

FINAL STATEMENT OF REASONS  
22 CALIFORNIA CODE OF REGULATIONS

SECTIONS 12705(b) and 12705(d). SPECIFIC REGULATORY LEVELS POSING NO SIGNIFICANT RISK

SECTION 12805. SPECIFIC REGULATORY LEVELS: REPRODUCTIVE TOXICANTS

This is the Final Statement of Reasons for specific regulatory levels for 16 chemicals listed as known to the State to cause cancer or reproductive toxicity under the Safe Drinking Water and Toxic Enforcement Act of 1986 (hereinafter “the Act” or Proposition 65). On September 6, 2002, the Office of Environmental Health Hazard Assessment (OEHHA) issued a Notice of Proposed Rulemaking to adopt regulatory levels for 16 chemicals listed pursuant to the Act as known to the State to cause cancer or reproductive toxicity. The Notice set forth proposed regulatory levels for adoption in Title 22, California Code of Regulations, Section 12705 (22 CCR §12705) for 15 chemicals listed as known to the State to cause cancer in Title 22, California Code of Regulations, Section 12000. These chemicals are benzofuran, N-carboxymethyl-N-nitroso-urea, *p*-chloro-*o*-toluidine hydrochloride, 3,3'-dimethoxybenzidine, 3,3'-dimethoxybenzidine dihydrochloride, 3,3'-dimethylbenzidine, 3,3'-dimethylbenzidine dihydrochloride, isobutyl nitrite, 2-methylaziridine (propyleneimine), nalidixic acid, phenyl glycidyl ether, *o*-phenylenediamine, *o*-phenylenediamine dihydrochloride, tetranitromethane, and 2,6-xylydine. In addition, the Notice announced a proposed regulatory level for adoption in Title 22, California Code of Regulations, Section 12805 (22 CCR §12805) for one chemical listed as known to the State to cause reproductive toxicity in Title 22, California Code of Regulations, Section 12000. This chemical is linuron. The Initial Statement of Reasons sets forth the grounds for the proposed regulations.

Pursuant to the Notice of Proposed Rulemaking, a public comment period was held between September 6, 2002 and October 21, 2002, and a public hearing was held on October 21, 2002.

The regulation hereby adopts regulatory levels for 16 of the 16 chemicals included in the Notice of Proposed Rulemaking.

CLARIFICATION OF ONE REFERENCE CITED IN THE NOTICE OF PROPOSED RULEMAKING

The risk assessment document which was used in the derivation of the maximum allowable dose level (MADL) for the chemical linuron was mistakenly identified in the Notice of Proposed Rulemaking as the August 2002 document (Reference “OEHHA, 2002k”). It should be the July 2002 document that was made available to the public during the 45-day comment period.

## SUMMARY AND RESPONSE TO COMMENTS RECEIVED

No comments were received.

## ALTERNATIVES DETERMINATION

In accordance with Government Code Section 11346.5(a)(7), OEHHA has, throughout the adoption process of 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 the State to cause cancer, the Act exempts discharges to sources of drinking water and exposures of people without provision of a warning if the discharge or exposure poses “no significant risk” of cancer (Health and Safety Code Section 25249.10(c)). 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 assuming exposure at 1,000 times the level in question, or the discharged amount is at or below this level (Id.). The Act does not specify numerical levels of exposure which represent the one one-thousandth of the no observable effect level, or no significant risk of cancer.

The purpose of this regulation is to provide “safe harbor” levels for certain chemical exposures. In other words, this regulation establishes the numerical no significant risk levels for 15 carcinogens. At or below these levels, the Act does not require a warning regarding cancer or prohibit discharges to sources of drinking water based on carcinogenicity concerns. Similarly, this regulation establishes a maximum allowable dose level for one chemical that causes reproductive toxicity. The discharge prohibition does not apply to amounts below this level and warnings regarding reproductive toxicity concerns are not required for exposures below this level. Thus, these levels will allow persons subject to the Act to determine whether a given discharge to sources of drinking water or exposure to people involving these chemicals is subject to the warning requirement and discharge prohibition provisions of the Act related to the risk of cancer or occurrence of reproductive toxicity (Health and Safety Code Sections 25249.6 and 25249.5 respectively). Although Title 22, Sections 12703 and 12803 describe 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 of several 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. The Office of Environmental Health Hazard Assessment has also determined that no nondiscretionary costs or savings to local agencies or school districts will result from the proposed regulatory action. It should also 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.