

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

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

**MAXIMUM ALLOWABLE DOSE LEVELS FOR
n-HEXANE (ORAL AND INHALATION)**

This is the Final Statement of Reasons for the adoption of Maximum Allowable Dose Levels (MADLs) for oral and inhalation exposures to n-hexane. On December 15, 2017, n-hexane was added to the Proposition 65¹ list as known to the state to cause reproductive toxicity (male reproductive endpoint). On October 5, 2018, the Office of Environmental Health Hazard Assessment (OEHHA) issued a Notice of Proposed Rulemaking to adopt a proposed oral MADL for n-hexane of 28,000 micrograms per day and a proposed inhalation MADL for n-hexane of 20,000 micrograms per day under Title 27, California Code of Regulations, section 25805(b)². The Initial Statement of Reasons sets forth the grounds for the amendments to the regulation. A public comment period was provided from October 5, 2018 to November 19, 2018. The Notice stated that a public hearing would be held only if requested. No request for a public hearing was received. No written public comments were received by OEHHA.

PEER REVIEW

OEHHA provided the Notice of Proposed Rulemaking and the Initial Statement of Reasons for the proposed MADLs for n-hexane to the members of the Developmental and Reproductive Toxicant Identification Committee for their review and comment as required by Section 25801(f). Comments were received from committee member Dr. Charles Plover.

¹ 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".

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

SUMMARY AND RESPONSE TO PEER REVIEW COMMENTS RECEIVED

Comment: Dr. Charles Plopper stated, “I reviewed the documents and believe the MADLs for n-Hexane are appropriate”.

Response: OEHHA acknowledges the comment. No changes to the proposal are required.

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. No alternatives have been suggested. 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 listed under the Act as known to cause reproductive toxicity, the Act exempts discharges to sources of drinking water and exposures of people without provision of a warning if the exposure will have no observable effect assuming exposure at one thousand (1,000) times the level in question for substances known to cause reproductive toxicity (Health and Safety Code, section 25249.10(c)). The Act does not specify numerical levels of exposure that will have no observable effect for reproductive toxicity.

The purpose of this regulation is to establish Maximum Allowable Dose Levels (MADLs) for n-hexane. At or below these levels, the Act does not require a warning or prohibit discharges of the chemical to sources of drinking water. Thus, adopting these levels will allow businesses subject to the Act to determine whether a given discharge to sources of drinking water or a given exposure to this chemical is subject to the warning requirement or discharge prohibition provisions of the Act (Health and Safety Code, section 25249.5 and 25249.6).

Although Section 25803 describes principles and assumptions for conducting quantitative assessments to derive MADLs, some businesses subject to the Act do not have the resources to perform these assessments. Yet each business with ten or more employees must determine whether its activities or products are subject to the discharge prohibition or warning requirements of the Act. Adopting a MADL for this chemical provides an efficient way of determining if a business is in compliance with the Act.

LOCAL MANDATE DETERMINATION

OEHHA has determined this regulatory action will 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 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.