INITIAL STATEMENT OF REASONS

TITLE 22, CALIFORNIA CODE OF REGULATIONS

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 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 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). 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 exposure or a discharge is exempt from the Act is by application of the specific regulatory level for the chemical in Section 12805[1]. 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.

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

This proposed regulation sets forth a maximum allowable dose level (MADL) for adoption into Section 12805 using scientific methods outlined in Section 12803.

Details on the scientific basis for the proposed number are provided in the reference cited below, which is also included in the rulemaking record. The reference is a risk assessment document prepared by OEHHA describing and summarizing the derivation of the regulatory level listed below.

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

Chemical	MADL, in units micrograms per day	Reference
Di(2-ethylhexyl)phthalate (DEHP)	4200 (intravenous)	OEHHA (2004)

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, 2004). Proposition 65 Maximum Allowable Dose Level (MADL) for Reproductive Toxicant for Di(2-ethylhexyl)phthalate (DEHP) by Intravenous Injection. OEHHA Reproductive and Cancer Hazard Assessment Section, California Environmental Protection Agency, Oakland, October, 2004.