

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

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

**MAXIMUM ALLOWABLE DOSE LEVEL FOR  
BISPHENOL A (BPA)  
(DERMAL EXPOSURE FROM SOLID MATERIALS)**

This is the Final Statement of Reasons for the adoption of a Maximum Allowable Dose Level (MADL) for dermal exposure to bisphenol A (BPA) from contact with solid materials under Proposition 65<sup>1</sup> in Title 27, California Code of Regulations, section 25805(b)<sup>2</sup>. BPA is a chemical known to the State of California to cause reproductive toxicity (female endpoint) under Proposition 65.<sup>3</sup> On April 1, 2016, the Office of Environmental Health Hazard Assessment (OEHHA) issued a Notice of Proposed Rulemaking to adopt a proposed MADL of 3 micrograms per day for BPA (dermal exposure from solid materials) under section 25805(b). “Solid materials” are materials in solid form and include but are not limited to items such as paper and plastics. The Initial Statement of Reasons set forth the grounds for the amendment to the regulation. A public comment period was provided from April 1, 2016 to May 16, 2016. The Notice stated that a public hearing would be held only on request. No request for a public hearing was received. No written comments were received by OEHHA.

**PEER REVIEW**

On April 10, 2016, OEHHA provided the notice of proposed rulemaking and the Initial Statement of Reasons for the proposed MADL for BPA (dermal exposure from solid materials) to the members of the Developmental and Reproductive

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<sup>1</sup> The Safe Drinking Water and Toxic Enforcement Act of 1986, codified at Health and Safety Code section 25249.5 *et. seq.*, hereafter referred to as “Proposition 65” or “The Act”.

<sup>2</sup> All subsequent citations are to Title 27, California Code of Regulations, unless otherwise noted.

<sup>3</sup> BPA was listed on May 11, 2015 by the State’s Qualified Experts, see <http://oehha.ca.gov/proposition-65/cnr/bisphenol-listed-known-state-california-cause-reproductive-toxicity>

Toxicant Identification Committee for their review as required by Section 25801(f). No comments were received from any committee members.

#### ALTERNATIVES DETERMINATION

In accordance with Government Code section 11346.9(a)(4), OEHHA has, throughout the adoption process for this regulation, considered available alternatives to determine whether any alternative would be more cost effective in carrying out the purpose for which the regulation was proposed, or would be as cost effective and less burdensome to affected private persons than the proposed action.

OEHHA has determined that no other reasonable alternative considered by OEHHA or that has otherwise been identified or brought to the attention of OEHHA would either 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, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law than the proposed regulation.

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 (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.