

CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

NOTICE OF PROPOSED RULEMAKING

TITLE 27, CALIFORNIA CODE OF REGULATIONS

AMENDMENT TO SECTION 25805
SPECIFIC REGULATORY LEVELS:
CHEMICALS CAUSING REPRODUCTIVE TOXICITY

MAXIMUM ALLOWABLE DOSE LEVEL: AVERMECTIN B1

NOTICE IS HEREBY GIVEN that the Office of Environmental Health Hazard Assessment (OEHHA) proposes to establish a specific regulatory level having a maximum allowable dose level (MADL) for Avermectin B1, and amend Title 27, California Code of Regulations, Section 25805¹.

PUBLIC PROCEEDINGS

Any written statements or arguments regardless of the form or method of transmission must be received by OEHHA by 5:00 p.m. on **July 5, 2011**, the designated close of the written comment period. We encourage you to submit comments in electronic form, rather than in paper form. Comments transmitted by e-mail should be addressed to sluong@oehha.ca.gov. Comments submitted in paper form may be mailed, faxed, or delivered in person to the addresses below:

Mailing Address:

Ms. Susan Luong
Office of Environmental Health Hazard Assessment
P.O. Box 4010, MS-19B
Sacramento, California 95812-4010
Fax:(916) 323-8803
Street Address:1001 I Street
Sacramento, California 95814

A public hearing to present oral comments will be scheduled only if one is requested. The request must be submitted in writing no later than 15 days before the close of the comment period on July 5, 2011. The written request must be sent to OEHHA at the address listed above no later than **June 20, 2011**. A notice for the public hearing, if one is requested, will be mailed to interested

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

parties who are on the Proposition 65 mailing list for regulatory public hearings. The notice will also be posted on the OEHHA web site at least ten days in advance of the public hearing date. The notice will provide the date, time, location and subject matter to be heard.

If a hearing is scheduled and you have special accommodation or language needs, please contact Susan Luong at (916) 327-3015 or sluong@oehha.ca.gov at least one week in advance of the hearing. TTY/TDD/Speech-to-Speech users may dial 7-1-1 for the California Relay Service.

CONTACT

Please direct inquiries concerning the substance and processing of the action described in this notice to Susan Luong, in writing at the address given above, or by telephone at (916) 445-6900. Ms. Cynthia Oshita is a back-up contact person for inquiries concerning processing of this action and is available at the same number.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

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 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 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 the person 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). 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 (Sections 25801-25821). 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.

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.

Details on the basis for the proposed level 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.

The proposed regulation would adopt into Section 25805 the following regulatory level for avermectin B1, a chemical known to cause reproductive toxicity:

Chemical	MADL, in units micrograms per day	Reference
Avermectin B1	4.4	OEHHA (2011)

The risk assessment which was used by OEHHA to determine the stated level is as follows:

OEHHA, 2011: Proposition 65 Maximum Allowable Dose Level (MADL) for Developmental and Reproductive Toxicity for Avermectin B1. OEHHA Reproductive and Cancer Hazard Assessment Branch, California Environmental Protection Agency, Sacramento, May, 2011.

AUTHORITY

Health and Safety Code Section 25249.12.

REFERENCE

Health and Safety Code Sections 25249.5, 25249.6, 25249.9, 25249.10 and 25249.11.

IMPACT ON LOCAL AGENCIES OR SCHOOL DISTRICTS

OEHHA has determined the proposed regulatory action would not impose a mandate on local agencies or school districts nor does it require reimbursement by the State pursuant to Part 7 (commencing with Section 17500) of Division 4 of the Government Code. OEHHA has also determined that no nondiscretionary costs or savings to local agencies or school districts will result from the proposed regulatory action.

COSTS OR SAVINGS TO STATE AGENCIES

OEHHA has determined that no savings or increased costs to any State agency will result from the proposed regulatory action.

EFFECT ON FEDERAL FUNDING TO THE STATE

OEHHA has determined that no costs or savings in federal funding to the State will result from the proposed regulatory action.

EFFECT ON HOUSING COSTS

OEHHA has determined that the proposed regulatory action will have no effect on housing costs.

SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS, INCLUDING ABILITY TO COMPETE

OEHHA has made an initial determination that the adoption of 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 proposed MADL will provide compliance assistance for businesses subject to the Act and may save costs to businesses that would otherwise pay for the calculation of a MADL.

IMPACT ON THE CREATION, ELIMINATION, OR EXPANSION OF JOBS/BUSINESSES

OEHHA has determined that the proposed regulatory action will not have any impact on the creation or elimination of jobs, the creation of new businesses or the elimination of existing businesses, or the expansion of businesses currently doing business within the State of California.

COST IMPACTS ON REPRESENTATIVE PRIVATE PERSONS OR BUSINESSES

The OEHHA is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

EFFECT ON SMALL BUSINESSES

OEHHA has determined that the proposed regulation will not impose any requirements on small business. Rather, the proposed regulation will assist small businesses subject to the Act in determining whether or not an exposure for which they are responsible is subject to the warning requirement or discharge prohibition.

CONSIDERATION OF ALTERNATIVES

In accordance with Government Code Section 11346.5(a)(13), OEHHA must determine that no reasonable alternative considered by OEHHA or that has otherwise been identified and brought to the attention of OEHHA would be more effective in carrying out the purpose for which the action is proposed, or would be as effective and less burdensome to affected private persons than the proposed action.

AVAILABILITY OF STATEMENT OF REASONS AND TEXT OF PROPOSED REGULATIONS

OEHHA has prepared and has available for public review an Initial Statement of Reasons for the regulation, all the critical information upon which the regulation is based, and the text of the regulation. A copy of the Initial Statement of Reasons, a copy of the text of the regulation and a copy of the risk assessment which was used by OEHHA to determine the MADL are available upon request from OEHHA's Proposition 65 Implementation Program at the address and telephone number indicated above. These documents are also posted on OEHHA's Web site at www.oehha.ca.gov.

AVAILABILITY OF CHANGED OR MODIFIED TEXT: The full text of any regulation which is changed or modified from the express terms of the proposed action will be made available at least 15 days prior to the date on which OEHHA adopts the resulting regulation. Notice of the comment period on changed regulations and the full text will be mailed to individuals who testified or submitted written comments at the public hearing, whose comments were received by OEHHA during the public comment period, and who request notification from OEHHA of availability of such changes. Copies of the notice and the changed regulation will also be available at OEHHA's Web site at www.oehha.ca.gov.

FINAL STATEMENT OF REASONS

A copy of the Final Statement of Reasons may be obtained, when it becomes available, from OEHHA's Proposition 65 Implementation Program at the address and telephone number indicated above. The Final Statement of Reasons will also be available at OEHHA's Web site at www.oehha.ca.gov.

OFFICE OF ENVIRONMENTAL
HEALTH HAZARD ASSESSMENT

Allan Hirsch
Chief Deputy Director

Dated: May 20, 2011