

## **Disclaimer**

This document has been submitted in response to a solicitation by the California Office of Environmental Health and Hazard Assessment (OEHHA) to BASF Corporation (BASF). The submission of this document to a public docket maintained by OEHHA is not a waiver of BASF's ownership rights. No consent is granted for third party use of this document for any purpose, in any jurisdiction. Specifically, no consent is granted for the use of this document in any regulatory activity or registration, whether international, national, or local, including, but not limited to the Regulation Evaluation Authorization and Restriction of Chemicals ("REACH") regulation in the European Union.



We create chemistry

**STUDY TITLE**

**Summary of Results**

[Not QAU-Checked]

**DHDPS**

Test Study in Male and Female Sprague Dawley Rats

Oral Administration (Gavage)

**FACILITY PROJECT IDENTIFICATION**

01R0066/05R032

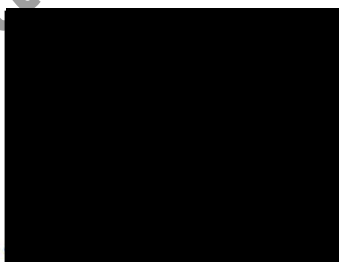
**TEST FACILITY**

BASF SE  
Experimental Toxicology and Ecology  
67056 Ludwigshafen, Germany

**SPONSOR**

List of Sponsors, see page 2

Study director:



29 Apr, 2020

This document contains manufacturing and trade secrets of the sponsor(s). It is the property of the sponsor(s) and may be used only for that purpose for which it was intended by the sponsor(s). Every other or additional use, exploitation, reproduction, publication or submission to other parties require the written permission of the sponsor(s), with the exception of regulatory agencies acting within the limits of their administrative authority.



We create chemistry

## Sponsors

LANXESS Deutschland GmbH  
Kennedyplatz 1  
50569 Köln  
Germany

SUMITOMO Chemical Co., Ltd.  
27-1, Shinkawa 2-chome, Chuo-ku, Tokyo 104-8260, Japan

Brunschwig Chemie bv, Hexaanweg 2, 1041AX Amsterdam, Holland

Volant-Chem GmbH  
HLFH, Salierring 47 – 53, 50677 Köln, Germany

Solvay Speciality Polymers Italy S.p.A.  
Viale Lombardia 20  
20021, Bollate, Italy

Jiangsu Aolunda High-Tech. Industry Co., Ltd.  
Zhoutie Town, Yixing, Jiangsu, China/214262

S. Goldmann GmbH & Co. KG  
Schillerstr. 79, 33609 Bielefeld, Germany

BASF SE  
67056 Ludwigshafen, Germany

## Summary

The following salient, test substance-related adverse effects/findings were noted:

### 600 mg/kg bw/d

- Reduced food consumption and body weight/body weight gain, reduced terminal body weight
- Reduced hemoglobin
- Increased relative (+12%) weights of the liver in males
- Axillary lymph nodes:
  - Discoloration in 2/5 males
  - Hypertrophy/hyperplasia of cortex in 3/5 males
- Kidneys:
  - macroscopically enlarged in 4/5 males,
  - increased relative weight in males (33%) and females (12%)
  - tubular degeneration/regeneration in 5/5 males
  - tubular hypertrophy in 5/5 males
- Liver:
  - Centrilobular hypertrophy in 5/5 males and 5/5 females
- Cecum:
  - dilated in 5/5 males and 2/5 females
- Mammary gland/mammary fatpad
  - diffuse atrophy in 4/5 males

### 300 mg/kg bw/d

- Kidneys:
  - macroscopically enlarged in 3/5 males,
  - tubular degeneration/regeneration in 5/5 males
  - tubular hypertrophy in 5/5 males
- Liver:
  - Centrilobular hypertrophy in 4/5 males

**100 mg/kg bw/d**

- Kidneys:
  - tubular degeneration/regeneration in 2/5 males
  - tubular hypertrophy in 1/5 males
- Liver:
  - Centrilobular hypertrophy in 1/5 males

As listed above, considerable clinical signs of systemic toxicity were observed in the high-dose animals (600 mg/kg bw/d), such as reduced food consumption and body weight gain. Males were more affected than females. In addition, discolored adrenals, dilated cecum, enlarged kidneys, enlarged livers, reduced terminal body weights and increased absolute/relative kidney weights were noted in the 600 mg/kg bw/d males at necropsy. Histopathology revealed dose-dependently increased incidences of findings in the cecum (enlarged), kidneys (tubular degeneration/regeneration, tubular hypertrophy) and liver (centrilobular hypertrophy), males again being more affected than females.

Based on these findings, dose levels of 30, 100 and 300 mg/kg bw/d DHDPS were tested in the subsequent Ranging Reproduction/Developmental Toxicity Study.

## Results

### Males

Parameter	Test group 0 0 mg/kg body weight/day	Test group 1 100 mg/kg body weight/day	Test group 2 300 mg/kg body weight/day	Test group 3 600 mg/kg body weight/day
Clinical observations:	NAD	Salivation (3/5)	Salivation (5/5)	Salivation (5/5) Piloerection (1/5)
WC (0 - 28)	27.5 g	33.2 g (20.5%)	31.7 g (15.0%)	31.1 g (13.1%)
WC (0 - 3)	28.2 g	<b>34.9 g (24.0%)*</b>	24.1 g (-14.5%)	26.5 g (-6.1%)
FC (0 - 28)	28.3 g	28.4 g (0.5%)	25.3 g (-10.6%)	<b>23.4 g (-17.1%)*</b>
FC (0 - 7)	29.3 g	27.4 g (-6.4%)	<b>23.6 g (-19.3%)*</b>	<b>19.3 g (-34.1%)**</b>
FC (7 - 14)	27.3 g	28.1 g (3.0%)	24.0 g (-12.2%)	<b>20.7 g (-24.1%)**</b>
BW (0)	367.0 g	378.8 g (3.2%)	375.9 g (2.4%)	372.8 g (1.6%)
BW (7)	405.8 g	413.3 g (1.9%)	397.6 g (-2.0%)	<b>374.5 g (-7.7%)*</b>
BW (14)	437.1 g	443.8 g (1.5%)	414.1 g (-5.3%)	<b>386.0 g (-11.7%)**</b>
BW (21)	462.4 g	470.0 g (1.6%)	431.5 g (-6.7%)	<b>410.0 g (-11.3%)*</b>
BW (28)	487.4 g	489.1 g (0.4%)	450.7 g (-7.5%)	430.1 g (-11.7%)
BWC (0 - 28)	120.3 g	110.3 g	74.9 g	<b>57.3 g*</b>
BWC (0 - 7)	38.8 g	34.5 g	21.7 g	<b>1.7 g**</b>
BWC (7 - 14)	31.3 g	30.5 g	<b>16.5 g*</b>	<b>11.4 g**</b>

## Females

Parameter	Test group 0 0 mg/kg body weight/day	Test group 1 100 mg/kg body weight/day	Test group 2 300 mg/kg body weight/day	Test group 3 600 mg/kg body weight/day
Clinical observations:	NAD	NAD	Salivation (4/5)	Salivation (5/5)
WC (0 - 28)	20.3 g	21.0 g (3.6%)	23.7 g (17.1%)	23.6 g (16.6%)
FC (0 - 28)	18.6 g	18.7 g (0.8%)	18.7 g (0.5%)	17.6 g (-5.5%)
BW (0)	215.4 g	216.9 g (0.7%)	217.7 g (1.1%)	218.4 g (1.4%)
BW (7)	231.6 g	230.1 g (-0.6%)	228.5 g (-1.3%)	225.2 g (-2.7%)
BW (14)	252.0 g	244.7 g (-2.9%)	244.1 g (-3.2%)	239.0 g (-5.2%)
BW (21)	264.0 g	257.5 g (-2.5%)	256.5 g (-2.8%)	252.4 g (-4.4%)
BW (28)	270.4 g	263.2 g (-2.7%)	263.9 g (-2.4%)	258.5 g (-4.4%)
BWC (0 - 28)	55.0 g	46.3 g	46.1 g	<b>40.0 g*</b>

**Clinical Pathology:****Males**

Parameter	Test group 0 0 mg/kg body weight/day	Test group 1 100 mg/kg body weight/day	Test group 2 300 mg/kg body weight/day	Test group 3 600 mg/kg body weight/day
HGB [mmol/L]	8.3	8.5	8.3	7.9*

**Females**

Parameter	Test group 0 0 mg/kg body weight/day	Test group 1 100 mg/kg body weight/day	Test group 2 300 mg/kg body weight/day	Test group 3 600 mg/kg body weight/day
All parameters	NAD	NAD	NAD	NAD



## Macroscopic Pathology:

### Males

Parameter	Test group 0 0 mg/kg body weight/day	Test group 1 100 mg/kg body weight/day	Test group 2 300 mg/kg body weight/day	Test group 3 600 mg/kg body weight/day
Organ weights (absolute):				
Terminal body weight:	450.22 g	451.84 g (100%)	411.6 g (91%)	<b>394.26 g (88%)*</b>
Adrenal glands:	69.6 mg	62.8 mg (90%)	76.0 mg (109%)	84.4 mg (121%)
Epididymides:	1.148 g	1.094 g (95%)	1.05 g (91%)	<b>0.974 g (85%)**</b>
Prostate:	1.158 g	1.118 g (97%)	1.072 g (93%)	<b>0.872 g (75%)**</b>
Seminal vesicle:	1.28 g	1.352 g (106%)	1.236 g (97%)	<b>0.958 g (75%)**</b>
Spleen:	0.852 g	0.8 g (94%)	0.74 g (87%)	<b>0.678 g (80%)**</b>
Thymus:	402.8 mg	431.6 mg (107%)	315.6 mg (78%)	<b>271.8 mg (67%)*</b>
Organ weights (relative):				
Adrenal glands:	0.016%	0.014% (89%)	0.018% (118%)	0.022% (139%)
Kidneys:	0.67%	0.747% (112%)	0.894% (133%)	<b>0.888% (133%)**</b>
Gross lesions:	Kidney cyst (1/5)  Liver focal constriction (1/5)  Liver focus (1/5)	Kidney cyst (1/5)	Kidney cyst (1/5)  Kidney enlarged (3/5)  Kidney retraction (2/5)  Renal lymph nodes enlarged (1/5)	Axillary lymph nodes discoloration (2/5)  Cecum dilation (2/5)  Kidney enlarged (4/5)

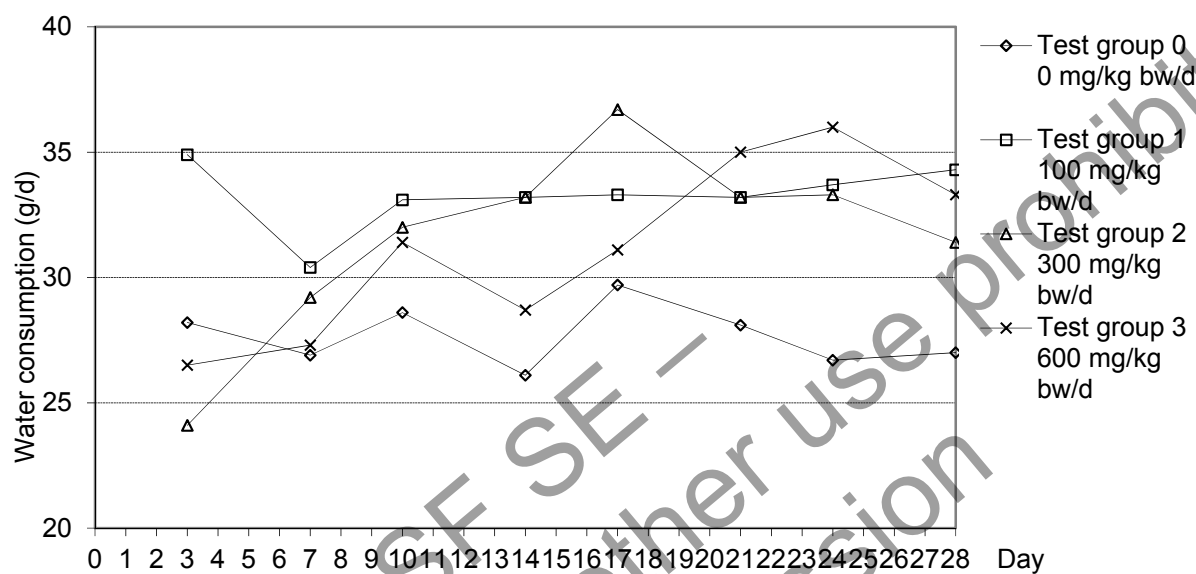
### Females:

Parameter	Test group 0 0 mg/kg body weight/day	Test group 1 100 mg/kg body weight/day	Test group 2 300 mg/kg body weight/day	Test group 3 600 mg/kg body weight/day
Organ weights (absolute):				
Thymus:	415.0 mg	354.0 mg (85%)	361.2 mg (87%)	<b>306.0 mg (74%)*</b>
Organ weights (relative):				
Kidneys:	0.708%	0.763% (108%)	0.795% (112%)	<b>0.793% (112%)*</b>
Gross lesions:	NAD	Axillary lymph nodes discoloration (1/5)	NAD	NAD

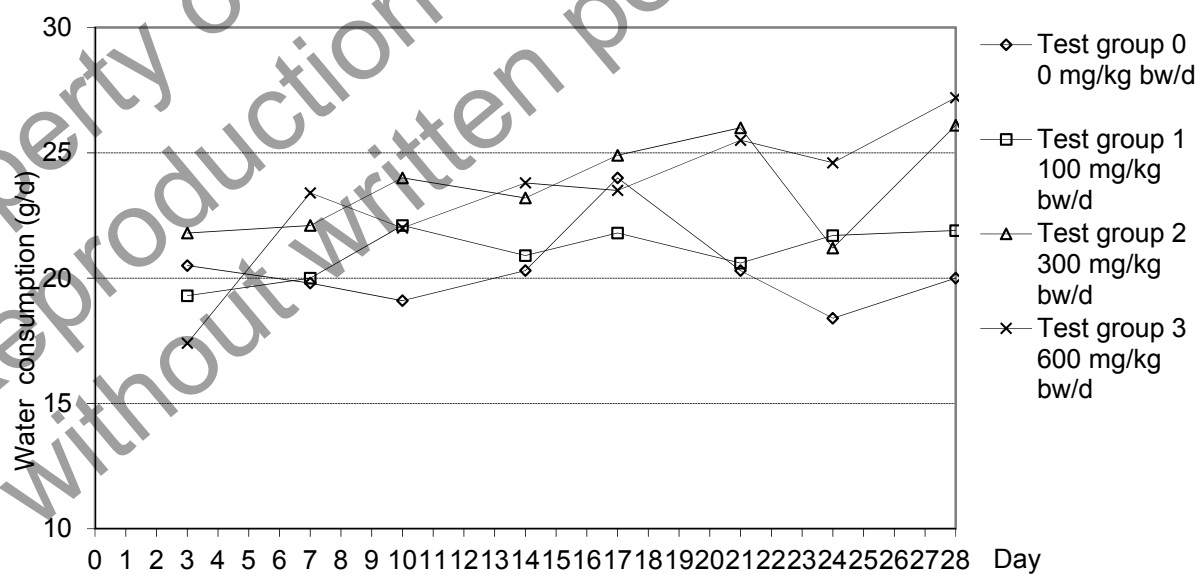
### Analytical Investigations:

Parameter	Test group 0 0 mg/kg body weight/day	Test group 1 100 mg/kg body weight/day	Test group 2 300 mg/kg body weight/day	Test group 3 600 mg/kg body weight/day
Concentration control Mean %	0	100.4	99.5	96.2

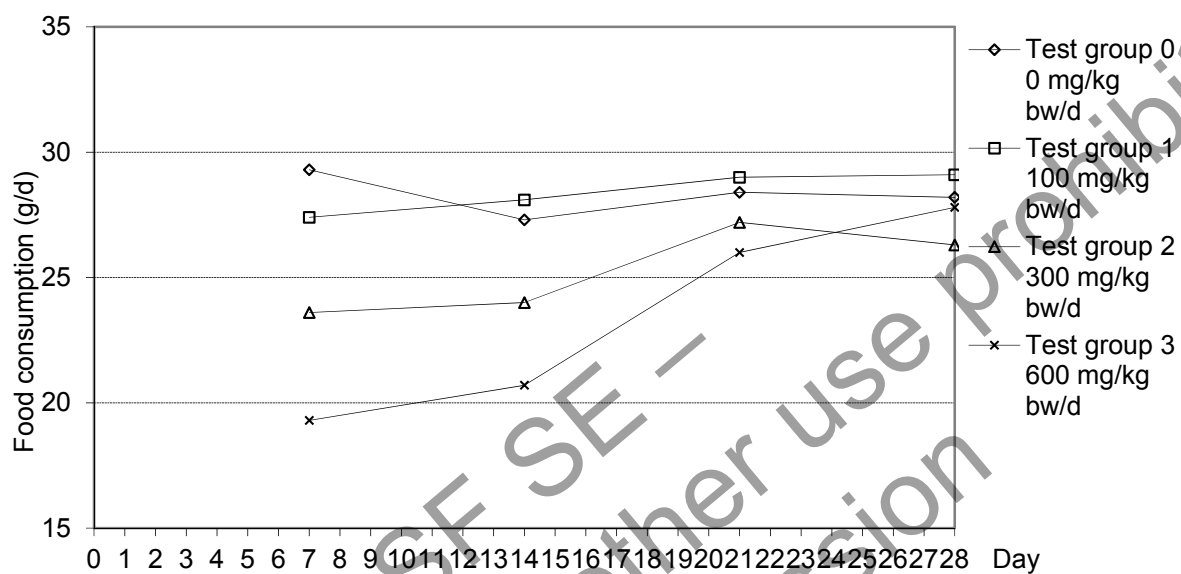
### Male water consumption



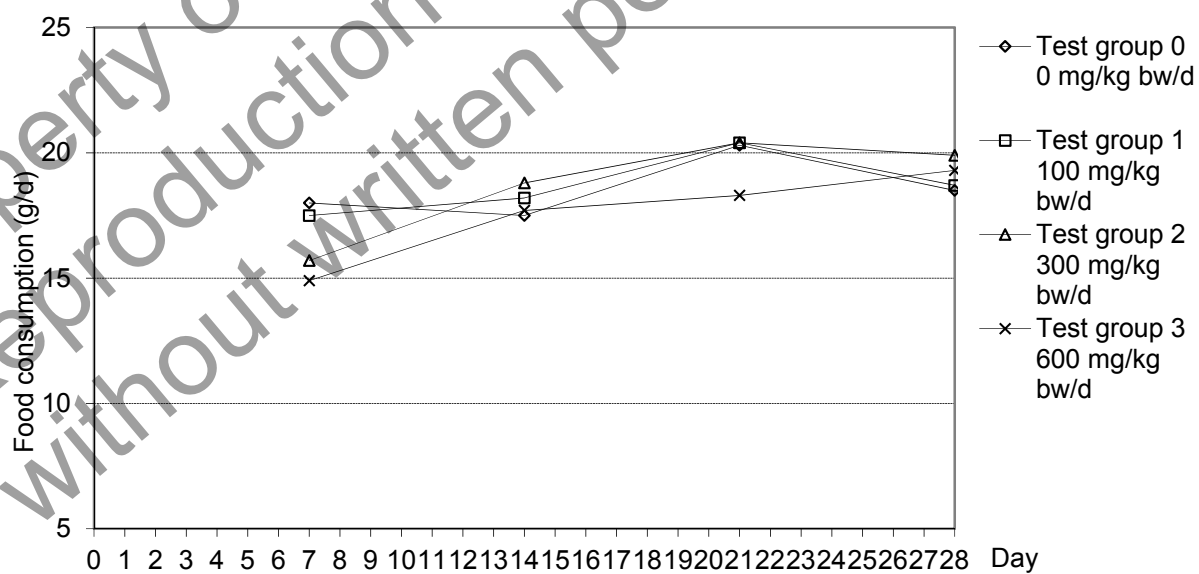
### Female water consumption



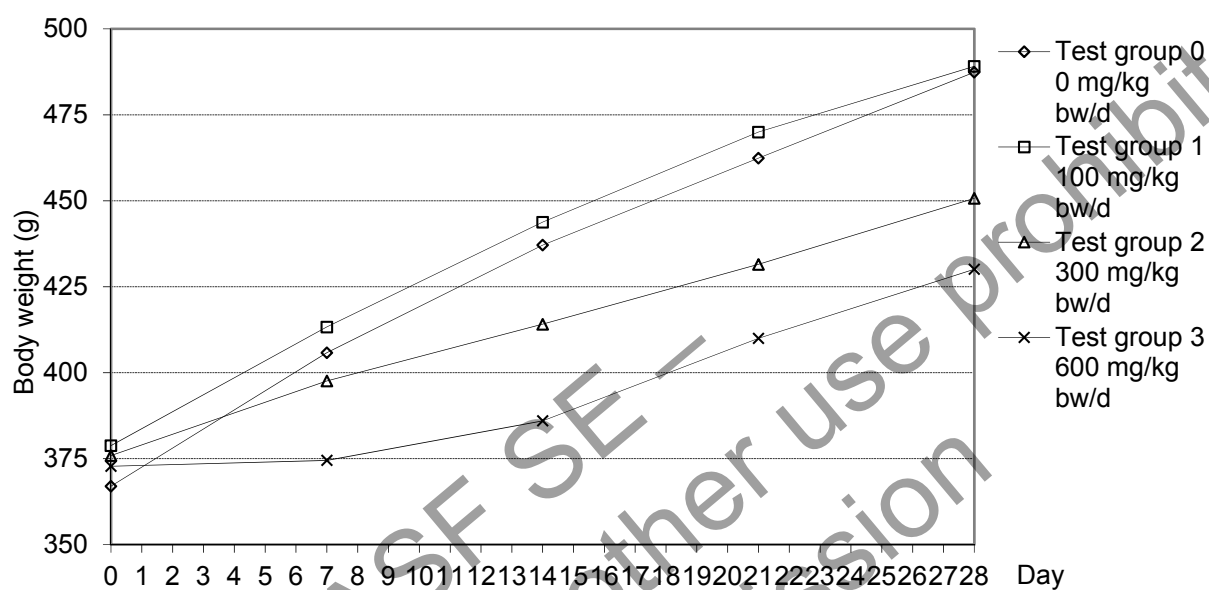
### Male food consumption



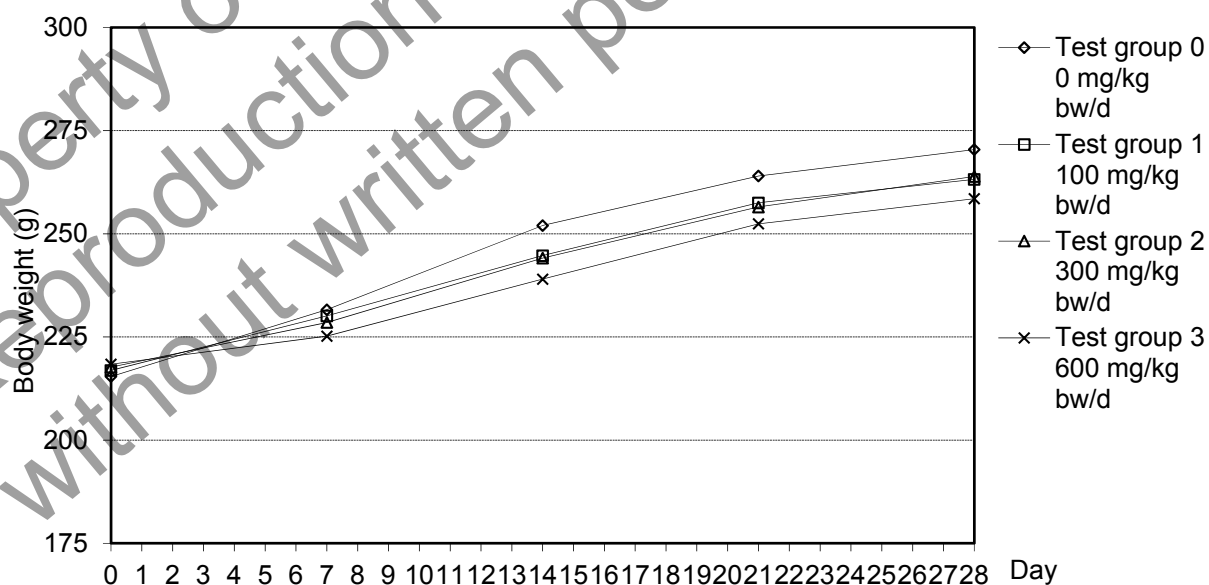
### Female food consumption



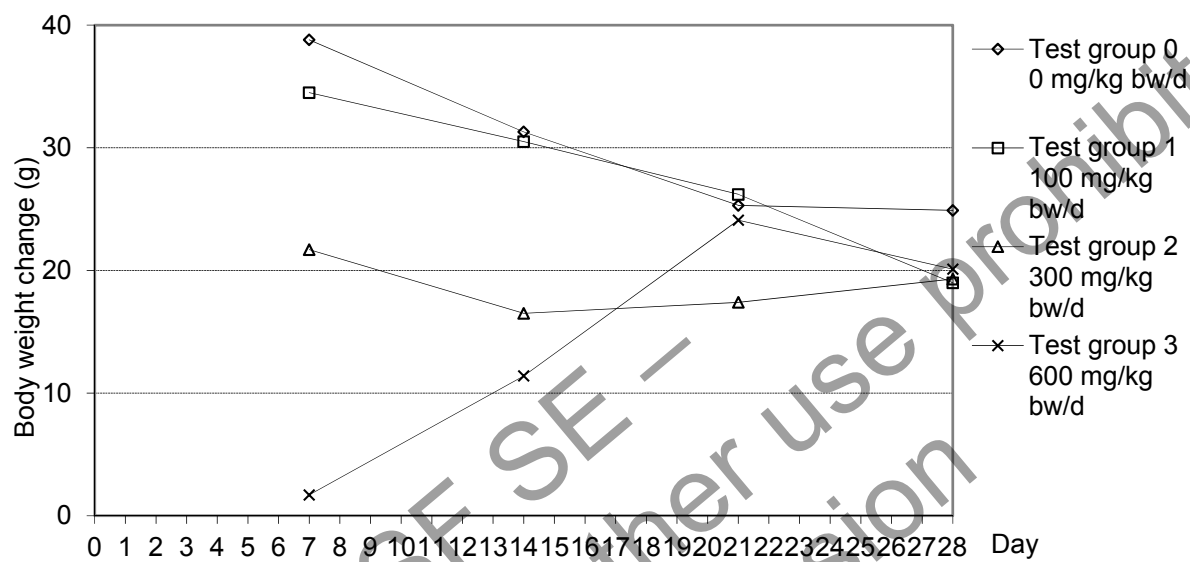
### Male body weight



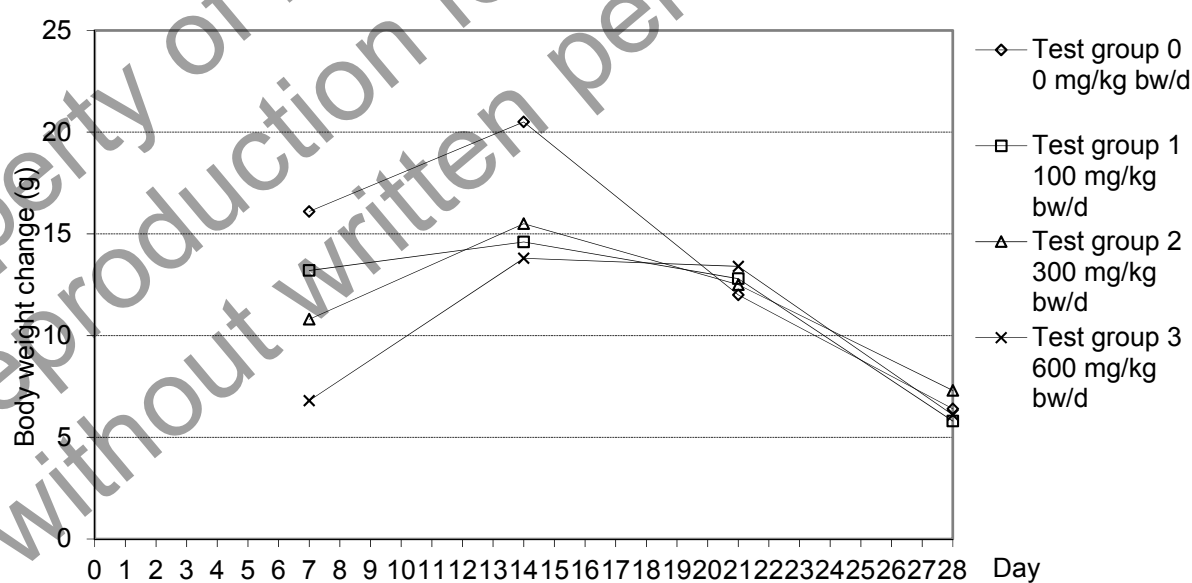
### Female body weight



### Male body weight change



### Female body weight change



Attached Summary and Individual Tables

Study

01R0066/05R032

21-Feb-2017 08:03

ToxData© System 3.0

**Summary - Clinical Observation**Sex: **Male** - Phase: **In-life**

			Test Group 0/ M 0 mg/kg bw/d	Test Group 1/ M 100 mg/kg bw/d	Test Group 2/ M 300 mg/kg bw/d	Test Group 3/ M 600 mg/kg bw/d
day 0 -> 29	Animals examined	N	5	5	5	5
	Animals with signs	N	0	3	5	5
	dead					
	<i>sacrificed scheduled</i>	N	5	5	5	5
	head					
	<i>salivation</i>	N	0	3	5	5
	fur					
	<i>piloerection</i>	N	0	0	0	1
	normal					
	<i>NAD</i>	N	5	5	5	5

Study

01R0066/05R032

21-Feb-2017 08:03

ToxData© System 3.0

**Summary - Clinical Observation**Sex: **Female** - Phase: **In-life**

			Test Group 0/ F 0 mg/kg bw/d	Test Group 1/ F 100 mg/kg bw/d	Test Group 2/ F 300 mg/kg bw/d	Test Group 3/ F 600 mg/kg bw/d
day 0 -> 29	Animals examined	N	5	5	5	5
	Animals with signs	N	0	0	4	5
	dead	N	5	5	5	5
	<i>sacrificed scheduled</i>					
	head	N	0	0	4	5
	<i>salivation</i>					
	normal	N	5	5	5	5
	<i>NAD</i>					



**Summary Water Consumption Per Animal And Day**Sex: **Male** - Phase: **In-life**

		Test Group 0/ M 0 mg/kg bw/d	Test Group 1/ M 100 mg/kg bw/d	Test Group 2/ M 300 mg/kg bw/d	Test Group 3/ M 600 mg/kg bw/d
d 0 -> 3	Mean [g]	28.2 n	34.9 *	24.1	26.5
	S.d.	3.2	5.4	1.8	4.5
	N	5	5	5	5
	Deviation Vs Control		24.0	-14.5	-6.1
d 3 -> 7	Mean [g]	26.9 n	30.4	29.2	27.3
	S.d.	1.8	5.1	5.1	10.8
	N	5	5	5	5
	Deviation Vs Control		12.9	8.6	1.3
d 7 -> 10	Mean [g]	28.6 n	33.1	32.0	31.4
	S.d.	2.9	7.0	8.4	14.2
	N	5	5	5	5
	Deviation Vs Control		15.8	12.1	9.9
d 10 -> 14	Mean [g]	26.1 n	33.2	33.2	28.7
	S.d.	3.7	4.3	4.3	11.2
	N	5	5	5	5
	Deviation Vs Control		27.5	27.5	10.0
d 14 -> 17	Mean [g]	29.7 n	33.3	36.7	31.1
	S.d.	2.2	3.7	13.6	10.4
	N	5	5	5	5
	Deviation Vs Control		12.3	23.8	5.0

Statistic Profile = Dunnett test (two-sided), \* p<=0.05, \*\* p <=0.01, X = Group excluded from statistics  
d = day, n=DUNNETT

**Summary Water Consumption Per Animal And Day**Sex: **Male** - Phase: **In-life**

		Test Group 0/ M 0 mg/kg bw/d	Test Group 1/ M 100 mg/kg bw/d	Test Group 2/ M 300 mg/kg bw/d	Test Group 3/ M 600 mg/kg bw/d
d 17 -> 21	Mean [g]	28.1 n	33.2	33.2	35.0
	S.d.	3.4	3.6	6.3	10.9
	N	5	5	5	5
	Deviation Vs Control		18.4	18.5	24.8
d 21 -> 24	Mean [g]	26.7 n	33.7	33.3	36.0
	S.d.	2.9	5.5	9.7	14.2
	N	5	5	5	5
	Deviation Vs Control		26.1	24.8	34.7
d 24 -> 28	Mean [g]	27.0 n	34.3	31.4	33.3
	S.d.	3.1	2.5	7.0	9.5
	N	5	5	5	5
	Deviation Vs Control		27.1	16.5	23.5
d 0 -> 28	Mean [g]	27.5 n	33.2	31.7	31.1
	S.d.	2.3	2.8	6.2	9.6
	N	5	5	5	5
	Deviation Vs Control		20.5	15.0	13.1

Statistic Profile = Dunnett test (two-sided), \*  $p \leq 0.05$ , \*\*  $p \leq 0.01$ , X = Group excluded from statistics  
n=DUNNETT; d = day

**Summary Water Consumption Per Animal And Day**Sex: **Female** - Phase: **In-life**

		Test Group 0/ F 0 mg/kg bw/d	Test Group 1/ F 100 mg/kg bw/d	Test Group 2/ F 300 mg/kg bw/d	Test Group 3/ F 600 mg/kg bw/d
d 0 -> 3	Mean [g]	20.5 n	19.3	21.8	17.4
	S.d.	2.7	4.6	2.5	4.1
	N	5	5	5	5
	Deviation Vs Control		-6.2	6.1	-15.1
d 3 -> 7	Mean [g]	19.8 n	20.0	22.1	23.4
	S.d.	3.0	6.8	1.7	6.2
	N	5	5	5	5
	Deviation Vs Control		0.9	11.8	18.2
d 7 -> 10	Mean [g]	19.1 n	22.1	24.0	22.0
	S.d.	3.1	7.7	3.4	5.5
	N	5	5	5	5
	Deviation Vs Control		15.6	25.4	14.9
d 10 -> 14	Mean [g]	20.3 n	20.9	23.2	23.8
	S.d.	2.4	6.4	1.6	5.3
	N	5	5	5	5
	Deviation Vs Control		2.6	14.0	16.8
d 14 -> 17	Mean [g]	24.0 n	21.8	24.9	23.5
	S.d.	4.9	5.9	1.7	6.6
	N	5	5	5	5
	Deviation Vs Control		-8.9	4.0	-2.0

Statistic Profile = Dunnett test (two-sided), \*  $p \leq 0.05$ , \*\*  $p \leq 0.01$ , X = Group excluded from statistics  
d = day, n=DUNNETT

**Summary Water Consumption Per Animal And Day**Sex: **Female** - Phase: **In-life**

		Test Group 0/ F 0 mg/kg bw/d	Test Group 1/ F 100 mg/kg bw/d	Test Group 2/ F 300 mg/kg bw/d	Test Group 3/ F 600 mg/kg bw/d
d 17 -> 21	Mean [g]	20.3 n	20.6	26.0	25.5
	S.d.	2.3	3.4	3.4	5.7
	N	5	5	5	5
	Deviation Vs Control		1.5	27.9	25.8
d 21 -> 24	Mean [g]	18.4 n	21.7	21.2	24.6
	S.d.	2.6	7.3	4.4	5.2
	N	5	5	5	5
	Deviation Vs Control		18.2	15.0	33.9
d 24 -> 28	Mean [g]	20.0 n	21.9	26.1	27.2
	S.d.	5.9	4.6	1.0	6.1
	N	5	5	5	5
	Deviation Vs Control		9.7	30.3	35.8
d 0 -> 28	Mean [g]	20.3 n	21.0	23.7	23.6
	S.d.	2.2	5.1	0.8	5.2
	N	5	5	5	5
	Deviation Vs Control		3.6	17.1	16.6

Statistic Profile = Dunnett test (two-sided), \*  $p \leq 0.05$ , \*\*  $p \leq 0.01$ , X = Group excluded from statistics  
n=DUNNETT; d = day

**Summary Food Consumption Per Animal And Day**Sex: **Male** - Phase: **In-life**

		Test Group 0/ M 0 mg/kg bw/d	Test Group 1/ M 100 mg/kg bw/d	Test Group 2/ M 300 mg/kg bw/d	Test Group 3/ M 600 mg/kg bw/d
d 0 -> 7	Mean [g]	29.3 n	27.4	23.6 *	19.3 **
	S.d.	3.4	1.4	1.9	4.7
	N	5	5	5	5
	Deviation Vs Control		-6.4	-19.3	-34.1
d 7 -> 14	Mean [g]	27.3 n	28.1	24.0	20.7 **
	S.d.	1.4	1.9	2.5	3.5
	N	5	5	5	5
	Deviation Vs Control		3.0	-12.2	-24.1
d 14 -> 21	Mean [g]	28.4 n	29.0	27.2	26.0
	S.d.	1.6	1.8	1.5	4.1
	N	5	5	5	5
	Deviation Vs Control		2.0	-4.3	-8.5
d 21 -> 28	Mean [g]	28.2 n	29.1	26.3	27.8
	S.d.	1.9	4.0	3.5	4.9
	N	5	5	5	5
	Deviation Vs Control		3.4	-6.5	-1.3
d 0 -> 28	Mean [g]	28.3 n	28.4	25.3	23.4 *
	S.d.	2.0	2.0	1.8	3.5
	N	5	5	5	5
	Deviation Vs Control		0.5	-10.6	-17.1

Statistic Profile = Dunnett test (two-sided), \* p<=0.05, \*\* p <=0.01, X = Group excluded from statistics  
d = day, n=DUNNETT

**Summary Food Consumption Per Animal And Day**Sex: **Female** - Phase: **In-life**

		Test Group 0/ F 0 mg/kg bw/d	Test Group 1/ F 100 mg/kg bw/d	Test Group 2/ F 300 mg/kg bw/d	Test Group 3/ F 600 mg/kg bw/d
d 0 -> 7	Mean [g]	18.0 n	17.5	15.7	14.9
	S.d.	2.3	3.5	2.0	2.5
	N	5	5	5	5
	Deviation Vs Control		-2.9	-13.1	-17.4
d 7 -> 14	Mean [g]	17.5 n	18.2	18.8	17.7
	S.d.	3.2	2.4	0.8	1.6
	N	5	5	5	5
	Deviation Vs Control		3.8	7.3	0.7
d 14 -> 21	Mean [g]	20.3 n	20.4	20.4	18.3
	S.d.	1.8	2.8	1.1	2.4
	N	5	5	5	5
	Deviation Vs Control		0.5	0.6	-9.6
d 21 -> 28	Mean [g]	18.5 n	18.7	19.9	19.3
	S.d.	0.8	2.4	0.5	2.9
	N	5	5	5	5
	Deviation Vs Control		1.5	7.8	4.6
d 0 -> 28	Mean [g]	18.6 n	18.7	18.7	17.6
	S.d.	1.1	2.7	0.4	2.2
	N	5	5	5	5
	Deviation Vs Control		0.8	0.5	-5.5

Statistic Profile = Dunnett test (two-sided), \* p<=0.05, \*\* p <=0.01, X = Group excluded from statistics  
d = day, n=DUNNETT

**Summary Body Weights - BW / Body Weights [g]**Sex: **Male** - Phase: **In-life**

		Test Group 0/ M 0 mg/kg bw/d	Test Group 1/ M 100 mg/kg bw/d	Test Group 2/ M 300 mg/kg bw/d	Test Group 3/ M 600 mg/kg bw/d
<b>day 0</b>	<b>Mean</b>	367.0 n	378.8	375.9	372.8
	<b>S.d.</b>	7.7	13.1	8.8	7.1
	<b>N</b>	5	5	5	5
	<b>Deviation Vs Control</b>		3.2	2.4	1.6
<b>day 7</b>	<b>Mean</b>	405.8 n	413.3	397.6	374.5 *
	<b>S.d.</b>	17.1	19.0	7.9	20.9
	<b>N</b>	5	5	5	5
	<b>Deviation Vs Control</b>		1.9	-2.0	-7.7
<b>day 14</b>	<b>Mean</b>	437.1 n	443.8	414.1	386.0 **
	<b>S.d.</b>	23.6	22.3	14.1	22.7
	<b>N</b>	5	5	5	5
	<b>Deviation Vs Control</b>		1.5	-5.3	-11.7
<b>day 21</b>	<b>Mean</b>	462.4 n	470.0	431.5	410.0 *
	<b>S.d.</b>	33.3	24.3	21.7	30.0
	<b>N</b>	5	5	5	5
	<b>Deviation Vs Control</b>		1.6	-6.7	-11.3
<b>day 28</b>	<b>Mean</b>	487.4 n	489.1	450.7	430.1
	<b>S.d.</b>	39.7	35.1	33.0	33.5
	<b>N</b>	5	5	5	5
	<b>Deviation Vs Control</b>		0.4	-7.5	-11.7

Statistic Profile = Dunnett test (two-sided), \* p<=0.05, \*\* p <=0.01, X = Group excluded from statistics  
n=DUNNETT

**Summary Body Weights - BW / Body Weights [g]**Sex: **Female** - Phase: **In-life**

		Test Group 0/ F 0 mg/kg bw/d	Test Group 1/ F 100 mg/kg bw/d	Test Group 2/ F 300 mg/kg bw/d	Test Group 3/ F 600 mg/kg bw/d
<b>day 0</b>	<b>Mean</b>	215.4 n	216.9	217.7	218.4
	<b>S.d.</b>	10.3	14.2	9.0	11.0
	<b>N</b>	5	5	5	5
	<b>Deviation Vs Control</b>		0.7	1.1	1.4
<b>day 7</b>	<b>Mean</b>	231.6 n	230.1	228.5	225.2
	<b>S.d.</b>	13.5	16.0	10.9	14.0
	<b>N</b>	5	5	5	5
	<b>Deviation Vs Control</b>		-0.6	-1.3	-2.7
<b>day 14</b>	<b>Mean</b>	252.0 n	244.7	244.1	239.0
	<b>S.d.</b>	15.5	17.6	9.3	16.7
	<b>N</b>	5	5	5	5
	<b>Deviation Vs Control</b>		-2.9	-3.2	-5.2
<b>day 21</b>	<b>Mean</b>	264.0 n	257.5	256.5	252.4
	<b>S.d.</b>	15.8	19.9	9.6	19.0
	<b>N</b>	5	5	5	5
	<b>Deviation Vs Control</b>		-2.5	-2.8	-4.4
<b>day 28</b>	<b>Mean</b>	270.4 n	263.2	263.9	258.5
	<b>S.d.</b>	16.8	21.0	10.0	18.7
	<b>N</b>	5	5	5	5
	<b>Deviation Vs Control</b>		-2.7	-2.4	-4.4

Statistic Profile = Dunnett test (two-sided), \* p<=0.05, \*\* p <=0.01, X = Group excluded from statistics  
n=DUNNETT



**Summary Changes Body Weights - BW / Body Weights [g]**Sex: **Male** - Phase: **In-life**

		Test Group 0/ M 0 mg/kg bw/d	Test Group 1/ M 100 mg/kg bw/d	Test Group 2/ M 300 mg/kg bw/d	Test Group 3/ M 600 mg/kg bw/d
<b>d 0 -&gt; 7</b>	<b>Mean</b>	38.8 n	34.5	21.7	1.7 **
	<b>S.d.</b>	9.8	11.2	7.9	16.0
	<b>N</b>	5	5	5	5
<b>d 7 -&gt; 14</b>	<b>Mean</b>	31.3 n	30.5	16.5 *	11.4 **
	<b>S.d.</b>	7.5	5.0	10.2	10.5
	<b>N</b>	5	5	5	5
<b>d 14 -&gt; 21</b>	<b>Mean</b>	25.3 n	26.2	17.4	24.1
	<b>S.d.</b>	9.8	6.5	8.0	10.6
	<b>N</b>	5	5	5	5
<b>d 21 -&gt; 28</b>	<b>Mean</b>	24.9 n	19.0	19.3	20.1
	<b>S.d.</b>	7.7	15.1	12.5	13.8
	<b>N</b>	5	5	5	5
<b>d 0 -&gt; 28</b>	<b>Mean</b>	120.3 n	110.3	74.9	57.3 *
	<b>S.d.</b>	32.1	26.5	31.9	29.3
	<b>N</b>	5	5	5	5

Statistic Profile = Dunnett test (two-sided), \* p&lt;=0.05, \*\* p &lt;=0.01, X = Group excluded from statistics

d = day; n=DUNNETT

**Summary Changes Body Weights - BW / Body Weights [g]**Sex: **Female** - Phase: **In-life**

		Test Group 0/ F 0 mg/kg bw/d	Test Group 1/ F 100 mg/kg bw/d	Test Group 2/ F 300 mg/kg bw/d	Test Group 3/ F 600 mg/kg bw/d
d 0 -> 7	Mean	16.1 n	13.2	10.8	6.8
	S.d.	4.6	4.2	7.8	7.1
	N	5	5	5	5
d 7 -> 14	Mean	20.5 n	14.6	15.5	13.8
	S.d.	6.8	7.6	4.9	7.1
	N	5	5	5	5
d 14 -> 21	Mean	12.0 n	12.8	12.5	13.4
	S.d.	3.7	3.3	4.6	4.4
	N	5	5	5	5
d 21 -> 28	Mean	6.4 n	5.8	7.3	6.1
	S.d.	3.6	3.9	3.8	7.1
	N	5	5	5	5
d 0 -> 28	Mean	55.0 n	46.3	46.1	40.0 *
	S.d.	8.5	7.6	4.6	11.1
	N	5	5	5	5

Statistic Profile = Dunnett test (two-sided), \* p&lt;=0.05, \*\* p &lt;=0.01, X = Group excluded from statistics

d = day; n=DUNNETT

01R0066/05R032

21-Feb-2017 10:18

### Individual Signs By Interval - Clinical Observation

[illegible]

01R0066/05R032

ToxData© System 3.0

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

[illegible]

### Individual Signs By Interval - Clinical Observation

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

[illegible]

01R0066/05R032

21-Feb-2017 10:18

ToxData© System 3.0

### Individual Signs By Interval - Clinical Observation

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

[illegible]

01R0066/05R032

ToxData© System 3.0

### Individual Signs By Interval - Clinical Observation

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

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	Day									
						0	1	2	3	4	5	6	7	8	9
Test Group 3/ M 600 mg/kg bw/d	16	normal	NAD			3	3	2	3	3	3	3	2	3	3
		head	salivation	Grade: moderate				1					1		
				Grade: slight											
		dead	sacrificed scheduled												
	17	normal	NAD			3	3	3	3	3	3	3	3	3	3
		head	salivation	Grade: slight											
		dead	sacrificed scheduled												
	18	normal	NAD			3	3	2	3	3	2	3	2	2	3
		head	salivation	Grade: moderate				1			1		1	1	
				Grade: slight											
				Grade: severe											
		dead	sacrificed scheduled												
	19	normal	NAD			3	3	2	2	2	2	2	2	2	2
		head	salivation	Grade: moderate				1					1	1	1
				Grade: severe					1	1	1	1			
				Grade: slight											
dead		sacrificed scheduled													
20...	normal	NAD			3	3	3	3	3	3	3	2	2	3	
	head	salivation	Grade: slight									1	1		

01R0066/05R032

21-Feb-2017 10:18

ToxData© System 3.0

### Individual Signs By Interval - Clinical Observation

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

[illegible]



01R0066/05R032

ToxData© System 3.0

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

[illegible]

01R0066/05R032

ToxData© System 3.0

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

[illegible]

### Individual Signs By Interval - Clinical Observation

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

[illegible]



Study

01R0066/05R032

21-Feb-2017 10:18

ToxData© System 3.0

## Individual Signs By Interval - Clinical Observation

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	Day									
						10	11	12	13	14	15	16	17	18	19
Test Group 3/ M 600 mg/kg bw/d	16	normal	NAD			3	3	3	2	3	3	3	3	3	3
		head	salivation	Grade: moderate											
				Grade: slight					1						
		dead	sacrificed scheduled												
	17	normal	NAD			3	3	3	3	3	3	3	3	2	3
		head	salivation	Grade: slight										1	
		dead	sacrificed scheduled												
	18	normal	NAD			2	3	3	3	2	3	2	2	2	2
		head	salivation	Grade: moderate		1						1	1		
				Grade: slight						1					
				Grade: severe										1	1
		dead	sacrificed scheduled												
	19	normal	NAD			2	2	2	3	2	2	2	2	2	2
		head	salivation	Grade: moderate			1				1				
				Grade: severe		1						1	1	1	1
				Grade: slight				1		1					
		dead	sacrificed scheduled												
	20...	normal	NAD			2	3	2	2	2	2	3	2	2	2
		head	salivation	Grade: slight		1				1				1	1



01R0066/05R032

ToxData© System 3.0

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

[illegible]

01R0066/05R032

ToxData© System 3.0

### Individual Signs By Interval - Clinical Observation

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

[illegible]



### Individual Signs By Interval - Clinical Observation

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

[illegible]

01R0066/05R032

ToxData© System 3.0

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

[illegible]

Study

01R0066/05R032

21-Feb-2017 10:18

ToxData© System 3.0

## Individual Signs By Interval - Clinical Observation

Sex: Male - Phase: In-life

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	Day									
						20	21	22	23	24	25	26	27	28	29
Test Group 3/ M 600 mg/kg bw/d	16	normal	NAD			3	3	3	3	3	3	3	3	3	1
		head	salivation	Grade: moderate											
				Grade: slight											
		dead	sacrificed scheduled												1
	17	normal	NAD			3	3	3	3	3	3	3	3	3	1
		head	salivation	Grade: slight											
		dead	sacrificed scheduled												1
	18	normal	NAD			2	2	2	3	3	2	2	3	3	1
		head	salivation	Grade: moderate											
				Grade: slight		1	1	1			1	1			
				Grade: severe											
		dead	sacrificed scheduled												1
	19	normal	NAD			2	3	3	3	3	2	3	2	3	1
		head	salivation	Grade: moderate											
				Grade: severe		1									
				Grade: slight							1		1		
		dead	sacrificed scheduled												1
	20...	normal	NAD			2	2	2	2	2	2	2	2	2	1
		head	salivation	Grade: slight			1								

01R0066/05R032

21-Feb-2017 10:18

### Individual Signs By Interval - Clinical Observation

[illegible]

01R0066/05R032

21-Feb-2017 10:18

### Individual Signs By Interval - Clinical Observation

Test  
Group 0/  
F  
0 mg/kg  
bw/d

[illegible]

01R0066/05R032

21-Feb-2017 10:18

### Individual Signs By Interval - Clinical Observation

[illegible]

01R0066/05R032

ToxData© System 3.0

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

[illegible]

### Individual Signs By Interval - Clinical Observation

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

[illegible]



01R0066/05R032

21-Feb-2017 10:18

### Individual Signs By Interval - Clinical Observation

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

[illegible]

01R0066/05R032

21-Feb-2017 10:18

### Individual Signs By Interval - Clinical Observation

[illegible]

01R0066/05R032

21-Feb-2017 10:18

### Individual Signs By Interval - Clinical Observation

[illegible]

01R0066/05R032

ToxData© System 3.0

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

[illegible]

01R0066/05R032

ToxData© System 3.0

### Individual Signs By Interval - Clinical Observation

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

[illegible]

01R0066/05R032

21-Feb-2017 10:18

### Individual Signs By Interval - Clinical Observation

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

[illegible]

01R0066/05R032

21-Feb-2017 10:18

### Individual Signs By Interval - Clinical Observation

[illegible]

01R0066/05R032

21-Feb-2017 10:18

### Individual Signs By Interval - Clinical Observation

[illegible]



01R0066/05R032

ToxData© System 3.0

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

[illegible]

01R0066/05R032

ToxData© System 3.0

### Individual Signs By Interval - Clinical Observation

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

[illegible]

01R0066/05R032

21-Feb-2017 10:18

ToxData© System 3.0

### Individual Signs By Interval - Clinical Observation

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

[illegible]

## Individual Water Consumption Per Animal And Day [g/Day]

Sex: Male - Phase: In-life

Group	Cage	Animals	d 0 -> 3	d 3 -> 7	d 7 -> 10	d 10 -> 14	d 14 -> 17	d 17 -> 21	d 21 -> 24	d 24 -> 28
Test Group 0/ M 0 mg/kg bw/d	01	01	32.2	27.4	30.6	29.2	30.9	33.2	31.3	31.4
	02	02	30.3	24.2	28.4	23.0	30.8	27.4	24.0	24.6
	03	03	28.3	29.1	29.0	30.8	32.0	29.5	25.2	29.0
	04	04	25.3	26.8	23.7	22.8	26.9	25.3	25.6	25.6
	05	05	24.8	27.0	31.1	24.6	27.7	24.9	27.5	24.2
Test Group 1/ M 100 mg/kg bw/d	06	06	38.7	31.6	32.2	36.6	32.5	33.4	39.5	36.4
	07	07	34.5	33.6	32.0	31.9	39.4	27.8	38.5	34.6
	08	08	31.5	24.9	28.4	28.3	29.5	37.3	33.7	35.5
	09	09	28.3	25.3	27.7	30.6	32.5	32.3	30.2	30.0
	10	10	41.7	36.5	45.1	38.8	32.6	35.3	26.6	34.8
Test Group 2/ M 300 mg/kg bw/d	11	11	22.7	25.0	32.5	31.1	31.5	32.8	29.1	33.0
	12	12	22.6	37.9	45.5	39.5	60.7	44.3	50.4	41.6
	13	13	25.1	26.5	27.5	27.9	27.4	29.9	31.6	31.5
	14	14	26.7	28.5	31.3	33.4	32.7	30.0	29.5	28.6
	15	15	23.3	28.2	23.3	34.3	31.3	29.2	26.1	22.4
Test Group 3/ M 600 mg/kg bw/d	16	16	31.6	42.2	51.0	43.8	40.0	45.1	50.0	36.1
	17	17	24.0	16.2	15.1	16.2	16.4	17.0	15.1	20.4
	18	18	28.8	28.9	31.0	35.8	38.4	38.0	37.2	29.8
	19	19	27.9	31.8	38.5	21.0	36.9	41.4	47.6	46.4
	20	20	20.0	17.2	21.3	26.6	24.0	33.6	30.0	33.8

d = day

## Individual Water Consumption Per Animal And Day [g/Day]

Sex: Female - Phase: In-life

Group	Cage	Animals	d 0 -> 3	d 3 -> 7	d 7 -> 10	d 10 -> 14	d 14 -> 17	d 17 -> 21	d 21 -> 24	d 24 -> 28
Test Group 0/ F 0 mg/kg bw/d	101	101	16.9	19.3	14.3	16.4	18.3	18.3	15.4	17.6
	102	102	23.2	23.4	20.1	21.8	21.3	21.8	21.7	29.4
	103	103	19.5	18.0	22.6	22.5	24.4	23.6	20.4	17.2
	104	104	19.9	16.0	18.5	19.6	31.4	18.8	16.8	14.2
	105	105	23.2	22.3	20.1	21.4	24.4	19.0	17.7	21.6
Test Group 1/ F 100 mg/kg bw/d	106	106	20.9	29.2	31.4	30.5	25.1	23.4	29.0	28.6
	107	107	16.3	15.2	14.5	17.1	14.4	19.5	11.8	19.8
	108	108	14.3	12.2	20.4	13.5	17.9	15.3	18.3	16.3
	109	109	26.2	23.7	28.7	21.4	29.4	23.2	28.7	21.1
	110	110	18.6	19.6	15.5	21.8	22.3	21.6	20.9	23.9
Test Group 2/ F 300 mg/kg bw/d	111	111	22.8	20.0	25.3	21.4	25.6	31.4	25.1	25.2
	112	112	19.2	22.5	25.4	22.0	26.1	22.7	19.3	27.5
	113	113	20.0	20.7	21.4	22.8	21.9	26.4	26.2	25.8
	114	114	21.5	23.9	28.2	25.4	25.8	26.0	19.4	26.7
	115	115	25.5	23.6	19.6	24.3	25.2	23.3	15.8	25.1
Test Group 3/ F 600 mg/kg bw/d	116	116	11.2	13.2	13.0	15.2	12.1	16.1	16.4	17.7
	117	117	21.2	25.9	22.2	25.0	25.9	28.5	29.6	34.0
	118	118	20.5	27.4	21.7	23.4	27.6	28.8	23.1	28.0
	119	119	15.8	28.4	26.9	25.4	23.4	24.3	27.3	26.0
	120	120	18.5	22.1	26.0	29.8	28.4	30.0	26.8	30.1

d = day

**Individual Food Consumption Per Animal And Day [g/Day]**Sex: **Male** - Phase: **In-life**

Group	Cage	Animals	d 0 -> 7	d 7 -> 14	d 14 -> 21	d 21 -> 28
<b>Test Group 0/ M</b> <b>0 mg/kg bw/d</b>	01	01	35.0	29.4	30.1	31.1
	02	02	28.2	26.6	30.0	27.2
	03	03	26.9	26.3	27.0	27.1
	04	04	26.7	26.0	26.8	26.5
	05	05	29.5	28.2	28.2	28.9
<b>Test Group 1/ M</b> <b>100 mg/kg bw/d</b>	06	06	28.4	29.7	30.9	33.3
	07	07	27.5	27.5	28.3	27.8
	08	08	28.2	29.1	30.7	33.2
	09	09	24.9	25.1	26.8	27.1
	10	10	28.0	29.2	28.3	24.2
<b>Test Group 2/ M</b> <b>300 mg/kg bw/d</b>	11	11	23.7	21.7	26.6	26.9
	12	12	25.6	27.4	29.3	31.1
	13	13	21.0	25.0	25.1	26.6
	14	14	22.4	24.5	27.3	21.3
	15	15	25.3	21.3	27.7	25.8
<b>Test Group 3/ M</b> <b>600 mg/kg bw/d</b>	16	16	22.1	25.2	29.5	30.4
	17	17	14.6	18.2	19.3	20.8
	18	18	23.7	23.0	28.4	26.5
	19	19	22.3	16.6	27.9	34.0
	20	20	13.7	20.6	24.9	27.3

d = day

**Individual Food Consumption Per Animal And Day [g/Day]**Sex: **Female** - Phase: **In-life**

Group	Cage	Animals	d 0 -> 7	d 7 -> 14	d 14 -> 21	d 21 -> 28
<b>Test Group 0/ F</b> <b>0 mg/kg bw/d</b>	101	101	16.9	17.4	18.7	17.6
	102	102	21.8	18.4	20.1	19.2
	103	103	17.8	20.2	20.6	19.3
	104	104	15.6	12.1	23.2	18.0
	105	105	18.0	19.6	18.8	18.2
<b>Test Group 1/ F</b> <b>100 mg/kg bw/d</b>	106	106	17.4	18.3	18.8	20.0
	107	107	14.5	15.1	17.6	15.2
	108	108	14.4	17.1	18.9	17.7
	109	109	22.9	21.5	24.4	21.5
	110	110	18.3	19.0	22.2	19.3
<b>Test Group 2/ F</b> <b>300 mg/kg bw/d</b>	111	111	17.2	17.6	20.2	20.1
	112	112	14.0	19.2	22.1	19.1
	113	113	15.4	18.5	19.9	20.0
	114	114	13.5	19.2	20.6	19.9
	115	115	18.2	19.6	19.2	20.4
<b>Test Group 3/ F</b> <b>600 mg/kg bw/d</b>	116	116	10.5	15.1	14.6	16.1
	117	117	15.5	17.1	18.6	19.2
	118	118	15.7	19.3	21.4	24.1
	119	119	17.2	18.7	18.2	18.5
	120	120	15.5	18.1	18.9	18.6

d = day

Study

01R0066/05R032

21-Feb-2017 10:27

ToxData© System 3.0

**Individual Body Weights - BW / Body Weights [g]**Sex: **Male** - Phase: **In-life**

<b>Dose Group</b>	<b>Animal Number</b>	<b>day 0</b>	<b>day 7</b>	<b>day 14</b>	<b>day 21</b>	<b>day 28</b>
<b>Test Group 0/ M</b> <b>0 mg/kg bw/d</b>	01	377.7	431.7	469.9	509.4	548.0
	02	370.3	408.3	446.2	475.9	496.8
	03	367.6	405.9	439.8	464.7	487.4
	04	358.3	384.9	408.8	425.0	446.1
	05	361.2	398.1	420.9	437.1	458.5
<b>Test Group 1/ M</b> <b>100 mg/kg bw/d</b>	06	398.8	440.1	475.7	500.7	530.1
	07	363.6	395.8	429.7	448.5	466.7
	08	378.6	425.6	457.8	491.8	521.0
	09	381.2	398.5	422.0	453.6	478.8
	10	371.9	406.5	434.0	455.6	448.8
<b>Test Group 2/ M</b> <b>300 mg/kg bw/d</b>	11	368.0	400.3	414.2	436.3	461.7
	12	378.0	402.7	436.7	464.2	498.9
	13	377.6	388.9	404.4	417.2	438.2
	14	367.1	389.8	400.4	407.4	409.0
	15	388.7	406.4	414.7	432.2	445.9
<b>Test Group 3/ M</b> <b>600 mg/kg bw/d</b>	16	367.8	381.6	404.0	435.8	449.8
	17	366.3	354.3	358.2	365.0	376.0
	18	383.7	400.9	413.5	439.3	456.7
	19	375.7	383.8	381.7	404.4	448.8
	20	370.6	352.1	372.4	405.6	419.4



Study

01R0066/05R032

21-Feb-2017 10:27

ToxData© System 3.0

**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
Test Group 0/ F 0 mg/kg bw/d	101	200.2	211.0	229.4	241.9	244.8
	102	212.2	233.4	244.4	253.6	264.8
	103	214.9	227.2	254.5	271.6	275.7
	104	223.3	239.8	266.8	280.2	289.4
	105	226.5	246.4	265.1	272.7	277.5
Test Group 1/ F 100 mg/kg bw/d	106	213.2	224.6	244.0	255.2	260.6
	107	197.5	212.1	218.8	229.9	231.1
	108	212.6	219.9	241.3	250.4	262.5
	109	233.7	247.6	267.2	282.7	287.6
	110	227.5	246.2	252.2	269.1	274.4
Test Group 2/ F 300 mg/kg bw/d	111	211.8	220.1	239.5	252.6	257.6
	112	208.8	213.8	230.7	245.2	251.2
	113	220.4	237.1	246.2	251.8	263.9
	114	231.8	234.7	255.1	266.3	276.8
	115	215.9	237.0	248.9	266.8	269.9
Test Group 3/ F 600 mg/kg bw/d	116	215.4	210.2	229.2	234.8	249.9
	117	202.8	213.6	221.6	236.5	244.5
	118	232.2	242.0	265.2	281.5	290.9
	119	224.8	237.1	243.6	257.7	257.0
	120	217.0	223.1	235.5	251.5	250.0

**Individual Changes Body Weights - BW / Body Weights [g]**Sex: **Male** - Phase: **In-life**

<b>Dose Group</b>	<b>Animal Number</b>	<b>d 0 -&gt; 7</b>	<b>d 7 -&gt; 14</b>	<b>d 14 -&gt; 21</b>	<b>d 21 -&gt; 28</b>
<b>Test Group 0/ M</b> <b>0 mg/kg bw/d</b>	01	54.0	38.2	39.5	38.6
	02	38.0	37.9	29.7	20.9
	03	38.3	33.9	24.9	22.7
	04	26.6	23.9	16.2	21.1
	05	36.9	22.8	16.2	21.4
<b>Test Group 1/ M</b> <b>100 mg/kg bw/d</b>	06	41.3	35.6	25.0	29.4
	07	32.2	33.9	18.8	18.2
	08	47.0	32.2	34.0	29.2
	09	17.3	23.5	31.6	25.2
	10	34.6	27.5	21.6	-6.8
<b>Test Group 2/ M</b> <b>300 mg/kg bw/d</b>	11	32.3	13.9	22.1	25.4
	12	24.7	34.0	27.5	34.7
	13	11.3	15.5	12.8	21.0
	14	22.7	10.6	7.0	1.6
	15	17.7	8.3	17.5	13.7
<b>Test Group 3/ M</b> <b>600 mg/kg bw/d</b>	16	13.8	22.4	31.8	14.0
	17	-12.0	3.9	6.8	11.0
	18	17.2	12.6	25.8	17.4
	19	8.1	-2.1	22.7	44.4
	20	-18.5	20.3	33.2	13.8

d = day

**Individual Changes Body Weights - BW / Body Weights [g]**Sex: **Female** - Phase: **In-life**

<b>Dose Group</b>	<b>Animal Number</b>	<b>d 0 -&gt; 7</b>	<b>d 7 -&gt; 14</b>	<b>d 14 -&gt; 21</b>	<b>d 21 -&gt; 28</b>
<b>Test Group 0/ F</b> <b>0 mg/kg bw/d</b>	101	10.8	18.4	12.5	2.9
	102	21.2	11.0	9.2	11.2
	103	12.3	27.3	17.1	4.1
	104	16.5	27.0	13.4	9.2
	105	19.9	18.7	7.6	4.8
<b>Test Group 1/ F</b> <b>100 mg/kg bw/d</b>	106	11.4	19.4	11.2	5.4
	107	14.6	6.7	11.1	1.2
	108	7.3	21.4	9.1	12.1
	109	13.9	19.6	15.5	4.9
	110	18.7	6.0	16.9	5.3
<b>Test Group 2/ F</b> <b>300 mg/kg bw/d</b>	111	8.3	19.4	13.1	5.0
	112	5.0	16.9	14.5	6.0
	113	16.7	9.1	5.6	12.1
	114	2.9	20.4	11.2	10.5
	115	21.1	11.9	17.9	3.1
<b>Test Group 3/ F</b> <b>600 mg/kg bw/d</b>	116	-5.2	19.0	5.6	15.1
	117	10.8	8.0	14.9	8.0
	118	9.8	23.2	16.3	9.4
	119	12.3	6.5	14.1	-0.7
	120	6.1	12.4	16.0	-1.5

d = day

**Red blood cell + coagulation parameters**Sex: **Male** - Phase: **In-life**

		Test Group 0/ M 0 mg/kg bw/d	Test Group 1/ M 100 mg/kg bw/d	Test Group 2/ M 300 mg/kg bw/d	Test Group 3/ M 600 mg/kg bw/d
RBC [tera/L] day 29	Mean	7.45 k	7.66	7.76	7.31
	S.d.	0.35	0.30	0.34	0.31
	N	5	5	5	5
	Median	7.31	7.61	7.74	7.34
HGB [mmol/L] day 29	Mean	8.3 v	8.5	8.3	7.9*
	S.d.	0.2	0.4	0.2	0.2
	N	5	5	5	5
	Median	8.3	8.4	8.3	7.9
HCT [L/L] day 29	Mean	0.386 k	0.397	0.390	0.372
	S.d.	0.011	0.021	0.013	0.010
	N	5	5	5	5
	Median	0.386	0.396	0.391	0.373
MCV [fL] day 29	Mean	51.9 k	51.8	50.3	50.9
	S.d.	1.8	1.3	0.8	1.2
	N	5	5	5	5
	Median	52.2	52.1	50.5	50.8
MCH [fmol] day 29	Mean	1.12 k	1.11	1.07	1.09
	S.d.	0.04	0.03	0.03	0.03
	N	5	5	5	5
	Median	1.13	1.10	1.06	1.08
MCHC [mmol/L] day 29	Mean	21.47 k	21.35	21.20	21.38
	S.d.	0.16	0.23	0.35	0.14
	N	5	5	5	5
	Median	21.47	21.41	21.20	21.32
RETA [giga/L] day 29	Mean	181.2 k	158.4	152.1	139.0
	S.d.	39.1	56.5	55.4	60.3
	N	5	5	5	5
	Median	173.1	176.2	141.8	124.8
PLT [giga/L] day 29	Mean	940 k	874	1,017	820
	S.d.	61	139	199	138
	N	5	5	5	5
	Median	904	817	1,004	843
HQT [sec] day 29	Mean	37.6 k	37.8	40.3	38.4
	S.d.	2.3	3.6	3.0	4.9
	N	5	5	5	5
	Median	38.5	35.9	41.3	37.8

Statistic Profile = Kruskal-Wallis + Wilcoxon test (two-sided), \* p<=0.05, \*\* p <=0.01, X = Group excluded from statistics  
k=KRUSKAL-WALLIS; v=KRUSKAL-WALLIS-WILCOX

**Red blood cell + coagulation parameters**Sex: **Female** - Phase: **In-life**

		Test Group 0/ F 0 mg/kg bw/d	Test Group 1/ F 100 mg/kg bw/d	Test Group 2/ F 300 mg/kg bw/d	Test Group 3/ F 600 mg/kg bw/d
RBC [tera/L] day 29	Mean	7.36 k	7.37	7.12	7.27
	S.d.	0.34	0.27	0.11	0.27
	N	5	5	5	5
	Median	7.45	7.34	7.09	7.31
HGB [mmol/L] day 29	Mean	8.4 k	8.4	8.3	8.1
	S.d.	0.2	0.1	0.2	0.2
	N	5	5	5	5
	Median	8.3	8.4	8.3	8.0
HCT [L/L] day 29	Mean	0.388 k	0.386	0.383	0.375
	S.d.	0.011	0.011	0.006	0.019
	N	5	5	5	5
	Median	0.394	0.383	0.384	0.369
MCV [fL] day 29	Mean	52.7 k	52.4	53.8	51.5
	S.d.	1.3	2.4	0.6	1.7
	N	5	5	5	5
	Median	53.0	52.9	54.0	51.2
MCH [fmol] day 29	Mean	1.14 k	1.14	1.16	1.11
	S.d.	0.05	0.05	0.02	0.02
	N	5	5	5	5
	Median	1.16	1.15	1.16	1.10
MCHC [mmol/L] day 29	Mean	21.67 k	21.76	21.61	21.48
	S.d.	0.37	0.27	0.22	0.56
	N	5	5	5	5
	Median	21.79	21.75	21.59	21.50
RETA [giga/L] day 29	Mean	129.4 k	114.8	140.2	144.6
	S.d.	30.7	28.6	17.7	17.9
	N	5	5	5	5
	Median	122.1	118.2	138.3	149.9
PLT [giga/L] day 29	Mean	1,110 k	823	917	943
	S.d.	304	53	71	130
	N	5	5	5	5
	Median	1,038	801	940	928
HQT [sec] day 29	Mean	33.4 k	34.4	35.7	35.3
	S.d.	2.3	2.1	1.3	3.6
	N	5	5	5	5
	Median	33.2	34.8	35.3	34.9

Statistic Profile = Kruskal-Wallis + Wilcoxon test (two-sided), \* p<=0.05, \*\* p <=0.01, X = Group excluded from statistics  
k=KRUSKAL-WALLIS

Study

01R0066/05R032

03-Mar-2017 17:05

ToxData© System 3.0

**Total white and differential blood cell count**Sex: **Male** - Phase: **In-life**

		Test Group 0/ M 0 mg/kg bw/d	Test Group 1/ M 100 mg/kg bw/d	Test Group 2/ M 300 mg/kg bw/d	Test Group 3/ M 600 mg/kg bw/d
WBC [giga/L] day 29	Mean	10.23 k	11.85	10.26	8.59
	S.d.	2.47	1.29	2.15	1.16
	N	5	5	5	5
	Median	9.08	11.72	10.80	8.40
NEUTA [giga/L] day 29	Mean	1.03 k	1.15	1.24	1.32
	S.d.	0.29	0.10	0.16	0.38
	N	5	5	5	5
	Median	0.91	1.16	1.28	1.15
LYMPHA [giga/L] day 29	Mean	8.76 k	10.21	8.59	6.82
	S.d.	2.11	1.10	2.07	0.96
	N	5	5	5	5
	Median	7.72	10.13	8.88	6.90
MONOA [giga/L] day 29	Mean	0.23 k	0.24	0.23	0.18
	S.d.	0.08	0.04	0.02	0.02
	N	5	5	5	5
	Median	0.24	0.25	0.23	0.17
EOSA [giga/L] day 29	Mean	0.12 k	0.12	0.11	0.22
	S.d.	0.02	0.04	0.02	0.29
	N	5	5	5	5
	Median	0.12	0.14	0.10	0.09
BASOA [giga/L] day 29	Mean	0.03 k	0.04	0.03	0.02
	S.d.	0.02	0.01	0.01	0.01
	N	5	5	5	5
	Median	0.04	0.04	0.02	0.02
LUCA [giga/L] day 29	Mean	0.05 v	0.09	0.07	0.03
	S.d.	0.03	0.05	0.02	0.00
	N	5	5	5	5
	Median	0.04	0.07	0.07	0.03
NEUT [%] day 29	Mean	10.2 v	9.7	12.5	15.5 *
	S.d.	1.5	0.3	2.3	4.7
	N	5	5	5	5
	Median	10.4	9.7	12.9	13.7
LYMPH [%] day 29	Mean	85.6 v	86.2	83.2	79.4 *
	S.d.	1.7	0.4	3.1	5.8
	N	5	5	5	5
	Median	85.2	86.3	82.2	82.1
MONO [%] day 29	Mean	2.2 k	2.0	2.3	2.1
	S.d.	0.4	0.3	0.5	0.3
	N	5	5	5	5
	Median	2.2	2.1	2.2	2.2
EOS [%] day 29	Mean	1.2 k	1.0	1.1	2.3
	S.d.	0.3	0.3	0.2	2.7
	N	5	5	5	5
	Median	1.1	1.1	1.1	1.1
BASO [%] day 29	Mean	0.3 k	0.3	0.3	0.2
	S.d.	0.1	0.1	0.1	0.1
	N	5	5	5	5
	Median	0.3	0.3	0.3	0.3
LUC [%] day 29	Mean	0.5 k	0.7	0.7	0.4
	S.d.	0.2	0.3	0.2	0.1
	N	5	5	5	5
	Median	0.4	0.5	0.6	0.4

Statistic Profile = Kruskal-Wallis + Wilcoxon test (two-sided), \* p<=0.05, \*\* p <=0.01, X = Group excluded from statistics  
k=KRUSKAL-WALLIS; v=KRUSKAL-WALLIS-WILCOX

Study

01R0066/05R032

03-Mar-2017 17:05

ToxData© System 3.0

**Total white and differential blood cell count**Sex: **Female** - Phase: **In-life**

		Test Group 0/ F 0 mg/kg bw/d	Test Group 1/ F 100 mg/kg bw/d	Test Group 2/ F 300 mg/kg bw/d	Test Group 3/ F 600 mg/kg bw/d
WBC [giga/L] day 29	Mean	5.82 k	7.21	7.24	6.97
	S.d.	0.50	1.35	1.00	1.38
	N	5	5	5	5
	Median	5.59	7.23	6.93	6.42
NEUTA [giga/L] day 29	Mean	0.45 k	0.58	0.67	0.62
	S.d.	0.16	0.13	0.14	0.21
	N	5	5	5	5
	Median	0.43	0.55	0.61	0.56
LYMPHA [giga/L] day 29	Mean	5.14 k	6.36	6.29	6.04
	S.d.	0.46	1.23	0.94	1.15
	N	5	5	5	5
	Median	4.91	6.33	5.94	5.61
MONOA [giga/L] day 29	Mean	0.09 k	0.13	0.13	0.11
	S.d.	0.01	0.03	0.03	0.03
	N	5	5	5	5
	Median	0.10	0.13	0.11	0.11
EOSA [giga/L] day 29	Mean	0.08 k	0.09	0.12	0.15
	S.d.	0.01	0.01	0.05	0.08
	N	5	5	5	5
	Median	0.09	0.09	0.10	0.14
BASOA [giga/L] day 29	Mean	0.03 k	0.02	0.02	0.02
	S.d.	0.01	0.01	0.00	0.01
	N	5	5	5	5
	Median	0.03	0.01	0.02	0.02
LUCA [giga/L] day 29	Mean	0.03 k	0.02	0.03	0.03
	S.d.	0.01	0.01	0.01	0.01
	N	5	5	5	5
	Median	0.03	0.02	0.02	0.03
NEUT [%] day 29	Mean	7.8 k	8.1	9.3	8.7
	S.d.	2.5	1.2	2.2	1.8
	N	5	5	5	5
	Median	7.7	7.7	8.8	8.7
LYMPH [%] day 29	Mean	88.3 k	88.2	86.7	86.8
	S.d.	2.6	1.3	1.7	2.3
	N	5	5	5	5
	Median	88.0	88.2	86.9	87.4
MONO [%] day 29	Mean	1.6 k	1.8	1.8	1.6
	S.d.	0.2	0.3	0.4	0.4
	N	5	5	5	5
	Median	1.5	1.7	1.6	1.5
EOS [%] day 29	Mean	1.4 k	1.3	1.6	2.1
	S.d.	0.1	0.4	0.5	1.0
	N	5	5	5	5
	Median	1.4	1.3	1.4	1.6
BASO [%] day 29	Mean	0.5 k	0.2	0.2	0.3
	S.d.	0.2	0.1	0.1	0.1
	N	5	5	5	5
	Median	0.5	0.2	0.2	0.2
LUC [%] day 29	Mean	0.5 k	0.3	0.3	0.4
	S.d.	0.1	0.1	0.2	0.2
	N	5	5	5	5
	Median	0.5	0.3	0.3	0.4

Statistic Profile = Kruskal-Wallis + Wilcoxon test (two-sided), \* p<=0.05, \*\* p <=0.01, X = Group excluded from statistics  
k=KRUSKAL-WALLIS

Study

01R0066/05R032

IB 5

03-Mar-2017 17:05

ToxData© System 3.0

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

		Test Group 0/ M 0 mg/kg bw/d	Test Group 1/ M 100 mg/kg bw/d	Test Group 2/ M 300 mg/kg bw/d	Test Group 3/ M 600 mg/kg bw/d
ALT [µkat/L] day 29	Mean	0.75 k	0.87	0.76	0.90
	S.d.	0.12	0.13	0.22	0.16
	N	5	5	5	5
	Median	0.69	0.86	0.71	0.89
AST [µkat/L] day 29	Mean	1.87 k	2.23	1.90	1.88
	S.d.	0.39	0.30	0.46	0.41
	N	5	5	5	5
	Median	1.81	2.18	1.81	1.87
ALP [µkat/L] day 29	Mean	2.06 k	1.88	2.17	2.33
	S.d.	0.45	0.47	0.57	0.50
	N	5	5	5	5
	Median	2.04	1.78	2.10	2.32
GGT_C [nkat/L] day 29	Mean	25	25	25	25
	S.d.	0	0	0	0
	N	5	5	5	5
	Median	25	25	25	25

Statistic Profile = Wilcoxon test (one-sided+), Kruskal-Wallis + Wilcoxon test (two-sided), \* p<=0.05, \*\* p <=0.01, X = Group excluded from statistics  
k=KRUSKAL-WALLIS



Study

01R0066/05R032

03-Mar-2017 17:05

ToxData© System 3.0

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

		Test Group 0/ F 0 mg/kg bw/d	Test Group 1/ F 100 mg/kg bw/d	Test Group 2/ F 300 mg/kg bw/d	Test Group 3/ F 600 mg/kg bw/d
ALT [µkat/L] day 29	Mean	0.65 k	0.70	0.63	0.76
	S.d.	0.12	0.14	0.07	0.23
	N	5	5	5	5
	Median	0.62	0.69	0.67	0.63
AST [µkat/L] day 29	Mean	1.88 k	1.64	1.86	1.74
	S.d.	0.28	0.15	0.16	0.25
	N	4	4	5	5
	Median	1.81	1.62	1.81	1.68
ALP [µkat/L] day 29	Mean	1.36 k	1.14	1.38	1.54
	S.d.	0.13	0.16	0.26	0.28
	N	5	5	5	5
	Median	1.36	1.13	1.36	1.53
GGT_C [nkat/L] day 29	Mean	25	25	25	25
	S.d.	0	0	0	0
	N	5	5	5	5
	Median	25	25	25	25

Statistic Profile = Wilcoxon test (one-sided+), Kruskal-Wallis + Wilcoxon test (two-sided), \* p<=0.05, \*\* p <=0.01, X = Group excluded from statistics

k=KRUSKAL-WALLIS

Study

01R0066/05R032

03-Mar-2017 17:06

ToxData© System 3.0

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

		Test Group 0/ M 0 mg/kg bw/d	Test Group 1/ M 100 mg/kg bw/d	Test Group 2/ M 300 mg/kg bw/d	Test Group 3/ M 600 mg/kg bw/d
UREA [mmol/L] day 29	Mean	5.07 k	4.36	4.79	5.18
	S.d.	0.56	0.73	0.60	0.81
	N	5	5	5	5
	Median	4.84	4.06	4.84	5.04
CREA [mmol/L] day 29	Mean	20.8 k	21.5	20.8	27.0
	S.d.	3.5	2.5	2.3	3.9
	N	5	5	5	5
	Median	20.0	21.6	21.1	27.6
GLUC [mmol/L] day 29	Mean	6.49 k	6.34	6.12	5.86
	S.d.	0.35	0.78	0.65	1.23
	N	5	5	5	5
	Median	6.51	6.37	6.05	5.46
TBIL_C [µmol/L] day 29	Mean	2.20 k	1.80	1.76	2.03
	S.d.	0.19	0.56	0.41	0.31
	N	5	5	5	5
	Median	2.16	1.70	1.78	1.91
TPROT [g/L] day 29	Mean	61.17 k	59.92	60.22	63.65
	S.d.	1.82	2.66	3.58	0.97
	N	5	5	5	5
	Median	61.08	59.02	61.25	63.71
ALB [g/L] day 29	Mean	36.12 k	35.33	35.79	36.35
	S.d.	0.46	1.01	1.68	0.37
	N	5	5	5	5
	Median	36.01	35.29	35.62	36.40
GLOB [g/L] day 29	Mean	25.05 k	24.59	24.43	27.30
	S.d.	1.61	1.79	2.06	0.72
	N	5	5	5	5
	Median	24.61	24.44	24.84	27.31
CHOL [mmol/L] day 29	Mean	1.93 v	1.60	1.03 *	1.23 *
	S.d.	0.29	0.31	0.40	0.37
	N	5	5	5	5
	Median	1.92	1.72	0.90	1.17
TRIG [mmol/L] day 29	Mean	0.81 k	0.77	0.85	1.13
	S.d.	0.17	0.13	0.34	0.45
	N	5	5	5	5
	Median	0.76	0.79	0.88	1.05

Statistic Profile = Kruskal-Wallis + Wilcoxon test (two-sided), \* p<=0.05, \*\* p <=0.01, X = Group excluded from statistics  
k=KRUSKAL-WALLIS; v=KRUSKAL-WALLIS-WILCOX

Study

01R0066/05R032

03-Mar-2017 17:06

ToxData© System 3.0

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

		Test Group 0/ F 0 mg/kg bw/d	Test Group 1/ F 100 mg/kg bw/d	Test Group 2/ F 300 mg/kg bw/d	Test Group 3/ F 600 mg/kg bw/d
UREA [mmol/L] day 29	Mean	5.28 k	4.28	4.62	5.03
	S.d.	0.84	0.36	0.49	1.12
	N	5	5	5	5
	Median	5.02	4.13	4.68	4.37
CREA [mmol/L] day 29	Mean	24.4 k	23.1	25.1	23.3
	S.d.	1.5	1.6	2.1	1.7
	N	5	5	5	5
	Median	24.9	22.4	25.2	22.4
GLUC [mmol/L] day 29	Mean	5.48 k	5.96	5.44	5.87
	S.d.	0.90	0.68	0.31	0.43
	N	5	5	5	5
	Median	5.21	5.90	5.36	5.93
TBIL_C [µmol/L] day 29	Mean	1.74 k	1.84	1.98	1.87
	S.d.	0.12	0.25	0.28	0.43
	N	5	5	5	5
	Median	1.67	1.77	2.01	1.83
TPROT [g/L] day 29	Mean	61.72 k	61.63	60.68	63.27
	S.d.	2.61	2.65	3.27	1.14
	N	5	5	5	5
	Median	61.24	61.84	59.60	63.83
ALB [g/L] day 29	Mean	37.64 k	37.64	36.55	37.38
	S.d.	1.92	1.13	2.38	1.69
	N	5	5	5	5
	Median	37.45	37.13	36.17	37.99
GLOB [g/L] day 29	Mean	24.07 k	23.99	24.14	25.89
	S.d.	0.90	1.84	1.19	0.75
	N	5	5	5	5
	Median	23.95	24.47	23.79	25.84
CHOL [mmol/L] day 29	Mean	2.09 k	1.64	1.59	1.35
	S.d.	0.47	0.43	0.25	0.41
	N	5	5	5	5
	Median	1.99	1.46	1.58	1.35
TRIG [mmol/L] day 29	Mean	0.41 k	0.46	0.46	0.67
	S.d.	0.10	0.17	0.08	0.33
	N	5	5	5	5
	Median	0.40	0.40	0.50	0.48

Statistic Profile = Kruskal-Wallis + Wilcoxon test (two-sided), \* p<=0.05, \*\* p <=0.01, X = Group excluded from statistics  
k=KRUSKAL-WALLIS

Study

01R0066/05R032

03-Mar-2017 17:07

ToxData© System 3.0

**Electrolytes + minerals**Sex: **Male** - Phase: **In-life**

		Test Group 0/ M 0 mg/kg bw/d	Test Group 1/ M 100 mg/kg bw/d	Test Group 2/ M 300 mg/kg bw/d	Test Group 3/ M 600 mg/kg bw/d
NA [mmol/L] day 29	Mean	143.6 k	143.1	143.2	142.5
	S.d.	0.9	1.9	1.1	1.2
	N	5	5	5	5
	Median	143.4	144.1	143.7	141.9
K [mmol/L] day 29	Mean	4.95 k	5.02	4.99	5.18
	S.d.	0.33	0.16	0.18	0.29
	N	5	5	5	5
	Median	4.81	5.01	5.02	5.13
CL [mmol/L] day 29	Mean	99.9 k	98.6	98.9	97.6
	S.d.	0.9	2.0	2.4	0.6
	N	5	5	5	5
	Median	100.1	99.3	99.2	97.6
INP [mmol/L] day 29	Mean	2.20 k	2.21	2.30	2.34
	S.d.	0.17	0.15	0.17	0.32
	N	5	5	5	5
	Median	2.26	2.26	2.36	2.43
CA [mmol/L] day 29	Mean	2.56 k	2.54	2.54	2.63
	S.d.	0.05	0.03	0.06	0.06
	N	5	5	5	5
	Median	2.58	2.56	2.53	2.64

Statistic Profile = Kruskal-Wallis + Wilcoxon test (two-sided), \*  $p \leq 0.05$ , \*\*  $p \leq 0.01$ , X = Group excluded from statistics  
 k=KRUSKAL-WALLIS

**Electrolytes + minerals**Sex: **Female** - Phase: **In-life**

		Test Group 0/ F 0 mg/kg bw/d	Test Group 1/ F 100 mg/kg bw/d	Test Group 2/ F 300 mg/kg bw/d	Test Group 3/ F 600 mg/kg bw/d
NA [mmol/L] day 29	Mean	142.1 k	140.9	141.9	141.1
	S.d.	1.3	1.6	1.2	2.1
	N	5	5	5	5
	Median	142.1	141.9	141.7	141.0
K [mmol/L] day 29	Mean	4.76 v	4.61	4.43	4.93
	S.d.	0.64	0.19	0.17	0.18
	N	4	4	5	5
	Median	4.67	4.65	4.41	4.98
CL [mmol/L] day 29	Mean	99.6 k	99.0	98.3	98.3
	S.d.	1.0	1.2	1.3	1.5
	N	5	5	5	5
	Median	99.1	99.1	98.5	98.9
INP [mmol/L] day 29	Mean	1.81 k	1.80	1.74	1.84
	S.d.	0.18	0.17	0.10	0.14
	N	5	5	5	5
	Median	1.75	1.76	1.76	1.82
CA [mmol/L] day 29	Mean	2.56 k	2.55	2.55	2.57
	S.d.	0.09	0.04	0.09	0.07
	N	5	5	5	5
	Median	2.55	2.55	2.56	2.55

Statistic Profile = Kruskal-Wallis + Wilcoxon test (two-sided), \*  $p \leq 0.05$ , \*\*  $p \leq 0.01$ , X = Group excluded from statistics  
 k=KRUSKAL-WALLIS; v=KRUSKAL-WALLIS-WILCOX

Study

01R0066/05R032

IIB 1

03-Mar-2017 17:08

ToxData© System 3.0

**Red blood cell + coagulation parameters**Sex: **Male** - Phase: **In-life**

Dose Group	Animal Number	RBC [tera/L] day 29	HGB [mmol/L] day 29	HCT [L/L] day 29	MCV [fL] day 29	MCH [fmol] day 29	MCHC [mmol/L] day 29	RETA [giga/L] day 29	PLT [giga/L] day 29	HQT [sec] day 29
Test Group 0/ M 0 mg/kg bw/d	01	8.06	8.5	0.401	49.7	1.06	21.25	234.5	904	38.7
	02	7.22	8.2	0.377	52.2	1.13	21.67	197.8	900	36.3
	03	7.31	8.5	0.393	53.8	1.16	21.55	127.9	1,044	38.5
	04	7.22	8.3	0.386	53.4	1.15	21.47	172.6	904	40.2
	05	7.43	8.0	0.375	50.5	1.08	21.42	173.1	949	34.2
Test Group 1/ M 100 mg/kg bw/d	06	7.32	7.9	0.368	50.3	1.08	21.50	205.7	1,059	34.7
	07	7.61	8.4	0.396	52.1	1.10	21.09	201.7	983	35.9
	08	7.53	8.7	0.404	53.7	1.16	21.61	139.3	757	38.8
	09	7.73	8.4	0.393	50.8	1.09	21.41	176.2	817	35.8
	10	8.13	9.0	0.426	52.3	1.11	21.12	69.1	753	43.6
Test Group 2/ M 300 mg/kg bw/d	11	8.15	8.5	0.400	49.1	1.04	21.20	141.8	829	44.1
	12	7.74	8.2	0.391	50.5	1.06	21.09	194.3	1,051	41.3
	13	7.32	8.0	0.370	50.5	1.09	21.56	216.7	1,004	36.5
	14	7.55	8.3	0.388	51.4	1.11	21.49	132.1	870	38.0
	15	8.05	8.3	0.402	49.9	1.03	20.68	75.7	1,333	41.4
Test Group 3/ M 600 mg/kg bw/d	16	6.85	7.8	0.362	52.8	1.14	21.56	85.6	786	38.9
	17	7.34	7.9	0.373	50.8	1.08	21.22	124.8	949	37.8
	18	7.72	8.2	0.385	49.8	1.06	21.31	115.0	601	33.1
	19	7.25	7.8	0.362	49.9	1.07	21.48	242.9	843	35.9
	20	7.37	8.0	0.376	51.0	1.09	21.32	126.8	921	46.1

Study

01R0066/05R032

IIB 2

03-Mar-2017 17:08

ToxData© System 3.0

**Red blood cell + coagulation parameters**

Sex: Female - Phase: In-life

Dose Group	Animal Number	RBC [tera/L] day 29	HGB [mmol/L] day 29	HCT [L/L] day 29	MCV [fL] day 29	MCH [fmol] day 29	MCHC [mmol/L] day 29	RETA [giga/L] day 29	PLT [giga/L] day 29	HQT [sec] day 29
Test Group 0/ F 0 mg/kg bw/d	101	7.49	8.7	0.399	53.4	1.16	21.74	97.4	1,051	30.5
	102	7.17	8.3	0.380	52.9	1.16	21.95	169.2	879	35.7
	103	6.90	8.1	0.372	53.9	1.18	21.84	122.1	944	33.2
	104	7.79	8.3	0.394	50.5	1.06	21.01	152.7	1,640	35.8
	105	7.45	8.6	0.395	53.0	1.15	21.79	105.8	1,038	31.8
Test Group 1/ F 100 mg/kg bw/d	106	7.34	8.4	0.388	52.9	1.15	21.71	118.2	800	34.8
	107	7.23	8.3	0.378	52.3	1.15	22.00	94.0	918	31.3
	108	7.80	8.2	0.377	48.4	1.05	21.75	85.0	801	36.2
	109	7.09	8.4	0.383	54.1	1.19	22.01	118.4	796	36.2
	110	7.41	8.6	0.403	54.4	1.16	21.34	158.6	802	33.4
Test Group 2/ F 300 mg/kg bw/d	111	7.29	8.4	0.386	53.0	1.15	21.79	125.4	837	37.8
	112	7.09	8.3	0.384	54.2	1.17	21.59	161.7	975	35.8
	113	7.06	8.0	0.376	53.3	1.13	21.28	154.6	987	35.3
	114	7.16	8.5	0.390	54.5	1.19	21.84	121.0	940	34.5
	115	7.02	8.2	0.379	54.0	1.16	21.54	138.3	846	35.0
Test Group 3/ F 600 mg/kg bw/d	116	7.41	8.2	0.371	50.0	1.10	22.04	160.8	864	40.8
	117	7.20	7.9	0.369	51.2	1.10	21.37	123.1	1,085	34.9
	118	7.31	8.0	0.365	49.9	1.09	21.89	149.9	928	32.4
	119	6.86	7.8	0.362	52.8	1.14	21.50	128.3	1,059	32.0
	120	7.58	8.4	0.408	53.8	1.11	20.62	160.7	777	36.2

Study

01R0066/05R032

IIB 3

03-Mar-2017 17:10

ToxData© System 3.0

**Total white and differential blood cell count**Sex: **Male** - Phase: **In-life**

Dose Group	Animal Number	WBC [giga/L] day 29	NEUTA [giga/L] day 29	LYMPHA [giga/L] day 29	MONOA [giga/L] day 29	EOSA [giga/L] day 29	BASOA [giga/L] day 29	LUCA [giga/L] day 29	NEUT [%] day 29	LYMPH [%] day 29	MONO [%] day 29	EOS [%] day 29	BASO [%] day 29	LUC [%] day 29
Test Group 0/ M 0 mg/kg bw/d	01	13.72	1.55	11.51	0.35	0.15	0.06	0.10	11.3	83.9	2.6	1.1	0.4	0.7
	02	9.08	0.93	7.72	0.24	0.14	0.02	0.03	10.2	85.0	2.6	1.6	0.3	0.4
	03	11.91	0.91	10.54	0.25	0.12	0.04	0.04	7.7	88.5	2.1	1.0	0.3	0.3
	04	8.34	0.87	7.12	0.15	0.11	0.04	0.06	10.4	85.3	1.7	1.4	0.5	0.7
	05	8.12	0.91	6.92	0.18	0.09	0.01	0.02	11.2	85.2	2.2	1.1	0.1	0.3
Test Group 1/ M 100 mg/kg bw/d	06	11.72	1.16	10.13	0.25	0.08	0.03	0.06	9.9	86.4	2.1	0.7	0.3	0.5
	07	13.53	1.26	11.62	0.28	0.15	0.04	0.17	9.3	85.9	2.1	1.1	0.3	1.2
	08	12.64	1.23	10.91	0.21	0.16	0.06	0.07	9.7	86.3	1.6	1.3	0.5	0.5
	09	11.13	1.06	9.53	0.27	0.14	0.04	0.09	9.6	85.6	2.4	1.2	0.3	0.8
	10	10.22	1.04	8.85	0.18	0.07	0.03	0.06	10.2	86.6	1.8	0.7	0.3	0.5
Test Group 2/ M 300 mg/kg bw/d	11	12.86	1.34	11.09	0.22	0.12	0.02	0.06	10.5	86.2	1.7	1.0	0.2	0.4
	12	11.55	1.14	9.99	0.25	0.08	0.02	0.07	9.9	86.5	2.2	0.7	0.2	0.6
	13	7.98	1.03	6.55	0.24	0.09	0.02	0.04	12.9	82.1	3.0	1.1	0.3	0.5
	14	10.80	1.43	8.88	0.23	0.14	0.04	0.08	13.3	82.2	2.1	1.3	0.4	0.8
	15	8.12	1.28	6.42	0.20	0.10	0.03	0.08	15.7	79.1	2.5	1.2	0.4	1.0
Test Group 3/ M 600 mg/kg bw/d	16	9.31	1.15	7.83	0.17	0.11	0.02	0.03	12.3	84.1	1.8	1.1	0.3	0.4
	17	7.88	0.87	6.68	0.17	0.09	0.02	0.04	11.1	84.7	2.2	1.2	0.3	0.5
	18	10.15	1.78	7.39	0.18	0.73	0.03	0.03	17.5	72.9	1.8	7.2	0.3	0.3
	19	7.21	1.64	5.29	0.16	0.08	0.01	0.03	22.7	73.4	2.3	1.1	0.1	0.5
	20	8.40	1.15	6.90	0.22	0.09	0.02	0.03	13.7	82.1	2.6	1.0	0.2	0.3



Study

01R0066/05R032

IIB 4

03-Mar-2017 17:10

ToxData© System 3.0

**Total white and differential blood cell count**

Sex: Female - Phase: In-life

Dose Group	Animal Number	WBC [giga/L] day 29	NEUTA [giga/L] day 29	LYMPHA [giga/L] day 29	MONOA [giga/L] day 29	EOSA [giga/L] day 29	BASOA [giga/L] day 29	LUCA [giga/L] day 29	NEUT [%] day 29	LYMPH [%] day 29	MONO [%] day 29	EOS [%] day 29	BASO [%] day 29	LUC [%] day 29
Test Group 0/ F 0 mg/kg bw/d	101	5.59	0.43	4.91	0.11	0.08	0.04	0.02	7.7	88.0	1.9	1.4	0.7	0.3
	102	6.20	0.72	5.24	0.08	0.09	0.04	0.03	11.6	84.6	1.3	1.4	0.6	0.6
	103	5.28	0.30	4.78	0.08	0.07	0.03	0.02	5.8	90.5	1.5	1.3	0.5	0.4
	104	6.48	0.34	5.90	0.10	0.09	0.02	0.03	5.2	91.1	1.5	1.4	0.3	0.5
	105	5.55	0.47	4.86	0.10	0.09	0.01	0.03	8.5	87.5	1.8	1.5	0.2	0.5
Test Group 1/ F 100 mg/kg bw/d	106	5.38	0.42	4.73	0.09	0.11	0.01	0.01	7.8	88.0	1.7	2.0	0.2	0.2
	107	7.34	0.75	6.33	0.13	0.08	0.03	0.02	10.2	86.2	1.8	1.1	0.4	0.3
	108	6.93	0.51	6.18	0.11	0.09	0.01	0.02	7.4	89.2	1.6	1.3	0.1	0.3
	109	7.23	0.55	6.38	0.16	0.10	0.01	0.02	7.7	88.2	2.2	1.4	0.2	0.3
	110	9.17	0.67	8.20	0.14	0.09	0.03	0.04	7.3	89.5	1.5	0.9	0.3	0.5
Test Group 2/ F 300 mg/kg bw/d	111	8.97	0.61	7.94	0.17	0.21	0.02	0.02	6.8	88.4	1.9	2.4	0.3	0.2
	112	6.37	0.52	5.62	0.10	0.11	0.02	0.02	8.1	88.1	1.5	1.7	0.2	0.3
	113	7.11	0.73	6.10	0.11	0.10	0.02	0.05	10.3	85.8	1.6	1.4	0.3	0.7
	114	6.83	0.60	5.94	0.16	0.09	0.02	0.02	8.8	86.9	2.4	1.3	0.2	0.3
	115	6.93	0.87	5.84	0.10	0.09	0.01	0.02	12.6	84.2	1.4	1.3	0.2	0.2
Test Group 3/ F 600 mg/kg bw/d	116	6.42	0.56	5.61	0.13	0.08	0.02	0.01	8.7	87.5	2.1	1.2	0.3	0.2
	117	5.87	0.54	5.06	0.07	0.17	0.01	0.02	9.1	86.2	1.3	2.8	0.2	0.3
	118	7.87	0.89	6.56	0.10	0.27	0.02	0.03	11.2	83.3	1.3	3.5	0.2	0.4
	119	5.76	0.35	5.16	0.11	0.09	0.01	0.03	6.1	89.6	2.0	1.6	0.2	0.5
	120	8.94	0.76	7.81	0.14	0.14	0.04	0.05	8.6	87.4	1.5	1.5	0.4	0.6

Study

01R0066/05R032

IIB 5

03-Mar-2017 17:11

ToxData© System 3.0

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

Dose Group	Animal Number	ALT [µkat/L] day 29	AST [µkat/L] day 29	ALP [µkat/L] day 29	GGT_C [nkat/L] day 29
Test Group 0/ M 0 mg/kg bw/d	01	0.92	2.44	2.51	25
	02	0.66	1.81	2.04	25
	03	0.69	1.96	1.52	25
	04	0.82	1.76	2.51	25
	05	0.65	1.37	1.70	25
	06	0.88	2.12	1.47	25
Test Group 1/ M 100 mg/kg bw/d	07	1.09	2.54	2.69	25
	08	0.79	2.51	1.78	25
	09	0.74	1.81	1.69	25
	10	0.86	2.18	1.79	25
Test Group 2/ M 300 mg/kg bw/d	11	1.10	2.49	2.10	25
	12	0.84	2.23	2.93	25
	13	0.71	1.68	1.74	25
	14	0.59	1.81	1.53	25
	15	0.55	1.31	2.54	25
Test Group 3/ M 600 mg/kg bw/d	16	1.05	1.87	2.40	25
	17	0.72	1.97	2.32	25
	18	1.06	2.51	1.93	25
	19	0.76	1.68	1.86	25
	20	0.89	1.39	3.12	25

Study

01R0066/05R032

IIB 6

03-Mar-2017 17:11

ToxData© System 3.0

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

Dose Group	Animal Number	ALT [μkat/L] day 29	AST [μkat/L] day 29	ALP [μkat/L] day 29	GGT_C [nkat/L] day 29
Test Group 0/ F 0 mg/kg bw/d	101	0.64	3.37OL	1.18	25
	102	0.62	1.61	1.43	25
	103	0.85	1.87	1.36	25
	104	0.51	2.26	1.52	25
	105	0.62	1.76	1.31	25
Test Group 1/ F 100 mg/kg bw/d	106	0.69	1.83	0.99	25
	107	0.84	5.43OL	0.99	25
	108	0.55	1.64	1.37	25
	109	0.83	1.61	1.22	25
	110	0.58	1.47	1.13	25
Test Group 2/ F 300 mg/kg bw/d	111	0.67	1.87	1.36	25
	112	0.67	1.78	1.13	25
	113	0.63	1.70	1.57	25
	114	0.51	1.81	1.11	25
	115	0.69	2.12	1.71	25
Test Group 3/ F 600 mg/kg bw/d	116	0.63	1.86	1.53	25
	117	0.53	1.49	1.66	25
	118	0.61	2.12	1.91	25
	119	1.00	1.57	1.47	25
	120	1.01	1.68	1.14	25

OL = Outlier

Study

01R0066/05R032

IIB 7

03-Mar-2017 17:12

ToxData© System 3.0

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

Dose Group	Animal Number	UREA [mmol/L] day 29	CREA [mmol/L] day 29	GLUC [mmol/L] day 29	TBIL_C [μmol/L] day 29	TPROT [g/L] day 29	ALB [g/L] day 29	GLOB [g/L] day 29	CHOL [mmol/L] day 29	TRIG [mmol/L] day 29
Test Group 0/ M 0 mg/kg bw/d	01	5.12	26.8	5.98	2.16	63.54	36.01	27.53	1.89	0.69
	02	4.80	20.2	6.52	2.30	61.08	36.47	24.61	1.92	0.99
	03	4.84	18.0	6.51	2.45	58.67	35.51	23.16	2.04	0.76
	04	6.01	20.0	6.96	1.94	60.45	35.95	24.50	1.49	0.63
	05	4.56	18.9	6.49	2.15	62.10	36.67	25.43	2.30	0.98
Test Group 1/ M 100 mg/kg bw/d	06	5.11	18.9	5.65	2.73	62.47	35.79	26.68	1.72	0.79
	07	5.17	23.8	6.37	1.70	62.83	36.77	26.06	1.84	0.89
	08	4.06	24.3	5.65	1.44	56.58	34.22	22.36	1.62	0.84
	09	3.58	19.1	6.51	1.84	59.02	34.58	24.44	1.74	0.78
	10	3.90	21.6	7.54	1.31	58.72	35.29	23.43	1.07	0.54
Test Group 2/ M 300 mg/kg bw/d	11	4.07	21.1	5.73	1.36	65.15	38.29	26.86	0.68	1.23
	12	4.84	20.5	5.30	1.78	61.25	36.41	24.84	0.73	0.88
	13	4.44	17.2	6.05	1.90	61.25	35.62	25.63	1.23	0.54
	14	4.91	23.0	6.62	2.35	57.17	33.95	23.22	1.63	0.48
	15	5.67	22.4	6.89	1.40	56.29	34.70	21.59	0.90	1.13
Test Group 3/ M 600 mg/kg bw/d	16	5.04	29.8	4.75	1.91	63.31	35.95	27.36	0.91	0.74
	17	4.67	21.3	5.90	1.76	65.07	36.67	28.40	1.78	1.79
	18	5.98	31.2	5.26	2.36	63.76	36.73	27.03	1.41	0.73
	19	4.19	27.6	7.93	2.36	63.71	36.40	27.31	1.17	1.34
	20	6.03	25.2	5.46	1.76	62.39	35.99	26.40	0.90	1.05

Study

01R0066/05R032

IIB 8

03-Mar-2017 17:12

ToxData© System 3.0

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

Dose Group	Animal Number	UREA [mmol/L] day 29	CREA [mmol/L] day 29	GLUC [mmol/L] day 29	TBIL_C [μmol/L] day 29	TPROT [g/L] day 29	ALB [g/L] day 29	GLOB [g/L] day 29	CHOL [mmol/L] day 29	TRIG [mmol/L] day 29
Test Group 0/ F 0 mg/kg bw/d	101	6.66	24.9	4.48	1.93	65.71	40.75	24.96	1.99	0.40
	102	4.70	23.0	6.82	1.66	59.30	36.53	22.77	1.97	0.35
	103	5.43	26.2	5.21	1.65	59.64	35.69	23.95	2.09	0.28
	104	4.60	25.2	5.87	1.81	62.69	37.80	24.89	1.56	0.51
	105	5.02	22.7	5.04	1.67	61.24	37.45	23.79	2.84	0.52
Test Group 1/ F 100 mg/kg bw/d	106	3.92	22.4	5.05	1.54	60.50	37.13	23.37	1.46	0.37
	107	4.05	25.2	6.91	1.97	65.52	39.60	25.92	1.84	0.75
	108	4.77	24.3	5.90	1.72	62.02	37.55	24.47	1.33	0.32
	109	4.13	22.1	5.74	2.21	58.25	37.11	21.14	1.27	0.40
	110	4.54	21.3	6.22	1.77	61.84	36.81	25.03	2.31	0.47
Test Group 2/ F 300 mg/kg bw/d	111	4.68	25.2	5.36	1.58	59.21	34.48	24.73	1.60	0.50
	112	4.46	21.9	5.16	2.22	58.23	34.94	23.29	1.99	0.34
	113	5.30	27.9	5.54	2.01	59.96	36.17	23.79	1.36	0.50
	114	3.94	25.7	5.22	2.26	66.42	40.51	25.91	1.58	0.44
	115	4.72	24.9	5.92	1.83	59.60	36.63	22.97	1.40	0.53
Test Group 3/ F 600 mg/kg bw/d	116	4.15	21.9	6.39	1.27	61.26	34.76	26.50	1.19	1.11
	117	4.14	22.4	6.06	1.83	63.44	36.65	26.79	1.35	0.35
	118	4.37	22.1	5.93	2.44	63.85	38.76	25.09	0.86	0.48
	119	6.24	24.3	5.24	2.04	63.97	38.72	25.25	1.98	0.48
	120	6.26	25.7	5.72	1.76	63.83	37.99	25.84	1.38	0.91

Study

01R0066/05R032

IIB 9

03-Mar-2017 17:13

ToxData© System 3.0

**Electrolytes + minerals**Sex: **Male** - Phase: **In-life**

Dose Group	Animal Number	NA [mmol/L] day 29	K [mmol/L] day 29	CL [mmol/L] day 29	INP [mmol/L] day 29	CA [mmol/L] day 29
Test Group 0/ M 0 mg/kg bw/d	01	143.6	5.03	99.0	2.35	2.53
	02	143.1	4.63	98.9	2.26	2.58
	03	142.7	5.48	100.7	2.36	2.61
	04	143.4	4.81	100.1	2.04	2.49
	05	145.1	4.81	100.6	2.01	2.61
	06	140.6	4.85	95.8	2.40	2.58
Test Group 1/ M 100 mg/kg bw/d	07	141.7	5.01	97.3	2.27	2.56
	08	145.2	5.06	99.3	2.26	2.56
	09	144.1	5.27	99.8	2.06	2.51
	10	144.1	4.93	100.6	2.07	2.51
Test Group 2/ M 300 mg/kg bw/d	11	142.0	4.94	96.0	2.38	2.64
	12	143.8	5.03	99.2	2.36	2.55
	13	142.2	4.74	97.1	2.25	2.52
	14	143.7	5.02	100.2	2.03	2.53
	15	144.5	5.23	101.9	2.46	2.48
Test Group 3/ M 600 mg/kg bw/d	16	141.4	5.13	97.0	2.65	2.69
	17	144.1	4.83	97.6	1.81	2.54
	18	141.9	5.58	97.1	2.52	2.65
	19	143.4	5.33	98.3	2.29	2.64
	20	141.8	5.04	98.1	2.43	2.61

Study

01R0066/05R032

IIB 10

03-Mar-2017 17:13

ToxData© System 3.0

**Electrolytes + minerals**Sex: **Female** - Phase: **In-life**

Dose Group	Animal Number	NA [mmol/L] day 29	K [mmol/L] day 29	CL [mmol/L] day 29	INP [mmol/L] day 29	CA [mmol/L] day 29
Test Group 0/ F 0 mg/kg bw/d	101	140.3	5.69OL	98.9	2.11	2.67
	102	142.4	4.09	101.2	1.70	2.44
	103	142.1	4.71	99.1	1.75	2.53
	104	141.8	5.62	98.9	1.82	2.55
	105	144.0	4.62	100.1	1.67	2.61
Test Group 1/ F 100 mg/kg bw/d	106	138.7	4.79	97.5	1.76	2.56
	107	139.7	5.76OL	98.1	2.07	2.60
	108	141.9	4.62	99.1	1.68	2.55
	109	141.9	4.34	100.1	1.86	2.49
	110	142.5	4.68	100.4	1.64	2.55
Test Group 2/ F 300 mg/kg bw/d	111	140.7	4.49	97.2	1.85	2.56
	112	141.0	4.41	99.7	1.72	2.62
	113	141.7	4.27	96.9	1.77	2.45
	114	143.4	4.70	98.5	1.76	2.67
	115	142.8	4.30	99.4	1.58	2.47
Test Group 3/ F 600 mg/kg bw/d	116	138.8	5.05	96.3	1.77	2.48
	117	142.3	5.15	99.0	1.68	2.54
	118	141.0	4.98	97.3	1.82	2.55
	119	139.4	4.72	98.9	2.06	2.63
	120	144.0	4.77	100.0	1.85	2.64

OL = Outlier

BASF

## PATHOLOGY REPORT

IC 1/11

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

## ABSOLUTE WEIGHTS - MEAN VALUES (MALE)

Sacrifice			F1			
Sex			M			
Group			0	1	2	3
.....						
Terminal body weight	g	M	450.22	451.84	411.6	394.26 *
		% dev	100	100	91	88
		SD	34.884	33.7	26.689	29.63
		n	5	5	5	5
.....						
Adrenal glands	mg	M	69.6	62.8	76.0	84.4
		% dev	100	90	109	121
		SD	7.635	11.432	10.886	14.536
		n	5	5	5	5
.....						
Brain	g	M	2.09	2.136	2.06	2.052
		% dev	100	102	99	98
		SD	0.046	0.082	0.04	0.063
		n	5	5	5	5
.....						
Epididymides	g	M	1.148	1.094	1.05	0.974**
		% dev	100	95	91	85
		SD	0.104	0.042	0.053	0.041
		n	5	5	5	5
.....						
Heart	g	M	1.384	1.39	1.35	1.258
		% dev	100	100	98	91
		SD	0.093	0.142	0.095	0.126
		n	5	5	5	5
.....						
Kidneys	g	M	2.994	3.368	3.656	3.506
		% dev	100	112	122	117
		SD	0.227	0.21	0.628	0.444
		n	5	5	5	5
.....						
Liver	g	M	12.024	11.676	11.56	11.7
		% dev	100	97	96	97
		SD	1.064	1.763	1.483	0.467
		n	5	5	5	5
.....						
Prostate	g	M	1.158	1.118	1.072	0.872**
		% dev	100	97	93	75
		SD	0.115	0.04	0.173	0.122
		n	5	5	5	5
.....						
Seminal vesicle	g	M	1.28	1.352	1.236	0.958**
		% dev	100	106	97	75
		SD	0.065	0.161	0.143	0.175
		n	5	5	5	5
.....						

\*: P &lt;= 0.05, \*\*: P &lt;= 0.01

Kruskal-Wallis H and Wilcoxon test, two sided



BASF

## PATHOLOGY REPORT

IC 2/11

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

## ABSOLUTE WEIGHTS - MEAN VALUES (MALE)

Sacrifice			F1			
Sex			M			
Group			0	1	2	3
.....						
Spleen	g	M	0.852	0.8	0.74	0.678**
	% dev		100	94	87	80
	SD		0.055	0.114	0.083	0.025
	n		5	5	5	5
.....						
Testes	g	M	3.482	3.212	3.322	3.272
	% dev		100	92	95	94
	SD		0.23	0.365	0.317	0.156
	n		5	5	5	5
.....						
Thymus	mg	M	402.8	431.6	315.6	271.8 *
	% dev		100	107	78	67
	SD		52.055	83.566	67.341	89.184
	n		5	5	5	5
.....						
Thyroid glands	mg	M	25.0	23.8	21.8	20.8
	% dev		100	95	87	83
	SD		2.345	7.563	3.564	2.588
	n		5	5	5	5
.....						

\*: P &lt;= 0.05, \*\*: P &lt;= 0.01

Kruskal-Wallis H and Wilcoxon test, two sided

BASF

## PATHOLOGY REPORT

IC 3/11

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

## ABSOLUTE WEIGHTS - MEAN VALUES (FEMALE)

Sacrifice			F1			
Sex			F			
Group			0	1	2	3
.....						
Terminal body weight	g	M	254.56	243.16	241.84	237.44
	%	dev	100	96	95	93
		SD	15.544	18.513	11.709	18.116
		n	5	5	5	5
.....						
Adrenal glands	mg	M	72.2	70.4	70.8	73.8
	%	dev	100	98	98	102
		SD	4.266	5.941	7.981	13.368
		n	5	5	5	5
.....						
Brain	g	M	1.914	1.894	1.934	1.902
	%	dev	100	99	101	99
		SD	0.103	0.055	0.072	0.077
		n	5	5	5	5
.....						
Heart	g	M	0.972	0.906	0.904	0.884
	%	dev	100	93	93	91
		SD	0.062	0.049	0.046	0.049
		n	5	5	5	5
.....						
Kidneys	g	M	1.806	1.86	1.922	1.882
	%	dev	100	103	106	104
		SD	0.193	0.209	0.17	0.166
		n	5	5	5	5
.....						
Liver	g	M	6.444	6.33	6.67	6.978
	%	dev	100	98	104	108
		SD	0.501	0.382	0.483	0.738
		n	5	5	5	5
.....						
Ovaries	mg	M	99.2	98.8	93.0	89.6
	%	dev	100	100	94	90
		SD	12.578	14.237	6.042	22.557
		n	5	5	5	5
.....						
Spleen	g	M	0.474	0.524	0.514	0.466
	%	dev	100	111	108	98
		SD	0.111	0.068	0.069	0.104
		n	5	5	5	5
.....						
Thymus	mg	M	415.0	354.0	361.2	306.0 *
	%	dev	100	85	87	74
		SD	59.0	67.238	35.871	45.409
		n	5	5	5	5
.....						

\*: P ≤ 0.05, \*\*: P ≤ 0.01

Kruskal-Wallis H and Wilcoxon test, two sided

BASF

## PATHOLOGY REPORT

IC 4/11

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

## ABSOLUTE WEIGHTS - MEAN VALUES (FEMALE)

Sacrifice			F1			
Sex			F			
Group			0	1	2	3
.....						
Thyroid glands	mg	M	12.6	12.8	11.4	13.4
		% dev	100	102	90	106
		SD	2.881	2.49	2.793	3.209
		n	5	5	5	5
	.....					
Uterus	g	M	0.766	0.636	0.646	0.688
		% dev	100	83	84	90
		SD	0.569	0.309	0.154	0.225
		n	5	5	5	5
	.....					

\*: P &lt;= 0.05, \*\*: P &lt;= 0.01

Kruskal-Wallis H and Wilcoxon test, two sided

BASF

## PATHOLOGY REPORT

IC 5/11

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

## RELATIVE WEIGHTS - MEAN VALUES (MALE)

Sacrifice			F1			
Sex			M			
Group			0	1	2	3
.....						
Terminal body weight	%	M	100.0	100.0	100.0	100.0
	%	dev	100	100	100	100
		n	5	5	5	5
.....						
Adrenal glands	%	M	0.016	0.014	0.018	0.022
	%	dev	100	89	118	139
		SD	0.002	0.002	0.002	0.005
		n	5	5	5	5
.....						
Brain	%	M	0.467	0.474	0.502	0.523
	%	dev	100	102	108	112
		SD	0.045	0.03	0.034	0.042
		n	5	5	5	5
.....						
Epididymides	%	M	0.257	0.243	0.255	0.248
	%	dev	100	95	99	96
		SD	0.036	0.018	0.011	0.017
		n	5	5	5	5
.....						
Heart	%	M	0.308	0.307	0.328	0.319
	%	dev	100	100	107	104
		SD	0.016	0.019	0.015	0.024
		n	5	5	5	5
.....						
Kidneys	%	M	0.67	0.747	0.894	0.888**
	%	dev	100	112	133	133
		SD	0.083	0.039	0.179	0.069
		n	5	5	5	5
.....						
Liver	%	M	2.67	2.575	2.8	2.988
	%	dev	100	96	105	112
		SD	0.092	0.223	0.189	0.343
		n	5	5	5	5
.....						
Prostate	%	M	0.259	0.248	0.262	0.22
	%	dev	100	96	101	85
		SD	0.033	0.02	0.055	0.017
		n	5	5	5	5
.....						
Seminal vesicle	%	M	0.286	0.301	0.302	0.241
	%	dev	100	105	106	84
		SD	0.033	0.046	0.049	0.029
		n	5	5	5	5
.....						

\*: P &lt;= 0.05, \*\*: P &lt;= 0.01

Kruskal-Wallis H and Wilcoxon test, two sided

BASF

## PATHOLOGY REPORT

IC 6/11

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

## RELATIVE WEIGHTS - MEAN VALUES (MALE)

Sacrifice			F1			
Sex			M			
Group			0	1	2	3
.....						
Spleen	%	M	0.191	0.176	0.18	0.173
	%	dev	100	93	95	91
		SD	0.023	0.014	0.025	0.011
		n	5	5	5	5
.....						
Testes	%	M	0.779	0.712	0.81	0.832
	%	dev	100	91	104	107
		SD	0.095	0.081	0.093	0.044
		n	5	5	5	5
.....						
Thymus	%	M	0.09	0.095	0.076	0.068
	%	dev	100	106	85	75
		SD	0.016	0.017	0.014	0.018
		n	5	5	5	5
.....						
Thyroid glands	%	M	0.006	0.005	0.005	0.005
	%	dev	100	96	96	95
		SD	0.0	0.002	0.001	0.001
		n	5	5	5	5
.....						

\*: P &lt;= 0.05, \*\*: P &lt;= 0.01

Kruskal-Wallis H and Wilcoxon test, two sided

BASF

## PATHOLOGY REPORT

IC 7/11

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

## RELATIVE WEIGHTS - MEAN VALUES (FEMALE)

Sacrifice			F1			
Sex			F			
Group			0	1	2	3
.....						
Terminal body weight	%	M	100.0	100.0	100.0	100.0
	%	dev	100	100	100	100
		n	5	5	5	5
.....						
Adrenal glands	%	M	0.028	0.029	0.029	0.031
	%	dev	100	102	103	109
		SD	0.003	0.003	0.003	0.004
		n	5	5	5	5
.....						
Brain	%	M	0.753	0.783	0.8	0.804
	%	dev	100	104	106	107
		SD	0.047	0.065	0.019	0.048
		n	5	5	5	5
.....						
Heart	%	M	0.382	0.373	0.374	0.373
	%	dev	100	98	98	98
		SD	0.011	0.017	0.008	0.016
		n	5	5	5	5
.....						
Kidneys	%	M	0.708	0.763	0.795	0.793*
	%	dev	100	108	112	112
		SD	0.046	0.037	0.063	0.037
		n	5	5	5	5
.....						
Liver	%	M	2.53	2.611	2.756**	2.937**
	%	dev	100	103	109	116
		SD	0.078	0.192	0.094	0.174
		n	5	5	5	5
.....						
Ovaries	%	M	0.039	0.041	0.039	0.037
	%	dev	100	104	99	96
		SD	0.004	0.005	0.004	0.007
		n	5	5	5	5
.....						
Spleen	%	M	0.185	0.215	0.212	0.195
	%	dev	100	116	115	106
		SD	0.036	0.017	0.024	0.033
		n	5	5	5	5
.....						
Thymus	%	M	0.163	0.145	0.15	0.129
	%	dev	100	89	92	79
		SD	0.021	0.019	0.02	0.018
		n	5	5	5	5
.....						

\*: P &lt;= 0.05, \*\*: P &lt;= 0.01

Kruskal-Wallis H and Wilcoxon test, two sided

BASF

## PATHOLOGY REPORT

IC 8/11

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

## RELATIVE WEIGHTS - MEAN VALUES (FEMALE)

Sacrifice			F1			
Sex			F			
Group			0	1	2	3
.....						
Thyroid glands	%	M	0.005	0.005	0.005	0.006
	%	dev	100	105	93	112
		SD	0.002	0.001	0.001	0.001
		n	5	5	5	5
.....						
Uterus	%	M	0.301	0.259	0.266	0.295
	%	dev	100	86	88	98
		SD	0.225	0.118	0.059	0.115
		n	5	5	5	5
.....						

\*: P &lt;= 0.05, \*\*: P &lt;= 0.01

Kruskal-Wallis H and Wilcoxon test, two sided

BASF

## PATHOLOGY REPORT

IC 9/11

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

## INCIDENCE OF GROSS LESIONS

Sacrifice	-----							
Sex	F1							
Group	M					F		
Animals in selected group	0	1	2	3	0	1	2	3
	5	5	5	5	5	5	5	5
No abnormalities	3	4	1	1	5	4	5	5
Axillary lymph nodes	.	.	.	.	.	.	.	.
Discoloration	.	.	.	2	.	1	.	.
Cecum	.	.	.	.	.	.	.	.
Dilation	.	.	.	2	.	.	.	.
Kidneys	.	.	.	.	.	.	.	.
Cyst	1	1	1	.	.	.	.	.
Enlarged	.	.	3	4	.	.	.	.
Retraction	.	.	2	.	.	.	.	.
Liver	.	.	.	.	.	.	.	.
Focal constriction	1	.	.	.	.	.	.	.
Focus	1	.	.	.	.	.	.	.
Renal lymph nodes	.	.	.	.	.	.	.	.
Enlarged	.	.	1	.	.	.	.	.



BASF

## PATHOLOGY REPORT

IC 10/11

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

## INCIDENCE OF ALL MICROSCOPIC FINDINGS

Sacrifice		F1							
Sex		M				F			
Group		0	1	2	3	0	1	2	3
Animals in selected group		5	5	5	5	5	5	5	5
Adrenal cortex exam.		5	5	5	5	5	5	5	5
Hypertrophy, hyperplasia		.	.	.	3	.	.	.	.
Adrenal medulla exam.		5	5	5	5	5	5	5	5
Axillary lymph nodes exam.		.	.	.	2	.	1	.	.
Blood resorption		.	.	.	2	.	1	.	.
Cecum exam.		5	5	5	5	5	5	5	5
Dilation		.	.	.	5	.	.	.	2
Hemolymphret system exam.		5	5	5	5	5	5	5	5
Lymphoma, malignant		.	.	1	.	.	.	.	.
Kidneys exam.		5	5	5	5	5	5	.	5
Tubules, basophilic, (m)f		5	3	.	.	1	2	.	2
Cast, tubular		.	.	.	.	.	.	.	1
Degeneration/regeneration tu		.	2	5	5	.	.	.	.
Hypertrophy, tubule, (m)f		.	1	5	5	.	.	.	1
Mineralization, medulla, (m)f		.	1	2	1	4	1	.	1
Renal amph.vacuolar tumor, b		.	.	1	.	.	.	.	.
Hyperplasia, (multi)focal		.	1	1	.	.	.	.	.
Scar(s), cortical		.	.	1	.	.	.	.	.
Cyst(s)		1	1	.	.	.	.	.	.
Liver exam.		5	5	5	5	5	5	5	5
Hypertrophy, centrilobular		.	1	4	5	.	.	.	5
Constriction, focal		1	.	.	.	.	.	.	.
Fibrosis, (multi)focal		1	.	.	.	.	.	.	.
Infiltration, lymphoid, (m)f		5	5	4	5	5	5	5	5
Infiltrates, lymphoma		.	.	1	.	.	.	.	.
Fatty change, periportal		.	.	.	.	1	2	1	1
Mammary gland exam.		5	5	5	5	5	5	5	5
Atrophy, diffuse		.	.	3	4	.	.	.	.
Renal lymph nodes exam.		.	.	1	.	.	.	.	.
Hyperplasia, lympho-reticulo		.	.	1	.	.	.	.	.
Spleen exam.		5	5	5	5	5	5	5	5
Hematopoiesis, extramedullar		5	4	4	5	3	4	4	3
Pigment storage		5	5	5	5	5	5	5	5
Uterus exam.		.	.	.	.	5	5	5	5

BASF

## PATHOLOGY REPORT

IC 11/11

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

INCIDENCE AND GRADING OF MICROSCOPIC FINDINGS IN TARGET  
ORGANS

Sacrifice		F1							
Sex		M				F			
Group		0	1	2	3	0	1	2	3
Animals in selected group		5	5	5	5	5	5	5	5
.....									
Adrenal cortex	exam.	5	5	5	5	5	5	5	5
Hypertrophy, hyperplasia		.	.	.	3	.	.	.	.
	. 1.	.	.	.	3	.	.	.	.
Cecum	exam.	5	5	5	5	5	5	5	5
Dilation		.	.	.	5	.	.	.	2
	. P.	.	.	.	5	.	.	.	2
Kidneys	exam.	5	5	5	5	5	5	.	5
Degeneration/regeneration tu		.	2	5	5	.	.	.	.
	. 1.	.	1	3	1	.	.	.	.
	. 2.	.	1	1	2	.	.	.	.
	. 3.	.	.	1	2	.	.	.	.
Hypertrophy, tubule, (m)f		.	1	5	5	.	.	.	1
	. 1.	.	1	4	1	.	.	.	1
	. 2.	.	.	1	.	.	.	.	.
	. 3.	.	.	.	4	.	.	.	.
Mineralization, medulla, (m)f		.	1	2	1	4	1	.	1
	. 1.	.	1	2	.	2	1	.	1
	. 2.	.	.	.	.	2	.	.	.
	. 3.	.	.	.	1	.	.	.	.
Liver	exam.	5	5	5	5	5	5	5	5
Hypertrophy, centrilobular		.	1	4	5	.	.	.	5
	. 1.	.	1	.	1	.	.	.	1
	. 2.	.	.	4	3	.	.	.	4
	. 3.	.	.	.	1	.	.	.	.
Mammary gland	exam.	5	5	5	5	5	5	5	5
Atrophy, diffuse		.	.	3	4	.	.	.	.
	. P.	.	.	3	4	.	.	.	.

BASF

## PATHOLOGY REPORT

IIC 1/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

## ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

Sacrifice	F1					
Sex	M					
Group	0					
	Term. body weight g	Adrenal glands mg	Brain g	Epididy- mides g	Heart g	Kidneys g
M	450.22	69.6	2.09	1.148	1.384	2.994
SD	34.884	7.635	0.046	0.104	0.093	0.227
n	5	5	5	5	5	5
1	502.1	67.0	2.03	1.06	1.53	2.66
2	460.6	62.0	2.09	1.05	1.3	3.07
3	449.3	80.0	2.06	1.3	1.41	3.17
4	409.9	75.0	2.14	1.2	1.31	2.87
5	429.2	64.0	2.13	1.13	1.37	3.2

BASF

## PATHOLOGY REPORT

IIC 2/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

## ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

Sacrifice	F1					
Sex	M					
Group	0					
	Liver	Prostate	Seminal	Spleen	Testes	Thymus
	g	g	vesicle	g	g	mg
			g			
M	12.024	1.158	1.28	0.852	3.482	402.8
SD	1.064	0.115	0.065	0.055	0.23	52.055
n	5	5	5	5	5	5
1	13.5	1.05	1.25	0.78	3.28	393.0
2	12.67	1.2	1.23	0.89	3.27	400.0
3	11.34	1.33	1.31	0.82	3.81	332.0
4	10.84	1.15	1.38	0.85	3.61	411.0
5	11.77	1.06	1.23	0.92	3.44	478.0

BASF

PATHOLOGY REPORT

IIC 3/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

Sacrifice F1  
Sex M  
Group 0

Thyroid  
glands  
mg

M 25.0  
SD 2.345  
n 5

1 27.0  
2 27.0  
3 22.0  
4 23.0  
5 26.0

Property of BASF SE -  
Reproduction for other use prohibited  
without written permission

BASF

## PATHOLOGY REPORT

IIC 4/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

## ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

Sacrifice	F1					
Sex	M					
Group	1					
	Term. body weight g	Adrenal glands mg	Brain g	Epididy- mides g	Heart g	Kidneys g
M	451.84	62.8	2.136	1.094	1.39	3.368
SD	33.7	11.432	0.082	0.042	0.142	0.21
n	5	5	5	5	5	5
6	499.1	77.0	2.13	1.11	1.51	3.68
7	427.5	64.0	2.13	1.03	1.2	3.2
8	473.9	70.0	2.27	1.11	1.55	3.41
9	439.8	54.0	2.05	1.08	1.33	3.15
10	418.9	49.0	2.1	1.14	1.36	3.4

BASF

## PATHOLOGY REPORT

IIC 5/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

## ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

Sacrifice	F1					
Sex	M					
Group	1					
	Liver	Prostate	Seminal	Spleen	Testes	Thymus
	g	g	vesicle	g	g	mg
			g			
M	11.676	1.118	1.352	0.8	3.212	431.6
SD	1.763	0.04	0.161	0.114	0.365	83.566
n	5	5	5	5	5	5
6	14.45	1.12	1.26	0.92	3.55	484.0
7	11.49	1.07	1.25	0.76	2.88	395.0
8	11.91	1.14	1.49	0.92	3.3	425.0
9	10.84	1.09	1.2	0.73	2.78	536.0
10	9.69	1.17	1.56	0.67	3.55	318.0

BASF

PATHOLOGY REPORT

IIC 6/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

Sacrifice F1  
Sex M  
Group 1

Thyroid  
glands  
mg

M 23.8  
SD 7.563  
n 5

6 18.0  
7 37.0  
8 22.0  
9 20.0  
10 22.0

Property of BASF SE -  
Reproduction for other use prohibited  
without written permission



BASF

## PATHOLOGY REPORT

IIC 7/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

## ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

Sacrifice	F1					
Sex	M					
Group	2					
	Term. body	Adrenal		Epididy-		
	weight	glands	Brain	mides	Heart	Kidneys
	g	mg	g	g	g	g
M	411.6	76.0	2.06	1.05	1.35	3.656
SD	26.689	10.886	0.04	0.053	0.095	0.628
n	5	5	5	5	5	5
11	422.9	79.0	2.05	1.05	1.39	3.64
12	451.2	93.0	2.09	1.1	1.49	3.09
13	399.1	64.0	2.04	1.07	1.26	4.71
14	381.0	72.0	2.11	0.96	1.34	3.29
15	403.8	72.0	2.01	1.07	1.27	3.55

BASF

## PATHOLOGY REPORT

IIC 8/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

## ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

Sacrifice	F1					
Sex	M					
Group	2					
	Liver	Prostate	Seminal	Spleen	Testes	Thymus
	g	g	vesicle	g	g	mg
M	11.56	1.072	1.236	0.74	3.322	315.6
SD	1.483	0.173	0.143	0.083	0.317	67.341
n	5	5	5	5	5	5
11	12.42	0.91	1.13	0.66	2.86	406.0
12	13.47	1.07	1.2	0.76	3.44	346.0
13	11.03	1.15	1.37	0.87	3.38	328.0
14	9.54	1.32	1.4	0.73	3.21	252.0
15	11.34	0.91	1.08	0.68	3.72	246.0

BASF

PATHOLOGY REPORT

IIC 9/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

-----  
Sacrifice F1  
Sex M  
Group 2  
.....

Thyroid  
glands  
mg  
.....

M 21.8  
SD 3.564  
n 5

11 19.0  
12 21.0  
13 28.0  
14 21.0  
15 20.0  
.....

Property of BASF SE -  
Reproduction for other use prohibited  
without written permission

BASF

## PATHOLOGY REPORT

IIC 10/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 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	394.26	84.4	2.052	0.974	1.258	3.506
SD	29.63	14.536	0.063	0.041	0.126	0.444
n	5	5	5	5	5	5
16	414.5	93.0	1.99	1.02	1.24	4.05
17	351.0	88.0	2.07	0.96	1.2	3.17
18	423.5	68.0	2.15	0.96	1.41	3.89
19	404.5	71.0	2.04	1.01	1.35	3.38
20	377.8	102.0	2.01	0.92	1.09	3.04

BASF

## PATHOLOGY REPORT

IIC 11/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

## ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

Sacrifice	F1					
Sex	M					
Group	3					
	Liver	Prostate	Seminal	Spleen	Testes	Thymus
	g	g	vesicle	g	g	mg
M	11.7	0.872	0.958	0.678	3.272	271.8
SD	0.467	0.122	0.175	0.025	0.156	89.184
n	5	5	5	5	5	5
16	11.71	0.87	1.05	0.72	3.51	313.0
17	12.26	0.72	0.73	0.66	3.09	154.0
18	10.97	1.02	1.09	0.68	3.23	359.0
19	11.7	0.96	1.11	0.66	3.32	332.0
20	11.86	0.79	0.81	0.67	3.21	201.0

BASF

PATHOLOGY REPORT

IIC 12/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

-----  
Sacrifice F1  
Sex M  
Group 3  
.....

Thyroid  
glands  
mg  
.....

M 20.8  
SD 2.588  
n 5

16 24.0  
17 23.0  
18 20.0  
19 19.0  
20 18.0  
.....

Property of BASF SE -  
Reproduction for other use prohibited  
without written permission

BASF

PATHOLOGY REPORT

IIC 13/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

Sacrifice	F1					
Sex	F					
Group	0					
	Term. body	Adrenal	Brain	Heart	Kidneys	Liver
	weight	glands				
	g	mg	g	g	g	g
M	254.56	72.2	1.914	0.972	1.806	6.444
SD	15.544	4.266	0.103	0.062	0.193	0.501
n	5	5	5	5	5	5
101	228.9	74.0	1.85	0.87	1.56	5.63
102	252.9	76.0	1.9	1.01	1.75	6.47
103	258.6	65.0	1.83	0.97	1.74	6.47
104	269.2	72.0	1.9	1.03	1.91	6.67
105	263.2	74.0	2.09	0.98	2.07	6.98

BASF

## PATHOLOGY REPORT

IIC 14/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

## ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

Sacrifice F1  
Sex F  
Group 0

	Ovaries mg	Spleen g	Thymus mg	Thyroid glands mg	Uterus g
M	99.2	0.474	415.0	12.6	0.766
SD	12.578	0.111	59.0	2.881	0.569
n	5	5	5	5	5
101	93.0	0.34	346.0	17.0	0.44
102	89.0	0.37	458.0	14.0	1.78
103	96.0	0.56	491.0	11.0	0.56
104	121.0	0.52	378.0	11.0	0.53
105	97.0	0.58	402.0	10.0	0.52



BASF

## PATHOLOGY REPORT

IIC 15/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

## 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	243.16	70.4	1.894	0.906	1.86	6.33
SD	18.513	5.941	0.055	0.049	0.209	0.382
n	5	5	5	5	5	5
106	240.9	74.0	1.86	0.87	1.89	6.22
107	213.7	71.0	1.89	0.86	1.52	6.17
108	246.4	60.0	1.87	0.89	1.83	5.83
109	263.8	73.0	1.86	0.98	2.04	6.7
110	251.0	74.0	1.99	0.93	2.02	6.73

BASF

## PATHOLOGY REPORT

IIC 16/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

## ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

Sacrifice F1  
Sex F  
Group 1

	Ovaries mg	Spleen g	Thymus mg	Thyroid glands mg	Uterus g
M	98.8	0.524	354.0	12.8	0.636
SD	14.237	0.068	67.238	2.49	0.309
n	5	5	5	5	5
106	90.0	0.52	357.0	13.0	0.56
107	95.0	0.41	237.0	11.0	0.42
108	94.0	0.58	389.0	17.0	0.43
109	124.0	0.54	398.0	12.0	0.6
110	91.0	0.57	389.0	11.0	1.17

BASF

## PATHOLOGY REPORT

IIC 17/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

## ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

Sacrifice	F1					
Sex	F					
Group	2					
	Term. body	Adrenal	Brain	Heart	Kidneys	Liver
	weight	glands				
	g	mg	g	g	g	g
M	241.84	70.8	1.934	0.904	1.922	6.67
SD	11.709	7.981	0.072	0.046	0.17	0.483
n	5	5	5	5	5	5
111	230.1	68.0	1.83	0.85	1.86	6.21
112	231.0	66.0	1.92	0.87	1.86	6.15
113	243.6	67.0	1.96	0.94	1.72	6.7
114	258.3	68.0	2.03	0.96	2.0	7.13
115	246.2	85.0	1.93	0.9	2.17	7.16

BASF

## PATHOLOGY REPORT

IIC 18/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

## ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

Sacrifice F1  
Sex F  
Group 2

	Ovaries mg	Spleen g	Thymus mg	Thyroid glands mg	Uterus g
M	93.0	0.514	361.2	11.4	0.646
SD	6.042	0.069	35.871	2.793	0.154
n	5	5	5	5	5
111	99.0	0.49	414.0	9.0	0.48
112	97.0	0.52	357.0	10.0	0.53
113	96.0	0.43	314.0	12.0	0.84
114	87.0	0.62	353.0	16.0	0.61
115	86.0	0.51	368.0	10.0	0.77

BASF

## PATHOLOGY REPORT

IIC 19/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

## 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	237.44	73.8	1.902	0.884	1.882	6.978
SD	18.116	13.368	0.077	0.049	0.166	0.738
n	5	5	5	5	5	5
116	229.1	81.0	1.85	0.82	1.92	7.21
117	219.0	60.0	1.82	0.86	1.62	6.18
118	266.8	93.0	1.92	0.95	2.08	8.1
119	240.5	64.0	2.02	0.91	1.9	6.51
120	231.8	71.0	1.9	0.88	1.89	6.89

BASF

## PATHOLOGY REPORT

IIC 20/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

## ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

Sacrifice F1  
Sex F  
Group 3

	Ovaries mg	Spleen g	Thymus mg	Thyroid glands mg	Uterus g
M	89.6	0.466	306.0	13.4	0.688
SD	22.557	0.104	45.409	3.209	0.225
n	5	5	5	5	5
116	73.0	0.52	349.0	10.0	0.78
117	65.0	0.35	229.0	13.0	1.03
118	119.0	0.61	317.0	18.0	0.54
119	106.0	0.39	324.0	11.0	0.46
120	85.0	0.46	311.0	15.0	0.63

BASF

## PATHOLOGY REPORT

IIC 21/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

## RELATIVE WEIGHTS - INDIVIDUAL VALUES

Sacrifice	F1					
Sex	M					
Group	0					
	Term. body weight %	Adrenal glands %	Brain %	Epididymides %	Heart %	Kidneys %
M	100.0	0.016	0.467	0.257	0.308	0.67
SD		0.002	0.045	0.036	0.016	0.083
n	5	5	5	5	5	5
1	100.0	0.013	0.404	0.211	0.305	0.53
2	100.0	0.013	0.454	0.228	0.282	0.667
3	100.0	0.018	0.458	0.289	0.314	0.706
4	100.0	0.018	0.522	0.293	0.32	0.7
5	100.0	0.015	0.496	0.263	0.319	0.746

BASF

## PATHOLOGY REPORT

IIC 22/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

## RELATIVE WEIGHTS - INDIVIDUAL VALUES

Sacrifice	F1					
Sex	M					
Group	0					
	Liver	Prostate	Seminal	Spleen	Testes	Thymus
	%	%	vesicle	%	%	%
			%			
M	2.67	0.259	0.286	0.191	0.779	0.09
SD	0.092	0.033	0.033	0.023	0.095	0.016
n	5	5	5	5	5	5
1	2.689	0.209	0.249	0.155	0.653	0.078
2	2.751	0.261	0.267	0.193	0.71	0.087
3	2.524	0.296	0.292	0.183	0.848	0.074
4	2.645	0.281	0.337	0.207	0.881	0.1
5	2.742	0.247	0.287	0.214	0.801	0.111



BASF

PATHOLOGY REPORT

IIC 23/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

RELATIVE WEIGHTS - INDIVIDUAL VALUES

Sacrifice F1  
Sex M  
Group 0

Thyroid  
glands  
%

M 0.006  
SD 0.0  
n 5

1 0.005  
2 0.006  
3 0.005  
4 0.006  
5 0.006

Property of BASF SE -  
Reproduction for other use prohibited  
without written permission

BASF

## PATHOLOGY REPORT

IIC 24/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

## RELATIVE WEIGHTS - INDIVIDUAL VALUES

Sacrifice	F1					
Sex	M					
Group	1					
	Term. body	Adrenal	Brain	Epididy-	Heart	Kidneys
	weight	glands		mides		
	%	%	%	%	%	%
M	100.0	0.014	0.474	0.243	0.307	0.747
SD		0.002	0.03	0.018	0.019	0.039
n	5	5	5	5	5	5
6	100.0	0.015	0.427	0.222	0.303	0.737
7	100.0	0.015	0.498	0.241	0.281	0.749
8	100.0	0.015	0.479	0.234	0.327	0.72
9	100.0	0.012	0.466	0.246	0.302	0.716
10	100.0	0.012	0.501	0.272	0.325	0.812

IIC 25/67

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

Sacrifice	F1
Sex	M
Group	1

	Liver %	Prostate %	Seminal vesicle %	Spleen %	Testes %	Thymus %
M	2.575	0.248	0.301	0.176	0.712	0.095
SD	0.223	0.02	0.046	0.014	0.081	0.017
n	5	5	5	5	5	5
6	2.895	0.224	0.252	0.184	0.711	0.097
7	2.688	0.25	0.292	0.178	0.674	0.092
8	2.513	0.241	0.314	0.194	0.696	0.09
9	2.465	0.248	0.273	0.166	0.632	0.122
10	2.313	0.279	0.372	0.16	0.847	0.076

BASF

PATHOLOGY REPORT

IIC 26/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

RELATIVE WEIGHTS - INDIVIDUAL VALUES

Sacrifice F1  
Sex M  
Group 1

Thyroid  
glands  
%

M 0.005  
SD 0.002  
n 5

6 0.004  
7 0.009  
8 0.005  
9 0.005  
10 0.005

Property of BASF SE -  
Reproduction for other use prohibited  
without written permission

BASF

## PATHOLOGY REPORT

IIC 27/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

## RELATIVE WEIGHTS - INDIVIDUAL VALUES

Sacrifice	F1					
Sex	M					
Group	2					
	Term. body	Adrenal	Brain	Epididy-	Heart	Kidneys
	weight	glands		mides		
	%	%	%	%	%	%
M	100.0	0.018	0.502	0.255	0.328	0.894
SD		0.002	0.034	0.011	0.015	0.179
n	5	5	5	5	5	5
11	100.0	0.019	0.485	0.248	0.329	0.861
12	100.0	0.021	0.463	0.244	0.33	0.685
13	100.0	0.016	0.511	0.268	0.316	1.18
14	100.0	0.019	0.554	0.252	0.352	0.864
15	100.0	0.018	0.498	0.265	0.315	0.879

IIC 28/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

## RELATIVE WEIGHTS - INDIVIDUAL VALUES

## Sacrifice

F1

Sex

M

Group

2

	Liver %	Prostate %	Seminal vesicle %	Spleen %	Testes %	Thymus %
M	2.8	0.262	0.302	0.18	0.81	0.076
SD	0.189	0.055	0.049	0.025	0.093	0.014
n	5	5	5	5	5	5
11	2.937	0.215	0.267	0.156	0.676	0.096
12	2.985	0.237	0.266	0.168	0.762	0.077
13	2.764	0.288	0.343	0.218	0.847	0.082
14	2.504	0.346	0.367	0.192	0.843	0.066
15	2.808	0.225	0.267	0.168	0.921	0.061

BASF

PATHOLOGY REPORT

IIC 29/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

RELATIVE WEIGHTS - INDIVIDUAL VALUES

Sacrifice F1  
Sex M  
Group 2

Thyroid  
glands  
%

M 0.005  
SD 0.001  
n 5

11 0.004  
12 0.005  
13 0.007  
14 0.006  
15 0.005

Property of BASF SE -  
Reproduction for other use prohibited  
without written permission

BASF

## PATHOLOGY REPORT

IIC 30/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

## RELATIVE WEIGHTS - INDIVIDUAL VALUES

Sacrifice	F1					
Sex	M					
Group	3					
	Term. body weight %	Adrenal glands %	Brain %	Epididymides %	Heart %	Kidneys %
M	100.0	0.022	0.523	0.248	0.319	0.888
SD		0.005	0.042	0.017	0.024	0.069
n	5	5	5	5	5	5
16	100.0	0.022	0.48	0.246	0.299	0.977
17	100.0	0.025	0.59	0.274	0.342	0.903
18	100.0	0.016	0.508	0.227	0.333	0.919
19	100.0	0.018	0.504	0.25	0.334	0.836
20	100.0	0.027	0.532	0.244	0.289	0.805





BASF

PATHOLOGY REPORT

IIC 32/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

RELATIVE WEIGHTS - INDIVIDUAL VALUES

Sacrifice F1  
Sex M  
Group 3

Thyroid  
glands  
%

M 0.005  
SD 0.001  
n 5

16 0.006  
17 0.007  
18 0.005  
19 0.005  
20 0.005

Property of BASF SE -  
Reproduction for other use prohibited  
without written permission

BASF

## PATHOLOGY REPORT

IIC 33/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

## RELATIVE WEIGHTS - INDIVIDUAL VALUES

Sacrifice	F1					
Sex	F					
Group	0					
	Term. body	Adrenal	Brain	Heart	Kidneys	Liver
	weight	glands				
	%	%	%	%	%	%
M	100.0	0.028	0.753	0.382	0.708	2.53
SD		0.003	0.047	0.011	0.046	0.078
n	5	5	5	5	5	5
101	100.0	0.032	0.808	0.38	0.682	2.46
102	100.0	0.03	0.751	0.399	0.692	2.558
103	100.0	0.025	0.708	0.375	0.673	2.502
104	100.0	0.027	0.706	0.383	0.71	2.478
105	100.0	0.028	0.794	0.372	0.786	2.652

BASF

## PATHOLOGY REPORT

IIC 34/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

## RELATIVE WEIGHTS - INDIVIDUAL VALUES

Sacrifice F1  
Sex F  
Group 0

	Ovaries %	Spleen %	Thymus %	Thyroid glands %	Uterus %
M	0.039	0.185	0.163	0.005	0.301
SD	0.004	0.036	0.021	0.002	0.225
n	5	5	5	5	5
101	0.041	0.149	0.151	0.007	0.192
102	0.035	0.146	0.181	0.006	0.704
103	0.037	0.217	0.19	0.004	0.217
104	0.045	0.193	0.14	0.004	0.197
105	0.037	0.22	0.153	0.004	0.198

BASF

## PATHOLOGY REPORT

IIC 35/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

## RELATIVE WEIGHTS - INDIVIDUAL VALUES

Sacrifice	F1					
Sex	F					
Group	1					
	Term. body weight %	Adrenal glands %	Brain %	Heart %	Kidneys %	Liver %
M	100.0	0.029	0.783	0.373	0.763	2.611
SD		0.003	0.065	0.017	0.037	0.192
n	5	5	5	5	5	5
106	100.0	0.031	0.772	0.361	0.785	2.582
107	100.0	0.033	0.884	0.402	0.711	2.887
108	100.0	0.024	0.759	0.361	0.743	2.366
109	100.0	0.028	0.705	0.371	0.773	2.54
110	100.0	0.029	0.793	0.371	0.805	2.681

BASF

## PATHOLOGY REPORT

IIC 36/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

## RELATIVE WEIGHTS - INDIVIDUAL VALUES

Sacrifice F1  
Sex F  
Group 1

	Ovaries %	Spleen %	Thymus %	Thyroid glands %	Uterus %
M	0.041	0.215	0.145	0.005	0.259
SD	0.005	0.017	0.019	0.001	0.118
n	5	5	5	5	5
106	0.037	0.216	0.148	0.005	0.232
107	0.044	0.192	0.111	0.005	0.197
108	0.038	0.235	0.158	0.007	0.175
109	0.047	0.205	0.151	0.005	0.227
110	0.036	0.227	0.155	0.004	0.466

BASF

## PATHOLOGY REPORT

IIC 37/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

## RELATIVE WEIGHTS - INDIVIDUAL VALUES

Sacrifice	F1					
Sex	F					
Group	2					
	Term. body	Adrenal	Brain	Heart	Kidneys	Liver
	weight	glands				
	%	%	%	%	%	%
M	100.0	0.029	0.8	0.374	0.795	2.756
SD		0.003	0.019	0.008	0.063	0.094
n	5	5	5	5	5	5
111	100.0	0.03	0.795	0.369	0.808	2.699
112	100.0	0.029	0.831	0.377	0.805	2.662
113	100.0	0.028	0.805	0.386	0.706	2.75
114	100.0	0.026	0.786	0.372	0.774	2.76
115	100.0	0.035	0.784	0.366	0.881	2.908

BASF

## PATHOLOGY REPORT

IIC 38/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

## RELATIVE WEIGHTS - INDIVIDUAL VALUES

Sacrifice F1  
Sex F  
Group 2

	Ovaries %	Spleen %	Thymus %	Thyroid glands %	Uterus %
M	0.039	0.212	0.15	0.005	0.266
SD	0.004	0.024	0.02	0.001	0.059
n	5	5	5	5	5
111	0.043	0.213	0.18	0.004	0.209
112	0.042	0.225	0.155	0.004	0.229
113	0.039	0.177	0.129	0.005	0.345
114	0.034	0.24	0.137	0.006	0.236
115	0.035	0.207	0.149	0.004	0.313



BASF

## PATHOLOGY REPORT

IIC 39/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

## RELATIVE WEIGHTS - INDIVIDUAL VALUES

Sacrifice	F1					
Sex	F					
Group	3					
	Term. body	Adrenal	Brain	Heart	Kidneys	Liver
	weight	glands				
	%	%	%	%	%	%
M	100.0	0.031	0.804	0.373	0.793	2.937
SD		0.004	0.048	0.016	0.037	0.174
n	5	5	5	5	5	5
116	100.0	0.035	0.808	0.358	0.838	3.147
117	100.0	0.027	0.831	0.393	0.74	2.822
118	100.0	0.035	0.72	0.356	0.78	3.036
119	100.0	0.027	0.84	0.378	0.79	2.707
120	100.0	0.031	0.82	0.38	0.815	2.972

BASF

## PATHOLOGY REPORT

IIC 40/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

## RELATIVE WEIGHTS - INDIVIDUAL VALUES

Sacrifice F1  
Sex F  
Group 3

	Ovaries %	Spleen %	Thymus %	Thyroid glands %	Uterus %
M	0.037	0.195	0.129	0.006	0.295
SD	0.007	0.033	0.018	0.001	0.115
n	5	5	5	5	5
116	0.032	0.227	0.152	0.004	0.34
117	0.03	0.16	0.105	0.006	0.47
118	0.045	0.229	0.119	0.007	0.202
119	0.044	0.162	0.135	0.005	0.191
120	0.037	0.198	0.134	0.006	0.272

BASF

PATHOLOGY REPORT

IIC 41/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 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 : 17.Feb.2017  
29 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.  
Spleen  
Hematopoiesis, extramedullary, (multi)focal, grade 2.  
Pigment storage, grade 1.  
All other organs examined without microscopic findings.

..... Animal 2

General information

Sex : Male  
Group : 0 (0 mg/kg)  
Sacrifice : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : 17.Feb.2017  
29 days after start of exposure  
1 day after end of exposure

Macroscopic findings

Kidneys  
Cyst, left side, diameter 1.0 mm.  
All other organs without macroscopic findings.

Microscopic findings

Kidneys  
Gross lesion(s) evaluated histopathologically.  
Tubules, basophilic, (multi)focal, unilateral, grade 2.  
Cyst(s), unilateral, correlates to gross lesion Cyst.  
Liver  
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),  
grade 1.

BASF

PATHOLOGY REPORT

IIC 42/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

SINGLE ANIMAL SHEET

(GROSS LESIONS AND MICROSCOPIC FINDINGS)

-----  
Sacrifice F1  
Sex M  
Group 0  
cont. Animal 2  
.....

Spleen

Hematopoiesis, extramedullary, (multi)focal, grade 1.

Pigment storage, grade 1.

All other organs examined without microscopic findings.

..... Animal 3  
.....

General information

Sex : Male

Group : 0 (0 mg/kg)

Sacrifice : Final sacrifice group

Necropsy status : Planned sacrifice

Date of death : 17.Feb.2017

29 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.

Spleen

Hematopoiesis, extramedullary, (multi)focal, grade 1.

Pigment storage, grade 1.

All other organs examined without microscopic findings.

..... Animal 4  
.....

General information

Sex : Male

Group : 0 (0 mg/kg)

Sacrifice : Final sacrifice group

Necropsy status : Planned sacrifice

Date of death : 17.Feb.2017

29 days after start of exposure

1 day after end of exposure

BASF

PATHOLOGY REPORT

IIC 43/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

SINGLE ANIMAL SHEET

(GROSS LESIONS AND MICROSCOPIC FINDINGS)

-----  
Sacrifice F1  
Sex M  
Group 0  
cont. Animal 4  
-----

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.

Spleen

Hematopoiesis, extramedullary, (multi)focal, grade 1.

Pigment storage, grade 1.

All other organs examined without microscopic findings.

-----  
Animal 5  
-----

General information

Sex : Male

Group : 0 (0 mg/kg)

Sacrifice : Final sacrifice group

Necropsy status : Planned sacrifice

Date of death : 17.Feb.2017

29 days after start of exposure

1 day after end of exposure

Macroscopic findings

Liver

Focal constriction, by diaphragmic herniation, between left medial lobe and  
right medial lobe, diameter 5.0 mm.

Focus, right medial lobe, diameter 3.0 mm, yellow.

All other organs without macroscopic findings.

Microscopic findings

Kidneys

Tubules, basophilic, (multi)focal, grade 1.

Liver

Gross lesion(s) evaluated histopathologically.

Constriction, focal, correlates to gross lesion Focal constriction, by  
diaphragmic herniation.

Fibrosis, (multi)focal, grade 1, correlates to gross lesion Focus, right  
medial lobe.

Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),  
grade 1.

Spleen

Hematopoiesis, extramedullary, (multi)focal, grade 2.

Pigment storage, grade 2.

All other organs examined without microscopic findings.

BASF

PATHOLOGY REPORT

IIC 44/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

SINGLE ANIMAL SHEET

(GROSS LESIONS AND MICROSCOPIC FINDINGS)

-----  
Sacrifice F1  
Sex M  
Group 1  
Animal 6  
.....

General information

Sex : Male  
Group : 1 (100 mg/kg)  
Sacrifice : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : 17.Feb.2017  
29 days after start of exposure  
1 day after end of exposure

Macroscopic findings

Kidneys  
Cyst, left side, diameter 1.0 mm.  
All other organs without macroscopic findings.

Microscopic findings

Kidneys  
Gross lesion(s) evaluated histopathologically.  
Degeneration/regeneration, tubular, (multi)focal, grade 2.  
Hypertrophy, tubule, (multi)focal, grade 1.  
Mineralization, at transition outer to inner medulla, (multi)focal, grade 1.  
Hyperplasia, (multi)focal, unilateral.  
Cyst(s), unilateral, correlates to gross lesion Cyst.  
Liver  
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),  
grade 1.  
Spleen  
Hematopoiesis, extramedullary, (multi)focal, grade 3.  
Pigment storage, grade 3.  
All other organs examined without microscopic findings.

Animal 7  
.....

General information

Sex : Male  
Group : 1 (100 mg/kg)  
Sacrifice : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : 17.Feb.2017  
29 days after start of exposure  
1 day after end of exposure

BASF

PATHOLOGY REPORT

IIC 45/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

SINGLE ANIMAL SHEET

(GROSS LESIONS AND MICROSCOPIC FINDINGS)

-----  
Sacrifice F1  
Sex M  
Group 1  
cont. Animal 7  
-----

Macroscopic findings

Animal without particular findings.

Microscopic findings

Kidneys

Tubules, basophilic, (multi)focal, unilateral, grade 1.

Liver

Hypertrophy, centrilobular, grade 1.

Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),  
grade 1.

Spleen

Hematopoiesis, extramedullary, (multi)focal, grade 1.

Pigment storage, grade 2.

All other organs examined without microscopic findings.

-----  
Animal 8  
-----

General information

Sex : Male

Group : 1 (100 mg/kg)

Sacrifice : Final sacrifice group

Necropsy status : Planned sacrifice

Date of death : 17.Feb.2017

29 days after start of exposure

1 day after end of exposure

Macroscopic findings

Animal without particular findings.

Microscopic findings

Kidneys

Degeneration/regeneration, tubular, (multi)focal, grade 1.

Liver

Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),  
grade 1.

Spleen

Hematopoiesis, extramedullary, (multi)focal, grade 1.

Pigment storage, grade 1.

All other organs examined without microscopic findings.

-----  
Animal 9  
-----

General information

Sex : Male

Group : 1 (100 mg/kg)

Sacrifice : Final sacrifice group

Necropsy status : Planned sacrifice

Date of death : 17.Feb.2017

29 days after start of exposure

BASF

PATHOLOGY REPORT

IIC 46/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

SINGLE ANIMAL SHEET

(GROSS LESIONS AND MICROSCOPIC FINDINGS)

-----  
Sacrifice F1  
Sex M  
Group 1  
cont. Animal 9  
.....  
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.

Spleen

Hematopoiesis, extramedullary, (multi)focal, grade 3.

Pigment storage, grade 1.

All other organs examined without microscopic findings.

..... Animal 10

General information

Sex : Male

Group : 1 (100 mg/kg)

Sacrifice : Final sacrifice group

Necropsy status : Planned sacrifice

Date of death : 17.Feb.2017

29 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.

Spleen

Pigment storage, grade 1.

All other organs examined without microscopic findings.



BASF

PATHOLOGY REPORT

IIC 47/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

SINGLE ANIMAL SHEET

(GROSS LESIONS AND MICROSCOPIC FINDINGS)

-----  
Sacrifice F1  
Sex M  
Group 2  
Animal 11  
.....

General information

Sex : Male  
Group : 2 (300 mg/kg)  
Sacrifice : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : 17.Feb.2017  
29 days after start of exposure  
1 day after end of exposure

Macroscopic findings

Kidneys  
Enlarged.  
All other organs without macroscopic findings.

Microscopic findings

Kidneys  
Gross lesion(s) evaluated histopathologically.  
Degeneration/regeneration, tubular, (multi)focal, grade 2.  
Hypertrophy, tubule, (multi)focal, grade 1, correlates to gross lesion  
Enlarged.  
Mineralization, at transition outer to inner medulla, (multi)focal, grade 1.  
Liver  
Hypertrophy, centrilobular, grade 2.  
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),  
grade 1.  
Spleen  
Hematopoiesis, extramedullary, (multi)focal, grade 2.  
Pigment storage, grade 2.  
All other organs examined without microscopic findings.

Animal 12  
.....

General information

Sex : Male  
Group : 2 (300 mg/kg)  
Sacrifice : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : 17.Feb.2017  
29 days after start of exposure  
1 day after end of exposure

BASF

PATHOLOGY REPORT

IIC 48/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

SINGLE ANIMAL SHEET

(GROSS LESIONS AND MICROSCOPIC FINDINGS)

-----  
Sacrifice F1  
Sex M  
Group 2  
cont. Animal 12  
.....

Macroscopic findings

Animal without particular findings.

Microscopic findings

Kidneys

Degeneration/regeneration, tubular, (multi)focal, grade 1.

Hypertrophy, tubule, (multi)focal, grade 1.

Liver

Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),  
grade 1.

Spleen

Hematopoiesis, extramedullary, (multi)focal, grade 3.

Pigment storage, grade 2.

All other organs examined without microscopic findings.

..... Animal 13  
.....

General information

Sex : Male

Group : 2 (300 mg/kg)

Sacrifice : Final sacrifice group

Necropsy status : Planned sacrifice

Date of death : 17.Feb.2017

29 days after start of exposure

1 day after end of exposure

Macroscopic findings

Kidneys

Enlarged.

Cyst, right side, diameter 1.0 mm.

Retraction, few (2-5), to diameter 2.0 mm.

All other organs without macroscopic findings.

Microscopic findings

Hemolymphoreticular system

Lymphoma, malignant neoplasm.

Kidneys

Gross lesion(s) evaluated histopathologically.

Degeneration/regeneration, tubular, (multi)focal, grade 3, correlates to  
gross lesion Retraction, few (2-5).

Hypertrophy, tubule, (multi)focal, grade 1, correlates to gross lesion  
Enlarged.

Mineralization, at transition outer to inner medulla, (multi)focal, grade 1.

Renal amphophilic vacuolar tumor, benign, unilateral, benign neoplasm,  
correlates to gross lesion Enlarged and Cyst, right side.

Hyperplasia, (multi)focal, unilateral.

BASF

PATHOLOGY REPORT

IIC 49/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

SINGLE ANIMAL SHEET

(GROSS LESIONS AND MICROSCOPIC FINDINGS)

-----

	Sacrifice	F1
	Sex	M
	Group	2
	cont. Animal	13

.....

Liver  
Hypertrophy, centrilobular, grade 2.  
Infiltrates of a malignant lymphoma, systemic neoplasm.

Mammary gland  
Atrophy, diffuse.

Spleen  
Hematopoiesis, extramedullary, (multi)focal, grade 2.  
Pigment storage, grade 2.

All other organs examined without microscopic findings.

	Animal	14
--	--------	----

.....

General information

Sex : Male  
Group : 2 (300 mg/kg)  
Sacrifice : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : 17.Feb.2017  
29 days after start of exposure  
1 day after end of exposure

Macroscopic findings

Kidneys  
Retraction, right side, diameter 2.0 mm.  
All other organs without macroscopic findings.

Microscopic findings

Kidneys  
Gross lesion(s) evaluated histopathologically.  
Degeneration/regeneration, tubular, (multi)focal, grade 1.  
Hypertrophy, tubule, (multi)focal, grade 1.  
Scar(s), cortical, unilateral, correlates to gross lesion Retraction.

Liver  
Hypertrophy, centrilobular, grade 2.  
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s), grade 1.

Mammary gland  
Atrophy, diffuse.

Spleen  
Pigment storage, grade 1.

All other organs examined without microscopic findings.

BASF

PATHOLOGY REPORT

IIC 50/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

SINGLE ANIMAL SHEET

(GROSS LESIONS AND MICROSCOPIC FINDINGS)

-----  
Sacrifice F1  
Sex M  
Group 2  
Animal 15  
.....

General information

Sex : Male  
Group : 2 (300 mg/kg)  
Sacrifice : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : 17.Feb.2017  
29 days after start of exposure  
1 day after end of exposure

Macroscopic findings

Kidneys  
Enlarged.  
Renal lymph nodes  
Enlarged, left side, tissue preserved in cassette.  
All other organs without macroscopic findings.

Microscopic findings

Kidneys  
Gross lesion(s) evaluated histopathologically.  
Degeneration/regeneration, tubular, (multi)focal, grade 1.  
Hypertrophy, tubule, (multi)focal, grade 2, correlates to gross lesion  
Enlarged.  
Liver  
Hypertrophy, centrilobular, grade 2.  
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),  
grade 1.  
Mammary gland  
Atrophy, diffuse.  
Renal lymph nodes  
Unilaterally investigated or present. Gross lesion(s) evaluated  
histopathologically.  
Hyperplasia, lympho-reticulocellular, unilateral, grade 3, correlates to  
gross lesion Enlarged.  
Spleen  
Hematopoiesis, extramedullary, (multi)focal, grade 1.  
Pigment storage, grade 1.  
All other organs examined without microscopic findings.

BASF

PATHOLOGY REPORT

IIC 51/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

SINGLE ANIMAL SHEET

(GROSS LESIONS AND MICROSCOPIC FINDINGS)

-----  
Sacrifice F1  
Sex M  
Group 3  
Animal 16  
.....

General information

Sex : Male  
Group : 3 (600 mg/kg)  
Sacrifice : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : 17.Feb.2017  
29 days after start of exposure  
1 day after end of exposure

Macroscopic findings

Kidneys  
Enlarged.  
All other organs without macroscopic findings.

Microscopic findings

Adrenal cortex  
Hypertrophy, hyperplasia, grade 1.  
Cecum  
Dilation.  
Kidneys  
Gross lesion(s) evaluated histopathologically.  
Degeneration/regeneration, tubular, (multi)focal, grade 2.  
Hypertrophy, tubule, (multi)focal, grade 3, correlates to gross lesion  
Enlarged.  
Liver  
Hypertrophy, centrilobular, grade 2.  
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),  
grade 1.  
Mammary gland  
Atrophy, diffuse.  
Spleen  
Hematopoiesis, extramedullary, (multi)focal, grade 2.  
Pigment storage, grade 2.  
All other organs examined without microscopic findings.

Animal 17  
.....

General information

Sex : Male  
Group : 3 (600 mg/kg)  
Sacrifice : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : 17.Feb.2017  
29 days after start of exposure  
1 day after end of exposure

BASF

PATHOLOGY REPORT

IIC 52/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

SINGLE ANIMAL SHEET

(GROSS LESIONS AND MICROSCOPIC FINDINGS)

-----  
Sacrifice F1  
Sex M  
Group 3  
cont. Animal 17  
.....

Macroscopic findings

Kidneys

Enlarged.

All other organs without macroscopic findings.

Microscopic findings

Adrenal cortex

Hypertrophy, hyperplasia, grade 1.

Cecum

Dilation.

Kidneys

Gross lesion(s) evaluated histopathologically.

Degeneration/regeneration, tubular, (multi)focal, grade 1.

Hypertrophy, tubule, (multi)focal, grade 1, correlates to gross lesion

Enlarged.

Liver

Hypertrophy, centrilobular, grade 2.

Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),  
grade 1.

Mammary gland

Atrophy, diffuse.

Spleen

Hematopoiesis, extramedullary, (multi)focal, grade 1.

Pigment storage, grade 2.

All other organs examined without microscopic findings.

..... Animal 18

General information

Sex : Male

Group : 3 (600 mg/kg)

Sacrifice : Final sacrifice group

Necropsy status : Planned sacrifice

Date of death : 17.Feb.2017

29 days after start of exposure

1 day after end of exposure

Macroscopic findings

Axillary lymph nodes

Discoloration, right side, red, tissue preserved in cassette.

Cecum

Dilation.

Kidneys

Enlarged.

All other organs without macroscopic findings.

BASF

PATHOLOGY REPORT

IIC 53/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

SINGLE ANIMAL SHEET

(GROSS LESIONS AND MICROSCOPIC FINDINGS)

-----  
Sacrifice F1  
Sex M  
Group 3  
cont. Animal 18  
.....

Microscopic findings

Axillary lymph nodes

Unilaterally investigated or present. Gross lesion(s) evaluated histopathologically.  
Blood resorption, unilateral, grade 3, correlates to gross lesion Discoloration.

Cecum

Gross lesion(s) evaluated histopathologically.  
Dilation, correlates to gross lesion Dilation.

Kidneys

Gross lesion(s) evaluated histopathologically.  
Degeneration/regeneration, tubular, (multi)focal, grade 3.  
Hypertrophy, tubule, (multi)focal, grade 3, correlates to gross lesion Enlarged.  
Mineralization, at transition outer to inner medulla, (multi)focal, grade 3.

Liver

Hypertrophy, centrilobular, grade 1.  
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s), grade 1.

Spleen

Hematopoiesis, extramedullary, (multi)focal, grade 1.  
Pigment storage, grade 2.

All other organs examined without microscopic findings.

..... Animal 19

General information

Sex : Male  
Group : 3 (600 mg/kg)  
Sacrifice : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : 17.Feb.2017  
29 days after start of exposure  
1 day after end of exposure

Macroscopic findings

Axillary lymph nodes

Discoloration, left side, red, tissue preserved in cassette.

Cecum

Dilation.

Kidneys

Enlarged.

All other organs without macroscopic findings.

BASF

PATHOLOGY REPORT

IIC 54/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

SINGLE ANIMAL SHEET

(GROSS LESIONS AND MICROSCOPIC FINDINGS)

-----  
Sacrifice F1  
Sex M  
Group 3  
cont. Animal 19  
.....

Microscopic findings

Axillary lymph nodes

Unilaterally investigated or present. Gross lesion(s) evaluated histopathologically.  
Blood resorption, unilateral, grade 3, correlates to gross lesion  
Discoloration.

Cecum

Gross lesion(s) evaluated histopathologically.  
Dilation, correlates to gross lesion Dilation.

Kidneys

Gross lesion(s) evaluated histopathologically.  
Degeneration/regeneration, tubular, (multi)focal, grade 3.  
Hypertrophy, tubule, (multi)focal, grade 3, correlates to gross lesion  
Enlarged.

Liver

Hypertrophy, centrilobular, grade 2.  
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s), grade 1.

Mammary gland

Atrophy, diffuse.

Spleen

Hematopoiesis, extramedullary, (multi)focal, grade 2.  
Pigment storage, grade 2.

All other organs examined without microscopic findings.

..... Animal 20

General information

Sex : Male  
Group : 3 (600 mg/kg)  
Sacrifice : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : 17.Feb.2017  
29 days after start of exposure  
1 day after end of exposure

Macroscopic findings

Animal without particular findings.

Microscopic findings

Adrenal cortex

Hypertrophy, hyperplasia, grade 1.

Cecum

Dilation.

Kidneys

Degeneration/regeneration, tubular, (multi)focal, grade 2.  
Hypertrophy, tubule, (multi)focal, grade 3.



BASF

PATHOLOGY REPORT

IIC 55/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

SINGLE ANIMAL SHEET

(GROSS LESIONS AND MICROSCOPIC FINDINGS)

-----  
Sacrifice F1  
Sex M  
Group 3  
cont. Animal 20  
.....

Liver

Hypertrophy, centrilobular, grade 3.

Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),  
grade 1.

Mammary gland

Atrophy, diffuse.

Spleen

Hematopoiesis, extramedullary, (multi)focal, grade 3.

Pigment storage, grade 2.

All other organs examined without microscopic findings.

Property of BASF SE  
Reproduction for other use prohibited  
without written permission

BASF

PATHOLOGY REPORT

IIC 56/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

SINGLE ANIMAL SHEET

(GROSS LESIONS AND MICROSCOPIC FINDINGS)

-----  
Sacrifice F1  
Sex F  
Group 0  
Animal 101  
.....

General information

Sex : Female  
Group : 0 (0 mg/kg)  
Sacrifice : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : 16.Feb.2017  
29 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.  
Mineralization, at transition outer to inner medulla, (multi)focal,  
unilateral, grade 2.  
Liver  
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),  
grade 1.  
Spleen  
Hematopoiesis, extramedullary, (multi)focal, grade 1.  
Pigment storage, grade 1.  
All other organs examined without microscopic findings.

..... Animal 102

General information

Sex : Female  
Group : 0 (0 mg/kg)  
Sacrifice : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : 16.Feb.2017  
29 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.  
Liver  
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),  
grade 1.

BASF

PATHOLOGY REPORT

IIC 57/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

SINGLE ANIMAL SHEET

(GROSS LESIONS AND MICROSCOPIC FINDINGS)

-----  
Sacrifice F1  
Sex F  
Group 0  
cont. Animal 102  
.....

Spleen

Pigment storage, grade 1.

All other organs examined without microscopic findings.

Animal 103  
.....

General information

Sex : Female  
Group : 0 (0 mg/kg)  
Sacrifice : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : 16.Feb.2017  
29 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.

Spleen

Hematopoiesis, extramedullary, (multi)focal, grade 1.

Pigment storage, grade 1.

All other organs examined without microscopic findings.

Animal 104  
.....

General information

Sex : Female  
Group : 0 (0 mg/kg)  
Sacrifice : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : 16.Feb.2017  
29 days after start of exposure  
1 day after end of exposure

Macroscopic findings

Animal without particular findings.

BASF

PATHOLOGY REPORT

IIC 58/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

SINGLE ANIMAL SHEET

(GROSS LESIONS AND MICROSCOPIC FINDINGS)

-----  
Sacrifice F1  
Sex F  
Group 0  
cont. Animal 104  
.....

Microscopic findings

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.

Fatty change, periportal, grade 3.

Spleen

Hematopoiesis, extramedullary, (multi)focal, grade 1.

Pigment storage, grade 1.

All other organs examined without microscopic findings.

..... Animal 105  
.....

General information

Sex : Female

Group : 0 (0 mg/kg)

Sacrifice : Final sacrifice group

Necropsy status : Planned sacrifice

Date of death : 16.Feb.2017

29 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.

Spleen

Pigment storage, grade 2.

All other organs examined without microscopic findings.

BASF

PATHOLOGY REPORT

IIC 59/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

SINGLE ANIMAL SHEET

(GROSS LESIONS AND MICROSCOPIC FINDINGS)

-----  
Sacrifice F1  
Sex F  
Group 1  
Animal 106  
.....

General information

Sex : Female  
Group : 1 (100 mg/kg)  
Sacrifice : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : 16.Feb.2017  
29 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.  
Spleen  
Hematopoiesis, extramedullary, (multi)focal, grade 2.  
Pigment storage, grade 2.  
All other organs examined without microscopic findings.

Animal 107  
.....

General information

Sex : Female  
Group : 1 (100 mg/kg)  
Sacrifice : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : 16.Feb.2017  
29 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.  
Spleen  
Pigment storage, grade 3.  
All other organs examined without microscopic findings.

BASF

PATHOLOGY REPORT

IIC 60/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

SINGLE ANIMAL SHEET

(GROSS LESIONS AND MICROSCOPIC FINDINGS)

-----  
Sacrifice F1  
Sex F  
Group 1  
Animal 108  
.....

General information

Sex : Female  
Group : 1 (100 mg/kg)  
Sacrifice : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : 16.Feb.2017  
29 days after start of exposure  
1 day after end of exposure

Macroscopic findings

Axillary lymph nodes  
Discoloration, left side.  
All other organs without macroscopic findings.

Microscopic findings

Axillary lymph nodes  
Gross lesion(s) evaluated histopathologically.  
Blood resorption, unilateral, grade 1, correlates to gross lesion  
Discoloration.  
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.  
Fatty change, periportal, grade 1.  
Spleen  
Hematopoiesis, extramedullary, (multi)focal, grade 1.  
Pigment storage, grade 1.  
All other organs examined without microscopic findings.

Animal 109  
.....

General information

Sex : Female  
Group : 1 (100 mg/kg)  
Sacrifice : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : 16.Feb.2017  
29 days after start of exposure  
1 day after end of exposure

BASF

PATHOLOGY REPORT

IIC 61/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

SINGLE ANIMAL SHEET

(GROSS LESIONS AND MICROSCOPIC FINDINGS)

-----  
Sacrifice F1  
Sex F  
Group 1  
cont. Animal 109  
.....

Macroscopic findings

Animal without particular findings.

Microscopic findings

Liver

Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),  
grade 1.

Fatty change, periportal, grade 3.

Spleen

Hematopoiesis, extramedullary, (multi)focal, grade 2.

Pigment storage, grade 2.

All other organs examined without microscopic findings.

..... Animal 110  
.....

General information

Sex : Female

Group : 1 (100 mg/kg)

Sacrifice : Final sacrifice group

Necropsy status : Planned sacrifice

Date of death : 16.Feb.2017

29 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.

Spleen

Hematopoiesis, extramedullary, (multi)focal, grade 2.

Pigment storage, grade 2.

All other organs examined without microscopic findings.

BASF

PATHOLOGY REPORT

IIC 62/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

SINGLE ANIMAL SHEET

(GROSS LESIONS AND MICROSCOPIC FINDINGS)

-----  
Sacrifice F1  
Sex F  
Group 2  
Animal 111  
.....

General information

Sex : Female  
Group : 2 (300 mg/kg)  
Sacrifice : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : 16.Feb.2017  
29 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.  
Spleen  
Hematopoiesis, extramedullary, (multi)focal, grade 1.  
Pigment storage, grade 2.  
All other organs examined without microscopic findings.

..... Animal 112

General information

Sex : Female  
Group : 2 (300 mg/kg)  
Sacrifice : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : 16.Feb.2017  
29 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.  
Spleen  
Hematopoiesis, extramedullary, (multi)focal, grade 3.  
Pigment storage, grade 2.  
All other organs examined without microscopic findings.



BASF

PATHOLOGY REPORT

IIC 63/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

SINGLE ANIMAL SHEET

(GROSS LESIONS AND MICROSCOPIC FINDINGS)

-----  
Sacrifice F1  
Sex F  
Group 2  
Animal 113  
.....

General information

Sex : Female  
Group : 2 (300 mg/kg)  
Sacrifice : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : 16.Feb.2017  
29 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.  
Spleen  
Hematopoiesis, extramedullary, (multi)focal, grade 1.  
Pigment storage, grade 1.  
All other organs examined without microscopic findings.

Animal 114  
.....

General information

Sex : Female  
Group : 2 (300 mg/kg)  
Sacrifice : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : 16.Feb.2017  
29 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.  
Spleen  
Hematopoiesis, extramedullary, (multi)focal, grade 1.  
Pigment storage, grade 2.  
All other organs examined without microscopic findings.

BASF

PATHOLOGY REPORT

IIC 64/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

SINGLE ANIMAL SHEET

(GROSS LESIONS AND MICROSCOPIC FINDINGS)

-----  
Sacrifice F1  
Sex F  
Group 2  
Animal 115  
.....

General information

Sex : Female  
Group : 2 (300 mg/kg)  
Sacrifice : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : 16.Feb.2017  
29 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.  
Fatty change, periportal, grade 1.  
Spleen  
Pigment storage, grade 1.  
All other organs examined without microscopic findings.

BASF

PATHOLOGY REPORT

IIC 65/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

SINGLE ANIMAL SHEET

(GROSS LESIONS AND MICROSCOPIC FINDINGS)

-----  
Sacrifice F1  
Sex F  
Group 3  
Animal 116  
-----

General information

Sex : Female  
Group : 3 (600 mg/kg)  
Sacrifice : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : 16.Feb.2017  
29 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.  
Cast, tubular, unilateral, grade 1.  
Liver  
Hypertrophy, centrilobular, grade 2.  
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),  
grade 1.  
Spleen  
Hematopoiesis, extramedullary, (multi)focal, grade 1.  
Pigment storage, grade 2.  
All other organs examined without microscopic findings.

Animal 117  
-----

General information

Sex : Female  
Group : 3 (600 mg/kg)  
Sacrifice : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : 16.Feb.2017  
29 days after start of exposure  
1 day after end of exposure

Macroscopic findings

Animal without particular findings.

Microscopic findings

Cecum  
Dilation.  
Liver  
Hypertrophy, centrilobular, grade 2.  
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),  
grade 1.

BASF

PATHOLOGY REPORT

IIC 66/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

SINGLE ANIMAL SHEET

(GROSS LESIONS AND MICROSCOPIC FINDINGS)

-----  
Sacrifice F1  
Sex F  
Group 3  
cont. Animal 117  
.....  
Spleen  
Pigment storage, grade 2.  
All other organs examined without microscopic findings.

Animal 118  
.....  
General information  
Sex : Female  
Group : 3 (600 mg/kg)  
Sacrifice : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : 16.Feb.2017  
29 days after start of exposure  
1 day after end of exposure

Macroscopic findings  
Animal without particular findings.

Microscopic findings  
Cecum  
Dilation.  
Kidneys  
Tubules, basophilic, (multi)focal, grade 1.  
Hypertrophy, tubule, (multi)focal, unilateral, grade 1.  
Liver  
Hypertrophy, centrilobular, grade 2.  
Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),  
grade 1.  
Fatty change, periportal, grade 1.  
Spleen  
Hematopoiesis, extramedullary, (multi)focal, grade 3.  
Pigment storage, grade 2.  
All other organs examined without microscopic findings.

Animal 119  
.....  
General information  
Sex : Female  
Group : 3 (600 mg/kg)  
Sacrifice : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : 16.Feb.2017  
29 days after start of exposure  
1 day after end of exposure

BASF

PATHOLOGY REPORT

IIC 67/67

01R0066/05R032

Test Study in Male and Female Sprague Dawley Rats  
Oral Administration (Gavage)

22.Mar.2017 HAMA

SINGLE ANIMAL SHEET

(GROSS LESIONS AND MICROSCOPIC FINDINGS)

-----  
Sacrifice F1  
Sex F  
Group 3  
cont. Animal 119  
.....

Macroscopic findings

Animal without particular findings.

Microscopic findings

Liver

Hypertrophy, centrilobular, grade 1.

Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),  
grade 1.

Spleen

Hematopoiesis, extramedullary, (multi)focal, grade 1.

Pigment storage, grade 1.

All other organs examined without microscopic findings.

..... Animal 120  
.....

General information

Sex : Female

Group : 3 (600 mg/kg)

Sacrifice : Final sacrifice group

Necropsy status : Planned sacrifice

Date of death : 16.Feb.2017

29 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

Hypertrophy, centrilobular, grade 2.

Infiltration, lymphoid cell and/or presence of Kupffer cell granuloma(s),  
grade 1.

Spleen

Pigment storage, grade 2.

All other organs examined without microscopic findings.

## Homogeneity and Concentration Control Analysis of DHDPS in 0.5 % carboxymethyl cellulose in drinking water

### 1. PROJECT AND TEST SUBSTANCE INFORMATION

Project No.: 01R0066/05R032  
Test item (= test substance): DHDPS  
Batch No.: 03508136W0

### 2. SAMPLE DATA

#### 2.1. HOMOGENEITY AND CONCENTRATION CONTROL ANALYSIS

Vehicle: 0.5 % carboxymethyl cellulose 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\_01-03.

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 procedure 05/0066\_01-03.

## 4. RESULTS AND DISCUSSION

### 4.1. HOMOGENEITY AND CONCENTRATION CONTROL ANALYSIS

The results obtained for the homogeneity and concentration control analysis of DHDPS in 0.5 % carboxymethyl cellulose 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.

Date of sample preparation:	18 Jan 2017
Date of sampling:	18 Jan 2017
Date of receipt sample:	18 Jan 2017
Starting date of analytical determination:	15 Feb 2017

Name	Amount	Nominal Conc	Nominal Conc	Mean	RSD
	g/100 ml	g/100 ml	%	%	%
Sample 03	1.013	1	101.3%		
Sample 04	0.992	1	99.2%		
Sample 05	1.007	1	100.7%	100.4%	1.1%
Sample 06	2.986	3	99.5%		
Sample 07	5.786	6	96.4%		
Sample 08	5.793	6	96.6%		
Sample 09	5.741	6	95.7%	96.2%	0.5%

No test substance could be detected in the vehicle control sample (sample 02) with a concentration of  $\geq 30$  % of the lowest calibration solution.

Considering the low relative standard deviation in the homogeneity analysis, it can be concluded that DHDPS was distributed homogeneously in 0.5 % carboxymethyl cellulose in drinking water.

The mean values (samples 03 – 05 and samples 07 – 09) and single value (sample 06) of DHDPS in 0.5 % carboxymethyl cellulose 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 0.5 % carboxymethyl cellulose in drinking water.

Figures of the calibration curve and examples of chromatograms will follow within this report.

Figure 1: Chromatogram of matrix solution, vehicle control sample (measured on 15 Feb 2017)

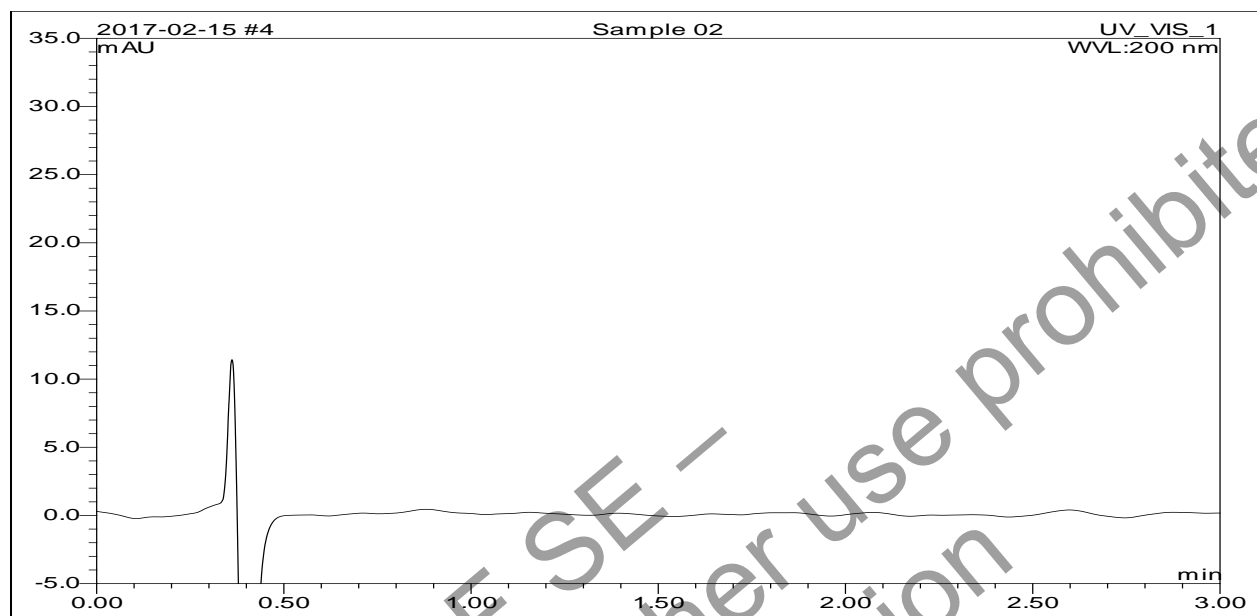


Figure 2: Chromatogram of calibration solution 1 (1.006 mg/100 mL, measured on 15 Feb 2017)

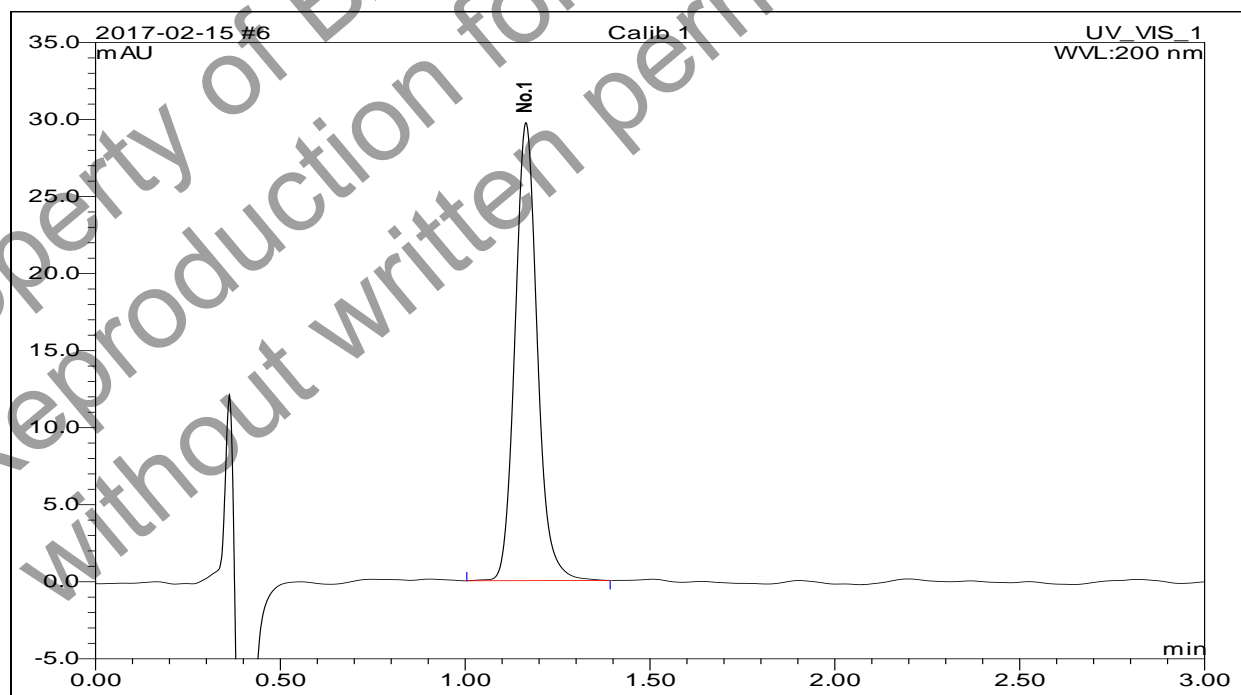




Figure 3: Chromatogram of sample 03 (measured on 15 Feb 2017)

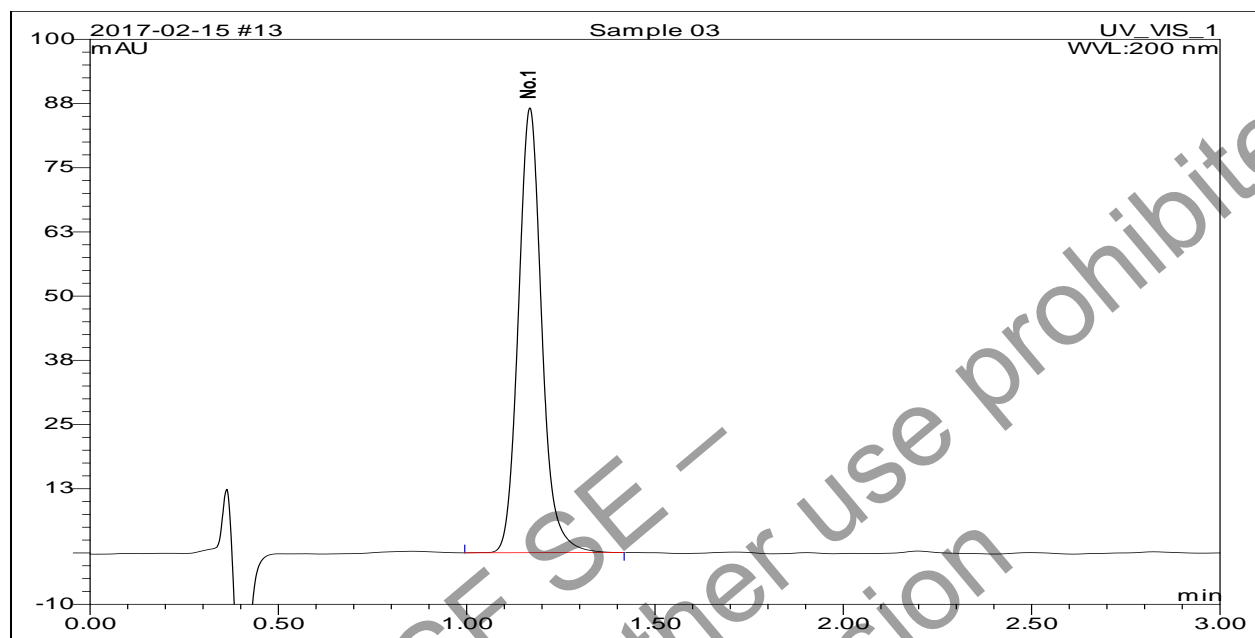
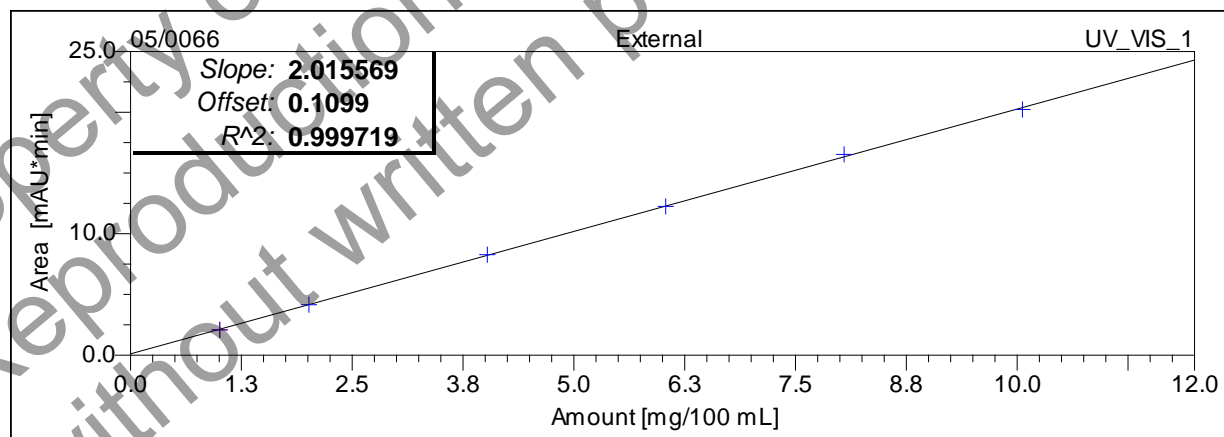


Figure 4: Calibration curve (measured on 15 Feb 2017, Concentration range 1.006 – 10.06 mg/100 mL)



## 5. APPENDIX

### 5.1. CONTROL PROCEDURE 05/0066\_01-03

BASF SE  
Test Facility  
Experimental Toxicology and Ecology / Analytical Chemistry



#### CONTROL TEST

Test substance number: 05/0066

No.: 05/0066\_01-03

Name of test substance: DHDPS

Effective from: 15 Feb 2017

Control procedure: Content (LC) / aqueous carboxymethylcellulose

Page 1 of 9

<b>Technique</b>	HPLC
System:	Agilent 1100 with autosampler, DAD, 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:	950 mL acetonitrile mixed with 50 mL water and 1 mL formic acid
Mobile Phase B:	950 mL water mixed with 50 mL acetonitrile and 1 mL formic acid
Isocratic:	
<b>Mobile Phase A</b> 20 %	<b>Mobile Phase B</b> 80 %
Injection volume:	5 µL
Flow rate:	4 mL/min
Detection:	200 nm
Column temperature:	25°C or 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\_01-03

Name of test substance: DHDPS

Effective from: 15 Feb 2017

Control procedure: Content (LC) / aqueous carboxymethylcellulose

Page 2 of 9

---

**Sample solution:**

The samples are transferred into appropriate volumetric flasks with approximately 10 mL water and filled up to the mark with acetonitrile to obtain sample solutions with test substance concentrations that fall within the calibration range.  
If required, all dilutions are sonicated for five minutes to ensure complete dissolution of the test substance.

The samples have to be diluted at least 1 + 9 (sample + solvents).

The samples are filtered (cellulose filter, 0.2 µm) prior HPLC analysis.

NOTE: If the amount of test substance in the sample solution is outside the calibration range (calibration solutions 1 – 6), an adequate dilution step with matrix solution has to be performed to reach 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.  
The matrix solution should represent the sample with the lowest test substance concentration.

Property of BASF SE –  
Reproduction for other use prohibited  
without written permission

BASF SE  
Test Facility  
Experimental Toxicology and Ecology / Analytical Chemistry



---

**CONTROL TEST**

---

Test substance number: 05/0066

No.: 05/0066\_01-03

Name of test substance: DHDPS

Effective from: 15 Feb 2017

Control procedure: Content (LC) / aqueous carboxymethylcellulose

Page 3 of 9

---

Stock solution ①: Approximately 50 mg test substance is dissolved to a final volume of 100 mL with acetonitrile (50 mg/100 mL).

Calibration solution 1: 0.2 mL stock solution ① is diluted with matrix solution to 10 mL (1.0 mg/100 mL).

Calibration solution 2: 0.4 mL stock solution ① is diluted with matrix solution to 10 mL (2.0 mg/100 mL).

Calibration solution 3: 0.8 mL stock solution ① is diluted with matrix solution to 10 mL (4.0 mg/100 mL).

Calibration solution 4: 1.2 mL stock solution ① is diluted with matrix solution to 10 mL (6.0 mg/100 mL).

Calibration solution 4: 1.6 mL stock solution ① is diluted with matrix solution to 10 mL (8.0 mg/100 mL).

Calibration solution 4: 2.0 mL stock solution ① is diluted with matrix solution to 10 mL (10.0 mg/100 mL).

**System-suitability solution:**

System-suitability solution is prepared with a second independent weighing according to calibration solution 3 (4.0 mg/100 mL)

**Procedure**

After conditioning the LC 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.

BASF SE  
Test Facility  
Experimental Toxicology and Ecology / Analytical Chemistry



---

**CONTROL TEST**

---

Test substance number: 05/0066	No.: 05/0066_01-03
Name of test substance: DHDPs	Effective from: 15 Feb 2017
Control procedure: Content (LC) / aqueous carboxymethylcellulose	Page 4 of 9

---

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 %. For complex measurements a system suitability of 90 % to 110 % can be considered valid.

The coefficient of determination ( $R^2$ ) has to be  $\geq 0.990$ . If the correlation coefficient (R) is used, this value has to be  $\geq 0.995$ .

Calculation:

The concentration control measurements are based on external calibration (calibration solutions 1 – 6).

Content calculation is performed electronically, (e.g. Dionex Chromeleon – Software, Microsoft Excel). Basic formulas for calculations are described below (e.g. Dionex Chromeleon – Software).

BASF SE  
Test Facility  
Experimental Toxicology and Ecology / Analytical Chemistry



---

**CONTROL TEST**

---

Test substance number: 05/0066

No.: 05/0066\_01-03

Name of test substance: DHDPs

Effective from: 15 Feb 2017

Control procedure: Content (LC) / aqueous carboxymethylcellulose

Page 5 of 9

---

**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\_01-03

Name of test substance: DHDPS

Effective from: 15 Feb 2017

Control procedure: Content (LC) / aqueous carboxymethylcellulose

Page 6 of 9

Control chart Basic Validation:

Selectivity	Linearity	Accuracy	LoQ	Stability	Carry over
Passed	Passed	Passed	12 mg/100 mL	-	No carry over

BASF SE  
Test Facility  
Experimental Toxicology and Ecology / Analytical Chemistry

**CONTROL TEST**

Test substance number: 05/0066

No.: 05/0066\_01-03

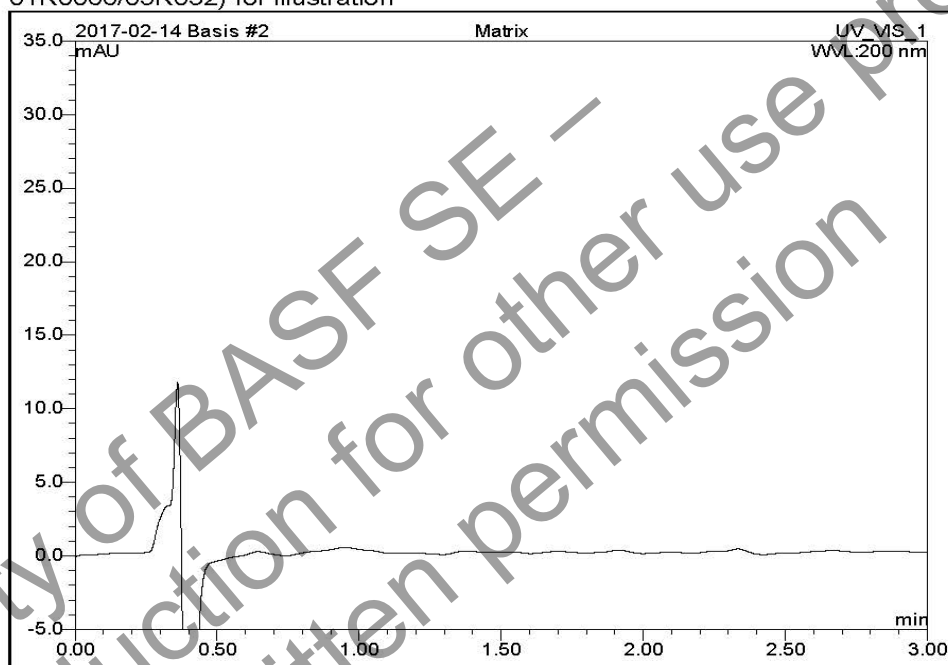
Name of test substance: DHDPS

Effective from: 15 Feb 2017

Control procedure: Content (LC) / aqueous carboxymethylcellulose

Page 7 of 9

Figure 1.1: Example chromatogram matrix solution (08 Feb 2017, Project no.: 01R0066/05R032) for illustration





BASF SE  
Test Facility  
Experimental Toxicology and Ecology / Analytical Chemistry

**CONTROL TEST**

Test substance number: 05/0066

No.: 05/0066\_01-03

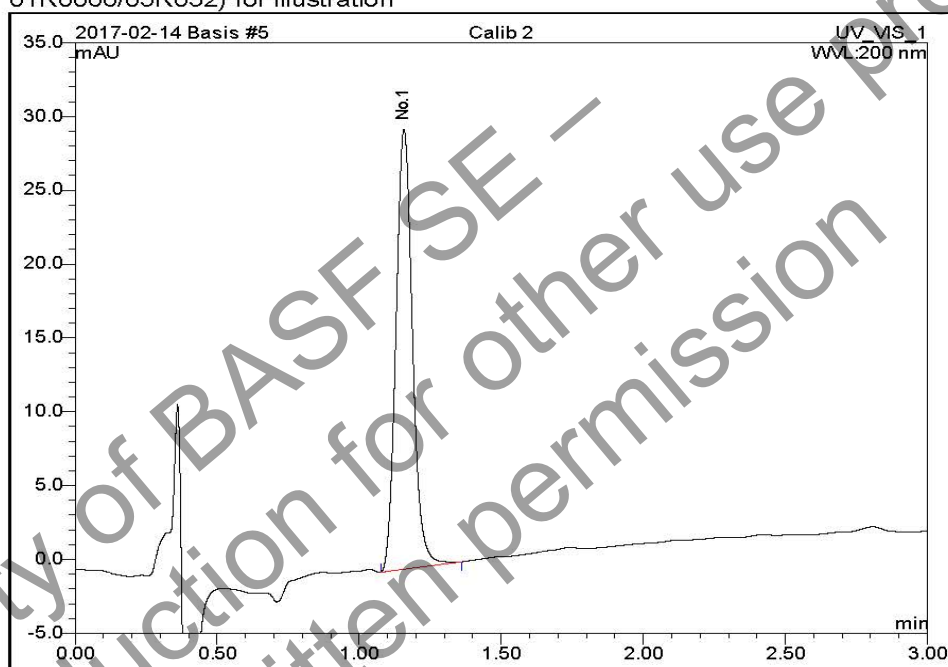
Name of test substance: DHDPS

Effective from: 15 Feb 2017

Control procedure: Content (LC) / aqueous carboxymethylcellulose

Page 8 of 9

Figure 1.2: Example chromatogram calibration solution (14 Feb 2017, Project no.: 01R0066/05R032) for illustration



BASF SE  
Test Facility  
Experimental Toxicology and Ecology / Analytical Chemistry

**CONTROL TEST**

Test substance number: 05/0066

No.: 05/0066\_01-03

Name of test substance: DHDPS

Effective from: 15 Feb 2017

Control procedure: Content (LC) / aqueous carboxymethylcellulose

Page 9 of 9

Figure 1.3: Example chromatogram LoQ (Sample 01, 14 Feb 2017, Project no.: 01R0066/05R032) for illustration

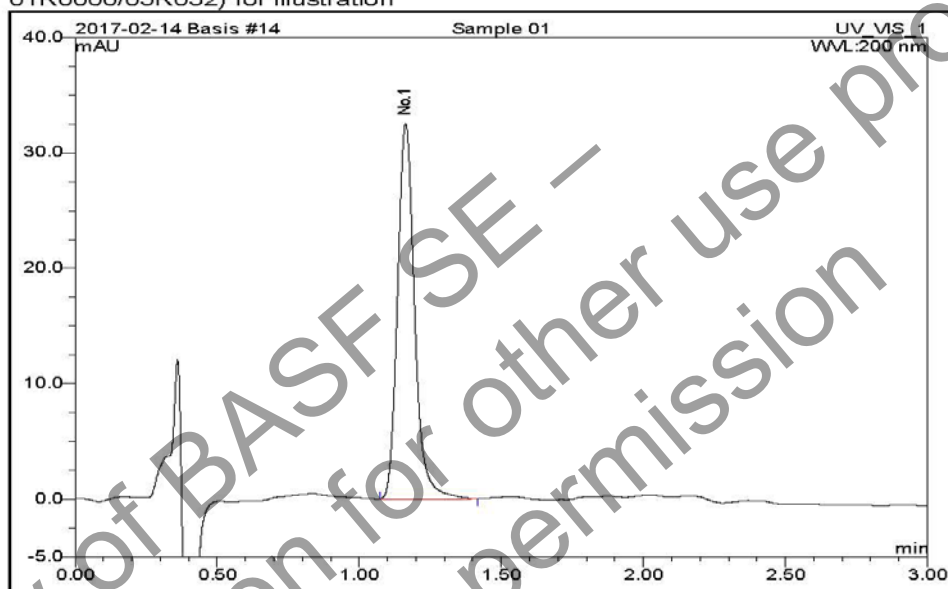


Figure 1.4 Example calibration curve (14 Feb 2017, Project no.: 01R0066/05R032) for illustration

