

INITIAL STATEMENT OF REASONS

TITLE 22, CALIFORNIA CODE OF REGULATIONS

SECTION 12705(b) and 12705(d). SPECIFIC REGULATORY LEVELS POSING NO SIGNIFICANT RISK

SECTION 12805. SPECIFIC REGULATORY LEVELS: REPRODUCTIVE TOXICANTS

The Safe Drinking Water and Toxic Enforcement Act of 1986 (hereinafter the Act) prohibits a person in the course of doing business from knowingly and intentionally exposing any individual to a chemical that has been listed as known to the State to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual (Health and Safety Code Section 25249.6). The Act also prohibits a business from knowingly discharging a listed chemical into water or onto or into land where such chemical passes or probably will pass into a source of drinking water (Health and Safety Code Section 25249.5).

For chemicals known to the state to cause cancer, an exemption from the warning requirement and the discharge prohibition is provided by the Act when a person in the course of doing business is able to demonstrate that an exposure for which it is responsible poses no significant risk, or that a discharge to drinking water which otherwise complies with applicable requirements would result in an exposure through drinking water at a level which poses no significant risk (Health and Safety Code Sections 25249.9 and 25249.10). A determination that a level of exposure poses no significant risk of cancer may be made utilizing regulations that have previously been adopted by the Office of Environmental Health Hazard Assessment (OEHHA) (Title 22, California Code of Regulations (22 CCR) Sections 12701 to 12721) (unless otherwise specified, all section references are to Title 22, California Code of Regulations). Section 12701 describes alternative methods for making such a determination. One such method is through the application of a specific regulatory level established for the chemical in question in Section 12705. Section 12705(b) supersedes Section 12709 (Exposure to Trace Elements) and Section 12711 (Levels Based on State or Federal Standards).

For chemicals known to the state to cause reproductive toxicity, an exemption from the warning requirement and the discharge prohibition is provided by the Act when a person in the course of doing business is able to demonstrate that an exposure for which it is responsible would result in no observable reproductive effect, or a discharge to drinking water which otherwise complies with applicable requirements would result in no observable reproductive effect, assuming exposure at 1,000 times the level in question (Health and Safety Code Sections 25249.9, 25249.10 and 25249.11). The maximum dose level at which a chemical has no observable reproductive effect is referred to as the no observable effect level (NOEL). Thus, the exemption applies when the exposure or discharge in question is at a level that does not exceed the NOEL divided by 1,000.

Regulations previously adopted by OEHHA provide guidance for determining whether an exposure to, or a discharge of, a chemical known to cause reproductive toxicity meets the statutory exemption (22 CCR, Sections 12801-12821). These regulations provide two ways by

which a person in the course of doing business may make such a determination: (1) by conducting a risk assessment in accordance with the principles described in Section 12803 to derive a NOEL, and dividing the NOEL by 1,000; or (2) by application of the specific regulatory level adopted for the chemical in Section 12805 or, in the absence of such a level, by using a risk assessment conducted by a state or federal agency, provided that such assessment substantially complies with Section 12803(a). The specific regulatory levels in Section 12805 represent one one-thousandth of the NOEL.

This proposed regulation sets forth no significant risk levels (NSRLs) for adoption in Section 12705(b) using a non-expedited approach, and for adoption in 12705(d) using an expedited approach. Both methods are consistent with procedures outlined in Section 12703. This proposed regulation also sets forth a maximum allowable dose level (MADL) for adoption in Section 12805 using methods outlined in Section 12803.

Details on the basis for the proposed numbers are provided in the references cited, which are also included in the rulemaking record. The references are risk assessment documents describing and summarizing the derivation of the regulatory levels listed below.

The proposed levels set out in Section 12705 represent the levels of exposure to the chemical which is calculated to result in no more than one excess case of cancer in an exposed population of 100,000, assuming exposure over a 70-year lifetime (10^{-5} lifetime risk of cancer), and is based on the following risk assessment document(s) prepared, or reviewed by the OEHHA, Reproductive and Cancer Hazard Assessment Section, in accordance with the principles in Section 12703.

This proposed regulation adopts the following NSRLs in Section 12705(b) for chemicals known to cause cancer according to methods outlined in Section 12703:

Chemical	NSRL, in units micrograms per day	Reference
Benzofuran	1.1	OEHHA (2002a)
N-Carboxymethyl-N-nitrosourea	0.70	OEHHA (2002b)
3,3'-Dimethoxybenzidine	0.15	OEHHA (2002c)
3,3'-Dimethoxybenzidine dihydrochloride	0.19	OEHHA (2002c)
3,3'-Dimethylbenzidine	0.044	OEHHA (2002d)
3,3'-Dimethylbenzidine dihydrochloride	0.059	OEHHA (2002d)
2-Methylaziridine (propyleneimine)	0.028	OEHHA (2002e)
Phenyl glycidyl ether	5.0	OEHHA (2002f)
Tetranitromethane	0.059	OEHHA (2002g)
2,6-Xylidine	110	OEHHA (2002h)

Levels established for carcinogens in Section 12705(b) supersede any existing levels for these carcinogens in Section 12705(c) and Section 12705(d).

This proposed regulation adopts the following NSRLs in Section 12705(d) for chemicals known to cause cancer, in accordance with the methods outlined in Section 12703:

Chemical	NSRL, in units micrograms per day	Reference
<i>p</i> -Chloro- <i>o</i> -toluidine hydrochloride	3.3	OEHHA (2002i)
Isobutyl nitrite	7.4	OEHHA (2002j)
Nalidixic acid	28	OEHHA (2002j)
<i>o</i> -Phenylenediamine	26	OEHHA (2002j)
<i>o</i> -Phenylenediamine dihydrochloride	44	OEHHA (2002j)

The proposed regulation adopts the following regulatory level for a chemical known to cause reproductive toxicity in Section 12805:

Chemical	MADL, in units micrograms per day	Reference
Linuron	460	OEHHA (2002k)

REASONABLE ALTERNATIVES TO THE REGULATION AND THE AGENCY'S REASONS FOR REJECTING THOSE ALTERNATIVES

OEHHA is not aware of any alternatives to the proposed regulatory action.

REASONABLE ALTERNATIVES TO THE PROPOSED REGULATORY ACTION THAT WOULD LESSEN ANY ADVERSE IMPACT ON SMALL BUSINESSES

The proposed regulatory action will not adversely impact small business. The proposed regulation identifies levels below which businesses are exempt from Proposition 65 warning requirements and the discharge prohibition. It does not impose any requirement upon any business, including small business.

EVIDENCE SUPPORTING FINDING OF NO SIGNIFICANT ADVERSE ECONOMIC IMPACT ON BUSINESS

The regulation will not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states. The regulation identifies levels below which businesses are exempt from Proposition 65 warning requirements and the discharge prohibition. No costs or expenses are incurred by businesses to comply with the proposed regulation. There is no significant adverse economic impact on any business. In fact, the proposed regulatory action makes it easier for affected businesses to comply with Proposition 65.

DUPLICATION OR CONFLICTS WITH FEDERAL REGULATIONS CONTAINED IN THE CODE OF FEDERAL REGULATIONS

Proposition 65 is a California law that has no federal counterpart. There are no federal regulations addressing the same issues and, thus, there is no duplication or conflict with federal regulations.

REFERENCES

Office of Environmental Health Hazard Assessment (OEHHA, 2002a). No Significant Risk Level (NSRL) for the Proposition 65 Carcinogen Benzofuran. OEHHA Reproductive and Cancer Hazard Assessment Section, California Environmental Protection Agency, Oakland.

Office of Environmental Health Hazard Assessment (OEHHA, 2002b). No Significant Risk Level (NSRL) for the Proposition 65 Carcinogen N-Carboxymethyl-N-nitrosourea. OEHHA Reproductive and Cancer Hazard Assessment Section, California Environmental Protection Agency, Oakland.

Office of Environmental Health Hazard Assessment (OEHHA, 2002c). No Significant Risk Levels (NSRLs) for the Proposition 65 Carcinogens 3,3'-Dimethoxybenzidine and 3,3'-Dimethoxybenzidine Dihydrochloride. OEHHA Reproductive and Cancer Hazard Assessment Section, California Environmental Protection Agency, Oakland.

Office of Environmental Health Hazard Assessment (OEHHA, 2002d). No Significant Risk Levels (NSRLs) for the Proposition 65 Carcinogens 3,3'-Dimethylbenzidine and 3,3'-Dimethylbenzidine Dihydrochloride. OEHHA Reproductive and Cancer Hazard Assessment Section, California Environmental Protection Agency, Oakland.

Office of Environmental Health Hazard Assessment (OEHHA, 2002e). No Significant Risk Level (NSRL) for the Proposition 65 Carcinogen 2-Methylaziridine (Propyleneimine). OEHHA Reproductive and Cancer Hazard Assessment Section, California Environmental Protection Agency, Oakland.

Office of Environmental Health Hazard Assessment (OEHHA, 2002f). No Significant Risk Level (NSRL) for the Proposition 65 Carcinogen Phenyl Glycidyl Ether. OEHHA Reproductive and Cancer Hazard Assessment Section, California Environmental Protection Agency, Oakland.

Office of Environmental Health Hazard Assessment (OEHHA, 2002g). No Significant Risk Level (NSRL) for the Proposition 65 Carcinogen Tetranitromethane. OEHHA Reproductive and Cancer Hazard Assessment Section, California Environmental Protection Agency, Oakland.

Office of Environmental Health Hazard Assessment (OEHHA, 2002h). No Significant Risk Level (NSRL) for the Proposition 65 Carcinogen 2,6-Xylidine. OEHHA Reproductive and Cancer Hazard Assessment Section, California Environmental Protection Agency, Oakland.

Office of Environmental Health Hazard Assessment (OEHHA, 2002i). No Significant Risk Level (NSRL) for the Proposition 65 Carcinogen *p*-Chloro-*o*-Toluidine Hydrochloride. OEHHA Reproductive and Cancer Hazard Assessment Section, California Environmental Protection Agency, Oakland.

Office of Environmental Health Hazard Assessment (OEHHA, 2002j). Expedited Cancer Potency Values and No Significant Risk Levels (NSRLs) for Four Proposition 65 Carcinogens: Isobutyl Nitrite, Nalidixic Acid, *o*-Phenylenediamine, *o*-Phenylenediamine Dihydrochloride. OEHHA Reproductive and Cancer Hazard Assessment Section, California Environmental Protection Agency, Oakland.

Office of Environmental Health Hazard Assessment (OEHHA, 2002k). Proposition 65 Maximum Allowable Dose Level (MADL) for Reproductive Toxicity for Linuron. OEHHA Reproductive and Cancer Hazard Assessment Section, California Environmental Protection Agency, Sacramento.