		1155		135		55		45		583		20		0	
45	733		502		308		154		0		14		10		2	
46	1473		775		520		237		456		80		249		212	
47	1095		869		392		179		227		151		293		71	
48	934		866		645		292		217		24		0		5	
49	2153		1459		794		472		716		920		382		442	
50	1177		759		548		415		59		16		50		3	
M	1350.9		865.1		517.9		216.2		175.8		182.3		104.9		101.9	
SD	458.5		291.8		207.9		143.3		239.7		313.5		144.4		152.8	
N	10		10		10		10		10		10		10		10	
51	1271		572		142		7		1		7		0		35	
52	909		722		444		288		386		142		148		1	
53	823		703		544		445		274		155		27		12	
54	876		682		402		238		249		38		9		12	
55	945		420		317		185		31		22		6		51	
56	995		591		202		92		6		38		28		3	
57	1034		597		373		274		111		5		0		89	
58	1360		567		207		0		404		107		2		15	
59	837		643		560		319		67		24		5		1	
60	1418		835		305		366		231		84		160		56	
M	1046.8		633.2		349.6		221.4		176.0		62.2		38.5		27.5	
SD	221.5		111.9		142.4		149.4		153.0		55.8		61.8		29.5	
N	10		10		10		10		10		10		10		10	

0 / F

1 / F

Table IIA-478

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BASF
Project Number 50C0066/05S019
INDIVIDUAL DATA LISTING WITH MEANS
MOTOR ACTIVITY WEEK 12

F E M A L E S

Animal No.	Interv. 1 Beam Interr.	Interv. 2 Beam Interr.	Interv. 3 Beam Interr.	Interv. 4 Beam Interr.	Interv. 5 Beam Interr.	Interv. 6 Beam Interr.	Interv. 7 Beam Interr.	Interv. 8 Beam Interr.
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2 / F

61	859	756	676	296	275	29	0	13
62	748	455	315	147	32	5	5	10
63	688	500	164	267	182	189	252	180
64	669	317	350	193	268	76	12	94
65	697	458	442	465	131	251	115	3
66	705	538	323	213	42	8	0	125
67	562	305	167	90	0	3	9	1
68	1144	998	356	359	62	46	6	39
69	1209	969	540	225	339	105	0	19
70	1215	591	584	268	411	29	34	14
M	849.6	588.7	391.7	252.3	174.2	74.1	43.3	49.8
SD	246.2	244.9	169.4	106.6	143.3	84.7	81.3	61.8
N	10	10	10	10	10	10	10	10

3 / F

71	1100	755	506	409	190	74	11	67
72	773	344	256	232	239	25	3	2
73	650	470	294	122	0	0	5	31
74	629	423	233	174	175	124	49	81
75	945	695	107	10	16	11	0	12
76	925	450	304	199	277	74	34	0
77	1041	1029	423	400	494	351	121	0
78	1194	1031	560	425	311	360	21	274
79	748	713	375	444	424	366	126	22
80	963	546	661	327	387	222	291	255
M	896.8	645.6	371.9	274.2	251.3	160.7	66.1	74.4
SD	190.9	243.6	167.7	148.6	163.2	150.9	91.7	104.0
N	10	10	10	10	10	10	10	10

Table IIA-479

PRINT DATE 19NOV13

BASF
Project Number 50C0066/05S019
INDIVIDUAL DATA LISTING WITH MEANS
MOTOR ACTIVITY WEEK 12

F E M A L E S		Interv. 9			Interv. 10			Interv. 11			Interv. 12		
		Animal No.	Beam	Interr.	Beam	Interr.	Beam	Interr.	Beam	Interr.	Beam	Interr.	Beam
0 / F		41	185	1	189	0	1	0	0	0	2	0	2
		42	281	1	189	0	1	0	0	0	6	1	6
		43	4	0	0	0	13	0	13	0	0	0	0
		44	234	0	314	0	0	0	0	0	15	0	15
		45	89	263	274	181	181	181	181	181	181	181	181
		46	178	6	6	18	19	18	18	18	19	18	19
		47	12	36	36	3	213	3	213	3	213	3	213
		48	66	1	1	0	1	0	1	0	1	0	1
		49	351	200	222	11	9	11	9	11	9	11	9
		50	2	17	36	9	36	9	36	9	36	9	36
		M	140.2	102.7	56.7	45.7	45.7	45.7	45.7	45.7	45.7	45.7	45.7
		SD	124.1	124.6	102.2	80.3	80.3	80.3	80.3	80.3	80.3	80.3	80.3
		N	10	10	10	10	10	10	10	10	10	10	10
1 / F													
		51	27	401	298	83	83	83	83	83	83	83	83
		52	182	45	0	1	1	1	1	1	1	1	1
		53	107	294	2	10	10	10	10	10	10	10	10
		54	25	329	20	13	13	13	13	13	13	13	13
		55	70	310	112	40	40	40	40	40	40	40	40
		56	3	8	153	0	0	0	0	0	0	0	0
		57	14	12	6	37	37	37	37	37	37	37	37
		58	4	19	7	12	12	12	12	12	12	12	12
		59	2	4	7	236	236	236	236	236	236	236	236
		60	3	144	54	87	87	87	87	87	87	87	87
		M	43.7	156.6	65.9	51.9	51.9	51.9	51.9	51.9	51.9	51.9	51.9
		SD	59.6	159.8	97.1	72.0	72.0	72.0	72.0	72.0	72.0	72.0	72.0
		N	10	10	10	10	10	10	10	10	10	10	10

Table IIA-480

PRINT DATE 19NOV13

BASF
Project Number 50C0066/05S019
INDIVIDUAL DATA LISTING WITH MEANS
MOTOR ACTIVITY WEEK 12

F E M A L E S		MOTOR ACTIVITY WEEK 12			
Animal No.		Interv. 9		Interv. 10	
		Beam Interr.	Beam Interr.	Beam Interr.	Beam Interr.
61		17	274	335	239
62		88	336	50	36
63		157	168	394	129
64		14	17	6	22
65		34	324	444	194
66		0	8	25	220
67		0	118	27	11
68		33	11	10	4
69		9	5	15	354
70		37	21	72	36
M		38.9	128.2	137.8	124.5
SD		48.8	138.1	177.7	121.7
N		10	10	10	10
3 / F					
71		159	382	163	9
72		0	0	3	3
73		33	205	123	285
74		175	149	46	20
75		21	16	0	2
76		183	129	255	263
77		244	50	4	4
78		244	363	341	430
79		27	16	99	281
80		47	158	27	16
M		113.3	146.8	106.1	131.3
SD		96.9	137.9	117.0	164.2
N		10	10	10	10

Table IIA - 481

OPHTHALMOLOGICAL FINDINGS

Project No. 50C0066/05S019

day -1

Individual values

male animals

Animal No.	test group 0		test group 3	
	left eye	right eye	left eye	right eye
1	cs	cs	cs	cs, rpm
2	cs	cs	cs, rpm	cs, rpm
3	cs, rpm	cs, rpm	cs, rpm	cs
4	cs	cs	cs, rpm	cs, rpm
5	cs	cs, rpm	cs	cs
6	cs, rpm	cs, rpm	cs, rpm	cs
7	cs, rpm	cs, rpm	cs, rpm	cs, rpm
8	cs	cs	cs	cs
9	cs	cs	cs	cs
10	cs	cs	cs	cs, rpm

cs = corneal stippings

rpm = remainders of the pupillary membrane

Table IIA - 482

OPHTHALMOLOGICAL FINDINGS

Project No. 50C0066/05S019

day -1

Individual values

male animals

Animal No.	test group 1		test group 2	
	left eye	right eye	left eye	right eye
21	cs	cs	cs	cs
22	cs	cs	cs	cs
23	cs	cs	cs	cs
24	cs	cs	cs	cs
25	cs	cs	cs	cs
26	cs	cs	cs	cs
27	cs	cs	cs, rpm	cs, rpm
28	cs, rpm	cs, rpm	cs	cs
29	cs	cs, rpm	cs, rpm	cs, rpm
30	cs	cs, rpm	cs, rpm	cs

cs = corneal stipplings

rpm = remainders of the pupillary membrane

Table IIA - 483

OPHTHALMOLOGICAL FINDINGS

Project No. 50C0066/05S019

day 91

Individual values

male animals

Animal No.	test group 0		test group 3	
	left eye	right eye	left eye	right eye
1	cs	cs	cs	cs
2	cs	cs	cs, rpm	cs
3	cs	cs	cs	cs
4	cs	cs	cs	cs
5	cs	cs	cs	cs
6	cs	cs	cs	cs
7	cs, rpm	cs, rpm	cs, rpm	cs
8	cs	cs	cs	cs
9	cs	cs	cs	cs
10	cs	cs	cs	cs

cs = corneal stipplings

rpm = remainders of the pupillary membrane

Table IIA - 484

OPHTHALMOLOGICAL FINDINGS

Project No. 50C0066/05S019

female animals		Individual values		day -1	
Animal No.		test group 0		left eye	right eye
		left eye	right eye		
41		cs, rpm	cs	cs	cs
42		cs	cs	cs	cs
43		cs	cs	cs	cs, rpm
44		cs	cs	cs, rpm	cs
45		cs, rpm	cs, rpm	cs, rpm	cs
46		cs	cs	cs	cs
47		cs	cs	cs	cs
48		cs, rpm	cs	cs	cs
49		cs, rpm	cs, rpm	rpm	cs, rpm
50		cs	cs	cs	cs

Animal No.		test group 3	
		left eye	right eye
71		cs	cs
72		cs	cs
73		cs	cs, rpm
74		cs, rpm	cs
75		cs, rpm	cs
76		cs	cs
77		cs	cs
78		cs	cs
79		rpm	cs, rpm
80		cs	cs

cs = corneal stipplings

rpm = remainders of the pupillary membrane

Table IIA - 485

OPHTHALMOLOGICAL FINDINGS

Project No. 50C0066/05S019

day -1

Individual values

female animals

Animal No.	test group 1		test group 2	
	left eye	right eye	left eye	right eye
51	cs, rpm	cs	rpm	rpm
52	rpm	-	cs	cs, rpm
53	cs, rpm	cs, rpm	cs	cs
54	rpm	cs, rpm	cs	cs, rpm
55	cs	cs	cs	cs
56	cs	cs	cs, rpm	cs
57	cs	cs	cs	cs
58	cs, rpm	cs	cs, rpm	cs, rpm
59	cs	cs	cs	cs
60	cs	cs	cs	cs
61			rpm	rpm
62			cs	cs, rpm
63			cs	cs
64			cs	cs, rpm
65			cs	cs
66			cs, rpm	cs
67			cs	cs
68			cs, rpm	cs, rpm
69			cs	cs
70			cs	cs

cs = corneal stippings

rpm = remainders of the pupillary membrane

- =animal without ophthalmological finding

Table IIA - 486

OPHTHALMOLOGICAL FINDINGS

Project No. 50C0066/05S019

day 91

Individual values

female animals

Animal No.	test group 0		test group 3	
	left eye	right eye	left eye	right eye
41	CS	CS	CS	CS
42	CS	CS	CS	CS
43	CS	CS	CS	CS
44	CS	CS	CS	CS
45	CS	CS	CS	CS
46	CS	CS	CS	CS
47	CS	CS	CS	CS
48	CS	CS	CS	CS
49	CS	CS	CS	CS
50	CS	CS	CS	CS
71			CS	CS
72			CS	CS
73			CS	CS
74			CS	CS
75			CS	CS
76			CS	CS
77			CS	CS
78			CS	CS
79			CS	CS
80			CS	CS

CS = corneal stipplings

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Study 50C0066/05S019

Red blood cell parameters

Sex: Male - Phase: In-life

Dose Group	Animal Number	RBC [10 ¹² /L]	HGB [mmol/L]	HCT [L/L]	MCV [fL]	MCH [fmol]	MCHC [mmol/L]	RET [%]	PLT [giga/L]	HQT [sec]
		day 92	day 92	day 92	day 92	day 92	day 92	day 92	day 92	day 92
0 / M 0 mg/kg bw/d	01	9.14	9.4	0.451	49.3	1.02	20.75	1.4	755	35.8
	02	8.89	9.0	0.433	48.7	1.02	20.90	1.5	757	40.0
	03	8.20	8.7	0.409	49.9	1.06	21.35	1.3	653	39.1
	04	8.60	8.9	0.432	50.2	1.04	20.72	1.4	784	43.2
	05	8.72	8.8	0.413	47.3	1.01	21.38	1.5	826	36.3
	06	9.14	9.1	0.434	47.5	1.00	21.03	1.7	787	38.1
	07	8.14	8.7	0.406	49.9	1.06	21.34	1.7	742	37.2
	08	8.77	9.2	0.438	49.9	1.05	21.00	1.4	664	36.2
	09	8.96	9.0	0.434	48.4	1.00	20.66	1.5	696	38.5
	10	8.54	9.0	0.422	49.5	1.06	21.37	1.5	781	37.9
1 / M 100 mg/kg bw/d	11	8.70	8.7	0.405	46.6	1.00	21.47	0.0	717	39.3
	12	8.54	8.3	0.393	46.0	0.97	21.08	1.8	1,206	33.8
	13	8.97	8.8	0.430	48.0	0.99	20.55	1.0	702	39.5
	14	8.81	9.0	0.413	46.9	1.02	21.73	1.7	841	37.9
	15	8.67	9.0	0.407	47.0	1.03	22.04	1.4	684	37.4
	16	8.92	9.2	0.439	49.3	1.03	20.83	1.2	821	41.2
	17	9.36	9.7	0.465	49.7	1.04	20.90	1.5	752	43.7
	18	9.35	9.5	0.450	48.1	1.02	21.11	0.9	901	39.3
	19	8.58	8.9	0.430	50.2	1.04	20.79	1.3	837	42.4
	20	8.44	9.1	0.428	50.6	1.07	21.23	1.4	660	38.0
2 / M 300 mg/kg bw/d	21	8.69	9.0	0.436	50.2	1.04	20.63	1.4	705	41.1
	22	8.28	9.0	0.420	50.7	1.08	21.36	1.4	634	39.5
	23	8.12	8.7	0.414	51.0	1.08	21.11	1.4	762	38.0
	24	8.38	8.3	0.392	46.8	0.99	21.26	1.4	743	40.7
	25	8.27	8.6	0.405	48.9	1.04	21.33	1.8	748	36.8
	26	8.23	8.7	0.403	48.9	1.06	21.61	1.7	656	38.9
	27	8.79	9.4	0.454	51.7	1.07	20.60	1.5	791	39.1
	28	8.53	8.7	0.418	49.0	1.02	20.74	1.7	752	34.9
	29	8.43	8.8	0.426	50.5	1.04	20.59	1.8	614	41.3
	30	8.88	8.7	0.427	48.1	0.98	20.46	1.8	868	44.6
3 / M 1000/600 mg/kg bw/d	31	8.52	8.8	0.427	50.2	1.03	20.52	1.4	747	42.8
	32	7.95	8.6	0.407	51.3	1.08	21.02	1.8	752	37.4
	33	8.10	8.6	0.411	50.7	1.06	20.91	1.6	697	42.5
	34	7.67	8.8	0.410	53.5	1.14	21.40	1.8	684	41.0
	35	7.46	8.2	0.379	50.8	1.10	21.68	2.2	672	42.0
	36	8.54	8.7	0.413	48.4	1.02	21.08	1.9	695	41.4
	37	8.65	8.7	0.421	48.7	1.01	20.76	1.3	699	39.4
	38	8.07	8.8	0.422	52.2	1.09	20.93	2.7	691	40.2
	39	8.07	8.7	0.425	52.7	1.08	20.48	2.2	752	40.5
	40	7.80	8.3	0.401	51.4	1.06	20.72	2.2	596	38.3

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Study 50C0066/05S019

Red blood cell parameters

Sex: Female - Phase: In-life

Dose Group	Animal Number	RBC [tera/L] day 93	HGB [mmol/L] day 93	HCT [L/L] day 93	MCV [fL] day 93	MCH [fmol] day 93	MCHC [mmol/L] day 93	RET [%] day 93	PLT [giga/L] day 93	HQT [sec] day 93
0 / F 0 mg/kg bw/d	41	8.01	9.2	0.421	52.6	1.15	21.83	1.3	669	35.3
	42	7.86	9.1	0.415	52.7	1.16	21.93	2.2	692	36.6
	43	7.54	8.9	0.408	54.2	1.19	21.88	2.2	651	36.9
	44	7.93	8.8	0.402	50.7	1.11	21.91	1.6	787	33.5
	45	7.60	8.3	0.385	50.6	1.09	21.58	1.8	896	36.5
	46	7.95	8.7	0.404	50.8	1.09	21.43	1.3	784	33.3
	47	7.66	8.8	0.406	52.9	1.15	21.79	1.5	893	33.7
	48	7.65	8.6	0.401	52.4	1.13	21.55	3.0	858	32.2
	49	8.59	9.0	0.425	49.4	1.05	21.25	1.1	725	38.6
	50	8.08	8.8	0.416	51.5	1.09	21.10	1.7	824	38.3
1 / F 100 mg/kg bw/d	51	7.88	8.6	0.400	50.7	1.09	21.57	1.6	633	33.8
	52	7.53	8.8	0.416	55.2	1.17	21.27	2.6	675	34.7
	53	7.96	8.6	0.410	51.5	1.08	20.88	1.7	608	34.4
	54	7.84	8.6	0.404	51.6	1.09	21.17	2.5	777	35.3
	55	7.84	8.8	0.423	53.9	1.12	20.74	2.0	750	34.2
	56	8.09	8.5	0.406	50.2	1.05	20.84	1.3	744	38.0
	57	7.47	8.7	0.405	54.3	1.17	21.52	1.7	771	35.8
	58	8.07	8.6	0.408	50.5	1.07	21.16	2.6	858	34.0
	59	7.77	8.9	0.410	52.7	1.15	21.76	2.2	607	36.2
	60	7.74	8.3	0.381	49.3	1.08	21.89	2.0	850	35.8
2 / F 300 mg/kg bw/d	61	7.97	8.9	0.414	51.9	1.12	21.47	1.5	855	39.1
	62	7.64	8.9	0.406	53.1	1.17	22.06	1.5	798	36.3
	63	7.59	8.4	0.405	53.3	1.11	20.74	2.3	778	37.8
	64	6.96	8.0	0.372	53.4	1.15	21.60	2.8	703	37.3
	65	8.07	8.8	0.410	50.8	1.09	21.36	2.6	762	36.0
	66	7.41	8.1	0.375	50.6	1.09	21.48	2.4	838	33.9
	67	8.05	8.5	0.406	50.4	1.06	21.01	2.8	733	35.7
	68	7.89	8.7	0.413	52.4	1.10	20.99	1.4	825	36.8
	69	7.99	8.5	0.409	51.2	1.07	20.80	2.6	627	38.8
	70	8.03	8.6	0.412	51.3	1.07	20.92	1.6	770	36.4
3 / F 1000 mg/kg bw/d	71	7.75	8.1	0.396	51.0	1.05	20.55	2.7	714	39.5
	72	7.57	8.1	0.388	51.2	1.07	20.87	3.4	764	39.3
	73	7.45	7.6	0.366	49.1	1.03	20.89	2.4	728	38.2
	74	7.38	8.3	0.375	50.8	1.12	22.12	2.0	754	39.6
	75	7.57	8.5	0.403	53.2	1.12	21.02	1.7	758	38.4
	76	7.57	7.7	0.367	48.4	1.02	21.08	2.4	762	35.9
	77	7.59	8.0	0.380	50.1	1.05	20.99	2.1	722	38.4
	78	7.33	8.0	0.384	52.3	1.09	20.77	2.3	712	36.8
	79	7.50	7.8	0.372	49.6	1.04	21.00	2.2	680	37.5
	80	6.81	7.9	0.370	54.2	1.16	21.41	1.9	715	38.6

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Study 50C0066/05S019

White blood cell parameters

Sex: Male - Phase: In-life

Dose Group	Animal Number	WBC [giga/L]	NEUTA [giga/L]	LYMPHA [giga/L]	MONOA [giga/L]	EOSA [giga/L]	BASOA [giga/L]	LUCA [giga/L]	NEUT [%]	LYMPH [%]	MONO [%]	EOS [%]	BASO [%]	LUC [%]
0 / M	01	5.72	0.80	4.57	0.13	0.17	0.02	0.04	13.9	79.8	2.3	3.0	0.3	0.6
	02	5.98	1.12	4.47	0.25	0.10	0.01	0.02	18.8	74.9	4.2	1.6	0.2	0.3
	03	7.30	1.37	5.60	0.14	0.13	0.02	0.03	18.8	76.8	1.9	1.8	0.3	0.3
	04	5.89	1.19	4.39	0.11	0.15	0.02	0.02	20.3	74.6	1.9	2.5	0.4	0.3
	05	4.39	0.89	3.29	0.10	0.10	0.01	0.01	20.2	74.9	2.3	2.2	0.2	0.2
	06	6.27	0.79	5.19	0.10	0.12	0.02	0.04	12.6	82.9	1.7	1.9	0.3	0.6
	07	4.09	0.74	3.19	0.06	0.06	0.02	0.02	18.2	78.1	1.5	1.5	0.4	0.4
	08	4.86	0.79	3.82	0.13	0.07	0.02	0.04	16.3	78.6	2.7	1.4	0.3	0.7
	09	5.56	0.71	4.62	0.09	0.11	0.01	0.02	12.8	83.0	1.7	2.0	0.2	0.3
	10	5.08	1.03	3.83	0.07	0.10	0.01	0.03	20.3	75.4	1.3	2.0	0.2	0.7
1 / M	11	6.22	0.70	5.24	0.09	0.16	0.02	0.01	11.2	84.3	1.5	2.5	0.3	0.2
	12	6.99	2.04	4.33	0.38	0.19	0.02	0.03	29.2	61.9	5.4	2.7	0.3	0.4
	13	3.75	0.69	2.89	0.09	0.06	0.00	0.01	18.4	77.1	2.4	1.6	0.1	0.3
	14	6.05	0.98	4.76	0.12	0.12	0.02	0.03	16.2	78.7	2.4	2.0	0.3	0.5
	15	5.42	0.65	4.59	0.07	0.08	0.02	0.02	12.0	84.6	1.2	1.5	0.3	0.3
	16	3.41	0.76	2.49	0.06	0.09	0.01	0.01	22.2	73.0	1.6	2.6	0.4	0.2
	17	4.86	0.85	3.79	0.11	0.09	0.01	0.02	17.5	78.0	2.2	1.8	0.2	0.4
	18	5.31	0.95	4.18	0.08	0.08	0.01	0.02	17.9	78.6	1.5	1.5	0.2	0.3
	19	3.86	0.91	2.77	0.06	0.09	0.00	0.02	23.6	71.8	1.5	2.4	0.1	0.5
	20	5.18	0.69	4.24	0.42	0.09	0.01	0.02	13.4	81.8	2.4	1.8	0.3	0.4
2 / M	21	4.49	1.14	3.10	0.11	0.11	0.01	0.01	25.4	69.1	2.5	2.5	0.2	0.3
	22	5.68	1.49	3.96	0.07	0.13	0.01	0.01	26.2	69.7	1.3	2.2	0.2	0.3
	23	5.23	0.78	4.18	0.10	0.13	0.02	0.03	14.9	79.9	1.9	2.4	0.4	0.6
	24	4.88	1.65	2.74	0.38	0.08	0.01	0.01	33.9	56.2	7.9	1.5	0.2	0.2
	25	4.03	0.91	2.92	0.06	0.11	0.02	0.01	22.6	72.6	1.6	2.6	0.4	0.2
	26	4.48	1.01	3.24	0.12	0.10	0.01	0.01	22.5	72.2	2.8	2.1	0.3	0.1
	27	3.73	0.95	2.62	0.06	0.07	0.01	0.01	25.5	70.3	1.6	2.0	0.4	0.2
	28	4.38	1.01	3.19	0.08	0.09	0.01	0.02	22.9	72.8	1.8	2.0	0.1	0.4
	29	4.85	0.69	4.00	0.06	0.07	0.00	0.02	14.2	82.5	1.3	1.5	0.1	0.5
	30	4.14	0.95	2.99	0.07	0.09	0.01	0.01	23.0	72.4	1.8	2.3	0.2	0.4
3 / M	31	4.27	0.95	3.12	0.12	0.06	0.00	0.02	22.2	73.0	2.9	1.5	0.1	0.4
	32	4.66	1.21	3.28	0.07	0.07	0.01	0.02	25.9	70.4	1.6	1.4	0.2	0.4
	33	5.63	1.64	3.69	0.11	0.16	0.02	0.01	29.2	65.6	1.9	2.8	0.3	0.2
	34	5.51	1.35	3.88	0.12	0.10	0.01	0.04	24.5	70.5	2.3	1.7	0.2	0.8
	35	4.08	0.77	3.17	0.06	0.06	0.00	0.02	18.8	77.6	1.6	1.4	0.1	0.4
	36	4.53	1.07	3.28	0.07	0.09	0.01	0.01	23.6	72.5	1.6	1.9	0.2	0.2
	37	2.98	0.87	2.00	0.04	0.04	0.01	0.01	29.3	67.3	1.3	1.5	0.2	0.3
	38	4.47	1.46	2.83	0.06	0.10	0.01	0.01	32.6	63.2	1.3	2.3	0.2	0.3
	39	3.66	1.07	2.43	0.06	0.08	0.02	0.01	29.2	66.3	1.5	2.1	0.4	0.4
	40	3.02	0.75	2.10	0.07	0.08	0.00	0.01	24.7	69.8	2.3	2.6	0.2	0.3

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Study 50C0066/05S019

White blood cell parameters

Sex: Female - Phase: In-life

Dose Group	Animal Number	WBC [giga/L] day 93	NEUTA [giga/L] day 93	LYMPHA [giga/L] day 93	MONOA [giga/L] day 93	EOSA [giga/L] day 93	BASOA [giga/L] day 93	LUCA [giga/L] day 93	NEUT [%] day 93	LYMPH [%] day 93	MONO [%] day 93	EOS [%] day 93	BASO [%] day 93	LUC [%] day 93
0 / F 0 mg/kg bw/d	41	3.32	0.62	2.53	0.06	0.08	0.02	0.01	18.7	76.2	1.8	2.4	0.6	0.3
	42	4.05	0.56	3.32	0.07	0.06	0.01	0.03	13.9	81.9	1.8	1.5	0.3	0.6
	43	3.60	0.38	3.07	0.07	0.06	0.02	0.01	10.4	85.3	2.0	1.5	0.5	0.3
	44	4.61	0.65	3.70	0.11	0.10	0.01	0.03	14.1	80.4	2.4	2.2	0.3	0.6
	45	3.61	0.63	2.73	0.09	0.12	0.01	0.01	17.6	75.8	2.4	3.4	0.4	0.4
	46	4.75	0.69	3.78	0.08	0.16	0.02	0.02	14.5	79.7	1.8	3.3	0.4	0.4
	47	3.87	0.43	3.26	0.07	0.09	0.01	0.01	11.0	84.4	1.8	2.3	0.2	0.3
	48	5.97	0.63	5.09	0.12	0.07	0.02	0.04	10.6	85.3	2.0	1.2	0.3	0.6
	49	3.69	0.55	2.94	0.07	0.10	0.02	0.02	14.8	79.7	1.8	2.6	0.4	0.7
	50	3.40	0.54	2.70	0.07	0.06	0.01	0.02	15.8	79.3	2.1	1.8	0.4	0.6
1 / F 100 mg/kg bw/d	51	5.47	0.61	4.66	0.09	0.08	0.02	0.02	11.1	85.2	1.6	1.4	0.3	0.4
	52	5.37	0.71	4.44	0.11	0.07	0.03	0.02	13.2	82.6	2.0	1.3	0.5	0.4
	53	5.18	0.54	4.38	0.12	0.09	0.02	0.03	10.4	84.6	2.4	1.8	0.3	0.5
	54	3.40	0.83	2.42	0.07	0.06	0.01	0.00	24.5	71.1	2.2	1.9	0.3	0.1
	55	4.05	0.42	3.45	0.08	0.07	0.01	0.01	10.5	85.2	1.9	1.8	0.4	0.2
	56	4.24	0.52	3.52	0.10	0.06	0.00	0.04	12.3	83.0	2.4	1.4	0.1	0.8
	57	4.45	0.39	3.90	0.06	0.06	0.01	0.02	8.7	87.8	1.4	1.4	0.2	0.5
	58	3.05	0.84	2.03	0.06	0.10	0.01	0.01	27.6	66.8	1.9	3.2	0.3	0.2
	59	4.34	1.12	2.95	0.14	0.12	0.01	0.01	25.8	67.9	3.3	2.7	0.2	0.2
	60	3.92	0.53	3.25	0.05	0.08	0.01	0.01	13.5	83.0	1.2	1.9	0.2	0.1
2 / F 300 mg/kg bw/d	61	4.29	0.54	3.55	0.09	0.07	0.01	0.01	12.7	82.8	2.2	1.7	0.3	0.3
	62	4.16	0.32	3.68	0.06	0.06	0.02	0.03	7.7	88.4	1.5	1.3	0.4	0.6
	63	4.57	0.62	3.75	0.08	0.09	0.01	0.02	13.5	82.2	1.8	1.9	0.2	0.4
	64	4.01	0.67	3.16	0.09	0.06	0.01	0.02	16.8	78.7	2.3	1.4	0.2	0.5
	65	3.07	0.58	2.36	0.08	0.03	0.00	0.01	19.0	76.9	2.5	1.1	0.2	0.3
	66	2.79	0.63	2.03	0.05	0.06	0.01	0.01	22.7	72.7	1.9	2.0	0.4	0.4
	67	3.10	0.60	2.38	0.05	0.05	0.01	0.01	19.4	76.9	1.6	1.5	0.4	0.3
	68	5.93	0.59	5.10	0.07	0.13	0.01	0.02	10.0	86.0	1.1	2.2	0.2	0.4
	69	2.88	0.42	2.34	0.05	0.05	0.01	0.01	14.5	81.3	1.7	1.8	0.3	0.4
	70	3.69	0.53	3.02	0.04	0.08	0.01	0.02	14.3	81.8	1.1	2.1	0.2	0.5
3 / F 1000 mg/kg bw/d	71	3.75	0.40	3.20	0.07	0.05	0.01	0.01	10.7	85.4	2.0	1.4	0.2	0.4
	72	3.96	0.67	3.05	0.11	0.10	0.01	0.02	16.9	77.1	2.8	2.5	0.2	0.5
	73	4.18	0.44	3.60	0.08	0.05	0.01	0.01	10.5	86.1	1.9	1.1	0.2	0.2
	74	3.13	0.42	2.61	0.05	0.03	0.00	0.01	13.4	83.4	1.5	1.1	0.2	0.4
	75	3.26	0.37	2.77	0.06	0.05	0.00	0.01	11.5	84.8	1.9	1.5	0.1	0.2
	76	3.62	0.75	2.67	0.09	0.07	0.01	0.04	20.7	73.7	2.4	1.9	0.2	1.0
	77	4.13	0.67	3.26	0.12	0.05	0.02	0.01	16.3	78.9	2.8	1.2	0.4	0.3
	78	3.06	0.47	2.48	0.05	0.04	0.01	0.01	15.3	81.2	1.6	1.3	0.3	0.3
	79	2.78	0.36	2.31	0.06	0.04	0.01	0.01	12.8	83.0	2.0	1.4	0.3	0.5
	80	3.78	0.57	3.07	0.07	0.06	0.00	0.01	15.0	81.2	1.6	1.6	0.1	0.3

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Study 50C0066/05S019

Enzymes

Sex: Male - Phase: In-life

Dose Group	Animal Number	ALT [µkat/L] day 92	AST [µkat/L] day 92	ALP [µkat/L] day 92	GGT_C [µkat/L] day 92
0 / M 0 mg/kg bw/d	01	0.81	1.33	1.23	0
	02	0.70	1.67	1.56	0
	03	0.60	1.33	1.13	0
	04	0.53	1.12	1.15	0
	05	0.59	1.12	1.08	0
	06	0.61	1.23	1.02	0
	07	0.61	1.61	1.41	0
	08	0.75	1.78	1.25	0
	09	0.92	3.43	1.62	0
	10	0.64	1.69	1.09	0
1 / M 100 mg/kg bw/d	11	0.60	1.41	1.19	0
	12	0.68	1.43	1.97	0
	13	0.54	1.09	1.49	0
	14	2.11	1.42	1.52	0
	15	0.65	1.27	1.38	0
	16	0.64	1.67	1.36	0
	17	0.76	1.42	1.16	0
	18	0.65	1.54	1.41	0
	19	0.69	1.58	1.21	0
	20	0.63	1.39	1.61	0
2 / M 300 mg/kg bw/d	21	1.09	1.75	1.13	0
	22	0.81	1.46	1.28	0
	23	0.73	1.30	1.12	0
	24	1.04	1.37	1.29	0
	25	0.79	1.11	1.63	0
	26	0.94	3.08	1.54	0
	27	1.02	1.69	1.28	0
	28	0.69	1.72	1.63	0
	29	1.17	2.32	1.93	0
	30	0.85	1.94	1.16	0
3 / M 1000/600 mg/kg bw/d	31	0.80	1.13	1.89	0
	32	1.05	1.61	1.72	0
	33	2.13	3.47	1.50	0
	34	0.84	1.14	0.92	0
	35	0.51	1.18	1.07	0
	36	0.88	2.30	1.51	0
	37	0.65	1.67	1.71	0
	38	1.03	2.26	1.12	0
	39	0.54	1.38	1.22	0
	40	0.76	1.95	1.46	0

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Study 50C0066/05S019

Enzymes

Sex: Female - Phase: In-life

Dose Group	Animal Number	ALT [µkat/L] day 93	AST [µkat/L] day 93	ALP [µkat/L] day 93	GGT_C [µkat/L] day 93
0 / F 0 mg/kg bw/d	41	0.47	1.39	0.47	0
	42	0.41	1.46	0.95	0
	43	0.64	2.12	0.62	0
	44	0.70	1.50	0.83	0
	45	0.84	1.57	0.84	0
	46	0.42	1.09	0.43	0
	47	0.58	1.17	0.60	0
	48	0.60	1.03	0.40	0
	49	0.57	1.11	0.69	0
	50	0.59	1.38	0.78	0
1 / F 100 mg/kg bw/d	51	0.80	1.97	0.73	0
	52	0.60	1.55	0.49	0
	53	0.64	2.29	0.47	0
	54	0.58	1.33	0.39	0
	55	0.71	2.01	0.53	0
	56	0.50	1.18	0.57	0
	57	0.82	1.40	0.62	0
	58	0.43	1.05	0.59	0
	59	0.83	1.33	0.61	0
	60	0.41	1.26	0.52	0
2 / F 300 mg/kg bw/d	61	0.53	1.64	0.66	0
	62	0.63	1.78	0.77	0
	63	0.62	1.63	0.60	0
	64	0.54	0.96	1.06	0
	65	0.74	1.48	1.17	0
	66	0.59	1.48	0.52	0
	67	0.47	1.08	0.55	0
	68	0.39	1.15	0.35	0
	69	0.60	1.04	0.71	0
	70	0.69	1.31	0.52	0
3 / F 1000 mg/kg bw/d	71	0.59	0.99	1.61	17
	72	1.18	1.61	1.34	7
	73	0.96	1.44	1.06	3
	74	0.71	0.98	1.52	0
	75	0.93	1.44	0.75	0
	76	0.70	0.98	0.57	0
	77	1.09	1.17	0.79	0
	78	0.52	1.26	0.67	0
	79	0.69	0.96	0.71	0
	80	0.58	1.05	1.12	0

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Study 50C0066/05S019

Substrates

Sex: Male - Phase: In-life

Dose Group	Animal Number	UREA [mmol/L] day 92	CREA [μmol/L] day 92	GLUC [mmol/L] day 92	TBIL_C [μmol/L] day 92	TPROT [g/L] day 92	ALB [g/L] day 92	GLOB [g/L] day 92	CHOL [mmol/L] day 92	TRIG [mmol/L] day 92
0 / M 0 mg/kg bw/d	01	5.23	27.5	5.98	1.71	65.27	38.86	26.41	2.02	0.97
	02	4.90	32.3	5.67	1.68	63.18	38.51	24.67	2.27	0.50
	03	4.97	32.0	5.44	1.56	62.11	38.14	23.97	1.89	0.75
	04	5.09	28.0	7.35	1.97	62.54	38.58	23.96	1.35	1.38
	05	4.67	26.6	6.01	1.67	64.22	39.24	24.98	2.14	1.12
	06	6.14	32.6	6.82	1.67	65.78	39.53	26.25	1.94	1.24
	07	4.58	31.7	6.12	1.26	62.39	38.31	24.08	1.45	0.85
	08	4.42	29.7	7.51	1.75	62.83	38.73	24.10	1.77	1.72
	09	5.86	31.7	6.40	1.55	60.00	37.56	22.44	1.74	0.64
	10	5.00	31.2	6.38	1.39	65.47	38.90	26.57	1.94	0.57
1 / M 100 mg/kg bw/d	11	4.69	27.2	5.29	1.37	64.86	38.86	26.00	1.52	1.88
	12	5.42	29.2	5.23	1.54	65.41	37.74	27.67	1.84	1.40
	13	4.89	28.6	7.16	1.69	63.13	37.98	25.15	2.07	2.14
	14	5.56	28.6	6.19	1.48	68.51	41.24	27.27	1.81	1.18
	15	4.25	29.5	6.98	1.57	66.25	39.23	27.02	2.19	1.67
	16	4.35	27.5	4.20	1.52	61.16	37.90	23.26	1.62	1.64
	17	4.72	28.9	6.07	1.60	66.10	39.49	26.61	1.08	0.93
	18	4.65	24.9	6.32	1.92	65.10	39.27	25.83	1.73	1.56
	19	4.81	29.7	6.66	1.44	60.22	38.28	21.94	1.10	1.78
	20	4.85	28.0	6.93	1.52	66.05	38.92	27.13	1.57	1.17
2 / M 300 mg/kg bw/d	21	4.36	31.4	4.54	1.78	61.51	37.67	23.84	1.00	1.18
	22	4.28	32.6	5.01	1.81	63.63	38.31	25.32	1.33	1.41
	23	4.58	27.8	5.25	1.82	62.72	38.50	24.22	1.29	1.61
	24	5.77	35.4	5.24	1.68	63.48	39.93	23.55	0.98	1.45
	25	4.13	31.4	5.49	0.93	66.46	40.33	26.13	1.22	1.58
	26	4.47	29.2	5.18	1.27	62.65	36.99	25.66	1.75	1.97
	27	4.48	25.8	6.14	1.46	62.45	37.74	24.71	1.24	1.25
	28	3.72	31.2	5.07	1.15	66.63	40.29	26.34	1.61	1.99
	29	4.27	30.3	6.28	1.82	63.59	38.80	24.79	0.80	1.24
	30	4.67	32.9	6.56	1.15	63.66	39.94	23.72	1.13	1.14
3 / M 1000/600 mg/kg bw/d	31	5.49	31.2	4.39	2.17	61.43	38.36	23.07	0.90	2.43
	32	5.28	38.8	5.85	1.03	62.53	37.78	24.75	1.26	2.92
	33	4.13	31.4	5.21	1.18	62.76	38.63	24.13	0.94	2.74
	34	5.17	30.0	5.38	1.33	64.21	38.17	26.04	0.90	2.12
	35	5.36	33.1	6.16	1.16	60.21	37.29	22.92	0.90	2.11
	36	5.69	40.8	4.19	1.24	67.34	39.47	27.87	1.19	1.50
	37	5.40	34.8	4.51	1.30	59.51	36.68	22.83	1.26	1.83
	38	5.62	34.8	4.90	1.34	62.15	38.25	23.90	0.88	1.36
	39	4.49	30.3	5.63	1.11	64.75	39.59	25.16	0.89	2.89
	40	6.33	36.5	5.37	0.73	61.51	38.12	23.39	1.21	3.27

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Study 50C0066/05S019

Substrates

Sex: Female - Phase: In-life

Dose Group	Animal Number	UREA [mmol/L] day 93	CREA [μmol/L] day 93	GLUC [mmol/L] day 93	TBIL_C [μmol/L] day 93	TPROT [g/L] day 93	ALB [g/L] day 93	GLOB [g/L] day 93	CHOL [mmol/L] day 93	TRIG [mmol/L] day 93
0 / F 0 mg/kg bw/d	41	5.41	28.0	4.89	2.73	70.67	43.97	26.70	1.49	0.37
	42	7.50	49.6	4.67	3.37	63.33	42.04	21.29	1.35	0.39
	43	4.94	33.4	5.09	3.06	67.97	42.00	25.97	1.71	0.47
	44	7.64	34.5	5.55	2.16	66.95	42.24	24.71	2.26	0.77
	45	7.12	39.9	5.82	2.18	70.46	43.34	27.12	1.04	0.61
	46	5.06	38.5	5.26	2.17	73.57	45.04	28.53	2.14	0.79
	47	6.75	38.5	4.86	2.44	68.02	43.13	24.89	1.76	1.03
	48	5.80	31.2	5.15	2.14	70.22	43.03	27.19	2.06	1.40
	49	6.03	38.5	4.63	2.10	66.74	41.69	25.05	1.27	0.74
	50	5.99	33.7	5.73	2.81	63.37	39.79	23.58	1.10	0.60
1 / F 100 mg/kg bw/d	51	6.59	35.7	4.83	2.07	68.02	40.71	27.31	2.14	0.88
	52	5.62	34.5	5.08	3.12	71.84	44.24	27.60	1.55	0.71
	53	6.65	35.7	5.65	3.03	70.39	43.53	26.86	1.41	0.65
	54	6.83	40.8	5.25	2.04	71.80	43.19	28.61	1.58	0.90
	55	6.92	36.0	5.05	2.68	70.02	43.41	26.61	1.73	0.92
	56	5.09	32.3	4.31	1.70	66.61	41.76	24.85	1.28	0.83
	57	6.88	34.0	4.47	1.78	64.52	41.03	23.49	1.67	1.25
	58	6.12	35.1	5.63	1.99	69.28	43.91	25.37	1.55	0.57
	59	5.32	34.0	5.23	1.62	67.23	42.68	24.55	1.41	1.07
	60	6.85	41.3	4.93	1.80	70.28	44.11	26.17	1.23	0.72
2 / F 300 mg/kg bw/d	61	5.56	34.8	4.89	1.68	67.17	40.33	26.84	1.11	1.16
	62	5.31	32.0	5.66	2.47	67.17	42.21	24.96	1.23	0.82
	63	6.67	38.8	5.41	2.04	73.63	42.38	31.25	1.20	0.75
	64	5.37	29.2	5.31	2.77	69.40	41.69	27.71	1.42	1.24
	65	5.57	34.0	5.71	1.65	66.77	40.84	25.93	1.45	0.69
	66	5.70	35.4	5.41	2.05	71.29	44.02	27.27	1.98	0.83
	67	6.30	37.4	5.51	1.53	65.67	40.09	25.58	1.45	0.56
	68	5.76	39.1	5.37	1.86	72.33	45.21	27.12	1.02	0.89
	69	4.70	27.5	5.88	1.87	67.75	40.38	27.37	1.09	0.46
	70	6.34	34.3	5.77	2.29	68.33	41.47	26.86	1.09	0.46
3 / F 1000 mg/kg bw/d	71	4.58	27.5	5.79	1.85	67.91	41.22	26.69	2.09	0.80
	72	5.93	31.7	5.67	2.78	68.35	41.94	26.41	1.38	1.48
	73	4.85	28.0	5.65	2.83	72.62	43.72	28.90	1.51	0.68
	74	5.53	30.6	5.03	2.32	68.19	42.74	25.45	1.28	0.94
	75	5.69	35.1	5.72	2.00	66.60	40.43	26.17	1.35	1.17
	76	5.63	30.6	5.31	2.17	68.37	43.20	25.17	1.41	0.83
	77	6.09	32.3	5.51	2.40	76.72	47.20	29.52	1.02	1.38
	78	5.61	41.3	6.45	2.59	76.59	47.13	29.46	0.98	0.63
	79	4.64	29.7	6.03	2.70	67.83	41.94	25.89	1.13	0.85
	80	5.69	34.0	5.44	1.61	68.04	43.32	24.72	1.17	1.10

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Study 50C0066/05S019

Electrolytes + minerals

Sex: Male - Phase: In-life

Dose Group	Animal Number	NA [mmol/L] day 92	K [mmol/L] day 92	CL [mmol/L] day 92	INP [mmol/L] day 92	CA [mmol/L] day 92
0 / M 0 mg/kg bw/d	01	142.3	4.91	101.1	1.71	2.61
	02	142.3	4.64	101.0	1.72	2.48
	03	143.5	4.66	102.2	1.54	2.49
	04	142.2	5.26	101.4	1.65	2.54
	05	144.1	4.51	101.3	1.65	2.64
	06	143.5	4.96	101.9	1.45	2.56
	07	144.6	4.95	101.8	1.95	2.53
	08	142.4	5.00	101.6	1.54	2.49
	09	143.2	4.71	100.9	1.74	2.47
	10	144.3	4.81	102.2	1.55	2.63
1 / M 100 mg/kg bw/d	11	142.2	4.96	100.1	1.60	2.60
	12	142.1	4.93	100.3	1.80	2.63
	13	141.4	4.80	101.5	1.19	2.52
	14	142.1	4.83	100.9	1.54	2.67
	15	143.3	4.30	101.1	1.58	2.58
	16	143.6	4.73	100.7	1.49	2.56
	17	142.7	4.79	100.1	1.77	2.56
	18	142.9	5.28	100.0	1.47	2.64
	19	142.7	4.88	101.2	1.57	2.49
	20	143.6	4.34	99.1	1.60	2.66
2 / M 300 mg/kg bw/d	21	142.2	4.52	99.6	1.91	2.49
	22	140.6	4.83	99.0	2.05	2.59
	23	143.3	4.29	100.7	2.03	2.58
	24	143.3	4.66	101.0	1.33	2.61
	25	143.9	4.80	101.6	1.70	2.65
	26	144.2	5.01	101.8	1.90	2.59
	27	142.8	5.10	100.2	1.60	2.51
	28	143.9	4.88	100.0	1.80	2.65
	29	145.1	5.06	101.0	1.68	2.48
	30	142.5	5.26	102.7	1.69	2.56
3 / M 1000/600 mg/kg bw/d	31	141.2	4.66	99.8	1.74	2.65
	32	142.0	4.36	102.0	2.07	2.61
	33	142.2	4.03	98.3	2.13	2.57
	34	141.9	4.61	97.2	1.84	2.58
	35	141.6	4.76	99.5	1.76	2.59
	36	143.1	5.21	100.1	1.80	2.56
	37	142.6	4.78	99.5	1.77	2.54
	38	142.9	4.76	99.7	2.38	2.59
	39	143.2	4.91	99.4	1.54	2.62
	40	143.2	4.75	100.6	1.81	2.65

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Study 50C0066/05S019

Electrolytes + minerals

Sex: Female - Phase: In-life

Dose Group	Animal Number	NA [mmol/L] day 93	K [mmol/L] day 93	CL [mmol/L] day 93	INP [mmol/L] day 93	CA [mmol/L] day 93
0 / F 0 mg/kg bw/d	41	140.1	4.50	99.1	1.52	2.64
	42	141.4	3.55	97.9	1.50	2.45
	43	142.4	4.23	99.4	1.39	2.62
	44	139.4	4.17	98.2	1.73	2.62
	45	139.7	4.34	99.1	1.77	2.69
	46	140.4	4.67	98.6	1.44	2.75
	47	139.9	4.71	99.7	1.71	2.63
	48	141.3	4.47	100.3	1.47	2.66
	49	140.8	4.37	100.2	1.33	2.61
	50	141.6	4.45	99.9	1.32	2.50
1 / F 100 mg/kg bw/d	51	139.3	4.37	98.2	1.64	2.65
	52	139.3	4.50	98.3	1.59	2.68
	53	139.5	4.57	97.3	1.86	2.65
	54	139.7	4.27	100.1	1.33	2.61
	55	141.2	4.47	100.1	1.60	2.65
	56	139.2	4.60	100.2	1.28	2.53
	57	140.8	4.76	99.8	1.59	2.64
	58	141.2	3.92	101.8	1.35	2.57
	59	143.4	4.35	102.3	1.26	2.53
	60	142.9	4.46	103.3	1.35	2.64
2 / F 300 mg/kg bw/d	61	138.9	4.94	98.7	1.54	2.64
	62	140.1	4.36	98.2	1.43	2.65
	63	140.2	4.27	98.9	1.94	2.63
	64	140.1	4.24	96.2	1.51	2.63
	65	139.3	4.61	98.7	1.50	2.57
	66	139.1	4.11	98.1	1.20	2.56
	67	139.9	4.31	99.4	1.09	2.55
	68	142.1	4.08	99.2	1.58	2.69
	69	141.8	4.03	101.1	1.18	2.48
	70	143.0	4.26	99.9	1.26	2.62
3 / F 1000 mg/kg bw/d	71	137.8	4.69	96.9	1.59	2.54
	72	139.0	4.63	95.2	1.65	2.65
	73	137.8	4.85	95.5	1.58	2.66
	74	139.9	4.17	96.9	2.36	2.71
	75	141.4	4.69	96.8	1.41	2.64
	76	139.3	4.26	97.6	1.61	2.62
	77	139.2	4.47	97.8	1.72	2.73
	78	140.5	4.03	97.3	1.29	2.77
	79	142.8	4.33	98.8	1.90	2.62
	80	142.6	4.45	100.4	1.48	2.67

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Study 50C0066/05S019

Urinalyses

Sex: **Male** - Phase: **In-life**

Dose Group	Animal Number	PH [---] day 85	PRO [---] day 85	GLU [---] day 85	KET [---] day 85	UBG [---] day 85	BIL [---] day 85	BLOOD [---] day 85	VOL [ml] day 85	COL [---] day 85	TURB [---] day 85	SP.GR._C [g/L] day 85
0 / M 0 mg/kg bw/d	01	6.5	0	0	1	0	0	0	6.0	Y	C	1.045
	02	7.0	0	0	0	0	0	0	6.0	Y	C	1.037
	03	7.0	0	0	0	0	0	0	6.2	Y	C	1.040
	04	7.0	0	0	0	0	0	0	6.0	Y	C	1.031
	05	7.0	0	0	0	0	0	0	6.7	Y	C	1.031
	06	7.0	1	0	1	0	0	0	3.4	Y	C	1.049
	07	6.5	1	0	1	0	0	0	4.3	Y	C	1.045
	08	7.0	1	0	1	0	0	0	4.6	Y	C	1.041
	09	7.0	0	0	0	0	0	0	4.8	Y	C	1.058
	10	6.5	1	0	1	0	0	0	5.0	Y	C	1.046

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Study 50C0066/05S019

Urinalyses

Sex: **Male** - Phase: **In-life**

Dose Group	Animal Number	PH [---] day 85	PRO [---] day 85	GLU [---] day 85	KET [---] day 85	UBG [---] day 85	BIL [---] day 85	BLOOD [---] day 85	VOL [ml] day 85	COL [---] day 85	TURB [---] day 85	SP.GR._C [g/L] day 85
1 / M 100 mg/kg bw/d	11	6.5	1	0	1	0	0	3	4.1	Y	C	1,048
	12	6.5	1	0	1	0	0	1	3.4	Y	C	1,100
	13	6.5	1	0	1	1	1	0	2.7	Y	C	1,064
	14	6.0	0	0	0	0	0	0	6.1	Y	C	1,041
	15	7.0	0	0	0	0	0	0	7.2	Y	C	1,038
	16	5.0	1	0	1	0	1	0	2.0	Y	C	1,070
	17	6.5	1	0	1	0	0	1	4.7	Y	C	1,050
	18	6.0	1	0	1	1	0	0	3.4	Y	C	1,060
	19	6.0	0	0	0	0	0	0	6.0	Y	C	1,040
	20	6.5	1	0	1	0	1	0	3.4	Y	C	1,060

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Study 50C0066/05S019

Urinalyses

Sex: **Male** - Phase: **In-life**

Dose Group	Animal Number	PH [---] day 85	PRO [---] day 85	GLU [---] day 85	KET [---] day 85	UBG [---] day 85	BIL [---] day 85	BLOOD [---] day 85	VOL [ml] day 85	COL [---] day 85	TURB [---] day 85	SP.GR._C [g/L] day 85
2 / M 300 mg/kg bw/d	21	6.5	1	0	2	0	0	1	3.0	Y	C	1.074
	22	5.0	1	0	1	0	0	0	4.5	Y	C	1.050
	23	5.0	1	0	1	0	0	0	3.4	Y	C	1.068
	24	6.0	0	0	1	0	0	0	3.5	Y	C	1.044
	25	6.5	0	0	0	0	0	0	5.3	Y	C	1.041
	26	5.0	1	0	1	0	0	0	3.3	Y	C	1.070
	27	5.0	1	0	1	0	0	2	4.0	Y	C	1.064
	28	5.0	2	0	2	1	1	1	1.9	Y	Cl	1.102
	29	6.5	0	0	0	0	0	0	6.9	Y	C	1.038
	30	6.0	0	0	0	0	0	0	6.9	Y	C	1.035

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Study 50C0066/05S019

Urinalyses

Sex: **Male** - Phase: **In-life**

Dose Group	Animal Number	PH [---] day 85	PRO [---] day 85	GLU [---] day 85	KET [---] day 85	UBG [---] day 85	BIL [---] day 85	BLOOD [---] day 85	VOL [ml] day 85	COL [---] day 85	TURB [---] day 85	SP.GR._C [g/L] day 85
3 / M 1000/600 mg/kg bw/d	31	6.5	1	0	1	0	0	0	4.0	Y	C	1.050
	32	5.0	1	0	1	0	0	0	3.6	Y	cl	1.068
	33	6.5	1	0	1	0	0	0	2.9	Y	C	1.084
	34	6.0	0	0	0	0	0	0	7.4	Y	C	1.041
	35	5.0	1	0	0	0	0	0	4.3	Y	C	1.062
	36	6.5	1	0	0	0	1	0	5.5	Y	C	1.044
	37	6.5	0	0	0	0	0	0	4.9	Y	C	1.045
	38	7.0	0	0	1	0	0	0	12.5	Y	C	1.029
	39	6.5	1	0	0	0	1	0	4.8	Y	cl	1.056
	40	6.0	0	0	0	0	0	0	7.9	Y	C	1.035

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Study 50C0066/05S019

Urinalyses

Sex: **Male** - Phase: **In-life**

Dose Group	Animal Number	CRYST [---] day 85	CRYST Remark day 85	RENAL EC [---] day 85	TRANSEC [---] day 85	TRANSEC Remark day 85	SQUAM EC [---] day 85	CASTS [---] day 85	CASTS Remark day 85	ERY [---] day 85	LEUCO [---] day 85
0 / M 0 mg/kg bw/d	01	3	3P	0	0		0	0		0	0
	02	3	3P	0	0		0	0		0	0
	03	2	2P	0	0		0	0		0	0
	04	3	3P	0	0		0	0		0	0
	05	2	2P	0	1	e	0	0		0	0
	06	2	2P	0	2	e	0	1	GC	0	0
	07	1	1P	0	0		0	0		0	0
	08	2	2P	0	0		0	0		0	0
	09	3	3P	0	0		0	0		0	0
	10	1	1P	0	2	e	0	1	GCE	0	0

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Study 50C0066/05S019

Urinalyses

Sex: **Male** - Phase: **In-life**

Dose Group	Animal Number	CRYST [---] day 85	CRYST Remark day 85	RENAL EC [---] day 85	TRANSEC [---] day 85	TRANSEC Remark day 85	SQUAM EC [---] day 85	CASTS [---] day 85	CASTS Remark day 85	ERY [---] day 85	LEUCO [---] day 85
1 / M 100 mg/kg bw/d	11	0		0	0		0	0		1	0
	12	3	3P	0	0		0	0		0	0
	13	3	3P	0	0		0	0		0	0
	14	3	3P	0	1	e	0	0		0	0
	15	3	3P	0	0		0	0		0	0
	16	2	2P	0	1	e	0	1	GCE	0	0
	17	1	1P	0	1	e	1	0		0	0
	18	3	3P	0	0		0	0		0	0
	19	1	1P	0	2	e	0	1	GC	0	0
	20	0		0	1	e	0	1	GC	0	0

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Study 50C0066/05S019

Urinalyses

Sex: **Male** - Phase: **In-life**

Dose Group	Animal Number	CRYST [---] day 85	CRYST Remark day 85	RENAL EC [---] day 85	TRANSEC [---] day 85	TRANSEC Remark day 85	SQUAM EC [---] day 85	CASTS [---] day 85	CASTS Remark day 85	ERY [---] day 85	LEUCO [---] day 85
2 / M 300 mg/kg bw/d	21	2	2P	0	1	e	0	1	GC	0	0
	22	1	10	0	0		0	0		0	0
	23	2	2P	0	2	e	0	1	GCE	0	1
	24	2	2P	0	1	e	0	1	GC	0	0
	25	3	3P	0	2	e	0	0		0	0
	26	1	1P	0	0		0	0		0	0
	27	0		0	2	e	0	2	GC	0	0
	28	3	3P	0	1	e	0	0		0	0
	29	0		0	2	2e	0	2	GC	0	0
	30	0		0	1	e	0	1	GC	0	0

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Study 50C0066/05S019

Urinalyses

Sex: **Male** - Phase: **In-life**

Dose Group	Animal Number	CRYST [---] day 85	CRYST Remark day 85	RENAL EC [---] day 85	TRANSEC [---] day 85	TRANSEC Remark day 85	SQUAM EC [---] day 85	CASTS [---] day 85	CASTS Remark day 85	ERY [---] day 85	LEUCO [---] day 85
3 / M 1000/600 mg/kg bw/d	31	3	3P	0	0		0	0		0	0
	32	2	2P10	0	0		0	0		0	0
	33	0		0	0		0	0		0	0
	34	0		0	1	e	1	0		0	0
	35	0		1	0		0	0		0	0
	36	3	3P	0	0		0	0		0	0
	37	0		0	1		1	0		0	0
	38	2	2P	0	1	e	0	1	GC	0	0
	39	1	1P	1	1		0	0		0	0
	40	0		0	0		1	0		0	0

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Study 50C0066/05S019

Urinalyses

Sex: Female - Phase: In-life

Dose Group	Animal Number	PH [---] day 85	PRO [---] day 85	GLU [---] day 85	KET [---] day 85	UBG [---] day 85	BIL [---] day 85	BLOOD [---] day 85	VOL [ml] day 85	COL [---] day 85	TURB [---] day 85	SP.GR_C [g/L] day 85
0 / F 0 mg/kg bw/d	41	6.0	1	0	0	0	0	0	2.4	Y	C	1.051
	42	6.0	1	0	0	0	0	0	2.4	Y	C	1.058
	43	6.0	1	0	0	0	0	0	2.4	Y	C	1.082
	44	5.0	1	0	1	0	0	0	2.0	Y	C	1.074
	45	6.5	2	0	0	1	1	0	1.3	Y	C	1.088
	46	5.0	1	0	0	0	0	0	2.7	Y	C	1.054
	47	6.5	2	0	1	1	1	0	0.7	Y	C	1.126
	48	6.0	0	0	1	0	0	0	2.0	Y	C	1.049
	49	6.5	0	0	0	0	0	0	4.2	Y	C	1.040
	50	6.5	0	0	0	0	0	0	5.8	Y	C	1.032

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Study 50C0066/05S019

Urinalyses

Sex: Female - Phase: In-life

Dose Group	Animal Number	PH [---] day 85	PRO [---] day 85	GLU [---] day 85	KET [---] day 85	UBG [---] day 85	BIL [---] day 85	BLOOD [---] day 85	VOL [ml] day 85	COL [---] day 85	TURB [---] day 85	SP.GR._C [g/L] day 85
1 / F 100 mg/kg bw/d	51	5.0	0	0	1	0	0	0	2.4	Y	C	1.066
	52	5.0	0	0	0	0	0	0	2.7	Y	C	1.046
	53	5.0	1	0	0	0	1	1	1.0	Y	C	1.078
	54	6.0	0	0	0	0	0	0	2.5	Y	C	1.046
	55	6.5	1	0	1	1	0	0	1.8	Y	C	1.082
	56	6.5	0	0	0	0	0	0	3.1	Y	C	1.040
	57	5.0	0	0	0	0	0	0	3.2	Y	C	1.048
	58	5.0	1	0	1	0	0	0	1.9	Y	C	1.076
	59	6.5	0	0	0	0	0	0	4.7	Y	C	1.035
	60	6.0	0	0	0	0	0	0	2.6	Y	C	1.043

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Study 50C0066/05S019

Urinalyses

Sex: Female - Phase: In-life

Dose Group	Animal Number	PH [---] day 85	PRO [---] day 85	GLU [---] day 85	KET [---] day 85	UBG [---] day 85	BIL [---] day 85	BLOOD [---] day 85	VOL [ml] day 85	COL [---] day 85	TURB [---] day 85	SP.GR._C [g/L] day 85
2 / F 300 mg/kg bw/d	61	5.0	1	0	1	0	0	0	2.5	Y	C	1,051
	62	6.5	2	0	1	1	1	0	1.0	Y	C	1,144
	63	6.0	0	0	0	0	0	0	3.9	Y	C	1,041
	64	6.5	2	0	1	1	1	0	2.0	Y	C	1,084
	65	6.5	0	0	0	0	0	0	3.9	Y	C	1,040
	66	6.0	0	0	0	0	0	0	2.9	Y	C	1,042
	67	5.0	0	0	0	0	0	0	3.1	Y	C	1,050
	68	5.0	0	0	0	0	0	0	3.8	Y	C	1,042
	69	6.5	1	0	0	0	0	0	3.9	Y	C	1,049
	70	6.5	0	0	0	0	0	0	2.9	Y	C	1,058

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Study 50C0066/05S019

Urinalyses

Sex: Female - Phase: In-life

Dose Group	Animal Number	PH [---] day 85	PRO [---] day 85	GLU [---] day 85	KET [---] day 85	UBG [---] day 85	BIL [---] day 85	BLOOD [---] day 85	VOL [ml] day 85	COL [---] day 85	TURB [---] day 85	SP.GR._C [g/L] day 85
3 / F 1000 mg/kg bw/d	71	6.5	1	0	0	0	0	0	4.9	Y	C	1,042
	72	6.5	2	0	0	0	1	0	4.4	Y	C	1,051
	73	6.5	1	0	0	0	1	0	3.3	Y	C	1,058
	74	7.0	1	0	0	0	0	0	4.9	Y	C	1,045
	75	6.5	2	0	0	1	1	0	2.9	Y	C	1,041
	76	6.5	1	0	0	0	0	0	5.6	Y	C	1,042
	77	5.0	0	0	0	0	0	0	5.4	Y	C	1,043
	78	5.0	1	0	0	0	0	0	6.1	Y	C	1,045
	79	6.5	0	0	0	0	0	0	7.9	Y	C	1,038
	80	6.5	1	0	0	1	1	0	2.5	Y	C	1,072

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Study 50C0066/05S019

Urinalyses

Sex: Female - Phase: In-life

Dose Group	Animal Number	CRYST [---] day 85	CRYST Remark day 85	RENAL EC [---] day 85	TRANSEC [---] day 85	TRANSEC Remark day 85	SQUAM EC [---] day 85	CASTS [---] day 85	CASTS Remark day 85	ERY [---] day 85	LEUCO [---] day 85
0 / F 0 mg/kg bw/d	41	0		0	0		0	0		0	1
	42	0		0	0		1	0		0	1
	43	0		0	0		0	0		0	0
	44	0		0	0		0	0		0	1
	45	0		0	0		0	0		0	0
	46	0		0	0		0	0		0	0
	47	1	1P	0	0		0	0		0	0
	48	1	101P	0	0		0	0		0	0
	49	2	2P	0	0		0	0		0	1
	50	2	2P	0	0		0	0		0	0

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Study 50C0066/05S019

Urinalyses

Sex: Female - Phase: In-life

Dose Group	Animal Number	CRYST [---] day 85	CRYST Remark day 85	RENAL EC [---] day 85	TRANSEC [---] day 85	TRANSEC Remark day 85	SQUAM EC [---] day 85	CASTS [---] day 85	CASTS Remark day 85	ERY [---] day 85	LEUCO [---] day 85
1 / F 100 mg/kg bw/d	51	0		0	1		1	0		0	0
	52	0		0	0		0	0		0	0
	53	1	10	0	0		0	0		0	0
	54	2	20	0	0		0	0		0	0
	55	0		0	0		0	0		0	0
	56	0		0	0		0	0		0	0
	57	0		0	0		1	0		0	0
	58	0		0	0		0	0		0	0
	59	1	1P	0	0		1	0		0	1
	60	0		0	0		0	0		0	0

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Study 50C0066/05S019

Urinalyses

Sex: Female - Phase: In-life

Dose Group	Animal Number	CRYST [---] day 85	CRYST Remark day 85	RENAL EC [---] day 85	TRANSEC [---] day 85	TRANSEC Remark day 85	SQUAM EC [---] day 85	CASTS [---] day 85	CASTS Remark day 85	ERY [---] day 85	LEUCO [---] day 85
2 / F 300 mg/kg bw/d	61	3	30	0	0		0	0		0	0
	62	0		0	0		0	0		0	0
	63	0		0	1	e	1	0		0	1
	64	0		0	0		0	0		0	0
	65	1	1P	0	0		0	0		0	0
	66	0		0	0		1	0		0	0
	67	0		0	0		0	0		1	0
	68	0		0	0		1	0		0	0
	69	1	1P	0	0		0	0		0	0
	70	2	2P	0	0		0	0		0	0

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Study 50C0066/05S019

Urinalyses

Sex: Female - Phase: In-life

Dose Group	Animal Number	CRYST [---] day 85	CRYST Remark day 85	RENAL EC [---] day 85	TRANSEC [---] day 85	TRANSEC Remark day 85	SQUAM EC [---] day 85	CASTS [---] day 85	CASTS Remark day 85	ERY [---] day 85	LEUCO [---] day 85
3 / F 1000 mg/kg bw/d	71	1	1P	0	0		1	0		0	0
	72	1	10	1	2	e	0	0		0	1
	73	0		0	1	e	0	0		0	0
	74	0		0	1	e	0	0		0	1
	75	2	2P	0	2	e	0	1	GC	0	0
	76	0		0	1	e	1	0		0	0
	77	1	1P	0	0		1	0		0	0
	78	0		0	1		0	0		0	0
	79	0		0	0		0	0		0	0
	80	3	3P1T	0	0		0	0		0	0

BASF

PATHOLOGY REPORT

IIC 1/85

50C0066/05S019

Repeated-dose 90-day oral toxicity study in Wistar rats
Administration by gavage

11.Apr.2014 HAMA

ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

Sacrifice	F1					
Sex	M					
Group	0					
	Term. body	Adrenal		Epididy-		
	weight	glands	Brain	mides	Heart	Kidneys
	g	mg	g	g	g	g
M	394.02	64.5	2.212	1.209	1.115	2.507
SD	30.946	6.671	0.059	0.102	0.088	0.265
n	10	10	10	10	10	10
1	419.7	71.0	2.14	1.24	1.18	2.6
2	340.2	61.0	2.26	1.24	1.04	2.18
3	389.1	75.0	2.24	1.23	1.18	2.44
4	450.0	61.0	2.22	1.36	1.14	2.85
5	398.7	67.0	2.16	1.14	1.12	2.74
6	379.3	56.0	2.14	1.04	1.0	1.99
7	376.7	73.0	2.15	1.31	0.97	2.38
8	371.0	59.0	2.3	1.16	1.1	2.66
9	392.6	58.0	2.26	1.08	1.24	2.54
10	422.9	64.0	2.25	1.29	1.18	2.69

BASF

PATHOLOGY REPORT

IIC 2/85

50C0066/05S019

Repeated-dose 90-day oral toxicity study in Wistar rats
Administration by gavage

11.Apr.2014 HAMA

ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

Sacrifice F1
Sex M
Group 0

	Liver g	Spleen g	Testes g	Thymus mg	Thyroid glands mg
M	8.936	0.628	3.914	327.5	25.3
SD	0.718	0.073	0.325	79.59	3.164
n	10	10	10	10	10
1	9.62	0.57	4.03	468.0	33.0
2	7.47	0.66	4.38	271.0	25.0
3	9.32	0.63	3.7	364.0	27.0
4	9.83	0.71	3.93	293.0	23.0
5	9.58	0.62	3.73	220.0	26.0
6	8.52	0.58	3.22	366.0	23.0
7	8.31	0.62	4.06	287.0	22.0
8	8.77	0.56	3.99	393.0	23.0
9	8.79	0.55	3.83	383.0	25.0
10	9.15	0.78	4.27	230.0	26.0

BASF

PATHOLOGY REPORT

IIC 3/85

50C0066/05S019

Repeated-dose 90-day oral toxicity study in Wistar rats
Administration by gavage

11.Apr.2014 HAMA

ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

Sacrifice	F1					
Sex	M					
Group	1					
	Term. body	Adrenal		Epididy-		
	weight	glands	Brain	mides	Heart	Kidneys
	g	mg	g	g	g	g
M	376.95	59.1	2.098	1.16	1.039	2.646
SD	43.639	9.158	0.029	0.096	0.093	0.388
n	10	10	10	10	10	10
11	361.3	61.0	2.09	1.03	1.1	2.71
12	393.8	61.0	2.11	1.22	1.06	2.54
13	333.9	42.0	2.1	1.15	0.92	1.92
14	441.1	75.0	2.07	1.33	1.1	2.92
15	405.8	49.0	2.07	1.12	1.06	2.77
16	308.5	55.0	2.13	1.15	0.89	2.11
17	392.9	56.0	2.09	1.18	1.07	3.01
18	322.8	63.0	2.07	1.09	0.96	2.54
19	390.6	64.0	2.09	1.05	1.03	2.77
20	418.8	65.0	2.16	1.28	1.2	3.17

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PATHOLOGY REPORT

IIC 4/85

50C0066/05S019

Repeated-dose 90-day oral toxicity study in Wistar rats
Administration by gavage

11.Apr.2014 HAMA

ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

Sacrifice	F1				
Sex	M				
Group	1				
	Liver	Spleen	Testes	Thymus	Thyroid
	g	g	g	mg	glands
					mg
M	8.402	0.585	3.862	269.4	21.6
SD	1.152	0.096	0.305	72.11	4.169
n	10	10	10	10	10
11	8.37	0.44	3.51	224.0	20.0
12	8.07	0.77	4.31	219.0	16.0
13	6.92	0.49	3.92	250.0	18.0
14	9.63	0.67	4.04	428.0	22.0
15	9.07	0.55	3.68	227.0	23.0
16	6.67	0.54	3.84	216.0	16.0
17	9.33	0.6	3.83	305.0	28.0
18	7.2	0.57	3.66	191.0	22.0
19	8.9	0.55	3.47	311.0	27.0
20	9.86	0.67	4.36	323.0	24.0

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PATHOLOGY REPORT

IIC 5/85

50C0066/05S019

Repeated-dose 90-day oral toxicity study in Wistar rats

11.Apr.2014 HAMA

Administration by gavage

ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

Sacrifice	F1					
Sex	M					
Group	2					
	Term. body weight g	Adrenal glands mg	Brain g	Epididymides g	Heart g	Kidneys g
M	356.6	63.7	2.074	1.126	1.026	2.762
SD	18.245	6.8	0.073	0.088	0.073	0.238
n	10	10	10	10	10	10
21	360.4	63.0	1.99	1.15	1.09	2.73
22	385.4	56.0	2.16	1.23	1.12	3.12
23	357.4	69.0	2.15	1.13	1.01	2.91
24	318.7	65.0	2.01	1.07	0.88	2.45
25	351.9	64.0	1.98	1.1	1.06	2.39
26	361.1	52.0	2.07	0.92	0.93	2.72
27	345.9	66.0	2.1	1.18	1.02	3.0
28	379.6	76.0	2.01	1.1	1.02	2.87
29	352.4	59.0	2.17	1.17	1.06	2.87
30	353.2	67.0	2.1	1.21	1.07	2.56

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PATHOLOGY REPORT

IIC 6/85

50C0066/05S019

Repeated-dose 90-day oral toxicity study in Wistar rats
Administration by gavage

11.Apr.2014 HAMA

ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

Sacrifice

F1

Sex

M

Group

2

	Liver g	Spleen g	Testes g	Thymus mg	Thyroid glands mg
M	8.415	0.535	3.636	271.3	23.7
SD	0.727	0.066	0.202	66.416	4.165
n	10	10	10	10	10
21	8.17	0.49	3.37	353.0	33.0
22	8.84	0.54	3.8	221.0	25.0
23	8.18	0.57	3.7	308.0	19.0
24	6.94	0.46	3.34	237.0	25.0
25	7.58	0.51	3.58	237.0	21.0
26	8.52	0.49	3.41	241.0	19.0
27	8.87	0.51	3.88	241.0	23.0
28	8.93	0.54	3.66	315.0	21.0
29	9.43	0.7	3.84	387.0	26.0
30	8.69	0.54	3.78	173.0	25.0

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Repeated-dose 90-day oral toxicity study in Wistar rats
Administration by gavage

11.Apr.2014 HAMA

ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

Sacrifice	F1					
Sex	M					
Group	3					
	Term. body	Adrenal		Epididy-		
	weight	glands	Brain	mides	Heart	Kidneys
	g	mg	g	g	g	g
M	311.89	90.1	2.084	1.072	0.958	2.485
SD	38.163	14.364	0.071	0.082	0.091	0.419
n	10	10	10	10	10	10
31	271.9	87.0	2.03	1.03	0.88	2.35
32	332.1	91.0	1.98	1.09	0.98	2.47
33	331.4	87.0	2.09	1.05	1.02	2.75
34	285.7	92.0	2.0	0.96	1.0	2.44
35	319.5	99.0	2.11	1.05	0.9	2.8
36	286.5	106.0	2.12	1.03	0.91	2.05
37	260.5	56.0	2.03	1.02	0.82	1.83
38	391.6	86.0	2.19	1.22	1.05	3.11
39	330.1	108.0	2.17	1.21	1.12	2.96
40	309.6	89.0	2.12	1.06	0.9	2.09

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PATHOLOGY REPORT

IIC 8/85

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Repeated-dose 90-day oral toxicity study in Wistar rats
Administration by gavage

11.Apr.2014 HAMA

ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

Sacrifice	F1				
Sex	M				
Group	3				
	Liver	Spleen	Testes	Thymus	Thyroid
	g	g	g	mg	glands
					mg
M	8.347	0.595	3.592	226.1	23.2
SD	1.173	0.118	0.226	54.834	3.938
n	10	10	10	10	10
31	6.71	0.5	3.59	155.0	18.0
32	8.56	0.52	3.53	212.0	27.0
33	8.77	0.66	3.63	198.0	24.0
34	8.83	0.53	3.35	174.0	17.0
35	8.12	0.66	3.67	243.0	23.0
36	8.39	0.57	3.52	322.0	26.0
37	6.36	0.44	3.44	205.0	21.0
38	10.56	0.86	3.8	209.0	26.0
39	8.93	0.64	4.08	227.0	21.0
40	8.24	0.57	3.31	316.0	29.0

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PATHOLOGY REPORT

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Repeated-dose 90-day oral toxicity study in Wistar rats
Administration by gavage

11.Apr.2014 HAMA

ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

Sacrifice	F1					
Sex	F					
Group	0					
	Term. body	Adrenal				
	weight	glands	Brain	Heart	Kidneys	Liver
	g	mg	g	g	g	g
M	221.72	65.6	2.007	0.752	1.5	5.106
SD	20.389	7.397	0.084	0.034	0.134	0.718
n	10	10	10	10	10	10
41	203.1	61.0	2.03	0.7	1.47	4.1
42	205.2	70.0	1.93	0.75	1.5	4.9
43	195.8	65.0	1.95	0.75	1.35	4.26
44	244.1	58.0	2.03	0.77	1.38	6.25
45	222.1	73.0	1.91	0.74	1.44	5.37
46	248.7	77.0	2.07	0.81	1.58	6.05
47	225.0	74.0	1.91	0.77	1.55	4.99
48	212.9	57.0	2.04	0.73	1.58	5.3
49	207.9	58.0	2.02	0.71	1.36	4.43
50	252.4	63.0	2.18	0.79	1.79	5.41

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Repeated-dose 90-day oral toxicity study in Wistar rats

11.Apr.2014 HAMA

Administration by gavage

ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

Sacrifice F1

Sex F

Group 0

	Ovaries mg	Spleen g	Thymus mg	Thyroid glands mg	Uterus g
M	104.7	0.44	303.2	17.4	0.724
SD	20.205	0.054	67.82	2.459	0.263
n	10	10	10	10	10
41	99.0	0.38	271.0	19.0	0.6
42	119.0	0.36	279.0	17.0	1.08
43	91.0	0.36	262.0	16.0	1.06
44	82.0	0.5	409.0	14.0	0.58
45	124.0	0.48	255.0	17.0	0.48
46	131.0	0.49	251.0	18.0	0.49
47	83.0	0.46	358.0	17.0	0.56
48	95.0	0.44	212.0	15.0	0.99
49	89.0	0.46	334.0	18.0	0.44
50	134.0	0.47	401.0	23.0	0.96

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Repeated-dose 90-day oral toxicity study in Wistar rats

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Administration by gavage

ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

Sacrifice	F1					
Sex	F					
Group	1					
	Term. body weight g	Adrenal glands mg	Brain g	Heart g	Kidneys g	Liver g
M	214.72	64.5	1.992	0.739	1.489	5.39
SD	13.154	8.759	0.089	0.081	0.104	0.763
n	10	10	10	10	10	10
51	220.3	54.0	1.98	0.77	1.55	5.76
52	211.4	59.0	2.03	0.76	1.49	5.14
53	231.5	74.0	1.8	0.85	1.65	6.84
54	220.2	62.0	2.02	0.71	1.4	5.03
55	203.4	69.0	1.95	0.65	1.44	4.74
56	187.9	54.0	1.94	0.65	1.39	4.15
57	225.3	64.0	1.97	0.66	1.63	6.27
58	208.0	81.0	2.03	0.88	1.57	5.5
59	210.9	59.0	2.07	0.7	1.39	5.14
60	228.3	69.0	2.13	0.76	1.38	5.33

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Repeated-dose 90-day oral toxicity study in Wistar rats
Administration by gavage

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ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

Sacrifice F1
Sex F
Group 1

	Ovaries mg	Spleen g	Thymus mg	Thyroid glands mg	Uterus g
M	104.0	0.447	292.4	15.5	0.864
SD	11.963	0.032	59.191	2.838	0.396
n	10	10	10	10	10
51	110.0	0.47	322.0	17.0	0.43
52	88.0	0.39	232.0	15.0	1.07
53	99.0	0.45	221.0	10.0	0.56
54	106.0	0.43	399.0	15.0	1.12
55	93.0	0.4	259.0	19.0	0.53
56	86.0	0.45	265.0	13.0	1.36
57	112.0	0.48	382.0	19.0	0.41
58	121.0	0.49	291.0	18.0	1.31
59	109.0	0.45	268.0	15.0	1.28
60	116.0	0.46	285.0	14.0	0.57

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PATHOLOGY REPORT

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Repeated-dose 90-day oral toxicity study in Wistar rats

11.Apr.2014 HAMA

Administration by gavage

ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

Sacrifice	F1					
Sex	F					
Group	2					
	Term. body weight g	Adrenal glands mg	Brain g	Heart g	Kidneys g	Liver g
M	207.95	74.6	1.99	0.755	1.584	5.688
SD	15.256	13.818	0.054	0.058	0.117	0.514
n	10	10	10	10	10	10
61	209.4	74.0	2.02	0.7	1.43	4.74
62	229.5	71.0	2.03	0.83	1.67	5.73
63	216.0	102.0	1.91	0.75	1.46	6.38
64	214.0	77.0	1.94	0.79	1.79	6.13
65	206.4	75.0	2.03	0.76	1.65	5.81
66	188.0	60.0	1.97	0.71	1.47	5.79
67	218.1	66.0	1.95	0.81	1.65	5.35
68	222.3	57.0	2.05	0.68	1.49	5.39
69	190.5	93.0	1.94	0.83	1.65	6.31
70	185.3	71.0	2.06	0.69	1.58	5.25

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Repeated-dose 90-day oral toxicity study in Wistar rats

11.Apr.2014 HAMA

Administration by gavage

ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

Sacrifice	F1				
Sex	F				
Group	2				
	Ovaries	Spleen	Thymus	Thyroid	Uterus
	mg	g	mg	glands	g
				mg	
M	106.9	0.465	245.3	17.2	1.284
SD	19.284	0.045	47.287	3.327	0.795
n	10	10	10	10	10
61	99.0	0.44	285.0	21.0	1.26
62	127.0	0.48	302.0	17.0	2.99
63	116.0	0.52	174.0	17.0	0.57
64	129.0	0.48	272.0	16.0	0.9
65	103.0	0.5	271.0	22.0	2.13
66	114.0	0.39	195.0	11.0	1.02
67	95.0	0.48	174.0	16.0	0.91
68	78.0	0.42	261.0	15.0	0.62
69	129.0	0.42	242.0	16.0	1.83
70	79.0	0.52	277.0	21.0	0.61

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Repeated-dose 90-day oral toxicity study in Wistar rats
Administration by gavage

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ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

Sacrifice	F1					
Sex	F					
Group	3					
	Term. body	Adrenal	Brain	Heart	Kidneys	Liver
	weight	glands				
	g	mg	g	g	g	g
M	205.6	80.4	1.913	0.763	1.644	7.043
SD	12.413	10.648	0.069	0.065	0.135	0.52
n	10	10	10	10	10	10
71	195.6	73.0	1.92	0.78	1.55	7.07
72	196.5	76.0	1.79	0.72	1.51	7.89
73	190.6	80.0	1.87	0.81	1.59	7.1
74	220.4	102.0	1.99	0.84	1.83	6.94
75	196.3	71.0	1.87	0.74	1.57	6.47
76	208.6	69.0	1.92	0.75	1.61	6.87
77	213.3	95.0	1.94	0.76	1.62	7.0
78	212.8	81.0	1.86	0.71	1.68	7.42
79	226.7	83.0	2.03	0.87	1.93	7.58
80	195.2	74.0	1.94	0.65	1.55	6.09

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PATHOLOGY REPORT

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Administration by gavage

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ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

Sacrifice F1
Sex F
Group 3

	Ovaries mg	Spleen g	Thymus mg	Thyroid glands mg	Uterus g
M	126.9	0.454	222.7	19.6	0.648
SD	30.33	0.062	38.43	2.633	0.145
n	10	10	10	10	10
71	93.0	0.39	261.0	18.0	0.55
72	105.0	0.45	191.0	15.0	0.97
73	134.0	0.45	188.0	17.0	0.48
74	127.0	0.48	267.0	24.0	0.69
75	102.0	0.34	185.0	20.0	0.48
76	109.0	0.44	172.0	21.0	0.69
77	147.0	0.56	208.0	22.0	0.64
78	177.0	0.48	231.0	21.0	0.67
79	173.0	0.52	250.0	18.0	0.74
80	102.0	0.43	274.0	20.0	0.57

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Repeated-dose 90-day oral toxicity study in Wistar rats

11.Apr.2014 HAMA

Administration by gavage

RELATIVE WEIGHTS - INDIVIDUAL VALUES

Sacrifice	F1					
Sex	M					
Group	0					
	Term. body weight %	Adrenal glands %	Brain %	Epididymides %	Heart %	Kidneys %
M	100.0	0.016	0.565	0.308	0.284	0.636
SD		0.002	0.05	0.029	0.021	0.05
n	10	10	10	10	10	10
1	100.0	0.017	0.51	0.295	0.281	0.619
2	100.0	0.018	0.664	0.364	0.306	0.641
3	100.0	0.019	0.576	0.316	0.303	0.627
4	100.0	0.014	0.493	0.302	0.253	0.633
5	100.0	0.017	0.542	0.286	0.281	0.687
6	100.0	0.015	0.564	0.274	0.264	0.525
7	100.0	0.019	0.571	0.348	0.257	0.632
8	100.0	0.016	0.62	0.313	0.296	0.717
9	100.0	0.015	0.576	0.275	0.316	0.647
10	100.0	0.015	0.532	0.305	0.279	0.636

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Sacrifice	F1
Sex	M
Group	0

	Liver %	Spleen %	Testes %	Thymus %	Thyroid glands %
M	2.269	0.16	0.999	0.084	0.006
SD	0.09	0.018	0.126	0.021	0.001
n	10	10	10	10	10
1	2.292	0.136	0.96	0.112	0.008
2	2.196	0.194	1.287	0.08	0.007
3	2.395	0.162	0.951	0.094	0.007
4	2.184	0.158	0.873	0.065	0.005
5	2.403	0.156	0.936	0.055	0.007
6	2.246	0.153	0.849	0.096	0.006
7	2.206	0.165	1.078	0.076	0.006
8	2.364	0.151	1.075	0.106	0.006
9	2.239	0.14	0.976	0.098	0.006
10	2.164	0.184	1.01	0.054	0.006

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RELATIVE WEIGHTS - INDIVIDUAL VALUES

Sacrifice	F1					
Sex	M					
Group	1					
	Term. body weight %	Adrenal glands %	Brain %	Epididymides %	Heart %	Kidneys %
M	100.0	0.016	0.564	0.31	0.277	0.702
SD		0.002	0.069	0.033	0.017	0.065
n	10	10	10	10	10	10
11	100.0	0.017	0.578	0.285	0.304	0.75
12	100.0	0.015	0.536	0.31	0.269	0.645
13	100.0	0.013	0.629	0.344	0.276	0.575
14	100.0	0.017	0.469	0.302	0.249	0.662
15	100.0	0.012	0.51	0.276	0.261	0.683
16	100.0	0.018	0.69	0.373	0.288	0.684
17	100.0	0.014	0.532	0.3	0.272	0.766
18	100.0	0.02	0.641	0.338	0.297	0.787
19	100.0	0.016	0.535	0.269	0.264	0.709
20	100.0	0.016	0.516	0.306	0.287	0.757

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RELATIVE WEIGHTS - INDIVIDUAL VALUES

	Liver %	Spleen %	Testes %	Thymus %	Thyroid glands %
M	2.226	0.156	1.035	0.071	0.006
SD	0.111	0.022	0.123	0.013	0.001
n	10	10	10	10	10
11	2.317	0.122	0.971	0.062	0.006
12	2.049	0.196	1.094	0.056	0.004
13	2.072	0.147	1.174	0.075	0.005
14	2.183	0.152	0.916	0.097	0.005
15	2.235	0.136	0.907	0.056	0.006
16	2.162	0.175	1.245	0.07	0.005
17	2.375	0.153	0.975	0.078	0.007
18	2.23	0.177	1.134	0.059	0.007
19	2.279	0.141	0.888	0.08	0.007
20	2.354	0.16	1.041	0.077	0.006

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RELATIVE WEIGHTS - INDIVIDUAL VALUES

Sacrifice	F1					
Sex	M					
Group	2					
	Term. body weight %	Adrenal glands %	Brain %	Epididymides %	Heart %	Kidneys %
M	100.0	0.018	0.583	0.316	0.288	0.775
SD		0.002	0.032	0.027	0.016	0.053
n	10	10	10	10	10	10
21	100.0	0.017	0.552	0.319	0.302	0.757
22	100.0	0.015	0.56	0.319	0.291	0.81
23	100.0	0.019	0.602	0.316	0.283	0.814
24	100.0	0.02	0.631	0.336	0.276	0.769
25	100.0	0.018	0.563	0.313	0.301	0.679
26	100.0	0.014	0.573	0.255	0.258	0.753
27	100.0	0.019	0.607	0.341	0.295	0.867
28	100.0	0.02	0.53	0.29	0.269	0.756
29	100.0	0.017	0.616	0.332	0.301	0.814
30	100.0	0.019	0.595	0.343	0.303	0.725

RELATIVE WEIGHTS - INDIVIDUAL VALUES

Sacrifice	F1
Sex	M
Group	2

	Liver %	Spleen %	Testes %	Thymus %	Thyroid glands %
M	2.359	0.15	1.021	0.076	0.007
SD	0.165	0.019	0.063	0.018	0.001
n	10	10	10	10	10
21	2.267	0.136	0.935	0.098	0.009
22	2.294	0.14	0.986	0.057	0.006
23	2.289	0.159	1.035	0.086	0.005
24	2.178	0.144	1.048	0.074	0.008
25	2.154	0.145	1.017	0.067	0.006
26	2.359	0.136	0.944	0.067	0.005
27	2.564	0.147	1.122	0.07	0.007
28	2.352	0.142	0.964	0.083	0.006
29	2.676	0.199	1.09	0.11	0.007
30	2.46	0.153	1.07	0.049	0.007

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PATHOLOGY REPORT

IIC 23/85

50C0066/05S019

Repeated-dose 90-day oral toxicity study in Wistar rats

11.Apr.2014 HAMA

Administration by gavage

RELATIVE WEIGHTS - INDIVIDUAL VALUES

Sacrifice	F1					
Sex	M					
Group	3					
	Term. body weight %	Adrenal glands %	Brain %	Epididymides %	Heart %	Kidneys %
M	100.0	0.029	0.675	0.346	0.309	0.795
SD		0.005	0.069	0.027	0.026	0.081
n	10	10	10	10	10	10
31	100.0	0.032	0.747	0.379	0.324	0.864
32	100.0	0.027	0.596	0.328	0.295	0.744
33	100.0	0.026	0.631	0.317	0.308	0.83
34	100.0	0.032	0.7	0.336	0.35	0.854
35	100.0	0.031	0.66	0.329	0.282	0.876
36	100.0	0.037	0.74	0.36	0.318	0.716
37	100.0	0.021	0.779	0.392	0.315	0.702
38	100.0	0.022	0.559	0.312	0.268	0.794
39	100.0	0.033	0.657	0.367	0.339	0.897
40	100.0	0.029	0.685	0.342	0.291	0.675

11.Apr.2014 HAMA

RELATIVE WEIGHTS - INDIVIDUAL VALUES

	Liver %	Spleen %	Testes %	Thymus %	Thyroid glands %
M	2.676	0.19	1.162	0.073	0.007
SD	0.201	0.018	0.115	0.02	0.001
n	10	10	10	10	10
31	2.468	0.184	1.32	0.057	0.007
32	2.578	0.157	1.063	0.064	0.008
33	2.646	0.199	1.095	0.06	0.007
34	3.091	0.186	1.173	0.061	0.006
35	2.541	0.207	1.149	0.076	0.007
36	2.928	0.199	1.229	0.112	0.009
37	2.441	0.169	1.321	0.079	0.008
38	2.697	0.22	0.97	0.053	0.007
39	2.705	0.194	1.236	0.069	0.006
40	2.661	0.184	1.069	0.102	0.009

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PATHOLOGY REPORT

IIC 25/85

50C0066/05S019

Repeated-dose 90-day oral toxicity study in Wistar rats
Administration by gavage

11.Apr.2014 HAMA

RELATIVE WEIGHTS - INDIVIDUAL VALUES

Sacrifice	F1					
Sex	F					
Group	0					
	Term. body weight %	Adrenal glands %	Brain %	Heart %	Kidneys %	Liver %
M	100.0	0.03	0.91	0.341	0.679	2.297
SD		0.004	0.069	0.021	0.054	0.182
n	10	10	10	10	10	10
41	100.0	0.03	1.0	0.345	0.724	2.019
42	100.0	0.034	0.941	0.365	0.731	2.388
43	100.0	0.033	0.996	0.383	0.689	2.176
44	100.0	0.024	0.832	0.315	0.565	2.56
45	100.0	0.033	0.86	0.333	0.648	2.418
46	100.0	0.031	0.832	0.326	0.635	2.433
47	100.0	0.033	0.849	0.342	0.689	2.218
48	100.0	0.027	0.958	0.343	0.742	2.489
49	100.0	0.028	0.972	0.342	0.654	2.131
50	100.0	0.025	0.864	0.313	0.709	2.143

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IIC 26/85

50C0066/05S019

Repeated-dose 90-day oral toxicity study in Wistar rats
Administration by gavage

11.Apr.2014 HAMA

RELATIVE WEIGHTS - INDIVIDUAL VALUES

Sacrifice F1
Sex F
Group 0

	Ovaries %	Spleen %	Thymus %	Thyroid glands %	Uterus %
M	0.047	0.198	0.136	0.008	0.332
SD	0.008	0.015	0.025	0.001	0.135
n	10	10	10	10	10
41	0.049	0.187	0.133	0.009	0.295
42	0.058	0.175	0.136	0.008	0.526
43	0.046	0.184	0.134	0.008	0.541
44	0.034	0.205	0.168	0.006	0.238
45	0.056	0.216	0.115	0.008	0.216
46	0.053	0.197	0.101	0.007	0.197
47	0.037	0.204	0.159	0.008	0.249
48	0.045	0.207	0.1	0.007	0.465
49	0.043	0.221	0.161	0.009	0.212
50	0.053	0.186	0.159	0.009	0.38

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PATHOLOGY REPORT

IIC 27/85

50C0066/05S019

Repeated-dose 90-day oral toxicity study in Wistar rats

11.Apr.2014 HAMA

Administration by gavage

RELATIVE WEIGHTS - INDIVIDUAL VALUES

Sacrifice	F1					
Sex	F					
Group	1					
	Term. body weight %	Adrenal glands %	Brain %	Heart %	Kidneys %	Liver %
M	100.0	0.03	0.931	0.344	0.695	2.502
SD		0.004	0.07	0.035	0.047	0.24
n	10	10	10	10	10	10
51	100.0	0.025	0.899	0.35	0.704	2.615
52	100.0	0.028	0.96	0.36	0.705	2.431
53	100.0	0.032	0.778	0.367	0.713	2.955
54	100.0	0.028	0.917	0.322	0.636	2.284
55	100.0	0.034	0.959	0.32	0.708	2.33
56	100.0	0.029	1.032	0.346	0.74	2.209
57	100.0	0.028	0.874	0.293	0.723	2.783
58	100.0	0.039	0.976	0.423	0.755	2.644
59	100.0	0.028	0.982	0.332	0.659	2.437
60	100.0	0.03	0.933	0.333	0.604	2.335

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PATHOLOGY REPORT

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50C0066/05S019

Repeated-dose 90-day oral toxicity study in Wistar rats

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Administration by gavage

RELATIVE WEIGHTS - INDIVIDUAL VALUES

Sacrifice	F1				
Sex	F				
Group	1				
	Ovaries	Spleen	Thymus	Thyroid	Uterus
	%	%	%	glands	%
M	0.048	0.209	0.136	0.007	0.41
SD	0.005	0.018	0.026	0.001	0.205
n	10	10	10	10	10
51	0.05	0.213	0.146	0.008	0.195
52	0.042	0.184	0.11	0.007	0.506
53	0.043	0.194	0.095	0.004	0.242
54	0.048	0.195	0.181	0.007	0.509
55	0.046	0.197	0.127	0.009	0.261
56	0.046	0.239	0.141	0.007	0.724
57	0.05	0.213	0.17	0.008	0.182
58	0.058	0.236	0.14	0.009	0.63
59	0.052	0.213	0.127	0.007	0.607
60	0.051	0.201	0.125	0.006	0.25

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PATHOLOGY REPORT

IIC 29/85

50C0066/05S019

Repeated-dose 90-day oral toxicity study in Wistar rats

11.Apr.2014 HAMA

Administration by gavage

RELATIVE WEIGHTS - INDIVIDUAL VALUES

Sacrifice	F1					
Sex	F					
Group	2					
	Term. body weight %	Adrenal glands %	Brain %	Heart %	Kidneys %	Liver %
M	100.0	0.036	0.962	0.364	0.765	2.75
SD		0.007	0.078	0.033	0.074	0.331
n	10	10	10	10	10	10
61	100.0	0.035	0.965	0.334	0.683	2.264
62	100.0	0.031	0.885	0.362	0.728	2.497
63	100.0	0.047	0.884	0.347	0.676	2.954
64	100.0	0.036	0.907	0.369	0.836	2.864
65	100.0	0.036	0.984	0.368	0.799	2.815
66	100.0	0.032	1.048	0.378	0.782	3.08
67	100.0	0.03	0.894	0.371	0.757	2.453
68	100.0	0.026	0.922	0.306	0.67	2.425
69	100.0	0.049	1.018	0.436	0.866	3.312
70	100.0	0.038	1.112	0.372	0.853	2.833

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PATHOLOGY REPORT

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Repeated-dose 90-day oral toxicity study in Wistar rats
Administration by gavage

11.Apr.2014 HAMA

RELATIVE WEIGHTS - INDIVIDUAL VALUES

Sacrifice	F1				
Sex	F				
Group	2				
	Ovaries	Spleen	Thymus	Thyroid	Uterus
	%	%	%	glands	%
				%	
M	0.052	0.224	0.118	0.008	0.615
SD	0.01	0.025	0.023	0.002	0.36
n	10	10	10	10	10
61	0.047	0.21	0.136	0.01	0.602
62	0.055	0.209	0.132	0.007	1.303
63	0.054	0.241	0.081	0.008	0.264
64	0.06	0.224	0.127	0.007	0.421
65	0.05	0.242	0.131	0.011	1.032
66	0.061	0.207	0.104	0.006	0.543
67	0.044	0.22	0.08	0.007	0.417
68	0.035	0.189	0.117	0.007	0.279
69	0.068	0.22	0.127	0.008	0.961
70	0.043	0.281	0.149	0.011	0.329

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PATHOLOGY REPORT

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Repeated-dose 90-day oral toxicity study in Wistar rats

11.Apr.2014 HAMA

Administration by gavage

RELATIVE WEIGHTS - INDIVIDUAL VALUES

Sacrifice	F1					
Sex	F					
Group	3					
	Term. body weight %	Adrenal glands %	Brain %	Heart %	Kidneys %	Liver %
M	100.0	0.039	0.932	0.371	0.799	3.433
SD		0.004	0.042	0.028	0.03	0.28
n	10	10	10	10	10	10
71	100.0	0.037	0.982	0.399	0.792	3.615
72	100.0	0.039	0.911	0.366	0.768	4.015
73	100.0	0.042	0.981	0.425	0.834	3.725
74	100.0	0.046	0.903	0.381	0.83	3.149
75	100.0	0.036	0.953	0.377	0.8	3.296
76	100.0	0.033	0.92	0.36	0.772	3.293
77	100.0	0.045	0.91	0.356	0.759	3.282
78	100.0	0.038	0.874	0.334	0.789	3.487
79	100.0	0.037	0.895	0.384	0.851	3.344
80	100.0	0.038	0.994	0.333	0.794	3.12

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Repeated-dose 90-day oral toxicity study in Wistar rats
Administration by gavage

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RELATIVE WEIGHTS - INDIVIDUAL VALUES

Sacrifice F1
Sex F
Group 3

	Ovaries %	Spleen %	Thymus %	Thyroid glands %	Uterus %
M	0.061	0.22	0.108	0.01	0.315
SD	0.012	0.023	0.018	0.001	0.069
n	10	10	10	10	10
71	0.048	0.199	0.133	0.009	0.281
72	0.053	0.229	0.097	0.008	0.494
73	0.07	0.236	0.099	0.009	0.252
74	0.058	0.218	0.121	0.011	0.313
75	0.052	0.173	0.094	0.01	0.245
76	0.052	0.211	0.082	0.01	0.331
77	0.069	0.263	0.098	0.01	0.3
78	0.083	0.226	0.109	0.01	0.315
79	0.076	0.229	0.11	0.008	0.326
80	0.052	0.22	0.14	0.01	0.292

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PATHOLOGY REPORT

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Repeated-dose 90-day oral toxicity study in Wistar rats
Administration by gavage

11.Apr.2014 HAMA

SINGLE ANIMAL SHEET

(GROSS LESIONS AND MICROSCOPIC FINDINGS)

	Sacrifice	F1
	Sex	M
	Group	0
	Animal	1

General information

Sex : Male
Group : 0 (0 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 21.Nov.2013
92 days after start of exposure
1 day after end of exposure

Macroscopic findings

Animal without particular findings.

Microscopic findings

Colon
Parasite(s) in lumen.
Liver
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s), grade 1.
Lungs
Inflammation, (multi)focal, grade 1.
Prostate
Inflammation, chronic, grade 1.
All other organs examined without microscopic findings.

	Animal	2
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General information

Sex : Male
Group : 0 (0 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 21.Nov.2013
92 days after start of exposure
1 day after end of exposure

Macroscopic findings

Animal without particular findings.

Microscopic findings

Heart
Necrosis/ fibrosis, myocardial, (multi)focal, grade 1.
Kidneys
Tubules, basophilic, (multi)focal, unilateral, grade 1.
Liver
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s), grade 2.
Peri-/vasculitis, grade 1.
All other organs examined without microscopic findings.

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PATHOLOGY REPORT

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SINGLE ANIMAL SHEET

(GROSS LESIONS AND MICROSCOPIC FINDINGS)

	Sacrifice	F1
	Sex	M
	Group	0
	Animal	3

General information

Sex : Male
Group : 0 (0 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 21.Nov.2013
92 days after start of exposure
1 day after end of exposure

Macroscopic findings

Animal without particular findings.

Microscopic findings

Colon
Parasite(s) in lumen.
Kidneys
Tubules, basophilic, (multi)focal, unilateral, grade 1.
Liver
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s), grade 2.
KV, GSTP
GSTP positive focus, (multi)focal.
All other organs examined without microscopic findings.

	Animal	4
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General information

Sex : Male
Group : 0 (0 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 21.Nov.2013
92 days after start of exposure
1 day after end of exposure

Macroscopic findings

Animal without particular findings.

Microscopic findings

Kidneys
Tubules, basophilic, (multi)focal, grade 1.
Liver
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s), grade 1.
All other organs examined without microscopic findings.

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SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)

..... Sacrifice F1
Sex M
Group 0
Animal 5

General information

Sex : Male
Group : 0 (0 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 21.Nov.2013
92 days after start of exposure
1 day after end of exposure

Macroscopic findings

Kidneys
Pelvic dilation, unilateral, right side.
All other organs without macroscopic findings.

Microscopic findings

Kidneys
Gross lesion(s) evaluated histopathologically.
Tubules, basophilic, (multi)focal, grade 1.
Nuclear crowding, grade 1.
Cast, hyaline, unilateral.
Hyperplasia, transitional cell, (multi)focal, unilateral, grade 2.
Dilation, renal pelvis, unilateral, grade 2, correlates to gross lesion
Pelvic dilation.
Liver
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),
grade 1.
Lungs
Histiocytosis, alveolar, (multi)focal, grade 1.
All other organs examined without microscopic findings.

..... Animal 6

General information

Sex : Male
Group : 0 (0 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 21.Nov.2013
92 days after start of exposure
1 day after end of exposure

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SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)

..... Sacrifice F1
Sex M
Group 0
cont. Animal 6

Macroscopic findings
Animal without particular findings.

Microscopic findings
Kidneys
Tubules, basophilic, (multi)focal, grade 1.
Liver
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),
grade 1.
All other organs examined without microscopic findings.

..... Animal 7

General information
Sex : Male
Group : 0 (0 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 21.Nov.2013
92 days after start of exposure
1 day after end of exposure

Macroscopic findings
Animal without particular findings.

Microscopic findings
Kidneys
Scar(s), cortical, unilateral.
Liver
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),
grade 1.
Lungs
Inflammation, (multi)focal, grade 1.
Prostate
Inflammation, chronic, grade 1.
All other organs examined without microscopic findings.

..... Animal 8

General information
Sex : Male
Group : 0 (0 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 21.Nov.2013
92 days after start of exposure
1 day after end of exposure

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PATHOLOGY REPORT

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SINGLE ANIMAL SHEET

(GROSS LESIONS AND MICROSCOPIC FINDINGS)

	Sacrifice	F1
	Sex	M
	Group	0
	cont. Animal	8

Macroscopic findings

Animal without particular findings.

Microscopic findings

Kidneys

Tubules, basophilic, (multi)focal, unilateral, grade 1.

Liver

Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s), grade 1.

Lungs

Histiocytosis, alveolar, (multi)focal, grade 1.

Pancreas

Ectopic spleen.

Prostate

Inflammation, chronic, grade 1.

Rectum

Parasite(s) in lumen.

All other organs examined without microscopic findings.

	Animal	9
--	--------	---

General information

Sex : Male

Group : 0 (0 mg/kg)

Sacrifice : Final sacrifice group

Necropsy status : Planned sacrifice

Date of death : 21.Nov.2013

92 days after start of exposure

1 day after end of exposure

Macroscopic findings

Animal without particular findings.

Microscopic findings

Kidneys

Tubules, basophilic, (multi)focal, unilateral, grade 1.

Liver

Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s), grade 1.

Peri-/vasculitis, grade 1.

Lungs

Inflammation, (multi)focal, grade 1.

Thymus

Hyperplasia, tubules and cords, (multi)focal, grade 1.

All other organs examined without microscopic findings.

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SINGLE ANIMAL SHEET

(GROSS LESIONS AND MICROSCOPIC FINDINGS)

.....	Sacrifice	F1
.....	Sex	M
.....	Group	0
.....	Animal	10

General information

Sex : Male
Group : 0 (0 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 21.Nov.2013
92 days after start of exposure
1 day after end of exposure

Macroscopic findings

Animal without particular findings.

Microscopic findings

Kidneys

Tubules, basophilic, (multifocal, unilateral, grade 1.
Cast, hyaline, unilateral.

Liver

Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),
grade 1.
Peri-/vasculitis, grade 1.

Rectum

Parasite(s) in lumen.

All other organs examined without microscopic findings.

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SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)

..... Sacrifice F1
Sex M
Group 1
Animal 11
.....

General information

Sex : Male
Group : 1 (100 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 21.Nov.2013
92 days after start of exposure
1 day after end of exposure

Macroscopic findings

Animal without particular findings.

Microscopic findings

Kidneys
Mineralization, at transition outer to inner medulla, (multi)focal, grade 2.
Tubules, basophilic, (multi)focal, grade 1.
Dilation, renal pelvis, unilateral, grade 2.
Liver
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s), grade 1.
Mammary gland
No or insufficient tissue present on slide.
All other organs examined without microscopic findings.

..... Animal 12
.....

General information

Sex : Male
Group : 1 (100 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 21.Nov.2013
92 days after start of exposure
1 day after end of exposure

Macroscopic findings

Axillary lymph nodes
Enlarged, left side, moderate, tissue preserved in cassette.
Skin
Abscess, axillary left side, diameter 15.0 mm.
All other organs without macroscopic findings.

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SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)

..... Sacrifice F1
Sex M
Group 1
cont. Animal 12

Microscopic findings

Axillary lymph nodes

Gross lesion(s) evaluated histopathologically.

Plasmocytosis, grade 2, correlates to gross lesion Enlarged.

Liver

Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),
grade 1.

Mammary gland

No or insufficient tissue present on slide.

Skin

Gross lesion(s) evaluated histopathologically.

Abscess, correlates to gross lesion Abscess.

All other organs examined without microscopic findings.

..... Animal 13

General information

Sex : Male

Group : 1 (100 mg/kg)

Sacrifice : Final sacrifice group

Necropsy status : Planned sacrifice

Date of death : 21.Nov.2013

92 days after start of exposure

1 day after end of exposure

Macroscopic findings

Animal without particular findings.

Microscopic findings

Kidneys

Mineralization, at transition outer to inner medulla, (multi)focal, grade 1.

Tubules, basophilic, (multi)focal, grade 1.

Liver

Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),
grade 1.

KV, GSTP

GSTP positive focus, (multi)focal.

All other organs examined without microscopic findings.

..... Animal 14

General information

Sex : Male

Group : 1 (100 mg/kg)

Sacrifice : Final sacrifice group

Necropsy status : Planned sacrifice

Date of death : 21.Nov.2013

92 days after start of exposure

1 day after end of exposure

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SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)

..... Sacrifice F1
Sex M
Group 1
cont. Animal 14

Macroscopic findings
Animal without particular findings.

Microscopic findings
Kidneys
Mineralization, at transition outer to inner medulla, (multi)focal, unilateral, grade 1.
Tubules, basophilic, (multi)focal, unilateral, grade 1.
Liver
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s), grade 1.
Focus of cellular alteration.
- Basophilic tigroid focus.
All other organs examined without microscopic findings.

..... Animal 15

General information
Sex : Male
Group : 1 (100 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 21.Nov.2013
92 days after start of exposure
1 day after end of exposure

Macroscopic findings
Animal without particular findings.

Microscopic findings
Cecum
Apoptosis, increased, grade 1.
Kidneys
Mineralization, at transition outer to inner medulla, (multi)focal, grade 1.
Tubules, basophilic, (multi)focal, unilateral, grade 1.
Liver
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s), grade 1.
All other organs examined without microscopic findings.

..... Animal 16

General information
Sex : Male
Group : 1 (100 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 21.Nov.2013
92 days after start of exposure

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SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)

..... Sacrifice F1
Sex M
Group 1
cont. Animal 16
.....
1 day after end of exposure

Macroscopic findings
Animal without particular findings.

Microscopic findings
Kidneys
Mineralization, at transition outer to inner medulla, (multi)focal, grade 2.
Tubules, basophilic, (multi)focal, grade 1.
Cast, hyaline.
Liver
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),
grade 1.
All other organs examined without microscopic findings.
..... Animal 17

General information
Sex : Male
Group : 1 (100 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 21.Nov.2013
92 days after start of exposure
1 day after end of exposure

Macroscopic findings
Animal without particular findings.

Microscopic findings
Kidneys
Mineralization, at transition outer to inner medulla, (multi)focal, grade 1.
Tubules, basophilic, (multi)focal, grade 1.
Liver
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),
grade 1.
KV, GSTP
GSTP positive focus, (multi)focal.
All other organs examined without microscopic findings.
..... Animal 18

General information
Sex : Male
Group : 1 (100 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 21.Nov.2013
92 days after start of exposure

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SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)

..... Sacrifice F1
Sex M
Group 1
cont. Animal 18
.....
1 day after end of exposure

Macroscopic findings
Animal without particular findings.

Microscopic findings
Cecum
Apoptosis, increased, grade 1.
Kidneys
Tubules, basophilic, (multi)focal, grade 1.
Cast, hyaline.
Liver
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),
grade 1.
All other organs examined without microscopic findings.
..... Animal 19

General information
Sex : Male
Group : 1 (100 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 21.Nov.2013
92 days after start of exposure
1 day after end of exposure

Macroscopic findings
Animal without particular findings.

Microscopic findings
Cecum
Apoptosis, increased, grade 1.
Liver
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),
grade 1.
All other organs examined without microscopic findings.
..... Animal 20

General information
Sex : Male
Group : 1 (100 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 21.Nov.2013
92 days after start of exposure
1 day after end of exposure

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SINGLE ANIMAL SHEET

(GROSS LESIONS AND MICROSCOPIC FINDINGS)

	Sacrifice	F1
	Sex	M
	Group	1
	cont. Animal	20

.....

Macroscopic findings

Animal without particular findings.

Microscopic findings

Kidneys

Mineralization, at transition outer to inner medulla, (multi)focal, grade 2.

Tubules, basophilic, (multi)focal, grade 1.

Liver

Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),
grade 1.

All other organs examined without microscopic findings.

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SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)

..... Sacrifice F1
Sex M
Group 2
Animal 21

General information

Sex : Male
Group : 2 (300 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 21.Nov.2013
92 days after start of exposure
1 day after end of exposure

Macroscopic findings

Animal without particular findings.

Microscopic findings

Kidneys

Mineralization, at transition outer to inner medulla, (multi)focal,
unilateral, grade 1.
Tubules, basophilic, (multi)focal, grade 1.
Proliferation, interstitial cell, focal, unilateral, grade 1.

Liver

Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),
grade 1.

All other organs examined without microscopic findings.

..... Animal 22

General information

Sex : Male
Group : 2 (300 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 21.Nov.2013
92 days after start of exposure
1 day after end of exposure

Macroscopic findings

Animal without particular findings.

Microscopic findings

Adrenal cortex

Unilaterally investigated or present. No histopathologic findings noted.

Adrenal medulla

Unilaterally investigated or present. No histopathologic findings noted.

Cecum

Apoptosis, increased, grade 1.

Kidneys

Mineralization, at transition outer to inner medulla, (multi)focal, grade 2.
Tubules, basophilic, (multi)focal, grade 1.

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SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)

	Sacrifice	F1
	Sex	M
	Group	2
	cont. Animal	22
.....		
Nuclear crowding, grade 1.		
Cast, hyaline, unilateral.		
Liver		
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s), grade 1.		
Mammary gland		
Atrophy, (multi)focal, grade 1.		
All other organs examined without microscopic findings.		
	Animal	23
.....		
General information		
Sex	: Male	
Group	: 2 (300 mg/kg)	
Sacrifice	: Final sacrifice group	
Necropsy status	: Planned sacrifice	
Date of death	: 21.Nov.2013	
	92 days after start of exposure	
	1 day after end of exposure	
Macroscopic findings		
Kidneys		
Pelvic dilation, unilateral, left side.		
All other organs without macroscopic findings.		
Microscopic findings		
Kidneys		
Gross lesion(s) evaluated histopathologically.		
Mineralization, at transition outer to inner medulla, (multi)focal, grade 1.		
Tubules, basophilic, (multi)focal, grade 1.		
Cast, hyaline, unilateral.		
Hyperplasia, transitional cell, (multi)focal, unilateral, grade 2.		
Dilation, renal pelvis, unilateral, grade 1, correlates to gross lesion		
Pelvic dilation.		
Liver		
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s), grade 1.		
Mammary gland		
Atrophy, (multi)focal, grade 1.		
All other organs examined without microscopic findings.		

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SINGLE ANIMAL SHEET

(GROSS LESIONS AND MICROSCOPIC FINDINGS)

	Sacrifice	F1
	Sex	M
	Group	2
	Animal	24

General information

Sex : Male
Group : 2 (300 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 21.Nov.2013
92 days after start of exposure
1 day after end of exposure

Macroscopic findings

Animal without particular findings.

Microscopic findings

Cecum
Apoptosis, increased, grade 1.
Kidneys
Mineralization, at transition outer to inner medulla, (multi)focal, unilateral, grade 1.
Liver
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s), grade 1.
Mammary gland
Atrophy, (multi)focal, grade 1.
All other organs examined without microscopic findings.

	Animal	25
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General information

Sex : Male
Group : 2 (300 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 21.Nov.2013
92 days after start of exposure
1 day after end of exposure

Macroscopic findings

Heart
Deposition, white.
Pericard
Inflammation.
All other organs without macroscopic findings.

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SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)

..... Sacrifice F1
Sex M
Group 2
cont. Animal 25

Microscopic findings

Heart
Gross lesion(s) evaluated histopathologically.
Inflammation, pericard, granulomatous, grade 2, correlates to gross lesion
Deposition.
Kidneys
Mineralization, at transition outer to inner medulla, (multi)focal,
unilateral, grade 1.
Tubules, basophilic, (multi)focal, grade 1.
Nuclear crowding, grade 1.
Liver
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),
grade 1.
KV, GSTP
GSTP positive focus, (multi)focal.
Pericard
Gross lesion(s) evaluated histopathologically.
Inflammation, granulomatous, correlates to gross lesion Inflammation.
All other organs examined without microscopic findings.

..... Animal 26

General information

Sex : Male
Group : 2 (300 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 21.Nov.2013
92 days after start of exposure
1 day after end of exposure

Macroscopic findings

Animal without particular findings.

Microscopic findings

Cecum
Apoptosis, increased, grade 1.
Kidneys
Mineralization, at transition outer to inner medulla, (multi)focal, grade 3.
Tubules, basophilic, (multi)focal, grade 1.
Nuclear crowding, grade 1.
Liver
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),
grade 1.
Mammary gland
Atrophy, (multi)focal, grade 1.
All other organs examined without microscopic findings.

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SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)

..... Sacrifice F1
Sex M
Group 2
Animal 27

General information

Sex : Male
Group : 2 (300 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 21.Nov.2013
92 days after start of exposure
1 day after end of exposure

Macroscopic findings

Animal without particular findings.

Microscopic findings

Kidneys

Mineralization, at transition outer to inner medulla, (multi)focal, grade 1.
Tubules, basophilic, (multi)focal, grade 1.
Cast, hyaline, unilateral.

Liver

Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s), grade 1.

Mammary gland

Atrophy, (multi)focal, grade 1.

All other organs examined without microscopic findings.

..... Animal 28

General information

Sex : Male
Group : 2 (300 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 21.Nov.2013
92 days after start of exposure
1 day after end of exposure

Macroscopic findings

Animal without particular findings.

Microscopic findings

Kidneys

Mineralization, at transition outer to inner medulla, (multi)focal, grade 2.
Tubules, basophilic, (multi)focal, grade 1.
Nuclear crowding, grade 1.
Cyst(s), unilateral.

Liver

Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s), grade 1.

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SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)

..... Sacrifice F1
Sex M
Group 2
cont. Animal 28
.....
Mammary gland
Atrophy, (multi)focal, grade 1.
All other organs examined without microscopic findings.

..... Animal 29
.....
General information
Sex : Male
Group : 2 (300 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 21.Nov.2013
92 days after start of exposure
1 day after end of exposure

Macroscopic findings
Animal without particular findings.

Microscopic findings
Kidneys
Tubules, basophilic, (multi)focal, grade 1.
Liver
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),
grade 1.
Mammary gland
Atrophy, (multi)focal, grade 1.
All other organs examined without microscopic findings.

..... Animal 30
.....
General information
Sex : Male
Group : 2 (300 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 21.Nov.2013
92 days after start of exposure
1 day after end of exposure

Macroscopic findings
Animal without particular findings.

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SINGLE ANIMAL SHEET

(GROSS LESIONS AND MICROSCOPIC FINDINGS)

.....	Sacrifice	F1
	Sex	M
	Group	2
	cont. Animal	30

Microscopic findings

Cecum

Apoptosis, increased, grade 1.

Kidneys

Mineralization, at transition outer to inner medulla, (multi)focal, grade 1.

Tubules, basophilic, (multi)focal, grade 1.

Cast, hyaline, unilateral.

Dilation, renal pelvis, unilateral, grade 2.

Liver

Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s), grade 1.

All other organs examined without microscopic findings.

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SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)

..... Sacrifice F1
Sex M
Group 3
Animal 31

General information

Sex : Male
Group : 3 (1000 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 21.Nov.2013
92 days after start of exposure
1 day after end of exposure

Macroscopic findings

Cecum
Dilation, moderate.
All other organs without macroscopic findings.

Microscopic findings

Cecum
Gross lesion(s) evaluated histopathologically.
Dilation, correlates to gross lesion Dilation.
Apoptosis, increased, grade 1.
Kidneys
Mineralization, at transition outer to inner medulla, (multi)focal,
unilateral, grade 1.
Tubules, basophilic, (multi)focal, unilateral, grade 1.
Liver
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),
grade 1.
Mammary gland
Atrophy, (multi)focal, grade 4.
All other organs examined without microscopic findings.

..... Animal 32

General information

Sex : Male
Group : 3 (1000 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 21.Nov.2013
92 days after start of exposure
1 day after end of exposure

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SINGLE ANIMAL SHEET

(GROSS LESIONS AND MICROSCOPIC FINDINGS)

	Sacrifice	F1
	Sex	M
	Group	3
	cont. Animal	32

Macroscopic findings

Cecum

Dilation, moderate.

All other organs without macroscopic findings.

Microscopic findings

Adrenal cortex

Hypertrophy/hyperplasia, cortical (zona fasciculata, reticularis).

Cecum

Gross lesion(s) evaluated histopathologically.

Dilation, correlates to gross lesion Dilation.

Apoptosis, increased, grade 1.

Kidneys

Mineralization, at transition outer to inner medulla, (multi)focal,
unilateral, grade 1.

Liver

Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),
grade 1.

Lungs

Histiocytosis, alveolar, (multi)focal, grade 1.

Mammary gland

Atrophy, (multi)focal, grade 2.

Spleen

Hematopoiesis, extramedullary, (multi)focal, grade 2.

All other organs examined without microscopic findings.

	Animal	33
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General information

Sex : Male

Group : 3 (1000 mg/kg)

Sacrifice : Final sacrifice group

Necropsy status : Planned sacrifice

Date of death : 21.Nov.2013

92 days after start of exposure

1 day after end of exposure

Macroscopic findings

Cecum

Dilation, moderate.

All other organs without macroscopic findings.

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SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)

..... Sacrifice F1
Sex M
Group 3
cont. Animal 33

Microscopic findings

Adrenal cortex
Hypertrophy/hyperplasia, cortical (zona fasciculata, reticularis).
Cecum
Gross lesion(s) evaluated histopathologically.
Dilation, correlates to gross lesion Dilation.
Apoptosis, increased, grade 1.
Kidneys
Mineralization, at transition outer to inner medulla, (multi)focal, unilateral, grade 1.
Tubules, basophilic, (multi)focal, unilateral, grade 1.
Liver
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s), grade 1.
Focus of cellular alteration.
- Basophilic tigroid focus.
Mammary gland
Atrophy, (multi)focal, grade 2.
Rectum
Parasite(s) in lumen.
Spleen
Hematopoiesis, extramedullary, (multi)focal, grade 1.
All other organs examined without microscopic findings.

..... Animal 34

General information

Sex : Male
Group : 3 (1000 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 21.Nov.2013
92 days after start of exposure
1 day after end of exposure

Macroscopic findings

Cecum
Dilation, moderate.
All other organs without macroscopic findings.

Microscopic findings

Adrenal cortex
Hypertrophy/hyperplasia, cortical (zona fasciculata, reticularis).
Cecum
Gross lesion(s) evaluated histopathologically.
Dilation, correlates to gross lesion Dilation.

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SINGLE ANIMAL SHEET

(GROSS LESIONS AND MICROSCOPIC FINDINGS)

	Sacrifice	F1
	Sex	M
	Group	3
	cont. Animal	34

Kidneys

Tubules, basophilic, (multi)focal, unilateral, grade 1.

Liver

Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s), grade 1.

Focus of cellular alteration.

- Eosinophilic focus.

- Basophilic tigroid focus.

Mammary gland

Atrophy, (multi)focal, grade 3.

Spleen

Hematopoiesis, extramedullary, (multi)focal, grade 1.

All other organs examined without microscopic findings.

Animal 35

General information

Sex : Male

Group : 3 (1000 mg/kg)

Sacrifice : Final sacrifice group

Necropsy status : Planned sacrifice

Date of death : 21.Nov.2013

92 days after start of exposure

1 day after end of exposure

Macroscopic findings

Cecum

Dilation, moderate.

All other organs without macroscopic findings.

Microscopic findings

Adrenal cortex

Hypertrophy/hyperplasia, cortical (zona fasciculata, reticularis).

Cecum

Gross lesion(s) evaluated histopathologically.

Dilation, correlates to gross lesion Dilation.

Kidneys

Tubules, basophilic, (multi)focal, unilateral, grade 1.

Liver

Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s), grade 1.

Mammary gland

Atrophy, (multi)focal, grade 3.

Spleen

Hematopoiesis, extramedullary, (multi)focal, grade 1.

All other organs examined without microscopic findings.

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SINGLE ANIMAL SHEET

(GROSS LESIONS AND MICROSCOPIC FINDINGS)

	Sacrifice	F1
	Sex	M
	Group	3
	Animal	36

General information

Sex	: Male
Group	: 3 (1000 mg/kg)
Sacrifice	: Final sacrifice group
Necropsy status	: Planned sacrifice
Date of death	: 21.Nov.2013
	92 days after start of exposure
	1 day after end of exposure

Macroscopic findings

Cecum
Dilation, slight.
All other organs without macroscopic findings.

Microscopic findings

Adrenal cortex
Hypertrophy/hyperplasia, cortical (zona fasciculata, reticularis).
Cecum
Gross lesion(s) evaluated histopathologically.
Dilation, correlates to gross lesion Dilation.
Parasite(s) in lumen.
Apoptosis, increased, grade 1.
Kidneys
Tubules, basophilic, (multi)focal, unilateral, grade 1.
Liver
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s), grade 1.
Mammary gland
Atrophy, (multi)focal, grade 4.
Spleen
Hematopoiesis, extramedullary, (multi)focal, grade 1.
All other organs examined without microscopic findings.

	Animal	37
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General information

Sex	: Male
Group	: 3 (1000 mg/kg)
Sacrifice	: Final sacrifice group
Necropsy status	: Planned sacrifice
Date of death	: 21.Nov.2013
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	1 day after end of exposure

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SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)

..... Sacrifice F1
Sex M
Group 3
cont. Animal 37

Macroscopic findings

Cecum
Dilation, slight.
All other organs without macroscopic findings.

Microscopic findings

Cecum
Gross lesion(s) evaluated histopathologically.
Dilation, correlates to gross lesion Dilation.
Apoptosis, increased, grade 1.
Kidneys
Mineralization, at transition outer to inner medulla, (multi)focal,
unilateral, grade 1.
Tubules, basophilic, (multi)focal, unilateral, grade 1.
Liver
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),
grade 1.
KV, GSTP
GSTP positive focus, (multi)focal.
Mammary gland
Atrophy, (multi)focal, grade 4.
Thymus
Hyperplasia, tubules and cords, (multi)focal, grade 1.
All other organs examined without microscopic findings.

..... Animal 38

General information

Sex : Male
Group : 3 (1000 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 21.Nov.2013
92 days after start of exposure
1 day after end of exposure

Macroscopic findings

Cecum
Dilation, moderate.
All other organs without macroscopic findings.

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SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)

..... Sacrifice F1
Sex M
Group 3
cont. Animal 38

Microscopic findings

Adrenal cortex
Hypertrophy/hyperplasia, cortical (zona fasciculata, reticularis).
Cecum
Gross lesion(s) evaluated histopathologically.
Dilation, correlates to gross lesion Dilation.
Apoptosis, increased, grade 1.
Colon
Parasite(s) in lumen.
Kidneys
Mineralization, at transition outer to inner medulla, (multi)focal, grade 1.
Tubules, basophilic, (multi)focal, grade 1.
Liver
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),
grade 1.
KV, GSTP
GSTP positive focus, (multi)focal.
Lungs
Inflammation, (multi)focal, grade 1.
Mammary gland
Atrophy, (multi)focal, grade 2.
Rectum
Parasite(s) in lumen.
Spleen
Hematopoiesis, extramedullary, (multi)focal, grade 2.
Thymus
Hyperplasia, tubules and cords, (multi)focal, grade 1.
All other organs examined without microscopic findings.

Animal 39

General information

Sex : Male
Group : 3 (1000 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 21.Nov.2013
92 days after start of exposure
1 day after end of exposure

Macroscopic findings

Cecum
Dilation, moderate.
All other organs without macroscopic findings.

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SINGLE ANIMAL SHEET

(GROSS LESIONS AND MICROSCOPIC FINDINGS)

	Sacrifice	F1
	Sex	M
	Group	3
	cont. Animal	39

Microscopic findings

Adrenal cortex

Hypertrophy/hyperplasia, cortical (zona fasciculata, reticularis).

Cecum

Gross lesion(s) evaluated histopathologically.

Dilation, correlates to gross lesion Dilation.

Apoptosis, increased, grade 1.

Kidneys

Mineralization, at transition outer to inner medulla, (multi)focal, grade 1.

Tubules, basophilic, (multi)focal, grade 1.

Liver

Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),
grade 1.

Mammary gland

Atrophy, (multi)focal, grade 2.

Spleen

Hematopoiesis, extramedullary, (multi)focal, grade 1.

All other organs examined without microscopic findings.

Animal 40

General information

Sex : Male

Group : 3 (1000 mg/kg)

Sacrifice : Final sacrifice group

Necropsy status : Planned sacrifice

Date of death : 21.Nov.2013

92 days after start of exposure

1 day after end of exposure

Macroscopic findings

Cecum

Dilation, moderate.

All other organs without macroscopic findings.

Microscopic findings

Adrenal cortex

Hypertrophy/hyperplasia, cortical (zona fasciculata, reticularis).

Cecum

Gross lesion(s) evaluated histopathologically.

Dilation, correlates to gross lesion Dilation.

Liver

Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),
grade 1.

Mammary gland

Atrophy, (multi)focal, grade 5.

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11.Apr.2014 HAMA

SINGLE ANIMAL SHEET

(GROSS LESIONS AND MICROSCOPIC FINDINGS)

.....	Sacrifice	F1
	Sex	M
	Group	3
.....	cont. Animal	40

Spleen

Hematopoiesis, extramedullary, (multi)focal, grade 2.

Thymus

Hyperplasia, tubules and cords, (multi)focal, grade 1.

All other organs examined without microscopic findings.

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SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)

..... Sacrifice F1
Sex F
Group 0
Animal 41
.....

General information

Sex : Female
Group : 0 (0 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 22.Nov.2013
93 days after start of exposure
1 day after end of exposure

Macroscopic findings

Animal without particular findings.

Microscopic findings

Kidneys
Mineralization, at transition outer to inner medulla, (multi)focal, grade 1.
Liver
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),
grade 1.
Lungs
Histiocytosis, alveolar, (multi)focal, grade 1.
All other organs examined without microscopic findings.

..... Animal 42
.....

General information

Sex : Female
Group : 0 (0 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 22.Nov.2013
93 days after start of exposure
1 day after end of exposure

Macroscopic findings

Animal without particular findings.

Microscopic findings

Adrenal medulla
Unilaterally investigated or present. No histopathologic findings noted.
Liver
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),
grade 1.
All other organs examined without microscopic findings.

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(GROSS LESIONS AND MICROSCOPIC FINDINGS)

	Sacrifice	F1
	Sex	F
	Group	0
	Animal	43

General information

Sex : Female
Group : 0 (0 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 22.Nov.2013
93 days after start of exposure
1 day after end of exposure

Macroscopic findings

Animal without particular findings.

Microscopic findings

Kidneys

Mineralization, at transition outer to inner medulla, (multi)focal,
unilateral, grade 1.
Tubules, basophilic, (multi)focal, unilateral, grade 1.

Liver

Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),
grade 1.

Thymus

Hyperplasia, tubules and cords, (multi)focal, grade 1.

All other organs examined without microscopic findings.

	Animal	44
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General information

Sex : Female
Group : 0 (0 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 22.Nov.2013
93 days after start of exposure
1 day after end of exposure

Macroscopic findings

Animal without particular findings.

Microscopic findings

Liver

Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),
grade 1.

Focus of cellular alteration.

- Basophilic tigroid focus.

* in Cresyl violet stain.

All other organs examined without microscopic findings.

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..... Sacrifice F1
Sex F
Group 0
Animal 45

General information

Sex : Female
Group : 0 (0 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 22.Nov.2013
93 days after start of exposure
1 day after end of exposure

Macroscopic findings

Animal without particular findings.

Microscopic findings

Liver
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),
grade 1.
Thymus
Hyperplasia, tubules and cords, (multi)focal, grade 1.
All other organs examined without microscopic findings.

..... Animal 46

General information

Sex : Female
Group : 0 (0 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 22.Nov.2013
93 days after start of exposure
1 day after end of exposure

Macroscopic findings

Animal without particular findings.

Microscopic findings

Kidneys
Mineralization, at transition outer to inner medulla, (multi)focal, grade 2.
Liver
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),
grade 1.
KV, GSTP
GSTP positive focus, (multi)focal.
Lungs
Histiocytosis, alveolar, (multi)focal, grade 1.
All other organs examined without microscopic findings.

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SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)

..... Sacrifice F1
Sex F
Group 0
Animal 47

General information

Sex : Female
Group : 0 (0 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 22.Nov.2013
93 days after start of exposure
1 day after end of exposure

Macroscopic findings

Animal without particular findings.

Microscopic findings

Kidneys
Mineralization, at transition outer to inner medulla, (multi)focal, grade 1.
Liver
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),
grade 1.
All other organs examined without microscopic findings.

..... Animal 48

General information

Sex : Female
Group : 0 (0 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 22.Nov.2013
93 days after start of exposure
1 day after end of exposure

Macroscopic findings

Animal without particular findings.

Microscopic findings

Liver
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),
grade 2.
KV, GSTP
GSTP positive cells, centrilobular, grade 3.
Spleen
Hematopoiesis, extramedullary, (multi)focal, grade 1.
All other organs examined without microscopic findings.

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SINGLE ANIMAL SHEET

(GROSS LESIONS AND MICROSCOPIC FINDINGS)

	Sacrifice	F1
	Sex	F
	Group	0
	Animal	49

General information

Sex : Female
Group : 0 (0 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 22.Nov.2013
93 days after start of exposure
1 day after end of exposure

Macroscopic findings

Animal without particular findings.

Microscopic findings

Kidneys

Mineralization, at transition outer to inner medulla, (multi)focal,
unilateral, grade 2.
Tubules, basophilic, (multi)focal, unilateral, grade 1.

Liver

Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),
grade 1.

All other organs examined without microscopic findings.

Animal 50

General information

Sex : Female
Group : 0 (0 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 22.Nov.2013
93 days after start of exposure
1 day after end of exposure

Macroscopic findings

Animal without particular findings.

Microscopic findings

Axillary lymph nodes

Unilaterally investigated or present. No histopathologic findings noted.

Liver

Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),
grade 1.

Spleen

Hematopoiesis, extramedullary, (multi)focal, grade 1.

All other organs examined without microscopic findings.

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(GROSS LESIONS AND MICROSCOPIC FINDINGS)

	Sacrifice	F1
	Sex	F
	Group	1
	Animal	51

General information

Sex : Female
Group : 1 (100 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 22.Nov.2013
93 days after start of exposure
1 day after end of exposure

Macroscopic findings

Forestomach
Focus, diameter 3.0 mm, organlike color, surface raised.
All other organs without macroscopic findings.

Microscopic findings

Forestomach
Gross lesion(s) evaluated histopathologically.
Cyst, squamous, correlates to gross lesion Focus.
Liver
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s), grade 1.
Hypertrophy, centrilobular, grade 1.
Focus of cellular alteration.
- Eosinophilic focus.
All other organs examined without microscopic findings.

	Animal	52
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General information

Sex : Female
Group : 1 (100 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 22.Nov.2013
93 days after start of exposure
1 day after end of exposure

Macroscopic findings

Animal without particular findings.

Microscopic findings

Liver
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s), grade 1.
All other organs examined without microscopic findings.

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..... Sacrifice F1
Sex F
Group 1
Animal 53

General information

Sex : Female
Group : 1 (100 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 22.Nov.2013
93 days after start of exposure
1 day after end of exposure

Macroscopic findings

Animal without particular findings.

Microscopic findings

Liver
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),
grade 1.
Hypertrophy, centrilobular, grade 2.
KV, GSTP
GSTP positive cells, centrilobular, grade 4.
Uterus
Metaplasia, squamous cell, (multi)focal, uterine epithelium, grade 1.
All other organs examined without microscopic findings.

..... Animal 54

General information

Sex : Female
Group : 1 (100 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 22.Nov.2013
93 days after start of exposure
1 day after end of exposure

Macroscopic findings

Animal without particular findings.

Microscopic findings

Cecum
Apoptosis, increased, grade 1.
Liver
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),
grade 1.
KV, GSTP
GSTP positive focus, (multi)focal.
All other organs examined without microscopic findings.

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..... Sacrifice F1
Sex F
Group 1
Animal 55

General information

Sex : Female
Group : 1 (100 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 22.Nov.2013
93 days after start of exposure
1 day after end of exposure

Macroscopic findings

Animal without particular findings.

Microscopic findings

Liver
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),
grade 1.
Uterus
Metaplasia, squamous cell, (multi)focal, uterine epithelium, grade 1.
All other organs examined without microscopic findings.

..... Animal 56

General information

Sex : Female
Group : 1 (100 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 22.Nov.2013
93 days after start of exposure
1 day after end of exposure

Macroscopic findings

Animal without particular findings.

Microscopic findings

Liver
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),
grade 1.
All other organs examined without microscopic findings.

..... Animal 57

General information

Sex : Female
Group : 1 (100 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 22.Nov.2013
93 days after start of exposure

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(GROSS LESIONS AND MICROSCOPIC FINDINGS)

	Sacrifice	F1
	Sex	F
	Group	1
	cont. Animal	57
.....		
1 day after end of exposure		

Macroscopic findings

Animal without particular findings.

Microscopic findings

Liver

Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),
grade 1.

KV, GSTP

GSTP positive cells, centrilobular, grade 3.

Spleen

Hematopoiesis, extramedullary, (multi)focal, grade 1.

All other organs examined without microscopic findings.

	Animal	58
.....		

General information

Sex : Female
Group : 1 (100 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 22.Nov.2013
93 days after start of exposure
1 day after end of exposure

Macroscopic findings

Animal without particular findings.

Microscopic findings

Liver

Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),
grade 1.

All other organs examined without microscopic findings.

	Animal	59
.....		

General information

Sex : Female
Group : 1 (100 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 22.Nov.2013
93 days after start of exposure
1 day after end of exposure

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(GROSS LESIONS AND MICROSCOPIC FINDINGS)

	Sacrifice	F1
	Sex	F
	Group	1
	cont. Animal	59

Macroscopic findings

Animal without particular findings.

Microscopic findings

Liver

Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s), grade 1.

All other organs examined without microscopic findings.

	Animal	60
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General information

Sex	: Female
Group	: 1 (100 mg/kg)
Sacrifice	: Final sacrifice group
Necropsy status	: Planned sacrifice
Date of death	: 22.Nov.2013
	: 93 days after start of exposure
	: 1 day after end of exposure

Macroscopic findings

Animal without particular findings.

Microscopic findings

Liver

Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s), grade 1.

All other organs examined without microscopic findings.

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SINGLE ANIMAL SHEET

(GROSS LESIONS AND MICROSCOPIC FINDINGS)

	Sacrifice	F1
	Sex	F
	Group	2
	Animal	61

General information

Sex : Female
Group : 2 (300 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 22.Nov.2013
93 days after start of exposure
1 day after end of exposure

Macroscopic findings

Animal without particular findings.

Microscopic findings

Liver
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s), grade 1.
All other organs examined without microscopic findings.

	Animal	62
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General information

Sex : Female
Group : 2 (300 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 22.Nov.2013
93 days after start of exposure
1 day after end of exposure

Macroscopic findings

Uterus
Dilation, moderate, content clear fluid.
All other organs without macroscopic findings.

Microscopic findings

Liver
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s), grade 1.
Hypertrophy, centrilobular, grade 2.
KV, GSTP
GSTP positive cells, centrilobular, grade 2.
Uterus
Gross lesion(s) evaluated histopathologically.
Dilation of horn(s), correlates to gross lesion Dilation.
All other organs examined without microscopic findings.

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SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)

..... Sacrifice F1
Sex F
Group 2
Animal 63

General information

Sex : Female
Group : 2 (300 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 22.Nov.2013
93 days after start of exposure
1 day after end of exposure

Macroscopic findings

Animal without particular findings.

Microscopic findings

Cecum
Apoptosis, increased, grade 1.
Liver
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s), grade 1.
Hypertrophy, centrilobular, grade 2.
Uterus
Metaplasia, squamous cell, (multi)focal, uterine epithelium, grade 1.
All other organs examined without microscopic findings.

..... Animal 64

General information

Sex : Female
Group : 2 (300 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 22.Nov.2013
93 days after start of exposure
1 day after end of exposure

Macroscopic findings

Animal without particular findings.

Microscopic findings

Liver
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s), grade 1.
Hypertrophy, centrilobular, grade 2.
KV, GSTP
GSTP positive cells, centrilobular, grade 1.
Spleen
Hematopoiesis, extramedullary, (multi)focal, grade 1.
All other organs examined without microscopic findings.

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SINGLE ANIMAL SHEET

(GROSS LESIONS AND MICROSCOPIC FINDINGS)

.....	Sacrifice	F1
.....	Sex	F
.....	Group	2
.....	Animal	65

General information

Sex : Female
Group : 2 (300 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 22.Nov.2013
93 days after start of exposure
1 day after end of exposure

Macroscopic findings

Glandular stomach
Erosion/ulcer, few (2-5), diameter 2.0 mm, black.
Uterus
Dilation, moderate, content clear fluid.
All other organs without macroscopic findings.

Microscopic findings

Cecum
Apoptosis, increased, grade 1.
Glandular stomach
Gross lesion(s) evaluated histopathologically.
Erosion/ ulcer, correlates to gross lesion Erosion/ulcer.
Liver
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s), grade 1.
Hypertrophy, centrilobular, grade 1.
Uterus
Gross lesion(s) evaluated histopathologically.
Dilation of horn(s), correlates to gross lesion Dilation.
All other organs examined without microscopic findings.

.....	Animal	66
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General information

Sex : Female
Group : 2 (300 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 22.Nov.2013
93 days after start of exposure
1 day after end of exposure

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(GROSS LESIONS AND MICROSCOPIC FINDINGS)

..... Sacrifice F1
Sex F
Group 2
cont. Animal 66

Macroscopic findings
Animal without particular findings.

Microscopic findings
Cecum
Dilation.
Apoptosis, increased, grade 1.
Liver
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),
grade 1.
KV, GSTP
GSTP positive cells, centrilobular, grade 3.
All other organs examined without microscopic findings.

..... Animal 67

General information
Sex : Female
Group : 2 (300 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 22.Nov.2013
93 days after start of exposure
1 day after end of exposure

Macroscopic findings
Animal without particular findings.

Microscopic findings
Cecum
Apoptosis, increased, grade 1.
Liver
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),
grade 1.
Spleen
Hematopoiesis, extramedullary, (multi)focal, grade 1.
All other organs examined without microscopic findings.

..... Animal 68

General information
Sex : Female
Group : 2 (300 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 22.Nov.2013
93 days after start of exposure
1 day after end of exposure

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SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)

..... Sacrifice F1
Sex F
Group 2
cont. Animal 68

Macroscopic findings
Animal without particular findings.

Microscopic findings
Liver
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),
grade 1.
Spleen
Hematopoiesis, extramedullary, (multi)focal, grade 1.
Uterus
Metaplasia, squamous cell, (multi)focal, uterine epithelium, grade 1.
All other organs examined without microscopic findings.

..... Animal 69

General information
Sex : Female
Group : 2 (300 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 22.Nov.2013
93 days after start of exposure
1 day after end of exposure

Macroscopic findings
Uterus
Dilation, slight, content clear fluid.
All other organs without macroscopic findings.

Microscopic findings
Liver
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),
grade 1.
Hypertrophy, centrilobular, grade 3.
KV, GSTP
GSTP positive cells, centrilobular, grade 1.
Spleen
Hematopoiesis, extramedullary, (multi)focal, grade 1.
Uterus
Gross lesion(s) evaluated histopathologically.
Dilation of horn(s), correlates to gross lesion Dilation.
All other organs examined without microscopic findings.

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SINGLE ANIMAL SHEET

(GROSS LESIONS AND MICROSCOPIC FINDINGS)

.....	Sacrifice	F1
.....	Sex	F
.....	Group	2
.....	Animal	70

General information

Sex : Female
Group : 2 (300 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 22.Nov.2013
93 days after start of exposure
1 day after end of exposure

Macroscopic findings

Animal without particular findings.

Microscopic findings

Liver

Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s), grade 1.

Focus of cellular alteration.

- Basophilic tigroid focus.

KV, GSTP

GSTP positive focus, (multi)focal.

All other organs examined without microscopic findings.

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SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)

..... Sacrifice F1
Sex F
Group 3
Animal 71
.....

General information

Sex : Female
Group : 3 (1000 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 22.Nov.2013
93 days after start of exposure
1 day after end of exposure

Macroscopic findings

Liver
Enlarged, moderate.
All other organs without macroscopic findings.

Microscopic findings

Cecum
Dilation.
Apoptosis, increased, grade 1.
Liver
Gross lesion(s) evaluated histopathologically.
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),
grade 1.
Hypertrophy, centrilobular, grade 3, correlates to gross lesion Enlarged.
KV, GSTP
GSTP positive cells, centrilobular, grade 3.
Parathyroid glands
Unilaterally investigated or present. No histopathologic findings noted.
Spleen
Hematopoiesis, extramedullary, (multi)focal, grade 2.
All other organs examined without microscopic findings.

..... Animal 72
.....

General information

Sex : Female
Group : 3 (1000 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 22.Nov.2013
93 days after start of exposure
1 day after end of exposure

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SINGLE ANIMAL SHEET

(GROSS LESIONS AND MICROSCOPIC FINDINGS)

.....	Sacrifice	F1
	Sex	F
	Group	3
	cont. Animal	72

Macroscopic findings

Liver

Enlarged, moderate.

All other organs without macroscopic findings.

Microscopic findings

Cecum

Dilation.

Apoptosis, increased, grade 1.

Colon

Parasite(s) in lumen.

Kidneys

Cyst(s), unilateral.

Liver

Gross lesion(s) evaluated histopathologically.

Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s), grade 2.

Hypertrophy, centrilobular, grade 3, correlates to gross lesion Enlarged.

Focus of cellular alteration.

- Eosinophilic focus.

KV, GSTP

GSTP positive cells, centrilobular, grade 3.

GSTP positive focus, (multi)focal.

Spleen

Hematopoiesis, extramedullary, (multi)focal, grade 2.

Uterus

Metaplasia, squamous cell, (multi)focal, uterine epithelium, grade 1.

All other organs examined without microscopic findings.

.....	Animal	73
-------	--------	----

General information

Sex : Female

Group : 3 (1000 mg/kg)

Sacrifice : Final sacrifice group

Necropsy status : Planned sacrifice

Date of death : 22.Nov.2013

93 days after start of exposure

1 day after end of exposure

Macroscopic findings

Liver

Enlarged, moderate.

All other organs without macroscopic findings.

BASF

PATHOLOGY REPORT

IIC 79/85

50C0066/05S019

Repeated-dose 90-day oral toxicity study in Wistar rats
Administration by gavage

11.Apr.2014 HAMA

SINGLE ANIMAL SHEET

(GROSS LESIONS AND MICROSCOPIC FINDINGS)

	Sacrifice	F1
	Sex	F
	Group	3
	cont. Animal	73

Microscopic findings

Cecum

Dilation.

Apoptosis, increased, grade 1.

Kidneys

Mineralization, at transition outer to inner medulla, (multi)focal,
unilateral, grade 1.

Liver

Gross lesion(s) evaluated histopathologically.

Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),
grade 1.

Hypertrophy, centrilobular, grade 3, correlates to gross lesion Enlarged.

Focus of cellular alteration.

- Eosinophilic focus.

- Basophilic focus (not otherwise specified).

KV, GSTP

GSTP positive focus, (multi)focal.

Spleen

Hematopoiesis, extramedullary, (multi)focal, grade 2.

All other organs examined without microscopic findings.

Animal 74

General information

Sex : Female

Group : 3 (1000 mg/kg)

Sacrifice : Final sacrifice group

Necropsy status : Planned sacrifice

Date of death : 22.Nov.2013

93 days after start of exposure

1 day after end of exposure

Macroscopic findings

Liver

Enlarged, slight.

All other organs without macroscopic findings.

Microscopic findings

Cecum

Dilation.

Liver

Gross lesion(s) evaluated histopathologically.

Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),
grade 1.

Hypertrophy, centrilobular, grade 3, correlates to gross lesion Enlarged.

Focus of cellular alteration.

- Eosinophilic focus.

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PATHOLOGY REPORT

IIC 80/85

50C0066/05S019

Repeated-dose 90-day oral toxicity study in Wistar rats
Administration by gavage

11.Apr.2014 HAMA

SINGLE ANIMAL SHEET

(GROSS LESIONS AND MICROSCOPIC FINDINGS)

	Sacrifice	F1
	Sex	F
	Group	3
	cont. Animal	74
<hr/>		
KV, GSTP		
GSTP positive cells, centrilobular, grade 1.		
Parathyroid glands		
Unilaterally investigated or present. No histopathologic findings noted.		
Spleen		
Hematopoiesis, extramedullary, (multi)focal, grade 1.		
All other organs examined without microscopic findings.		
	Animal	75
<hr/>		
General information		
Sex	: Female	
Group	: 3 (1000 mg/kg)	
Sacrifice	: Final sacrifice group	
Necropsy status	: Planned sacrifice	
Date of death	: 22.Nov.2013	
	93 days after start of exposure	
	1 day after end of exposure	
Macroscopic findings		
Animal without particular findings.		
Microscopic findings		
Cecum		
Dilation.		
Apoptosis, increased, grade 1.		
Liver		
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s), grade 1.		
Hypertrophy, centrilobular, grade 3.		
Focus of cellular alteration.		
- Eosinophilic focus.		
- Diffuse basophilic focus.		
* in Cresyl violet stain.		
KV, GSTP		
GSTP positive cells, centrilobular, grade 3.		
GSTP positive focus, (multi)focal.		
Spleen		
Hematopoiesis, extramedullary, (multi)focal, grade 2.		
All other organs examined without microscopic findings.		

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IIC 81/85

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Repeated-dose 90-day oral toxicity study in Wistar rats
Administration by gavage

11.Apr.2014 HAMA

SINGLE ANIMAL SHEET

(GROSS LESIONS AND MICROSCOPIC FINDINGS)

.....	Sacrifice	F1
.....	Sex	F
.....	Group	3
.....	Animal	76

General information

Sex	: Female
Group	: 3 (1000 mg/kg)
Sacrifice	: Final sacrifice group
Necropsy status	: Planned sacrifice
Date of death	: 22.Nov.2013
	93 days after start of exposure
	1 day after end of exposure

Macroscopic findings

Liver
Enlarged, slight.
All other organs without macroscopic findings.

Microscopic findings

Cecum
Dilation.
Apoptosis, increased, grade 1.

Kidneys
Mineralization, at transition outer to inner medulla, (multi)focal, unilateral, grade 1.
Cyst(s), unilateral.

Liver
Gross lesion(s) evaluated histopathologically.
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s), grade 1.
Hypertrophy, centrilobular, grade 3, correlates to gross lesion Enlarged.

KV, GSTP
GSTP positive cells, centrilobular, grade 3.
GSTP positive focus, (multi)focal.

Spleen
Hematopoiesis, extramedullary, (multi)focal, grade 2.

Uterus
Metaplasia, squamous cell, (multi)focal, uterine epithelium, grade 2.
Hyperplasia, glandular, (multi)focal.
All other organs examined without microscopic findings.

.....	Animal	77
-------	--------	----

General information

Sex	: Female
Group	: 3 (1000 mg/kg)
Sacrifice	: Final sacrifice group
Necropsy status	: Planned sacrifice
Date of death	: 22.Nov.2013
	93 days after start of exposure
	1 day after end of exposure

BASF PATHOLOGY REPORT IIC 82/85
50C0066/05S019
Repeated-dose 90-day oral toxicity study in Wistar rats
Administration by gavage 11.Apr.2014 HAMA

SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)

..... Sacrifice F1
Sex F
Group 3
cont. Animal 77

Macroscopic findings

Liver
Enlarged, slight.
All other organs without macroscopic findings.

Microscopic findings

Cecum
Dilation.
Apoptosis, increased, grade 1.
Kidneys
Tubules, basophilic, (multi)focal, unilateral, grade 1.
Liver
Gross lesion(s) evaluated histopathologically.
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s), grade 1.
Hypertrophy, centrilobular, grade 3, correlates to gross lesion Enlarged.
KV, GSTP
GSTP positive cells, centrilobular, grade 1.
Rectum
Parasite(s) in lumen.
Spleen
Hematopoiesis, extramedullary, (multi)focal, grade 2.
Uterus
Metaplasia, squamous cell, (multi)focal, uterine epithelium, grade 1.
All other organs examined without microscopic findings.

..... Animal 78

General information

Sex : Female
Group : 3 (1000 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 22.Nov.2013
93 days after start of exposure
1 day after end of exposure

Macroscopic findings

Liver
Enlarged, moderate.
All other organs without macroscopic findings.

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PATHOLOGY REPORT

IIC 83/85

50C0066/05S019

Repeated-dose 90-day oral toxicity study in Wistar rats
Administration by gavage

11.Apr.2014 HAMA

SINGLE ANIMAL SHEET

(GROSS LESIONS AND MICROSCOPIC FINDINGS)

	Sacrifice	F1
	Sex	F
	Group	3
	cont. Animal	78

Microscopic findings

Cecum

Dilation.

Kidneys

Tubules, basophilic, (multi)focal, unilateral, grade 1.

Liver

Gross lesion(s) evaluated histopathologically.

Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s), grade 1.

Hypertrophy, centrilobular, grade 3, correlates to gross lesion Enlarged.

Focus of cellular alteration.

- Eosinophilic focus.

- Diffuse basophilic focus.

KV, GSTP

GSTP positive cells, centrilobular, grade 3.

GSTP positive focus, (multi)focal.

Lungs

Inflammation, (multi)focal, grade 1.

Spleen

Hematopoiesis, extramedullary, (multi)focal, grade 1.

Thymus

Hyperplasia, tubules and cords, (multi)focal, grade 1.

All other organs examined without microscopic findings.

Animal

79

General information

Sex : Female

Group : 3 (1000 mg/kg)

Sacrifice : Final sacrifice group

Necropsy status : Planned sacrifice

Date of death : 22.Nov.2013

93 days after start of exposure

1 day after end of exposure

Macroscopic findings

Liver

Enlarged, moderate.

All other organs without macroscopic findings.

Microscopic findings

Cecum

Dilation.

Apoptosis, increased, grade 1.

Liver

Gross lesion(s) evaluated histopathologically.

Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s), grade 1.

BASF PATHOLOGY REPORT IIC 84/85
50C0066/05S019
Repeated-dose 90-day oral toxicity study in Wistar rats
Administration by gavage 11.Apr.2014 HAMA

SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)

..... Sacrifice F1
Sex F
Group 3
cont. Animal 79

.....
Hypertrophy, centrilobular, grade 3, correlates to gross lesion Enlarged.
Hyperplasia bile duct, diffuse, grade 1.
Focus of cellular alteration.
- Eosinophilic focus.
KV, GSTP
GSTP positive cells, centrilobular, grade 1.
GSTP positive focus, (multi)focal.
Parathyroid glands
Unilaterally investigated or present. No histopathologic findings noted.
Peyers patch
* on slide 20
Spleen
Hematopoiesis, extramedullary, (multi)focal, grade 2.
Thymus
Hyperplasia, tubules and cords, (multi)focal, grade 2.
Uterus
Metaplasia, squamous cell, (multi)focal, uterine epithelium, grade 1.
All other organs examined without microscopic findings.

..... Animal 80
.....

General information

Sex : Female
Group : 3 (1000 mg/kg)
Sacrifice : Final sacrifice group
Necropsy status : Planned sacrifice
Date of death : 22.Nov.2013
93 days after start of exposure
1 day after end of exposure

Macroscopic findings

Animal without particular findings.

Microscopic findings

Axillary lymph nodes
Unilaterally investigated or present. No histopathologic findings noted.
Cecum
Dilation.
Kidneys
Mineralization, at transition outer to inner medulla, (multi)focal, grade 2.
Tubules, basophilic, (multi)focal, unilateral, grade 1.
Liver
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),
grade 1.
Hypertrophy, centrilobular, grade 3.
Hyperplasia bile duct, diffuse, grade 1.

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PATHOLOGY REPORT

IIC 85/85

50C0066/05S019

Repeated-dose 90-day oral toxicity study in Wistar rats

11.Apr.2014 HAMA

Administration by gavage

SINGLE ANIMAL SHEET

(GROSS LESIONS AND MICROSCOPIC FINDINGS)

.....	Sacrifice	F1
.....	Sex	F
.....	Group	3
.....	cont. Animal	80

KV, GSTP

GSTP positive cells, centrilobular, grade 1.

Parathyroid glands

Unilaterally investigated or present. No histopathologic findings noted.

Spleen

Hematopoiesis, extramedullary, (multi)focal, grade 1.

Uterus

Metaplasia, squamous cell, (multi)focal, uterine epithelium, grade 1.

All other organs examined without microscopic findings.

STUDY TITLE

Report

DHDPS

Repeated-dose 90-day oral toxicity study in Wistar animals
Administration by gavage

TEST FACILITY

BASF SE
Experimental Toxicology and Ecology
67056 Ludwigshafen, Germany

TEST FACILITY PROJECT IDENTIFICATION

Project No. 50C0066/05S019

**PART III OF III
(SUPPLEMENT)**

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Characterization of "4,4'-Dihydroxydiphenylsulfon"
Study No. 12L00002

DHDPS

Stability Analysis in 1% Carboxymethylcellulose in Drinking Water
Study No. 01Y0066/05Y009

Homogeneity and Concentration Control Analysis of DHDPS in
1% carboxymethylcellulose in drinking water

Functional observational battery (FOB)

Detailed description of examinations, ranking and documentation procedures

Historical control data of clinical pathology testing

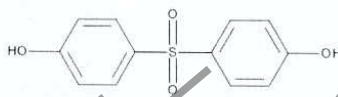
Historical control data of pathology

Competence Center Analytics

Final Report

Characterization of "4,4'-Dihydroxydiphenylsulfon"
Study No. 12L00002 (confidential)

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Test item	4,4'-Dihydroxydiphenylsulfon
Chemical identity	4,4'-Sulfonyldiphenol (DHDPS)
Chemical structure	
Batch identification	69611767J0
Date of production (test item)	Nov 28, 2011
Origin of test item	[REDACTED]
PSN	05/0066-4
CAS no.	80-09-1
Sponsor	[REDACTED]
Date of receipt of order	Dec 07, 2011
Date of receipt of test item	Dec 15, 2011
Testing facility	Competence Center Analytics, BASF SE, D-67056 Ludwigshafen
Study director	[REDACTED]
Storage cond. test item	Room temperature, moisture protection
Test period	Jan 13, 2012 – Feb 28, 2012
Storage of records	GLP archives, Competence Center Analytics
Storage of sample of test item	Archives, Competence Center Analytics

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Final Report
Characterization of "4,4'-Dihydroxydiphenylsulfon"
Study No. 12L00002 (confidential)

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Summary of results

The test item was characterized by spectroscopic and chromatographic methods.

¹H-NMR spectroscopy confirmed the structure of the test item. Furthermore, the test item was imaged by its HPLC fingerprint by reversed-phase chromatography. Two peaks with area fractions >0.1% were present. The main component with 99.3% and 99.5% and a by-product with 0.30% and 0.34% at a wavelength of 230 and 250 nm, respectively.

Quantitative ¹H-NMR spectroscopy using the internal standard method yielded a mean purity of the test item of 99.4 g/100 g.

1 Appearance and Homogeneity

Method	Visual Inspection
Result	The test item was a fine white powder. It was obviously homogeneous.
Date of test	Jan 13, 2012
Head of laboratory	[REDACTED]

2 Identity via ¹H-NMR-Spectroscopy

Method	¹ H-NMR spectroscopy
Apparatus	Bruker DPX 401
Reagents	Solvent: DMSO-d ₆ (Euriso-top) Reference standard: Tetramethylsilane TMS (Cambridge Isotope)
Sample preparation	An adequate mass of the test item was filled into a sample tube and dissolved in DMSO-d ₆ containing TMS.
Test parameters	Measuring frequency = 400 MHz, measuring temperature = 30 °C; further parameters see ¹ H-NMR spectrum page 6
Result	The ¹ H-NMR spectrum shows the expected signals for the given structure (see page 6).
Date of test	Feb 23, 2012
Head of laboratory	[REDACTED]

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Characterization of "4,4'-Dihydroxydiphenylsulfon"
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3 Content of Main Component and By-Products

Method ¹H-NMR spectroscopy with internal standard

Apparatus Bruker DPX 401

Reagents Solvent: DMSO-d₆ (Euriso-top)
Reference standard: Tetramethylsilane TMS (Cambridge Isotope)
Internal standard: 1,3,5-Trimethoxybenzene (Sigma Aldrich)
Purity: 100 % (for calc.)
Mol. weight: 168.19 g/mol

Sample preparation About 11-15 mg test item and about 10-15 mg of internal standard were weighed to the nearest 0.01 mg into sample tubes and dissolved in DMSO-d₆ containing TMS as reference standard.

Test parameters Measuring frequency = 400 MHz, measuring temperature = 30 °C; further parameters see at ¹H-NMR spectrum page 7

Result For quantitation, triplicate measurements were carried out. Evaluation was performed by using three protons/molecule of the internal standard (at ~ 6.1 ppm) and 4 protons/molecule of 4,4'-dihydroxydiphenylsulfone (at ~ 7.7 ppm). Exemplary spectrum see page 7.

Content of 4,4'-dihydroxydiphenylsulfone

Det.	test item		internal standard		Resulting mass fraction [g/100g]
	weight [mg]	peak intensity [area units]	weight [mg]	peak intensity [area units]	
1	11.12	400.00	10.40	420.14	99.4
2	11.70	400.00	15.09	578.85	99.5
3	14.40	400.00	10.29	320.86	99.4
mean					99.4

By-products were not detected.

Date of test Feb 28, 2012

Head of laboratory



Competence Center Analytics

Final Report
Characterization of "4,4'-Dihydroxydiphenylsulfon"
Study No. 12L00002 (confidential)

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4 HPLC Fingerprint

Method Reversed-phase high pressure liquid chromatography with UV detection at two wavelengths and area percent evaluation

Apparatus Automated HPLC system, equipped with an autosampler and a UV/Vis detector, connected to an electronical data processing system

Reagents Acetonitrile (Fluka)
Demineralized water obtained from a Milli-Q system

Sample preparation Approximately 30 mg of test item were weighed into a 25 mL volumetric flask and filled up to the mark with acetonitrile. Afterwards, a 2/25 dilution was carried out with a mixture of acetonitrile/water (1/1 v/v).

Test parameters

Column: LiChrospher 100, RP-18 ec, 5 μ m, 125 x 3 mm (Macherey Nagel)
Mobile phase A: Acetonitrile/water = 10/90 (V/V)
Mobile phase B: Acetonitrile/water = 90/10 (V/V)
Injection volume: 20 μ L
Flow rate: 0.7 mL/min
Oven temperature: 25 $^{\circ}$ C
UV detection: λ = 230 nm, λ = 250 nm

Gradient elution:

time [min]	0	25	30	31	46
A [%]	85	30	30	85	new
B [%]	15	70	70	15	injection

Result

The HPLC fingerprint shows two peaks with area fractions >0.1%. The peak area of the main component corresponds to 99.3 % at 230 nm and 99.5 % at 250 nm. A by-product with 0.30% and 0.34% was detected at 230 and 250 nm, respectively. These values are the means of two determinations. For details see pages 9-10.

For representative chromatograms of blank run and test item at both wavelengths see pages 8-10.

Date of test Jan 18, 2012 – Jan 19, 2012

Head of laboratory

May 21, 2012
Date

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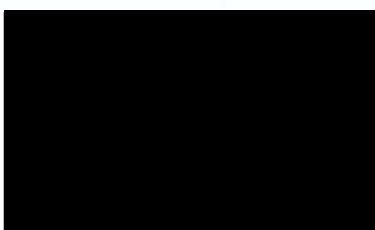
The Chemical Company

Final Report
Characterization of "4,4'-Dihydroxydiphenylsulfon"
Study No. 12L00002 (confidential)

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GLP Compliance Statement

This study was conducted in accordance with the OECD Principles of Good Laboratory Practice and the GLP Principles of the German "Chemikaliengesetz" (Chemicals Act).



May 21, 2012

Date

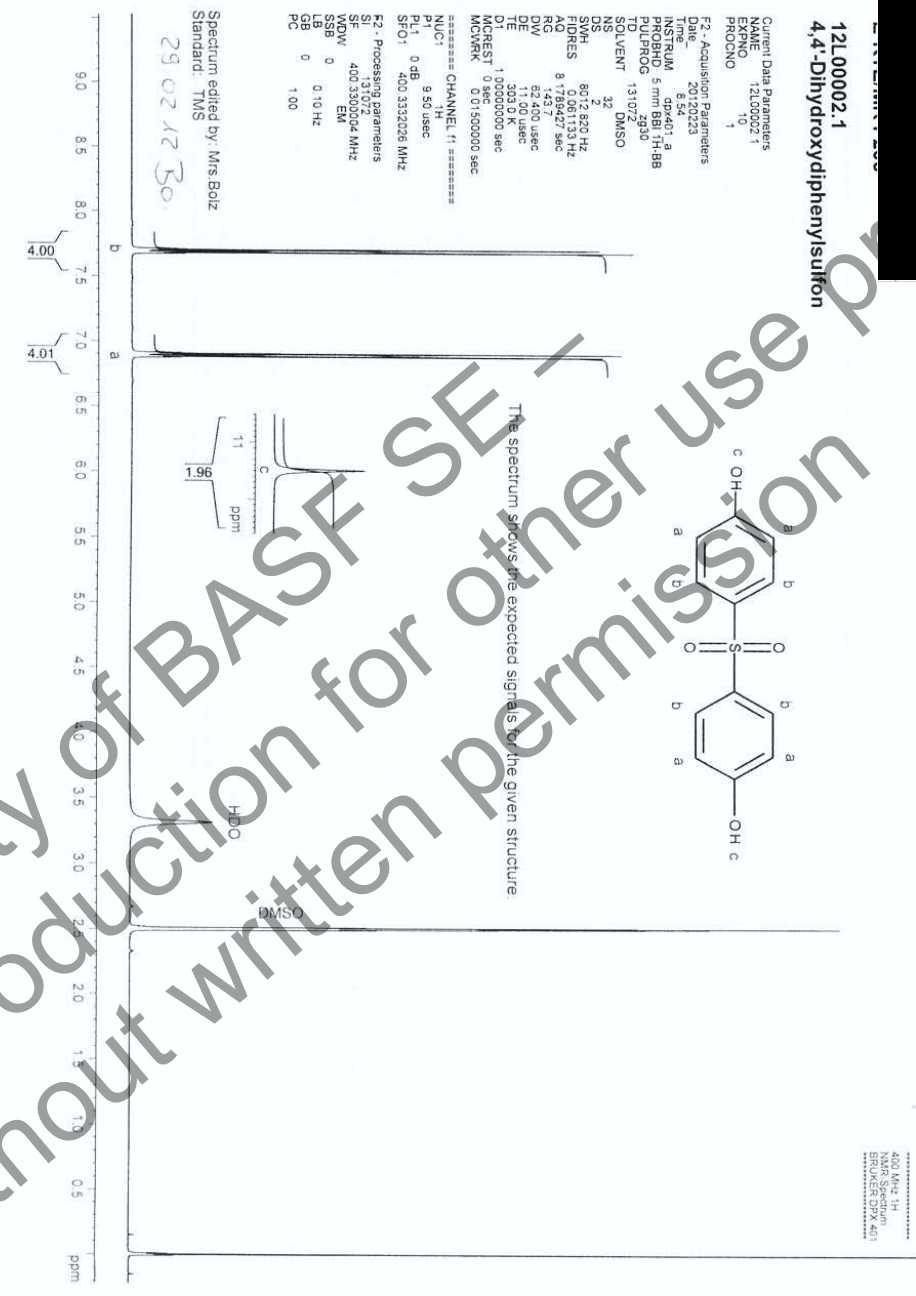
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Characterization of "4,4'-Dihydroxydiphenylsulfon"
Study No. 12L00002 (confidential)

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Identity of test item by ¹H-NMR spectroscopy

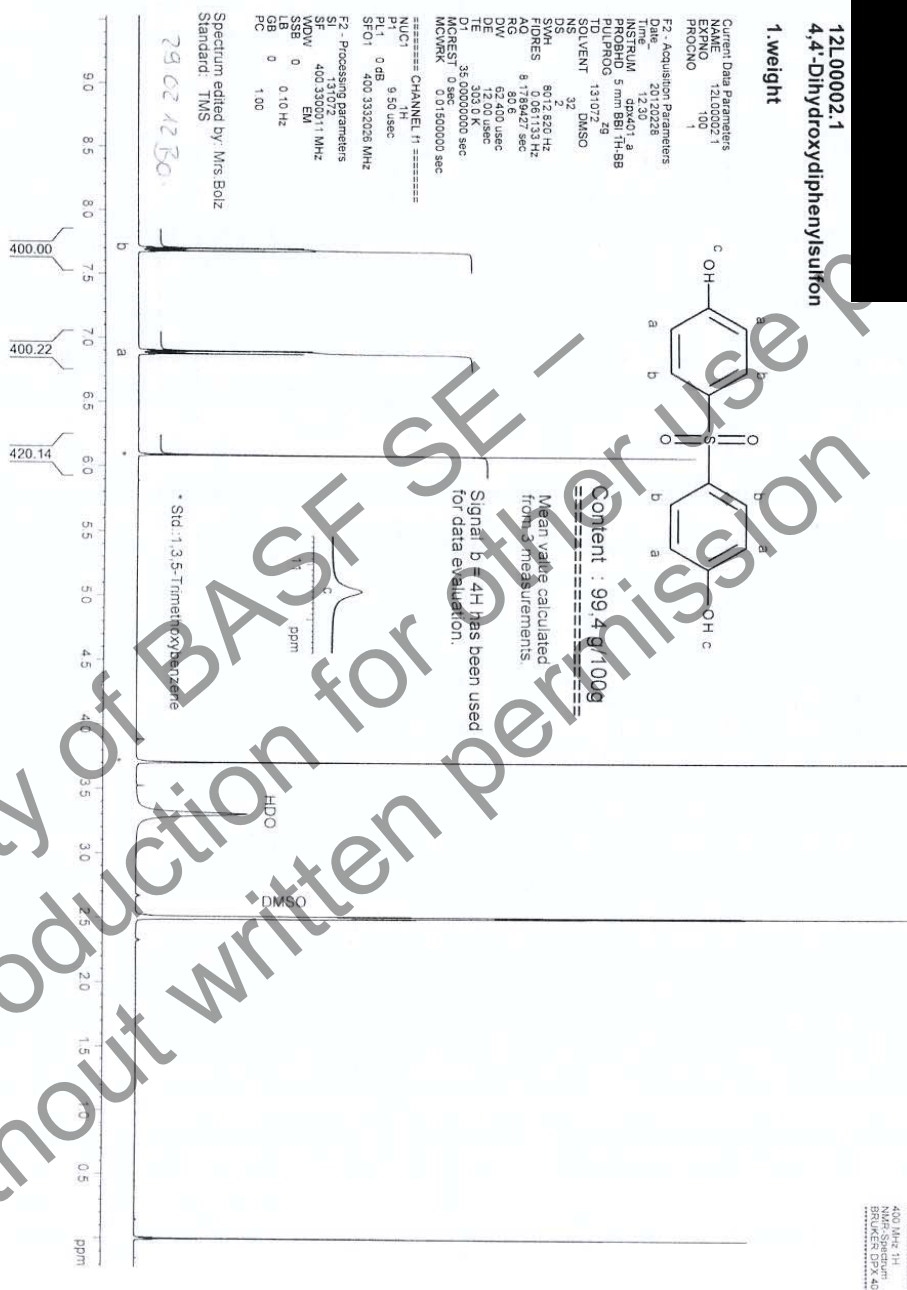


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Characterization of "4,4'-Dihydroxydiphenylsulfon"
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Quantitative ¹H-NMR spectrum of the test item



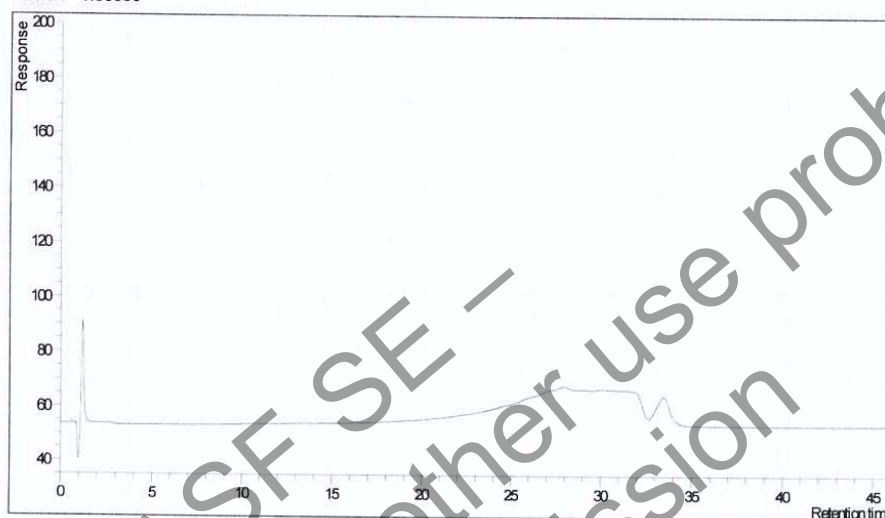
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Characterization of "4,4'-Dihydroxydiphenylsulfon"
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Blank run of HPLC-fingerprint at $\lambda = 230$ nm

Sample : Blindlauf (Acetonitril - 230 nm)
 Conc : 1.00000



Blank run of HPLC-fingerprint at 250 nm

Sample : Blindlauf (Acetonitril - 250 nm)
 Conc : 1.00000



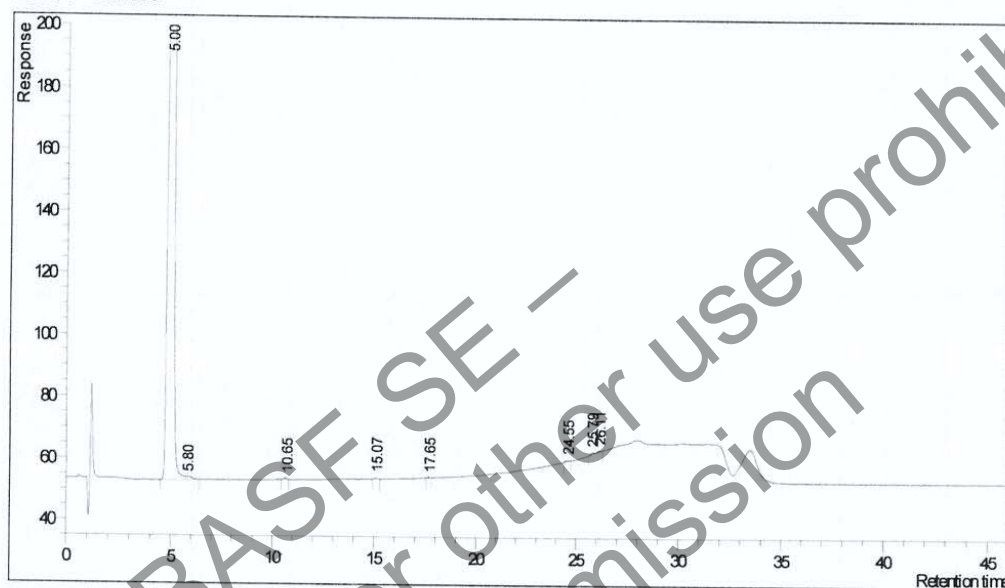
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Final Report
Characterization of "4,4'-Dihydroxydiphenylsulfon"
Study No. 12L00002 (confidential)

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HPLC-fingerprint of test item at 230 nm

Sample : 12L00002 (230 nm) - A
 Conc : 1.00000



Named Peaks					
RT [min]	Height [mV]	Area [mVs]	Area%	Peak Name	
5.000	416.364	6773.860	99.363		BL
5.800	0.953	18.976	0.278		BVU
10.653	0.521	5.218	0.077		BBU
15.073	0.367	3.285	0.048		BBU
17.653	0.235	1.862	0.027		BBU
24.547	0.366	3.884	0.057		BBU
25.793	0.557	6.629	0.097		BVU
26.113	0.332	3.556	0.052		BVU
Sum	419.695	6817.270	99.999		

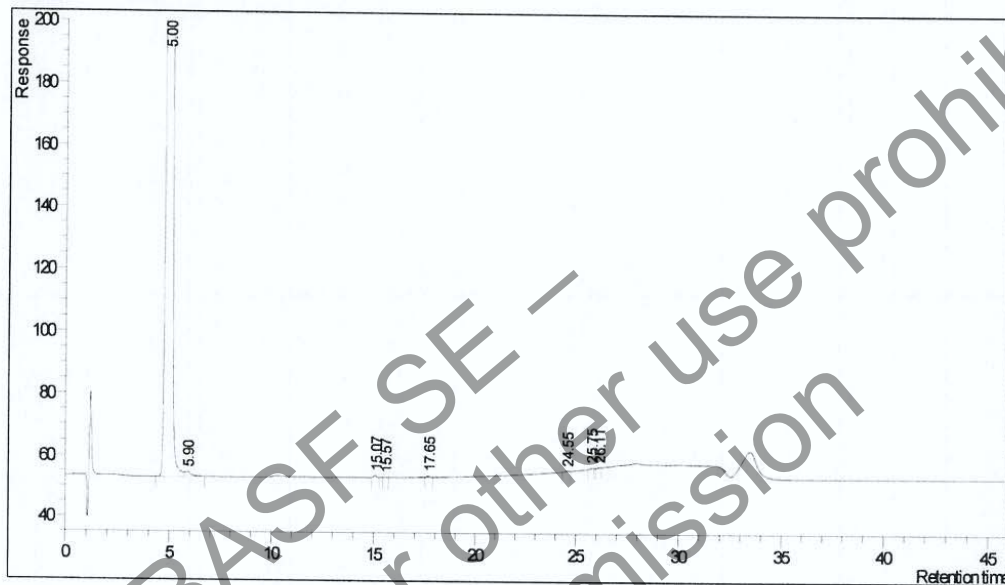
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Final Report
Characterization of "4,4'-Dihydroxydiphenylsulfon"
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HPLC-fingerprint of test item at 250 nm

Sample : 12L00002 (250 nm) - A
 Conc : 1.00000



Named Peaks

RT [min]	Height [mV]	Area [mVs]	Area%	Peak Name	BL
5.000	572.847	9341.446	99.478		BL
5.900	1.531	34.598	0.368		VBV
15.067	0.593	5.153	0.055		BBU
15.573	0.084	0.676	0.007		BBU
17.653	0.348	3.203	0.034		BBU
24.553	0.230	2.925	0.031		BBU
25.747	0.150	1.594	0.017		BBU
26.107	0.106	0.841	0.009		BBU
Sum	575.889	9390.436	99.999		

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Final Report
Characterization of "4,4'-Dihydroxydiphenylsulfon"
Study No. 12L00002 (confidential)

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Statement of the Quality Assurance Unit

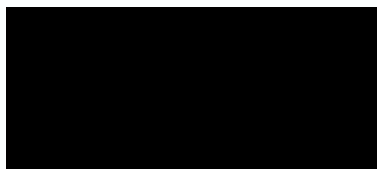
The Quality Assurance Unit inspects the laboratories of the department Competence Center Analytics in regular intervals. Besides these general inspections we inspected the following items of this study in accordance with the OECD Principles of Good Laboratory Practice and the GLP Principles of the German "Chemikaliengesetz" (Chemicals Act). Findings are reported to study director and to management.

Verification of study plan: Jan 10, 2012

Inspection of	Date of inspection	Reported to study director and to management
Conduct of study: HPLC fingerprint	Jan 18, 2012	Jan 18, 2012
Raw data:	May 16, 2012	May 21, 2012
Final report:	May 16, 2012	May 21, 2012

The final report reflects the raw data.

Ludwigshafen



May 21, 2012
Date

STUDY TITLE

ANALYTICAL REPORT

DHDPS

Stability Analysis in

1% Carboxymethylcellulose in Drinking Water

AUTHOR(S)**STUDY COMPLETION DATE**

29 August 2013

TEST FACILITYBASF SE
Experimental Toxicology and Ecology
67056 Ludwigshafen, Germany**TEST FACILITY PROJECT IDENTIFICATION**

Project No.: 01Y0066/05Y009

SPONSORBASF SE
67056 Ludwigshafen, Germany

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GLP COMPLIANCE STATEMENT

This study was conducted in accordance with the OECD Principles of Good Laboratory Practice and the GLP Principles of the German "Chemikaliengesetz" (Chemicals Act) which meet the United States Environmental Protection Agency Good Laboratory Practice Standards [40 CFR Part 160 (FIFRA) and Part 792 (TSCA)], with the exception that recognized differences exist between the GLP Principles/Standards of OECD and the Principles/Standards of FIFRA and TSCA.

Study Director

Typed name of Study Director:

Typed name of Laboratory:



Date: 29 Aug. 2013

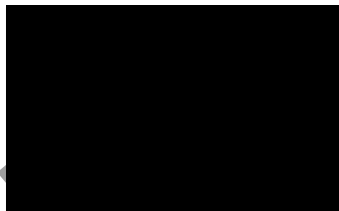
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Experimental Toxicology and Ecology
67056 Ludwigshafen
Germany

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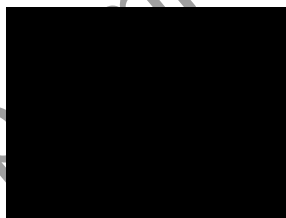
SIGNATURE PAGE

Study Director:



29 Aug. 2013

Management:



27 Aug 2013

STATEMENT OF THE QUALITY ASSURANCE UNIT

The Quality Assurance Unit (QAU) inspected the study and reported any inspection results to the Study Director and to Management.

The final report reflects the raw data.

Phase of study	Date of inspection (mm-dd-yyyy)	Reported to Study Director and to Management (mm-dd-yyyy)
Study Plan:	10-09-2012	10-09-2012
Conduct of study:	10-12-2012	10-12-2012
Report:	08-08-2013	08-08-2013

Ludwigshafen, 29 August 2013

GLP CERTIFICATE (FROM THE COMPETENT AUTHORITY)

Rheinland-Pfalz

Gute Laborpraxis / Good Laboratory Practice

GLP-Bescheinigung / Statement of GLP Compliance
(gem. / according to § 19 Abs. 1 Chemikaliengesetz)

Eine GLP-Inspektion zur Überwachung und der Einhaltung der GLP-Grundsätze gemäß Chemikaliengesetz bzw. Richtlinie 2004/9/EG wurde durchgeführt in:

Assessment of conformity with GLP according to Chemikaliengesetz and Directive 2004/9/EC at::

Prüfeinrichtung / Test facility

BASF SE
Experimentelle Toxikologie und Ökologie
67056 Ludwigshafen

BASF SE
Experimental Toxicology and Ecology
67056 Ludwigshafen, Germany

Prüfung nach Kategorien / Areas of Expertise
(gem. / according ChemVwV-GLP Nr. 53/OECD guidance)
1,2,3,4,5,8,9

Kat. 9 – Biochemische und pathologische Untersuchungen zu Wirkmechanismen /
Biochemical and pathological examinations concerning mode of action

Datum der Inspektion / Date of Inspection
(Tag/Monat/Jahr / day.month.year)
19.05.2009 & 06. bis 08.07.2009

Die genannte Prüfeinrichtung befindet sich im nationalen GLP-Überwachungsverfahren und wird regelmäßig auf Einhaltung der GLP-Grundsätze überwacht.

The above mentioned test facility is included in the national GLP Compliance Programme and is inspected on a regular basis.

Auf der Grundlage des Inspektionsberichtes wird hiermit bestätigt, dass in dieser Prüfeinrichtung die oben genannten Prüfungen unter Einhaltung der GLP-Grundsätze durchgeführt werden können. Eine erneute behördliche Überprüfung der Einhaltung der GLP-Grundsätze durch die Prüfeinrichtung ist so rechtzeitig zu beantragen, dass die Folgeinspektion spätestens vier Jahre nach dem Beginn der o.g. Inspektion stattfinden kann. Ohne diesen Antrag wird die Prüfeinrichtung nach Ablauf der Frist aus dem deutschen GLP-Überwachungsprogramm genommen und diese GLP-Bescheinigung verliert ihre Gültigkeit.

Based on the inspection report it can be confirmed, that the test facility is able to conduct the aforementioned studies in compliance with the Principles of GLP.

Verification of the compliance of the test facility with the Principles of the GLP has to be applied for in time to allow for a follow-up inspection to take place within four years after commencing the above mentioned inspection. Elapsing this term, the test facility will be taken out of the German GLP-Monitoring Programme and this GLP Certificate becomes invalid.

Unterschrift, Datum / Signature, Date


Dr. Pia Hirsch - stellv. Präsidentin -
(Name und Funktion der verantwortlichen Person / name and function of responsible person)

Landesamt für Umwelt, Wasserwirtschaft und Gewerbeaufsicht
Kaiser-Friedrich-Straße 7
55116 Mainz

(Name und Adresse der GLP-Überwachungsbehörde / Name and address of the GLP Monitoring Authority)


Landesamt für Umwelt, Wasserwirtschaft und Gewerbeaufsicht

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CONTENTS

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GLP COMPLIANCE STATEMENT

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SIGNATURE PAGE

STATEMENT OF THE QUALITY ASSURANCE UNIT

GLP CERTIFICATE (FROM THE COMPETENT AUTHORITY)

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5. RESULTS AND DISCUSSION
 - 5.1. ANALYSIS OF STABILITY
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- FIGURES
6. APPENDIX
 - 6.1. CONTROL PROCEDURE 05/0066_01-01

1. INTRODUCTION

In the context of toxicological studies the stability of the test substance DHDPS in the vehicle 1% carboxymethylcellulose in drinking water has to be verified. The results of these analyses are reported and discussed.

2. RETENTION OF RECORDS

GLP-relevant records and materials are stored at BASF SE for at least the period of time specified in the GLP principles. Details concerning responsibilities or locations of archiving can be seen from the respective SOPs and from the raw data.

3. TIME SCHEDULE

Study initiation date:	09 October 2012
Experimental starting date:	12 October 2012
Experimental completion date:	19 October 2012

4. MATERIAL AND METHODS

4.1. TEST ITEM

The analyses of the test item (= test substance) were carried out at the Competence Center Analytics of BASF SE, Ludwigshafen, Germany.

Name of test substance:	DHDPS
Test substance No.:	05/0066-4
Batch identification:	69611767J0
CAS No.:	80-09-1
Purity:	(1) 99.3 and 99.5 %, (HPLC) (2) 99.4 g/100 g, (1H-NMR) (according to the project number 12L00002)
Homogeneity:	Given
Storage stability:	stable until: 28 May 2013 The stability of the test substance under storage conditions over the test period was guaranteed by the sponsor, and the sponsor holds this responsibility.
Additional Test Substance Information	
Date of production:	28 Nov 2011
Physical state/ Appearance:	Solid / white
Storage conditions	Room temperature

4.2. SAMPLE DATA

Sponsor: [REDACTED]
Vehicle: 1% carboxymethylcellulose in drinking water
Target concentration: 0.05 g/100 mL
Duration of the stability test period: 7 days
Storage conditions of the samples during the stability period: Refrigerator

4.3. TEST SUBSTANCE PREPARATION

51.2 mg of the test substance were dissolved in 5 mL acetone. 0.5 mL of this solution were transferred into 100 mL volumetric flasks. After acetone evaporation at room temperature, 10 mL 1% carboxymethylcellulose in drinking water were added. For each time point a sample was prepared. The final nominal concentration was 0.0512 g / 100 mL.

4.4. SAMPLE PREPARATION AND ANALYSIS

The sample preparation and analysis of the test substance was carried out according to the valid control procedure 05/0066_01-01.

A detailed description of the control procedure is given in the appendix of this report.

4.5. LIST OF DEVIATIONS

4.5.1. LIST OF DEVIATIONS FROM THE CONTROL PROCEDURE

There were no deviations from the described control procedure 05/0066_01-01.

5. RESULTS AND DISCUSSION

5.1. ANALYSIS OF STABILITY

The results obtained for the stability of the test substance in 1% carboxymethylcellulose in drinking water are summarized in the following table.

All calculated values in the table are rounded. Calculations were performed with a full set of decimal places.

Nominal concentration [g/100 mL]	Time after starting	Concentration found [g/100 mL]	Nominal concentration (%)
0.0512	0h	0.055	107.3
0.0512	4h	0.053	104.9
0.0512	4d	0.055	108.5

The stability samples from 0 hours until 4 days were stored at room temperature

Nominal concentration [g/100 mL]	Time after starting	Concentration found [g/100 mL]	Nominal concentration (%)
0.0512	7d	0.054	106.6

The stability sample for the duration of 7 days was stored in the refrigerator.

5.2. DISCUSSION

Based on the analytical results it is concluded, that DHDPS is stable in 1% carboxymethylcellulose in drinking water over a period of 4 days at room temperature and 7 days in the refrigerator.

All determined concentrations were in the range of 90 % - 110 % of the nominal concentration.

FIGURES

Figure 1: Chromatogram of matrix solution (measured on 19 Oct 2012)

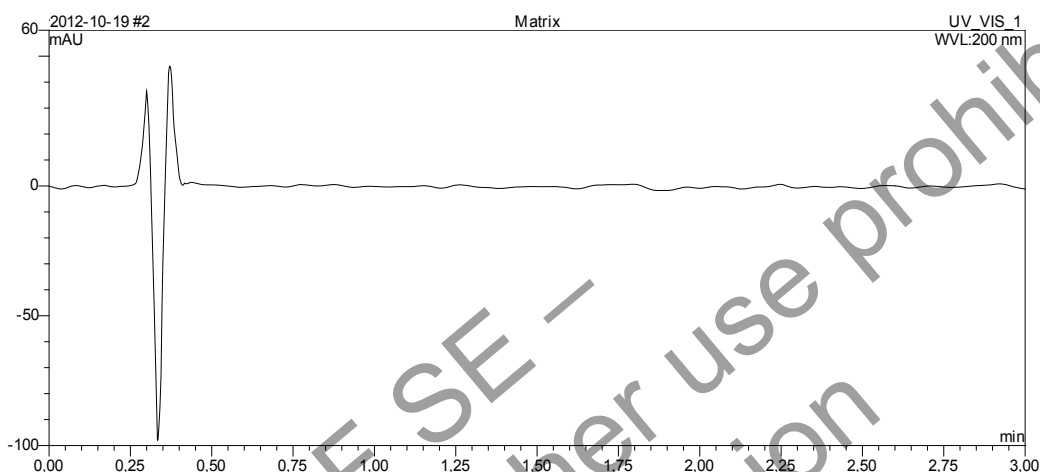


Figure 2: Chromatogram of calibration solution 1 (2.044 mg/100 mL, measured on 19 Oct 2012)

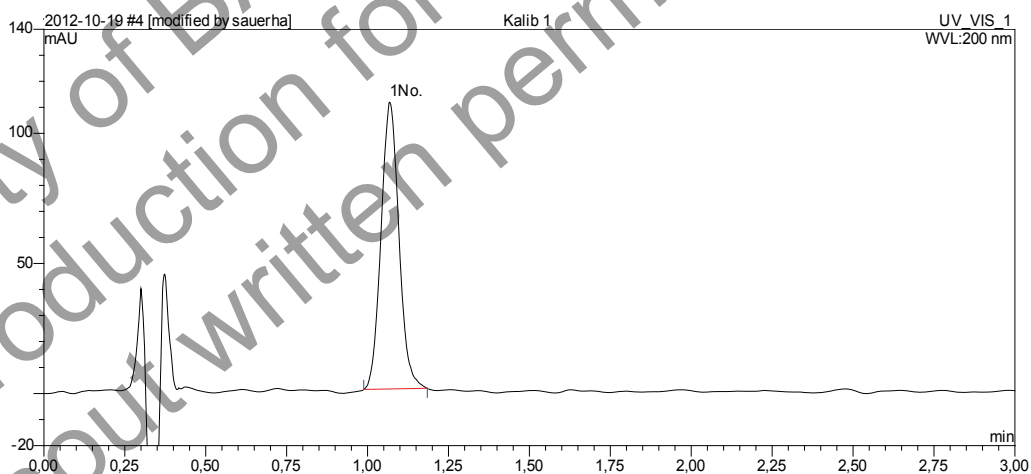


Figure 3: Chromatogram sample solution day 7 (measured on 19 Oct 2012)

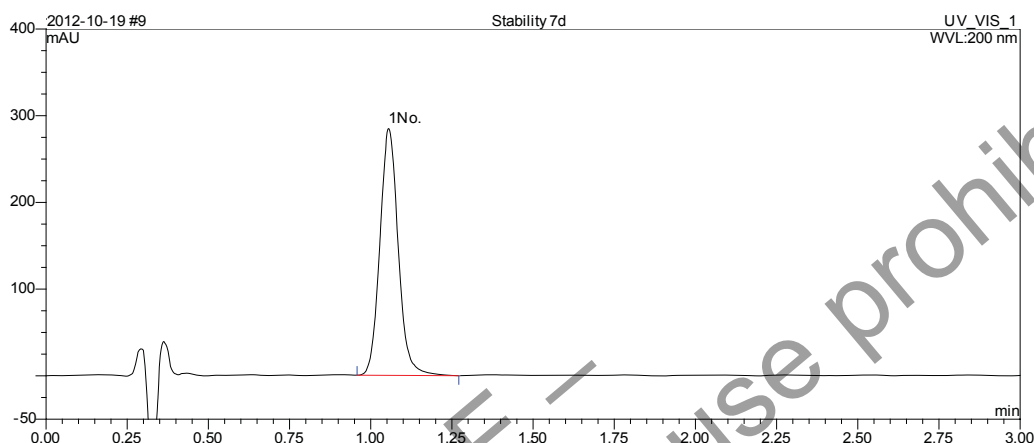
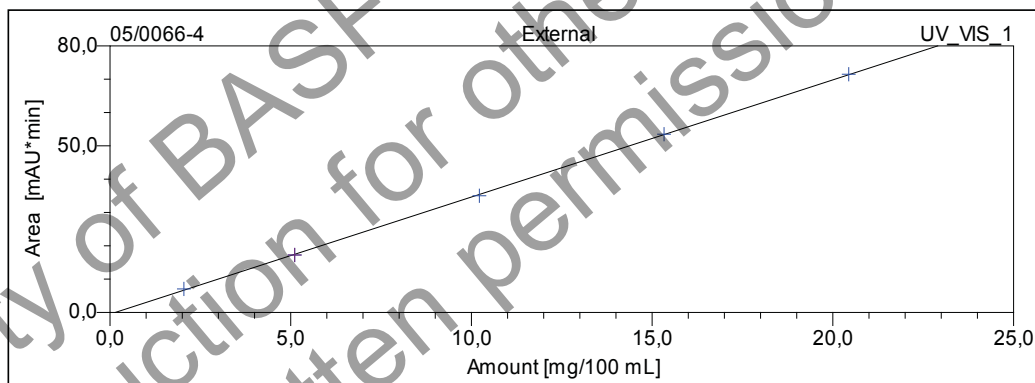


Figure 4: Calibration curve (19 Oct 2012, Concentration range 2.044 – 20.44 mg/100 mL)



6. APPENDIX

6.1. CONTROL PROCEDURE 05/0066_01-01

BASF SE
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Experimental Toxicology and Ecology / Analytical Chemistry



CONTROL TEST

Test substance number: 05/0066	No.: 05/0066_01-01
Name of test substance: DHDPs	Effective from: 09 Oct 2012
Control procedure: Content (LC) / Carboxymethylcellulose(CMC) in drinking water	Page 1 of 5

Technique	HPLC
System:	Waters alliance 2487 with auto sampler, Dionex Chromeleon-Software (Dionex), or equivalent system
Column:	Length: 100 mm Inner diameter: 4.6 mm
Stationary Phase:	Chromolith Performance RP 18e, Merck or equivalent
Mobile Phase A:	1000 mL acetonitrile are mixed with 1 mL formic acid (HCOOH)
Mobile Phase B:	1000 mL water are mixed with 1 mL formic acid (HCOOH)
Isocratic:	
Mobile Phase A 20 %	Mobile Phase B 80 %
Injection volume:	10 µL
Flow rate:	5 mL/min
Detection:	200 nm
Column temperature:	Ambient
Run time:	Approx. 3 min

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Experimental Toxicology and Ecology / Analytical Chemistry

CONTROL TEST

Test substance number: 05/0066	No.: 05/0066_01-01
Name of test substance: DHDPs	Effective from: 09 Oct 2012
Control procedure: Content (LC) / Carboxymethylcellulose(CMC) in drinking water	Page 2 of 5

Sample solution: Samples are diluted completely with methanol using appropriate volumetric flasks to obtain sample solutions with test substance concentrations that match the calibration range.
If required, all dilutions are sonicated for 5 minutes to ensure a complete dissolution of the test substance.

The samples are filtered (cellulose filter, 0.2 µm) prior HPLC analysis.

Annotation: If the amount of test substance in the sample solution is outside the calibration range (calibration solutions 1 – 5), an adequate dilution step with matrix solution has to be performed to match the described concentration range.

Matrix solution: The preparation of the matrix solution has to be performed according to the procedure described for sample solution preparation

Stock solution: Approx. 50 mg test substance are dissolved to a final volume of 100 mL with methanol (50 mg/100 mL)

Calibration solution 1: 1.0 mL stock solution are diluted with matrix solution to 25 mL (2 mg/100 mL)

Calibration solution 2: 1.0 mL stock solution are diluted with matrix solution to 10 mL (5 mg/100 mL)

Calibration solution 3: 1.0 mL stock solution are diluted with matrix solution to 5 mL (10 mg/100 mL)

Calibration solution 4: 1.5 mL stock solution are diluted with matrix solution to 5 mL (15 mg/100 mL)

Calibration solution 5: 2.0 mL stock solution are diluted with matrix solution to 5 mL (20 mg/100 mL)

System-suitability solution: System-suitability solution is prepared with a second independent weighing according to calibration solution 3 (10 mg/100 mL)

Procedure After conditioning the HPLC system, sample solutions, matrix solution, calibration solutions and system-suitability solution are injected according to the sequence described in the raw data. All solutions are injected at least once.

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CONTROL TEST

Test substance number: 05/0066	No.: 05/0066_01-01
Name of test substance: DHDPs	Effective from: 09 Oct 2012
Control procedure: Content (LC) / Carboxymethylcellulose(CMC) in drinking water	Page 3 of 5

Retention time:

Test substance : 4,4'-Dihydroxydiphenylsulfon:
Approx. 1 min

System suitability:

The calculated content of the system-suitability solution has to be in the range from 95 % to 105 %.

The coefficient of determination (R^2) has to be ≥ 0.990 . If the correlation coefficient (R) is used, this value has to be ≥ 0.995 .

Calculation:

The concentration control measurements are based on external calibration (calibration solutions 1 – 5).

The calculation of the content is performed electronically. (e.g. Dionex Chromeleon – Software, Microsoft Excel). Basic formulas for calculations are described below (e.g. Dionex Chromeleon – Software)

Formulas:

Calibration curve

$$Y = a \cdot x + b$$

a = slope of calibration curve
b = intercept

Analysed concentration (C_A)

$$C_A = \frac{(Y-b) \cdot V \cdot d}{a \cdot w}$$

or

$$C_A = \frac{(Y-b)}{a} \cdot \frac{V \cdot d}{v}$$

w = weight sample
V = final sample volume
d = dilution factor

v = volume sample
V = final sample volume
d = dilution factor

Analysed concentration (C_A)

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BASF
The Chemical Company

CONTROL TEST

Test substance number: 05/0066	No.: 05/0066_01-01
Name of test substance: DHDPs	Effective from: 09 Oct 2012
Control procedure: Content (LC) / Carboxymethylcellulose(CMC) in drinking water	Page 4 of 5

Figure 1.1: Example chromatogram matrix solution (08 Oct 2012, Project no.: 01Y0066/05Y009) for illustration

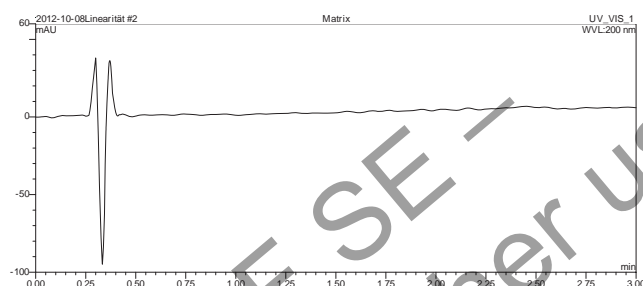
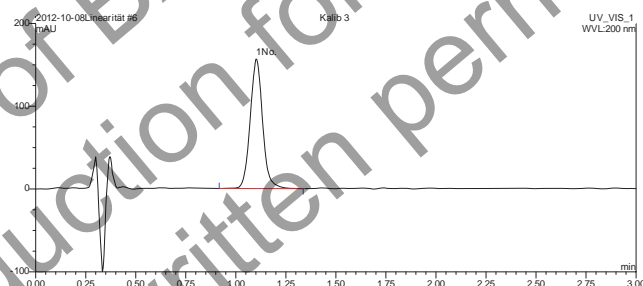


Figure 1.2: Example chromatogram calibration solution (08 Oct 2012, Project no.: 01Y0066/05Y009) for illustration



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Experimental Toxicology and Ecology / Analytical Chemistry



CONTROL TEST

Test substance number: 05/0066

No.: 05/0066_01-01

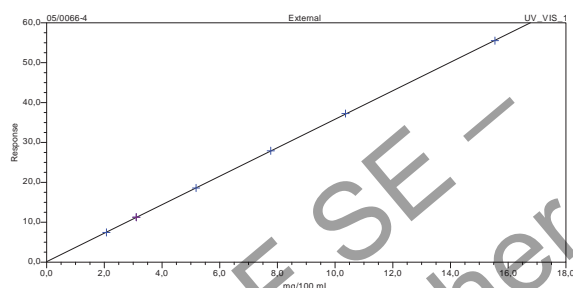
Name of test substance: DHDPs

Effective from: 09 Oct 2012

Control procedure: Content (LC) / Carboxymethylcellulose(CMC) in drinking water

Page 5 of 5

Figure 1.3 Example calibration curve (08 Oct 2012, Project no.: 01Y0066/05Y009) for illustration



Homogeneity and Concentration Control Analysis of DHDPS in 1% carboxymethylcellulose in drinking water

1. PROJECT AND TEST SUBSTANCE INFORMATION

Project No.: 50C0066/05S019

Test item (= test substance): DHDPS

Batch No.: 69611767J0

2. SAMPLE DATA

2.1. HOMOGENEITY AND CONCENTRATION CONTROL ANALYSIS

Vehicle: 1% carboxymethylcellulose in drinking water

Storage conditions of the
samples until analysis: Freezer

3. MATERIAL AND METHODS

3.1. SAMPLE PREPARATION AND ANALYSIS

The sample preparation and analysis of the test substance was carried out according to the valid control procedure 05/0066_01-01 and 05/0066_01-02.

Due to the correction of non quality relevant orthographical failures only the latest version (05/0066_01-02) of the control procedure is described in the appendix.

A detailed description of the control procedure is given in the appendix of this report.

3.2. LIST OF DEVIATIONS

3.2.1. List of deviations from the control procedure

There were no deviations from the described control procedures 05/0066_01-01 and 05/0066_01-02.

4. RESULTS AND DISCUSSION

4.1. HOMOGENEITY AND CONCENTRATION CONTROL ANALYSIS

The results obtained for the homogeneity and concentration control analysis of DHDPS in 1% carboxymethylcellulose in drinking water are summarized in the following tables:

All calculated values in the tables are rounded. Calculations were performed with a full set of decimal places

Date of sample preparation:

20 Aug 2013

Date of sampling:

20 Aug 2013

Date of receipt of sample in analytical laboratory:

20 Aug 2013

Starting date of analytical determination:

27 Aug 2013

Name	Amount	Average	Nominal Conc	Nominal Conc	Mean	RSD
	g/100mL	g/100mL	g/100mL	%	%	%
Sample 3	0.993	0.993	1	99.3%		
Sample 4	0.999	0.999	1	99.9%		
Sample 5	1.005	1.005	1	100.5%	99.9%	0.6%
Sample 6	2.967	2.967	3	98.9%		
Sample 7	10.014	10.014	10	100.1%		
Sample 8	9.989	9.989	10	99.9%		
Sample 9	10.025	10.025	10	100.3%	100.1%	0.2%

Date of sample preparation: **30 Oct 2013**
 Date of sampling: **30 Oct 2013**
 Date of receipt of sample in analytical laboratory: **30 Oct 2013**
 Starting date of analytical determination: **30 Oct 2013**

Name	Amount	Nominal Conc	Nominal Conc
	g/100 mL	g/100 mL	%
Sample 12	6.146	6	102.4%

Date of sample preparation: **19 Nov 2013**
 Date of sampling: **19 Nov 2013**
 Date of receipt of sample in analytical laboratory: **19 Nov 2013**
 Starting date of analytical determination: **21 Nov 2013**

Name	Amount	Nominal Conc	Nominal Conc
	g/100 mL	g/100 mL	%
Sample 15	0.965	1	96.5%
Sample 16	2.970	3	99.0%
Sample 17	6.061	6	101.0%
Sample 18	10.046	10	100.5%

Considering the low relative standard deviation in the homogeneity analysis, it can be concluded that DHDPS was distributed homogeneously in 1% carboxymethylcellulose in drinking water.

No test substance could be detected in the control samples (samples 2 ; 11 , 14) with a concentration of ≥ 30 % of the lowest calibration solution.

The mean values (samples 3 – 5 and samples 7 – 9) and single values (sample 6, sample 12 and samples 15-18) of DHDPS in 1% carboxymethylcellulose in drinking water were found to be in the range of 90 % – 110 % of the nominal concentrations.

These results demonstrated the correctness of the concentrations of DHDPS in 1% carboxymethylcellulose in drinking water.

Figures of the calibration curve and examples of chromatograms will follow within this report.

Figure 1: Chromatogram of matrix solution (measured on 21 Nov 2013)

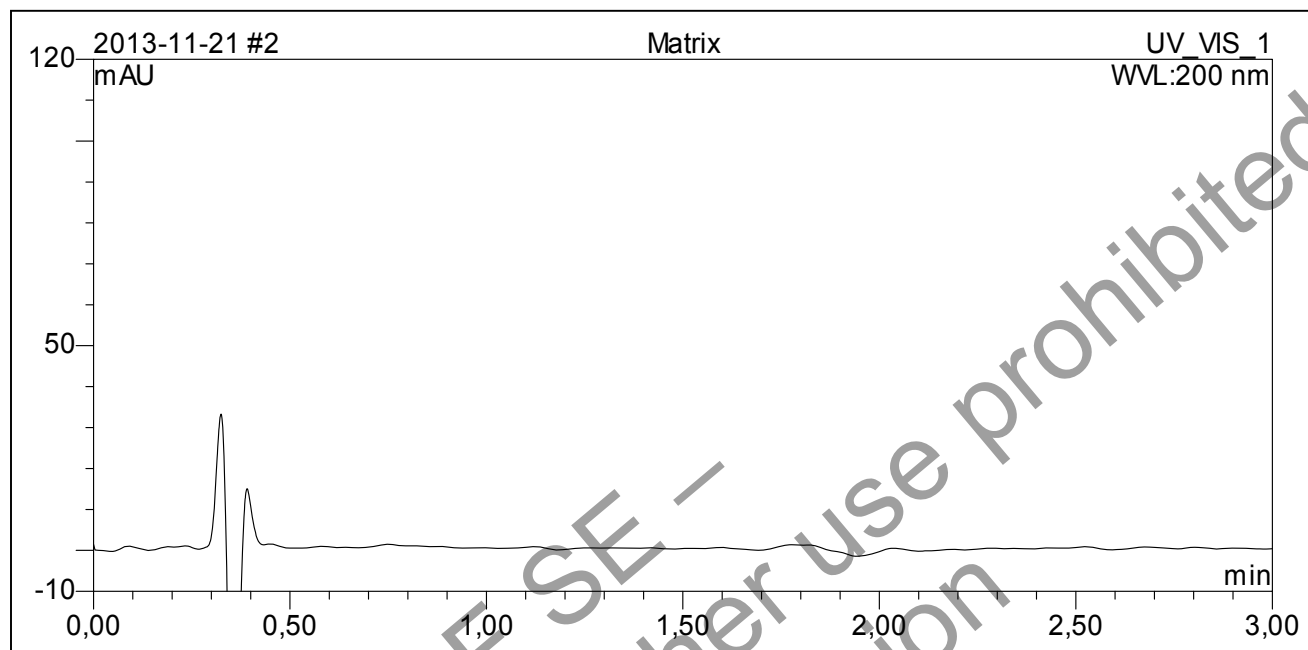


Figure 2: Chromatogram of calibration solution 1 (2.072 mg/100 mL, measured on 21 Nov 2013)

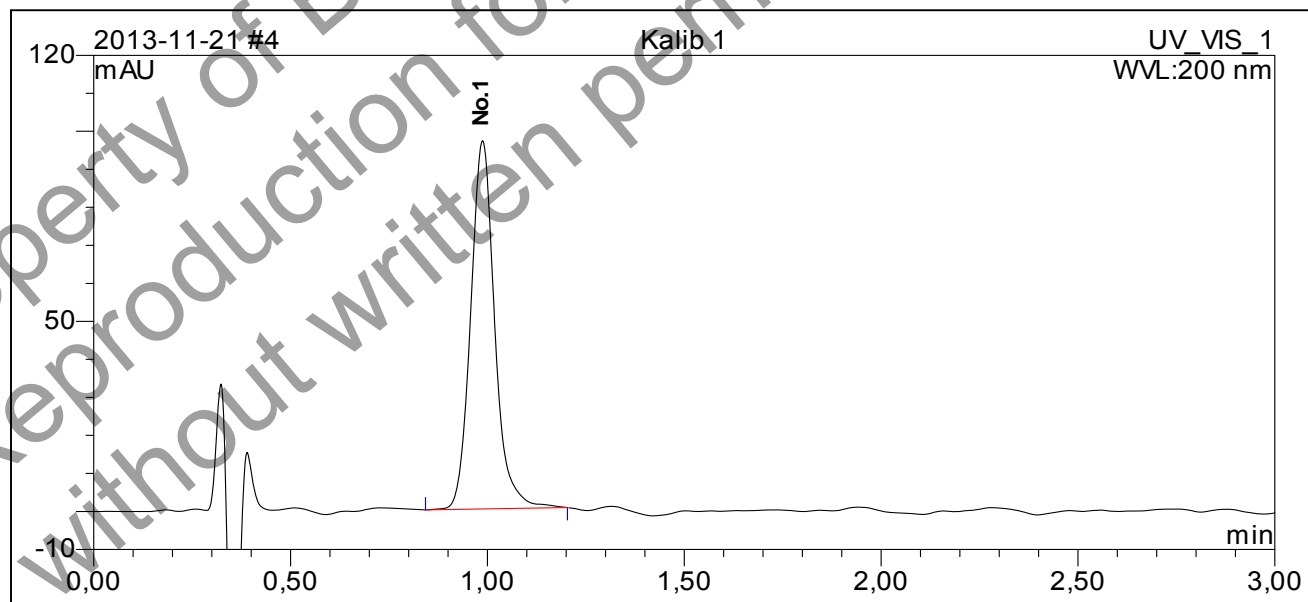


Figure 3: Chromatogram of sample 18 (measured on 21 Nov 2013)

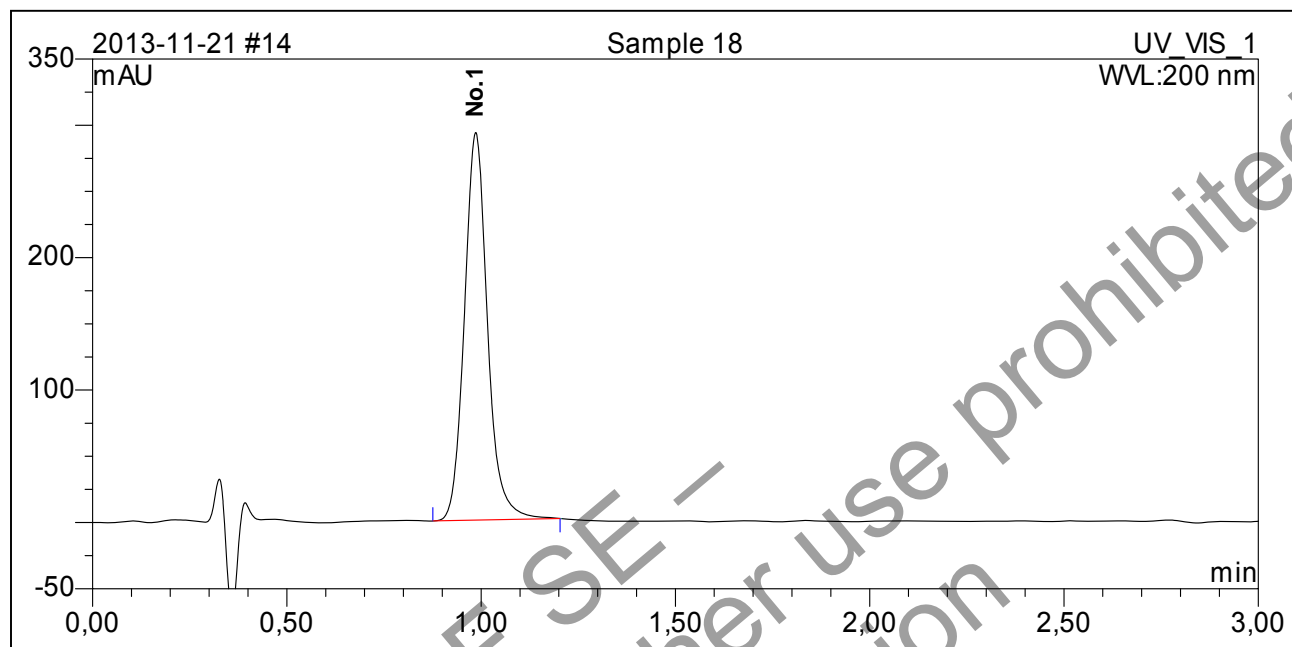
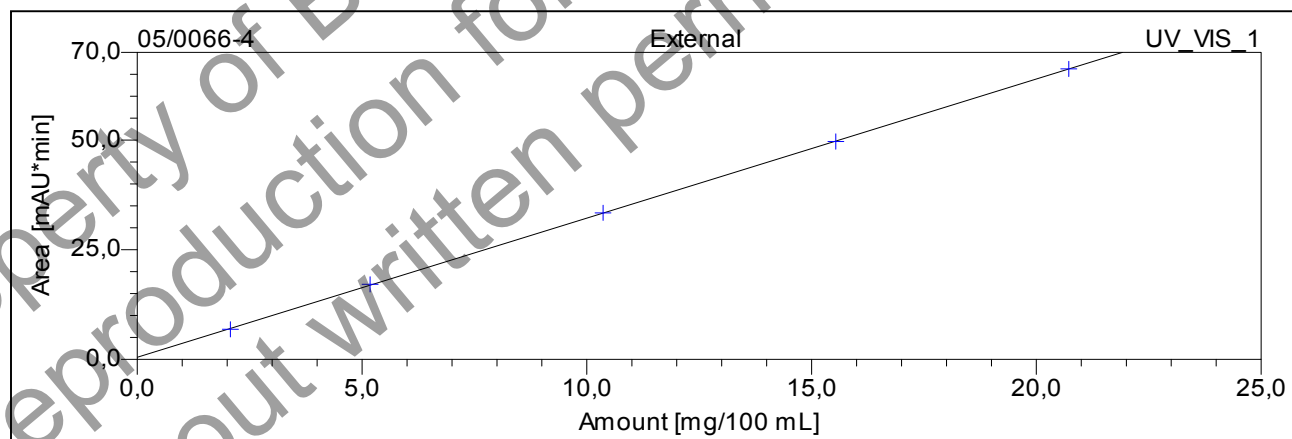


Figure 4: Calibration curve (measured on 21 Nov 2013, Concentration range 2.072 – 20.72 mg/100 mL)



5. APPENDIX

5.1. CONTROL PROCEDURE 05/0066_01-02

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Experimental Toxicology and Ecology / Analytical Chemistry



CONTROL TEST

Test substance number: 05/0066

No.: 05/0066_01-02

Name of test substance: DHDPS

Effective from: 05 Nov 2013

Control procedure: Content (LC) / aqueous carboxymethylcellulose

Page 1 of 5

Technique	HPLC
System:	Waters alliance 2487 with auto sampler, Dionex Chromeleon-Software (Dionex), or equivalent system
Column:	Length: 100 mm Inner diameter: 4.6 mm
Stationary Phase:	Chromolith Performance RP 18e, Merck or equivalent
Mobile Phase A:	1000 mL acetonitrile are mixed with 1 mL formic acid (HCOOH)
Mobile Phase B:	1000 mL water are mixed with 1 mL formic acid (HCOOH)
Isocratic:	
Mobile Phase A 20 %	Mobile Phase B 80 %
Injection volume:	10 µL
Flow rate:	5 mL/min
Detection:	200 nm
Column temperature:	Ambient
Run time:	Approx. 3 min

BASF SE
Test Facility
Experimental Toxicology and Ecology / Analytical Chemistry



CONTROL TEST

Test substance number: 05/0066

No.: 05/0066_01-02

Name of test substance: DHDPs

Effective from: 05 Nov 2013

Control procedure: Content (LC) / aqueous carboxymethylcellulose

Page 2 of 5

Sample solution: Samples are diluted completely with methanol using appropriate volumetric flasks to obtain sample solutions with test substance concentrations that match the calibration range.
If required, all dilutions are sonicated for 5 minutes to ensure a complete dissolution of the test substance.

The samples are filtered (cellulose filter, 0.2 µm) prior HPLC analysis.

Annotation: If the amount of test substance in the sample solution is outside the calibration range (calibration solutions 1 – 5), an adequate dilution step with matrix solution has to be performed to match the described concentration range.

Matrix solution: The preparation of the matrix solution has to be performed according to the procedure described for sample solution preparation

Stock solution: Approx. 50 mg test substance are dissolved to a final volume of 100 mL with methanol (50 mg/100 mL)

Calibration solution 1: 1.0 mL stock solution are diluted with matrix solution to 25 mL (2 mg/100 mL)

Calibration solution 2: 1.0 mL stock solution are diluted with matrix solution to 10 mL (5 mg/100 mL)

Calibration solution 3: 1.0 mL stock solution are diluted with matrix solution to 5 mL (10 mg/100 mL)

Calibration solution 4: 1.5 mL stock solution are diluted with matrix solution to 5 mL (15 mg/100 mL)

Calibration solution 5: 2.0 mL stock solution are diluted with matrix solution to 5 mL (20 mg/100 mL)

System-suitability solution:
System-suitability solution is prepared with a second independent weighing according to calibration solution 3 (10 mg/100 mL)

Procedure After conditioning the HPLC system, sample solutions, matrix solution, calibration solutions and system-suitability solution are injected according to the sequence described in the raw data. All solutions are injected at least once.

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Experimental Toxicology and Ecology / Analytical Chemistry



CONTROL TEST

Test substance number: 05/0066

No.: 05/0066_01-02

Name of test substance: DHDPS

Effective from: 05 Nov 2013

Control procedure: Content (LC) / aqueous carboxymethylcellulose

Page 3 of 5

Retention time:

Test substance: DHDPS:
Approx. 1 min

System suitability:

The calculated content of the system-suitability solution has to be in the range from 95 % to 105 %.

The coefficient of determination (R^2) has to be ≥ 0.990 . If the correlation coefficient (R) is used, this value has to be ≥ 0.995 .

Calculation:

The concentration control measurements are based on external calibration (calibration solutions 1 – 5).

The calculation of the content is performed electronically. (e.g. Dionex Chromeleon – Software, Microsoft Excel). Basic formulas for calculations are described below (e.g. Dionex Chromeleon – Software)

Formulas:

Calibration curve

$$Y = a \cdot x + b$$

a = slope of calibration curve

b = intercept

Analysed concentration (C_A)

$$C_A = \frac{(Y - b) \cdot V \cdot d}{a \cdot w}$$

or

$$C_A = \frac{(Y - b) \cdot V \cdot d}{a \cdot v}$$

w = weight sample

V = final sample volume

d = dilution factor

v = volume sample

V = final sample volume

d = dilution factor

BASF SE
Test Facility
Experimental Toxicology and Ecology / Analytical Chemistry



CONTROL TEST

Test substance number: 05/0066

No.: 05/0066_01-02

Name of test substance: DHDPs

Effective from: 05 Nov 2013

Control procedure: Content (LC) / aqueous carboxymethylcellulose

Page 4 of 5

Figure 1.1: Example chromatogram matrix solution (08 Oct 2012, Project no.: 01Y0066/05Y009) for illustration

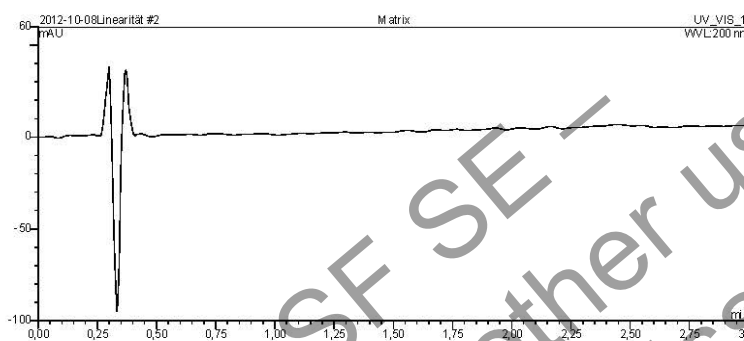
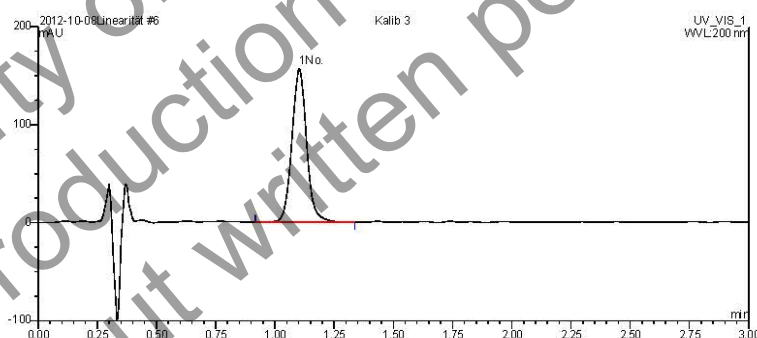


Figure 1.2: Example chromatogram calibration solution (08 Oct 2012, Project no.: 01Y0066/05Y009) for illustration



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Experimental Toxicology and Ecology / Analytical Chemistry



The Chemical Company

CONTROL TEST

Test substance number: 05/0066

No.: 05/0066_01-02

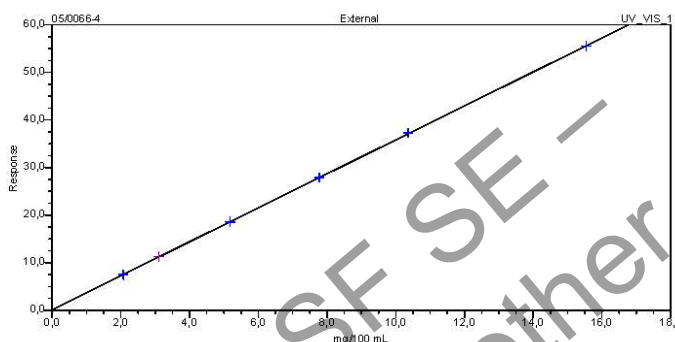
Name of test substance: DHDPS

Effective from: 05 Nov 2013

Control procedure: Content (LC) / aqueous carboxymethylcellulose

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Figure 1.3 Example calibration curve (08 Oct 2012, Project no.: 01Y0066/05Y009) for illustration



weg142

Functional Observational Battery (FOB):
Detailed description of examinations, ranking and documentation procedures

The following describes in detail the scope of examinations and the ranking of the findings.

HOME CAGE OBSERVATIONS:

Posture

The posture of the animals is examined for any abnormal findings.

Ranking:

- 0 animal is sitting or lying
- 1 animal is staying and moving
- 2 squatting posture
- 3 abdominal position
- 4 abdominal position with splayed limbs
- 5 lateral position
- 6 oblique head posture
- 7 opisthotonus

Tremors

Any tremors are documented.

Ranking:

- 0 no tremors
- 1 slight tremors
- 2 moderate tremors
- 3 severe tremors

Convulsions

If convulsions are seen, the severeness is assessed. If possible, also the type of convulsions, i.e. clonic (alternate muscular contraction and relaxation in rapid succession) or tonic (characterized by continuous tension) is documented.

Ranking:

- 0 no convulsions
- 1 slight convulsions
- 2 moderate convulsions
- 3 severe convulsions

Abnormal movements

Any abnormal movement or bizarre behaviour is documented.

Ranking:

- 0 no abnormalities
- 1 mane movements
- 2 head shaking
- 3 excessive cleaning
- 4 frequent chewing

Impairment of gait

Any abnormal movement or bizarre behavior is documented.

Ranking:

- 0 animal is not walking during observation
- 1 no impairment of gait
- 2 stiff gait
- 3 slight impairment of coordination, unsteady gait
- 4 moderate impairment of coordination, shuffling gait
- 5 severe impairment of coordination, dragging of the hindlimbs
- 6 severe impairment of coordination, with splayed limbs
- 7 animal is unable to walk (abdominal or lateral position)

Other findings*Ranking:*

- 0 no other findings
- * If findings appear which are not included in this grading system, they are described

Page 3

Functional observational battery

OPEN FIELD OBSERVATIONS**Behavior when removed from cage**

The animal is removed from the home cage, and the reaction is documented.

Ranking:

- 0 animal is tense, but it shows no resistance against handling
- 1 animal shows a slight resistance against the handling
- 2 animal shows no resistance against the handling but appears indifferent
- 3 animal is difficult to handle, it shows aggressiveness
- 4 animal is very difficult to handle, it shows severe aggressiveness

Fur

The fur of the animals is examined for any abnormal signs.

Ranking:

- 0 nothing abnormal detected
- 1 discolored fur
- 2 urine staining of anogenital region
- 3 Piloerection
- 4 Alopecia
- 5 reduced care on fur

Skin

The visible parts of the skin (e.g. nose) are examined for any abnormal signs.

Ranking:

- 0 nothing abnormal detected
- 1 discolored skin
- 2 reddening
- 3 paleness
- 4 Dehydration (exsiccosis)
- 5 Hypothermia (skin is cold during handling)
- 6 lesion(s)
- 7 crust(s)

Page 4

Functional observational battery

Salivation

The area around the mouth is examined for signs of discharge; if possible, also the color of discharge is documented.

Ranking:

- 0 no salivation
- 1 slight salivation (area around the mouth is moist)
- 2 moderate salivation (wet mouth)
- 3 severe salivation (mouth very wet, wet paws)

Nose discharge

Any discharge is documented.

Ranking

- 0 no discharge, dry nose
- 1 clear discharge
- 2 reddish discharge

Lacrimation

Any lacrimation or secretion of pigmented tears is documented. If possible, the color of the tears is also assessed.

Ranking:

- 0 no lacrimation
- 1 slight lacrimation
- 2 moderate lacrimation
- 3 severe lacrimation

Eyes/Pupils size*Ranking:*

- 0 Nothing abnormal detected, pupils contracted at room light
- 1 Chromodacryorrhea
- 2 Exophthalmus
- 3 Pupils dilated
- 4 Abnormal shape of pupils
- 5 Oblique eye posture
- 6 Opacity
- 7 Cataract

Page 5

Functional observational battery

Posture

The posture of the animals is examined for any abnormal findings.

Ranking:

- 0 animal is sitting or lying
- 1 animal is staying and moving
- 2 squatting posture
- 3 abdominal position
- 4 Abdominal position with splayed limbs
- 5 lateral position
- 6 oblique head posture
- 7 Opisthotonus

Palpebral closure

The level of eyelid closure is examined. Usually, the eyelids of rats are completely opened (except when blinking).

Ranking:

- 0 nothing abnormal detected
- 1 eyelid(s) slight closure
- 2 eyelid(s) half closure
- 3 eyelid(s) permanent closure

Respiration

The respiration is examined for any abnormalities.

Ranking:

- 0 nothing abnormal detected
- 1 respiration labored
- 2 gasping/respiratory sounds
- 3 respiration accelerated
- 4 respiration irregular

Tremors

Any tremors are documented.

Ranking:

- 0 no tremors
- 1 slight tremors
- 2 moderate tremors
- 3 severe tremors

Convulsions

If convulsions are seen, the severeness is assessed. If possible, also the type of convulsions, i.e. clonic (alternate muscular contraction and relaxation in rapid succession) or tonic (characterized by continuous tension) is documented.

Ranking:

- 0 no convulsions
- 1 slight convulsions
- 2 moderate convulsions
- 3 severe convulsions

Abnormal movements/stereotypy

Any abnormal movements or bizarre behavior are documented

Ranking:

- 0 no abnormalities
- 1 manege movements
- 2 head shaking
- 3 excessive cleaning
- 4 frequent chewing

Impairment of gait

If any impairment of gait is observed, the type and severeness is documented. Different types of gait impairment are ataxia (irregularity of muscular action), paralysis (loss of motor function) and paresis (slight or incomplete paralysis). If possible, also the affected limbs (forelimbs, hindlimbs) are documented.

Ranking:

- 0 animal is not walking during observation
- 1 no impairment of gait
- 2 stiff gait
- 3 slight impairment of coordination, unsteady gait
- 4 moderate impairment of coordination, shuffling gait
- 5 severe impairment of coordination, dragging of the hindlimbs
- 6 severe impairment of coordination, with splayed limbs
- 7 animal is unable to walk (abdominal or lateral position)

Activity/Arousal level

The activity of the animals in the open field and the arousal level is examined for any deviation from normal.

Ranking:

- 0 Normal exploration of the area
- 1 reduced exploration of the area
- 2 Severe reduced exploration of the area, animal apathetic
- 3 Increased exploration of the area, sudden or jerky movements
- 4 Hyperactivity

Feces excreted during the observation period

The appearance and consistency of the feces are described. The number of scybala is documented separately.

Ranking:

- 0 no defecation during observation period
- 1 Feces without abnormalities
- 2 discolored feces
- 3 crumbly feces
- 4 soft feces
- 5 muicid feces
- 6 diarrhea

Urine excreted during the observation period

The amount and color of the urine is described.

Ranking:

- 0 no urination during observation period
- 1 urine without abnormalities (some wet areas on the filter paper)
- 2 discoloration of urine
- 3 polyuria (great wet areas on the filter paper)

Number of rearings

In the open field, the animals usually rear several times in order to explore the new environment. A rear is counted, if both forelimbs are removed from the floor. The number of rearings is counted within a 2 minute observation period.

Ranking:

- (number)

SENSORY-MOTORIC TEST/REFLEXES**Approach response**

A stick is approached slowly to the head of the animal. Normal reaction of the animal is to approach to the object or to ignore the object.

Ranking:

- 0 no reaction
- 1 approaching to object
- 2 escape reaction
- 3 aggressive reaction and attacking of object

Touch Response

The animal is touched with a stick along the flank. Normal reaction is to orientate to the stimulus or to ignore the stimulus.

Ranking:

- 0 no reaction
- 1 orientation to the stimulus
- 2 escape after touch
- 3 aggressive reaction and attacking of object
- 4 reaction to the stimulus but no ability to localize (e.g. turning to wrong side)

Vision ("visual placing response")

The animal is held on the tail and moved slowly towards the wire cover of a cage. Normal reaction of the animal is to stretch the forelimbs in order to grasp the object.

Ranking:

- 0 nothing abnormal detected (grasping with forelimbs)
- 1 no grasping

Pupillary reflex

The capacity of the pupils to adapt to darkness and to light is examined. The animals are put into a dark box for about 10 seconds and the pupils are examined using an electric torch. Normally, the pupil dilates in the dark and contracts immediately in the light.

Ranking:

- 0 nothing abnormal detected, physiological adaptation of the pupil to light
- 1 retarded adaptation of the pupil to light
- 2 no adaptation of the pupil to light, pupils permanently contracted
- 3 no adaptation of the pupil to light, pupils permanently dilated

Pinna reflex

The pinna of the animal is touched with a small bristle. Normally, the animal jerks the pinna or head immediately after the stimulus.

Ranking:

- 0 immediate response to the stimulus
- 1 no response to the stimulus

Audition ("startle response")

The animal is exposed to a sharp, electrically produced noise and the reaction to the sound is tested. Normally the animal shows a startle response (e.g. moving the ears, jerking, jumping backwards).

Ranking:

- 0 nothing abnormal detected, immediate normal response to the stimulus
- 1 no response
- 2 increased response
- 3 hyperreaction

Coordination of movements ("righting response")

The animal is turned into dorsal position and released. Normal reaction is that the animal immediately turns to an upright position.

Ranking:

- 0 nothing abnormal detected, immediate righting response
- 1 retarded righting response
- 2 fails to turn into upright position, animal stays in lateral position
- 3 no righting response, animal stays in dorsal position

Behavior during handling*Ranking:*

- 0 normal behavior, easy to handle, animal is tense, but it shows no resistance against handling
- 1 very easy to handle, animal is limply hanging in the hand
- 2 slightly difficult to handle, animal shows a slight resistance against handling
- 3 difficult to handle, animal shows a severe resistance against handling

Vocalization*Ranking:*

- 0 No or only sporadic vocalizations when touched
- 1 very frequent vocalizations when touched
- 2 vocalizations always when touched
- 3 vocalization without touching

Pain perception ("tail pinch")

The tip of the tail is squeezed with a forceps. Normally the animal responds to the stimulus, e.g. it moves away.

Ranking:

- 0 nothing abnormal detected, immediate response to the stimulus
- 1 weak or retarded reaction to the stimulus
- 2 no response to the stimulus
- 3 hyperreaction to the stimulus

Other findings*Ranking:*

- 0 no other findings
- * If findings appear which are not included in this grading system, they are described

Grip strength of forelimbs and hindlimbs

Measurement of grip strength is performed according to the method described by Meyer et al. 1979 (Neurobehavioral Toxicology, 1, 233-236):

The animal is brought into a position that forelimbs/hindlimbs are able to grip the metal bar of a newtonmeter. Then the animal is pulled gently backwards until it releases the grid. The average of two measurements is taken for each hindlimbs and forelimbs.

Documentation:

- (number)

Landing foot splay test

The animal is held about 30 cm above and dropped onto a flat area covered with putty. This results in clearly visible footprints. The distance between the fourth digits of the left and right hindlimb is measured. The average of two measurements is taken for each rat.

Documentation:

- (number)

GENERAL REMARK:

Details of localization or color, or detailed descriptions of findings (e.g. tonic or clonic convulsions) are to be described using an abbreviation (letter or a combination of letters), if they are not already given in the SOP.

HISTORICAL CONTROL DATA OF CLINICAL PATHOLOGY TESTING¹⁾

Species: Rat
Sex: Male
Strain: Wistar
Age: 18 weeks
Study period: 3 months
Fasting before blood sampling: 16 hours
Anaesthesia: Isoflurane
Data print out at: 24-Jan-14
Clinical Chemistry Instrument: Hitachi 917, Roche
Haematology Analyzer: ADVIA 120, Bayer

Parameter:				WBC	NEUT	LYMPH	LYMPH	LUC	ALT	INP	GLUC
Unit:				GIGA/L	%	%	GIGA/L	GIGA/L	MYKAT/L	MMOL/L	MMOL/L
Study No,	Animals examined	administra tion via	Sampling month								
01170	10	diet	06/05	5.87	14.0	81.7	4.83	0.04	0.46	1.82	6.56
04076	10	diet	04/06	6.21	13.3	81.8	5.11	0.03	0.51	1.84	6.60
04066	10	diet	09/05	5.89	14.8	81.3	4.81	0.02	0.50	1.96	6.64
03078	10	diet	12/05	6.49	16.2	77.9	5.05	0.03	0.57	1.90	7.16
04072	10	diet	01/06	5.33	17.5	77.6	4.13	0.02	0.55	1.90	7.01
03085	15	gavage	08/06	5.33	18.1	76.5	4.11	0.02	0.47	1.61	6.99
05056	10	diet	09/06	6.25	17.1	77.2	4.81	0.02	0.57	1.92	6.42
05071	10	diet	05/07	5.62	16.5	79.3	4.49	0.01	0.61	1.71	5.90
06071	10	diet	07/07	5.41	16.3	79.1	4.30	0.03	0.81	1.79	6.13
07010	10	diet	08/07	6.48	17.5	77.5	5.04	0.03	0.63	1.73	6.32
01224	10	diet	09/07	5.97	18.6	75.9	4.56	0.03	0.71	1.73	5.55
05083	10	gavage	09/07	5.16	16.8	78.4	4.06	0.02	0.68	1.63	5.84
06084	10	gavage	11/07	5.04	15.8	78.4	3.96	0.03	0.67	1.80	5.78
06085	10	gavage	11/07	5.57	17.2	77.9	4.35	0.02	0.73	1.61	5.90
07091	10	diet	07/08	5.44	23.6	71.5	3.99	0.01	0.80	1.53	5.72
07097	15	gavage	09/08	4.95	21.1	73.0	3.64	0.01	0.76	1.51	6.32
07098	15	gavage	09/08	4.26	20.9	74.2	3.20	0.01	0.76	1.53	5.89
08020	10	diet	10/08	5.97	24.3	70.3	4.20	0.02	0.82	1.68	5.99
04114	10	inhalation	12/08	5.02	25.4	69.8	3.55	0.02	0.94	1.64	5.11
04117	10	diet	01/09	4.90	16.4	79.1	3.87	0.02	0.75	1.70	5.83
99178	10	diet	02/09	5.05	19.2	75.4	3.80	0.02	0.74	1.63	5.75
01233	10	diet	02/09	4.96	16.7	78.7	3.91	0.02	0.75	1.76	5.62
01236	10	drinking	07/09	6.25	16.4	78.6	4.98	0.03	0.69	1.79	6.42
07128	10	diet	09/09	5.80	23.5	71.4	4.17	0.02	0.66	1.67	6.50
05118	10	inhalation	11/09	4.81	22.5	73.3	3.54	0.02	0.91	1.68	5.50
08076	10	diet	11/09	4.85	18.2	78.6	3.82	0.02	0.59	1.87	6.06
09030	10	diet	12/09	5.86	18.4	76.8	4.52	0.02	0.81	1.74	6.41
07119	10	diet	04/09	4.94	18.1	77.4	3.86	0.02	0.67	1.77	6.63
08C004	10	diet	09/10	5.39	15.0	81.2	4.41	0.02	0.81	1.69	6.92
08S001	10	gavage	08/10	4.36	16.0	79.3	3.46	0.02	0.61	1.55	6.56
02I001	10	inhalation	07/10	3.71	22.9	72.2	2.71	0.02	0.71	1.36	6.18
06S003	10	gavage	12/10	4.49	17.9	77.9	3.51	0.01	0.62	1.60	6.41
07C018	10	diet	12/10	3.78	25.5	70.3	2.68	0.01	0.74	1.49	6.29
N				33	33	33	33	33	33	33	33
Mean				5.32	18.5	76.7	4.10	0.02	0.69	1.70	6.21
Minimum				3.71	13.3	69.8	2.68	0.01	0.46	1.36	5.11
Maximum				6.49	25.5	81.8	5.11	0.04	0.94	1.96	7.16

1) Source: All data were collected and archived at the test facility Experimental Toxicology and Ecology, BASF SE, 67056 Ludwigshafen, Germany, in accordance with the OECD principles of Good Laboratory Practice (GLP) and the GLP principles of the German "Chemikaliengesetz" (Chemicals Act)

HISTORICAL CONTROL DATA OF CLINICAL PATHOLOGY TESTING ¹⁾

Species: Rat
Sex: Female
Strain: Wistar
Age: 18 weeks
Study period: 3 months
Fasting before blood sampling: 16 hours
Anaesthesia: Isoflurane
Data print out at: #####
Clinical Chemistry Instrument: Hitachi 917, Roche
Haematology Analyzer: ADVIA 120, Bayer

Parameter: MCHC GLUC
Unit: MMOL/L MMOL/L

Study No,	Animals examined	Administration via	Sampling month	MCHC MMOL/L	GLUC MMOL/L
01170	10	diet	06/05	21.57	5.95
04076	10	diet	04/06	22.97	6.11
04066	10	diet	09/05	22.24	5.87
03078	10	diet	12/05	22.26	6.22
04072	10	diet	01/06	23.13	5.92
03085	15	gavage	08/06	23.28	6.05
05056	10	diet	09/06	23.72	5.72
05071	10	diet	05/07	22.34	5.11
06071	10	diet	07/07	23.19	5.95
07010	10	diet	08/07	23.39	5.31
01224	10	diet	09/07	23.48	5.15
05083	10	gavage	09/07	23.82	5.79
06084	10	gavage	11/07	23.32	5.76
06085	10	gavage	11/07	23.65	5.24
07091	10	diet	07/08	22.74	5.41
07097	15	gavage	09/08	22.59	5.12
07098	15	gavage	09/08	22.20	6.03
08020	10	diet	10/08	22.50	5.23
04114	10	inhalation	12/08	22.50	4.96
04117	10	diet	01/09	22.59	5.75
99178	10	diet	02/09	22.25	5.82
01233	10	diet	02/09	22.17	5.11
01236	10	drinking	07/09	22.60	5.44
07128	10	diet	09/09	22.06	5.52
05118	10	inhalation	11/09	22.70	4.93
08076	10	diet	11/09	22.11	5.20
09030	10	diet	12/09	22.44	5.52
07119	10	diet	04/09	22.23	5.58
08C004	10	diet	09/10	21.04	5.68
08S001	10	gavage	08/10	23.61	5.84
02I001	10	inhalation	07/10	22.79	5.67
06S003	10	gavage	12/10	20.91	5.25
07C018	10	diet	12/10	20.77	5.58
N				33	33
Mean				22.58	5.57
Minimum				20.77	4.93
Maximum				23.82	6.22

1) Source: All data were collected and archived at the test facility Experimental Toxicology and Ecology, BASF SE, 67056 Ludwigshafen, Germany, in accordance with the OECD principles of Good Laboratory Practice (GLP) and the GLP principles of the German "Chemikaliengesetz" (Chemicals Act)

Historical Control Data

Wistar
Ovaries - f

4/11/2009 - 4/11/2014

Species rat

Duration 3 months

study	application	study start	study end	No	abs. in mg	SD abs. in mg	rel.wght	SD rel.wght	age	supplier
02I001	inhalation head	4/1/2010	7/1/2010	10	98.800	15.845	0.046	0.006	8-9 weeks (56-63 days)	Charles River Deutschland
03S007	gavage	12/1/2012	8/1/2013	10	113.800	16.558	0.049	0.008	42 days	Charles River Deutschland
05I118	inha chamber	8/1/2009	11/1/2009	10	87.600	16.534	0.043	0.007	8-10 weeks (56-70 days)	Charles River Deutschland
05I006	inhalation head	9/1/2011	12/1/2011	10	104.700	12.979	0.047	0.005	7-8 weeks (49-56 days)	Charles River Deutschland
06S003	gavage	9/1/2010	12/1/2010	10	82.600	12.186	0.038	0.006	42 days	Charles River Deutschland
07C018	feeding	9/1/2010	12/1/2010	10	90.300	14.908	0.039	0.007	42 days	Charles River Deutschland
07C035	gavage	10/1/2011	1/1/2012	9	93.444	12.739	0.043	0.006	42 days	Charles River Deutschland
07S007	feeding	8/1/2010	11/1/2010	10	106.900	26.036	0.050	0.014	42 days	Charles River Deutschland
07S047	gavage	1/1/2013	4/1/2013	10	97.200	18.606	0.045	0.009	42 days	Charles River Deutschland
08076	feeding	8/1/2009	11/1/2009	10	90.300	17.727	0.047	0.010	42 days	Charles River Deutschland
08C004	feeding	6/1/2010	9/1/2010	10	101.100	12.749	0.045	0.008	42 days	Charles River Deutschland
08S001	gavage	5/1/2010	8/1/2010	9	104.778	16.169	0.045	0.007	42 days	Charles River Deutschland
09030	feeding	9/1/2009	12/1/2009	10	101.000	16.173	0.046	0.007	42 days	Charles River Deutschland
09C035	feeding	10/1/2010	1/1/2011	10	92.800	11.322	0.042	0.004	42 days	Charles River Deutschland
09C080	feeding	8/1/2012	11/1/2012	10	80.700	27.154	0.036	0.012	42 days	Charles River Deutschland
09C099	feeding	2/1/2012	5/1/2012	10	113.300	22.794	0.049	0.006	42 days	Charles River Deutschland
09C110	feeding	11/1/2012	2/1/2013	10	110.100	13.189	0.051	0.006	42 days	Charles River Deutschland
09C115	gavage	1/1/2013	4/1/2013	10	100.500	11.501	0.049	0.006	42 days	Charles River Deutschland
10C088	feeding	3/1/2011	6/1/2011	10	83.500	12.002	0.040	0.007	42 days	Charles River Deutschland

4/11/2014

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Historical Control Data

Wistar
Ovaries - f

4/11/2009 - 4/11/2014

Species rat Duration 3 months

study	application	study start	study end	No	abs. in mg	SD abs. in mg	rel.wght	SD rel.wght	age	supplier
10C113	gavage	6/1/2011	9/1/2011	10	99.000	22.925	0.046	0.010	42 days	Charles River Deutschland
10S037	feeding	1/1/2011	4/1/2011	10	92.000	12.000	0.042	0.005	42 days	Charles River Deutschland
10S110	gavage	5/1/2011	8/1/2011	10	88.100	15.481	0.041	0.008	42 days	Charles River Deutschland
10S112	feeding	6/1/2011	9/1/2011	10	90.000	17.010	0.041	0.008	42 days	Charles River Deutschland
10S117	feeding	11/1/2011	2/1/2012	10	100.100	9.927	0.047	0.005	42 days	Charles River Deutschland
10S145	gavage	5/1/2012	8/1/2012	10	107.900	12.827	0.047	0.006	42 days	Charles River Deutschland
10S148	feeding	5/1/2012	8/1/2012	10	106.400	15.086	0.047	0.007	42 days	Charles River Deutschland
11C007	feeding	5/1/2011	8/1/2011	10	97.400	12.358	0.043	0.005	42 days	Charles River Deutschland
11C097	gavage	12/1/2011	3/1/2012	10	101.500	18.940	0.048	0.010	42 days	Charles River Deutschland
11I142	inhalation head	4/1/2012	7/1/2012	10	96.800	12.874	0.049	0.007	8-9 weeks (56-63 days)	Charles River Deutschland
11S025	feeding	7/1/2011	10/1/2011	10	93.200	15.339	0.043	0.007	42 days	Charles River Deutschland
11S085	gavage	11/1/2011	2/1/2012	10	101.000	13.400	0.046	0.008	42 days	Charles River Deutschland
11S126	feeding	2/1/2012	5/1/2012	10	96.200	11.213	0.044	0.006	42 days	Charles River Deutschland
11S128	feeding	2/1/2012	5/1/2012	10	95.400	12.886	0.042	0.005	42 days	Charles River Deutschland
11S190	feeding	8/31/2012	12/1/2012	10	90.600	17.418	0.042	0.009	42 days	Charles River Deutschland
11S193	feeding	10/1/2012	1/1/2013	10	103.700	20.117	0.046	0.006	42 days	Charles River Deutschland
12C070	gavage	12/1/2012	3/1/2013	10	105.800	16.752	0.049	0.008	42 days	Charles River Deutschland
12C080	gavage	3/1/2013	6/1/2013	10	108.600	13.882	0.051	0.007	42 days	Charles River Deutschland
12S054	feeding	9/1/2012	12/1/2012	10	100.500	16.050	0.045	0.007	42 days	Charles River Deutschland

4/11/2014

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Historical Control Data

Wistar
Ovaries - f



The Chemical Company

4/11/2009 - 4/11/2014

Species rat

Duration 3 months

study	application	study start	study end	No	abs. in mg	SD abs. in mg	rel. wght	SD rel. wght	age	supplier
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total no of animals 378
total no of studies 38

max abs. wght. 113.800 mg
min abs. wght. 80.700 mg
mean abs. wght. 98.095 mg

max rel. wght. 0.051 %
min rel. wght. 0.036 %
mean rel. wght. 0.045 %

4/11/2014

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Historical Control Data

Wistar

Liver - m



The Chemical Company

4/11/2009 - 4/11/2014

Species rat

Duration 3 months

study	application	study start	study end	No	abs. in g	SD abs. in g	rel.wght	SD rel.wght	age	supplier
07C018	feeding	9/1/2010	12/1/2010	10	8.277	0.611	2.105	0.125	42 days	Charles River Deutschland
07S007	feeding	8/1/2010	11/1/2010	10	8.172	0.944	2.073	0.146	42 days	Charles River Deutschland
08C004	feeding	6/1/2010	9/1/2010	10	8.293	0.751	2.164	0.134	42 days	Charles River Deutschland
09030	feeding	9/1/2009	12/1/2009	10	8.691	0.756	2.191	0.090	42 days	Charles River Deutschland
09C035	feeding	10/1/2010	1/1/2011	10	8.825	0.859	2.165	0.103	42 days	Charles River Deutschland
09C080	feeding	8/1/2012	11/1/2012	10	8.354	0.755	2.184	0.144	42 days	Charles River Deutschland
09C099	feeding	2/1/2012	5/1/2012	10	8.988	0.865	2.312	0.141	42 days	Charles River Deutschland
10C088	feeding	3/1/2011	6/1/2011	10	8.734	1.425	2.224	0.215	42 days	Charles River Deutschland
10S037	feeding	1/1/2011	4/1/2011	10	8.307	1.021	2.127	0.138	42 days	Charles River Deutschland
10S112	feeding	6/1/2011	9/1/2011	10	7.939	1.088	2.077	0.135	42 days	Charles River Deutschland
10S117	feeding	11/1/2011	2/1/2012	10	8.269	0.823	2.211	0.158	42 days	Charles River Deutschland
10S148	feeding	5/1/2012	8/1/2012	10	8.859	0.991	2.216	0.153	42 days	Charles River Deutschland
11C007	feeding	5/1/2011	8/1/2011	10	8.477	1.140	2.181	0.154	42 days	Charles River Deutschland
11S025	feeding	7/1/2011	10/1/2011	10	7.694	0.450	2.068	0.091	42 days	Charles River Deutschland
11S126	feeding	2/1/2012	5/1/2012	10	8.160	0.740	2.120	0.088	42 days	Charles River Deutschland
11S128	feeding	2/1/2012	5/1/2012	10	8.015	1.102	2.159	0.081	42 days	Charles River Deutschland
11S190	feeding	8/31/2012	12/1/2012	10	8.366	0.614	2.248	0.087	42 days	Charles River Deutschland
11S193	feeding	10/1/2012	1/1/2013	10	9.261	1.463	2.390	0.164	42 days	Charles River Deutschland
12S054	feeding	9/1/2012	12/1/2012	10	8.782	0.642	2.261	0.093	42 days	Charles River Deutschland

8/5/2014

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Historical Control Data

Wistar

Liver - m



The Chemical Company

4/11/2009 - 4/11/2014

Species rat

Duration 3 months

study	application	study start	study end	No	abs. in g	SD abs. in g	rel. wght	SD rel. wght	age	supplier
total no of animals	190	max abs. wght.	9.261 g	max rel. wght.	2.39 %					
total no of studies	19	min abs. wght.	7.694 g	min rel. wght.	2.063 %					
		mean abs. wght.	8.421 g	mean rel. wght.	2.183 %					