

**FINAL STATEMENT OF REASONS
TITLE 27, CALIFORNIA CODE OF REGULATIONS**

**SECTION 25805. SPECIFIC REGULATORY LEVELS: CHEMICALS
CAUSING REPRODUCTIVE TOXICITY**

MAXIMUM ALLOWABLE DOSE LEVEL: AVERMECTIN B1

This is the Final Statement of Reasons for the adoption of a maximum allowable dose level (MADL) of 4.4 micrograms per day for avermectin B1. A MADL is established for chemicals listed as known to cause developmental or reproductive toxicity to provide compliance assistance to businesses subject to the Act. Avermectin B1 (*abamectin*) is listed as a chemical known to the State of California to cause developmental toxicity under Proposition 65¹.

On May 20, 2011, the Office of Environmental Health Hazard Assessment (OEHHA) issued a Notice of Proposed Rulemaking to adopt the proposed level for this chemical in Section 25805(b). The Initial Statement of Reasons set forth the grounds for the amendment to the regulation.

The Notice of Proposed Rulemaking opened a 45-day public comment period that commenced on May 20, 2011, and ended on July 5, 2011. The Notice stated that a public hearing would be held only on request. No request for a public hearing was received and no written comments were received by OEHHA.

On May 20, 2011, OEHHA provided the technical support document forming the basis for the proposed regulatory level for avermectin B1 to the members of OEHHA Science Advisory Board's Developmental and Reproductive Toxicant (DART) Identification Committee for their review and comment. No comments were received from any committee members.

ALTERNATIVES DETERMINATION

In accordance with Government Code, section 11346.5(a)(7), OEHHA has, throughout the adoption process for this regulation, considered available alternatives. OEHHA has not found any alternative more effective, or as effective and less burdensome to affected private persons, than the proposed action.

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,

¹ The Safe Drinking Water and Toxic Enforcement Act of 1986 (Health and Safety Code, section 25249.5 *et seq.*)

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.

LOCAL MANDATE DETERMINATION

OEHHA has determined this regulatory action will not pose 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 this regulatory action. Proposition 65 provides an express exemption from the warning requirement and discharge prohibition for all state and local agencies. Thus, these regulations do not impose any mandate on local agencies or school districts.