

## FINAL STATEMENT OF REASONS

### TITLE 27, CALIFORNIA CODE OF REGULATIONS

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

##### MAXIMUM ALLOWABLE DOSE LEVEL: Di-isodecyl Phthalate (DIDP)

This is the Final Statement of Reasons for the adoption of a maximum allowable dose level (MADL) for the chemical, Di-isodecyl Phthalate (DIDP), which is listed as known to the State to cause reproductive toxicity under Proposition 65<sup>1</sup>. On April 23, 2010, the Office of Environmental Health Hazard Assessment (OEHHA) issued a Notice of Proposed Rulemaking to adopt the proposed level for this chemical in Title 27, California Code of Regulations, section 25705(b)<sup>2</sup>. The Initial Statement of Reasons set forth the grounds for the proposed amendments to the regulations.

The Notice of Proposed Rulemaking opened a public comment period that commenced on April 23, 2010 and ended on June 7, 2010. The Notice stated that a public hearing would be held only on request. No request for a public hearing was received by OEHHA. Two written comments were received by OEHHA. Both comments stated opposition to the listing of DIDP under Proposition 65, which is irrelevant to the present action, but supported adoption of the proposed MADL.

#### ALTERNATIVES DETERMINATION

In accordance with Government Code, section 11346.5(a)(7), OEHHA has, throughout the adoption process of 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, 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

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

<sup>2</sup> All further references are to sections of Title 27 of the California Code of Regulations, unless otherwise noted.

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 25801-25821<sup>3</sup>). 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.

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<sup>3</sup> All further regulatory references are to Title 27 of the California Code of Regulations unless otherwise indicated.