INITIAL STATEMENT OF REASONS

TITLE 22, CALIFORNIA CODE OF REGULATIONS

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

SECTION 12805. SPECIFIC REGULATORY LEVELS: CHEMICALS CAUSING REPRODUCTIVE TOXICITY

The Safe Drinking Water and Toxic Enforcement Act of 1986, codified at Health and Safety Code section 25249.5 et seq. and commonly known as Proposition 65 (hereinafter referred to as "Proposition 65" or "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 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 such persons from knowingly discharging a listed chemical into water or onto or into land where such chemical passes or probably will pass into any source of drinking water (Health and Safety Code section 25249.5).

For chemicals known to the State to cause cancer, an exemption from the above requirements is provided by the Act when a person in the course of doing business is able to demonstrate that an exposure for which he or she is responsible poses no significant risk or that a discharge which otherwise complies with all applicable requirements would not cause any significant amount of the discharged or released chemical to enter any source of drinking water (Health and Safety Code sections 25249.9 and 25249.10). A determination that a level of exposure poses no significant risk may be made utilizing regulations that have previously been adopted by the Office of Environmental Health Hazard Assessment (Title 22, California Code of Regulations, Sections 12701-12721[1]). Section 12701 describes alternative methods for making such a determination. Section 12705 sets forth the process by which the Office of Environmental Health Hazard Assessment may identify specific regulatory levels for determining "no significant risk" for purposes of Proposition 65.

For chemicals known to the State to cause reproductive toxicity, an exemption from the warning requirement is provided by the Act when a person in the course of doing business is able to demonstrate that an exposure for which he or she is responsible produces no observable reproductive effect, assuming exposure at 1,000 times the level in question (Health and Safety Code sections 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). The Act also provides an exemption from the prohibition against discharging a listed chemical into sources of drinking water if the amount discharged does not constitute a "significant amount," as defined, and the discharge is in conformity with all other laws and regulatory requirements (Health and Safety Code sections 25249.9 and 25249.11). The term "significant amount" is defined in a manner that equates to the level that triggers the warning requirement. Thus, these exemptions apply when an exposure or discharge does not exceed the NOEL divided by 1,000. One method by which a person in the course of doing business may determine whether an

[1] All further references are to Title 22 of the California Code of Regulations, unless otherwise indicated.

exposure or a discharge is exempt from the Act is by application of the specific regulatory level for the chemical in Section 12805. The levels in Section 12805 represent the maximum dose level at which the chemical has no observable reproductive effect, given an exposure at one thousand (1,000) times the level in question.

Regulations previously adopted by the Office of Environmental Health Hazard Assessment (OEHHA) provide guidance for determining whether an exposure to, or a discharge of, a chemical known to cause reproductive toxicity meets the statutory exemption (Sections 12801-12821). These regulations provide three 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 (3) 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 into Section 12705(b) using scientific methods consistent with procedures outlined in Section 12703. This proposed regulation also sets forth maximum allowable dose levels (MADLs) for adoption into Section 12805 using scientific methods outlined in Section 12803.

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

The proposed levels described below for inclusion 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 by the OEHHA, Reproductive and Cancer Hazard Assessment Section, in accordance with the principles in Section 12703.

This amendment to Section 12705(b) would adopt the following “no significant risk” levels for chemicals listed under Proposition 65 as known to cause cancer:

Chemical	NSRL, in units micrograms per day	Reference
1,2-Dichloropropane	9.7	OEHHA (2004a)
Naphthalene	5.8	OEHHA (2004b)

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

This amendment to Section 12805 would adopt the following regulatory level for chemicals listed under Proposition 65 as known to cause reproductive toxicity:

Chemical	MADL, in units micrograms per day	Reference
1,2-Dibromo-3-chloropropane	4.3 (inhalation) 3.1 (oral)	OEHHA (2004c)
Disodium cyanodithioimidocarbonate	56 (oral) 170 (oral; as 32% pesticidal formulation)	OEHHA (2004d)
Ethyl dipropylthiocarbamate	700 (oral and inhalation) 6700 (dermal)	OEHHA (2004e)
Ethylene glycol monomethyl ether	63 (oral)	OEHHA (2004f)
Ethylene glycol monomethyl ether acetate	98 (oral)	OEHHA (2004g)
Methyl bromide as a structural fumigant	810 (inhalation)	OEHHA (2004h)
Sodium dimethyldithiocarbamate	23 (oral) 58 (oral; as 40% pesticidal formulation)	OEHHA (2004i)
Thiophanate-methyl	600 (oral)	OEHHA (2004j)

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 by helping them determine when the warning and discharge requirements may apply.

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, 2004a). No Significant Risk Level (NSRL) for the Proposition 65 Carcinogen 1,2-Dichloropropane. OEHHA Reproductive and Cancer Hazard Assessment Section, California Environmental Protection Agency, Oakland, May, 2004.

Office of Environmental Health Hazard Assessment (OEHHA, 2004b). No Significant Risk Level (NSRL) for the Proposition 65 Carcinogen Naphthalene. OEHHA Reproductive and Cancer Hazard Assessment Section, California Environmental Protection Agency, Oakland, May, 2004.

Office of Environmental Health Hazard Assessment (OEHHA, 2004c). Proposition 65 Maximum Allowable Dose Level (MADL) for Reproductive Toxicity for 1,2-Dibromo-3-chloropropane (DBCP). OEHHA Reproductive and Cancer Hazard Assessment Section, California Environmental Protection Agency, Oakland, June, 2004.

Office of Environmental Health Hazard Assessment (OEHHA, 2004d). Proposition 65 Maximum Allowable Dose Level (MADL) for Reproductive Toxicity for Disodium Cyanodithioimidocarbamate (DCDIC) for Oral Exposure. OEHHA Reproductive and Cancer Hazard Assessment Section, California Environmental Protection Agency, Oakland, June, 2004.

Office of Environmental Health Hazard Assessment (OEHHA, 2004e). Proposition 65 Maximum Allowable Dose Level (MADL) for Reproductive Toxicity for Ethyl Dipropylthiocarbamate (EPTC). OEHHA Reproductive and Cancer Hazard Assessment Section, California Environmental Protection Agency, Oakland, June, 2004.

Office of Environmental Health Hazard Assessment (OEHHA, 2004f). Proposition 65 Maximum Allowable Dose Level (MADL) for Reproductive Toxicity for Ethyl Glycol Monomethyl Ether. OEHHA Reproductive and Cancer Hazard Assessment Section, California Environmental Protection Agency, Oakland, June, 2004.

Office of Environmental Health Hazard Assessment (OEHHA, 2004g). Proposition 65 Maximum Allowable Dose Level (MADL) for Reproductive Toxicity for Ethyl Glycol

Monomethyl Ether Acetate. OEHHA Reproductive and Cancer Hazard Assessment Section, California Environmental Protection Agency, Oakland, May, 2004.

Office of Environmental Health Hazard Assessment (OEHHA, 2004h). Proposition 65 Maximum Allowable Dose Level (MADL) for Reproductive Toxicity for Methyl Bromide as A Structural Fumigant. OEHHA Reproductive and Cancer Hazard Assessment Section, California Environmental Protection Agency, Oakland, June, 2004.

Office of Environmental Health Hazard Assessment (OEHHA, 2004i). Proposition 65 Maximum Allowable Dose Level (MADL) for Reproductive Toxicity for Sodium Dimethyldithiocarbamate for Oral Exposures. OEHHA Reproductive and Cancer Hazard Assessment Section, California Environmental Protection Agency, Oakland, June, 2004.

Office of Environmental Health Hazard Assessment (OEHHA, 2004j). Proposition 65 Maximum Allowable Dose Level (MADL) for Reproductive Toxicity for Thiophanate-methyl for the Oral Route of Exposure. OEHHA Reproductive and Cancer Hazard Assessment Section, California Environmental Protection Agency, Oakland, May, 2004.