INITIAL STATEMENT OF REASONS

TITLE 22, CALIFORNIA CODE OF REGULATIONS

SECTION 12805. SPECIFIC REGULATORY LEVELS: REPRODUCTIVE TOXICANTS

The Safe Drinking Water and Toxic Enforcement Act of 1986 (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 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 it is responsible produces no observable reproductive effect assuming exposure at 1,000 times the level in question (Health and Safety Code Section 25249.10). 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) Thus, these exemptions apply when an exposure or discharge does not exceed the NOEL divided by 1,000.

Regulations previously adopted by 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 (22 California Code of Regulations (CCR), Sections 12801-12821). (All further regulatory citations are to Title 22 of the California Code of Regulations unless otherwise specified.) These regulations provide two principal 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 also sets forth maximum allowable dose levels (MADLs) 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 regulation adopts the regulatory levels for chemicals known to cause reproductive toxicity in Section 12805 given in the table below.

Chemical	MADL, in units micrograms per day	Reference
2,4-D butyric acid (2,4-DB, 2,4-dichlorophenoxybutyric acid)	910	OEHHA (2003a)
m-Dinitrobenzene	38 (oral)	OEHHA (2003b)
Hydramethylnon	120 (oral)	OEHHA (2003c)
N-Methylpyrrolidone	3,200 (inhalation) 17,000 (dermal)	OEHHA (2003d)

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, 2003a). Proposition 65 Maximum Allowable Dose Level (MADL) for Male Reproductive Toxicity for 2,4-D butyric acid. OEHHA Reproductive and Cancer Hazard Assessment Section, California Environmental Protection Agency, Sacramento.

Office of Environmental Health Hazard Assessment (OEHHA, 2003b). Proposition 65 Maximum Allowable Dose Level (MADL) for Reproductive Toxicity for *m*-Dinitrobenzene for Oral Exposure. OEHHA Reproductive and Cancer Hazard Assessment Section, California Environmental Protection Agency, Sacramento.

Office of Environmental Health Hazard Assessment (OEHHA, 2003c). Proposition 65 Maximum Allowable Dose Level (MADL) for Reproductive Toxicity for Hydramethylnon for Oral Exposure. OEHHA Reproductive and Cancer Hazard Assessment Section, California Environmental Protection Agency, Sacramento.

Office of Environmental Health Hazard Assessment (OEHHA, 2003d). Proposition 65 Maximum Allowable Dose Level (MADL) for Reproductive Toxicity for N-Methylpyrrolidone for Dermal and Inhalation Exposure. OEHHA Reproductive and Cancer Hazard Assessment Section, California Environmental Protection Agency, Sacramento.