

**FINAL STATEMENT OF REASONS  
TITLE 22, CALIFORNIA CODE OF REGULATIONS**

**SECTION 12805. SPECIFIC REGULATORY LEVELS:  
CHEMICALS CAUSING REPRODUCTIVE TOXICITY**

This is the Final Statement of Reasons for specific regulatory levels for ethylene glycol monoethyl ether (EGEE), ethylene glycol monoethyl ether acetate (EGEEA) and potassium dimethyldithiocarbamate. These three chemicals are listed as known to the State to cause reproductive toxicity under the Safe Drinking Water and Toxic Enforcement Act of 1986 (hereinafter “the Act” or Proposition 65; Health and Safety Code, Section 25249.5 *et seq.*). On March 30, 2007, the Office of Environmental Health Hazard Assessment (OEHHA) published a Notice of Proposed Rulemaking (California Regulatory Notice Register, 2007) to adopt regulatory levels for EGEE, EGEEA and potassium dimethyldithiocarbamate pursuant to Title 22, California Code of Regulations, sections 12801 and 12803. The Initial Statement of Reasons set forth the grounds for the proposed regulation. Pursuant to the Notice of Proposed Rulemaking, a public comment period was provided from the publication of the Notice until May 14, 2007. The Notice of Proposed Rulemaking stated that a public hearing would be held only on request. No request for a public hearing was received by OEHHA. No written comments were received by OEHHA.

**ALTERNATIVES DETERMINATION**

In accordance with Government Code section 11346.5(a)(7), OEHHA has, throughout the adoption process for this regulation, considered available alternatives to determine whether any alternative would be more effective in carrying out the purpose for which the regulations were proposed, or would be as effective and less burdensome to affected private persons than the proposed action. OEHHA has determined that no alternative considered would be more effective, or as effective and less burdensome to affected persons, 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 produces no observable effect on reproduction assuming exposure at 1,000 times the level in question, or the discharged amount is at or below this level (Health and Safety Code, sections 25249.10 and 25249.9 respectively). The Act does not specify numerical levels of exposure where there would be no observable effect given an exposure 1,000 times the level in question, i.e., the maximum allowable dose level (MADL).

The purpose of this regulation is to provide “safe harbor” levels for certain chemical exposures. This regulation establishes MADLs for a chemical that causes reproductive toxicity. The discharge prohibition does not apply and warnings regarding reproductive toxicity concerns are not required for exposures at or below these levels. Thus, these levels will allow persons subject to the Act to determine whether a given discharge to

sources of drinking water or exposure of people involving these chemicals is subject to the discharge prohibition and warning requirement provisions of the Act (Health and Safety Code, sections 25249.5 and 25249.6 respectively).

Although Title 22, California Code of Regulations, section 12803 describes principles and assumptions for conducting risk assessments to derive safe harbor levels, many businesses subject to the Act do not have the resources to perform these assessments. Yet each business with ten or more employees needs the ability to determine whether its activities or products are subject to the discharge prohibition or warning requirements of the Act. Given the wide use or occurrence of the chemicals covered by this regulation, the absence of this regulation would leave numerous businesses without an efficient way of determining if they are in compliance with the Act without the expenditure of significant resources on their part.

#### LOCAL MANDATE DETERMINATION

OEHHA has determined the 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 the proposed regulatory action. It should be noted that Proposition 65 provides an express exemption from the warning requirement and discharge prohibition for all state and local agencies. Thus, the proposed regulations do not impose any mandate on local agencies or school districts.