

INITIAL STATEMENT OF REASONS

TITLE 27, CALIFORNIA CODE OF REGULATIONS

SECTION 25805. SPECIFIC REGULATORY LEVELS: CHEMICALS CAUSING
REPRODUCTIVE TOXICITY

MAXIMUM ALLOWABLE DOSE LEVEL: ACRYLAMIDE

PURPOSE OF PROPOSED REGULATION

This proposed regulation sets forth a maximum allowable dose level (MADL) for adoption into Section 25805 that was derived using scientific methods outlined in Section 25803.

Note: Acrylamide is currently being considered for listing via the authoritative bodies listing mechanism as known to cause reproductive or developmental effects. See http://www.oehha.ca.gov/prop65/CRNR_notices/admin_listing/intent_to_list/pdf_zip/noil_arylamine022610.pdf. In the event the chemical is not listed for those endpoints, the Office of Environmental Health Hazard Assessment (OEHHA) will not proceed with the adoption of this regulation. Given the public interest in this chemical, OEHHA is proposing this MADL at this time to assist stakeholders and members of the public in assessing the potential impact of the listing. The proposed MADL is 140 micrograms per day. This is 700 times greater than 0.2 micrograms per day, which is the cancer No Significant Risk Level for acrylamide in regulation in Section 25705(c).

Details on the basis for this proposed level are provided in the document cited below, which is available on the OEHHA website at www.oehha.ca.gov and is also included in the rulemaking record. The document is a risk assessment document prepared by OEHHA describing and summarizing the derivation of the regulatory level listed below.

The proposed regulation would adopt the following regulatory level for one chemical known to cause reproductive toxicity into Section 25805:

Chemical	MADL, in units micrograms per day	Reference
Acrylamide	140	OEHHA (2010)

BACKGROUND

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 (hereafter 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 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 the person is responsible will have 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). 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 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 (Title 27, California Code of Regulations, sections 25801-25821¹). 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 25803 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 25805; 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 25803(a). The specific regulatory levels in Section 25805 represent one one-thousandth of the NOEL.

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

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

¹ All further regulatory references are to Title 27 of the California Code of Regulations unless otherwise indicated.

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 a level 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 a level 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, 2010). Proposition 65 Proposed Maximum Allowable Dose Level (MADL) for Reproductive Toxicity for Acrylamide. OEHHA Reproductive and Cancer Hazard Assessment Branch, California Environmental Protection Agency, Sacramento, February 2010.