FINAL STATEMENT OF REASONS
22 CALIFORNIA CODE OF REGULATIONS

SECTION 12805. SPECIFIC REGULATORY LEVELS: REPRODUCTIVE TOXICANTS

This is the Final Statement of Reasons for specific regulatory levels for four chemicals 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). On March 14, 2003, the Office of Environmental Health Hazard Assessment (OEHHA) issued a Notice of Proposed Rulemaking to adopt regulatory levels for four chemicals listed pursuant to the Act as known to the State to cause reproductive toxicity (Title 22, California Code of Regulations, Section 12000): 2,4-D butyric acid (2,4-DB, 2,4-dichlorophenoxybutyric acid), *m*-dinitrobenzene, hydramethylnon and N-methylpyrrolidone. The Notice announced proposed regulatory levels for adoption in Title 22, California Code of Regulations, Section 12805 (22 CCR §12805) for the four chemicals. The Initial Statement of Reasons set forth the grounds for the proposed regulations.

Pursuant to the Notice of Proposed Rulemaking, a public comment period was held between March 14, 2003 and April 28, 2003, and a public hearing was held on April 28, 2003.

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

UPDATE OF INITIAL STATEMENT OF REASONS

UPDATE OF TECHNICAL INFORMATION IN THE INITIAL STATEMENT OF REASONS

All data, studies, reports, or other documents relied on for this regulation were identified in the Initial Statement of Reasons of March 14, 2003, except as noted immediately below.

The document supporting the NSRL for N-methylpyrrolidone is modified. Modifications to the text of the N-methylpyrrolidone support document will not have any impact on the calculation of the MADL. This document is referred to in the Initial Statement of Reasons as OEHHA (2003d; Proposition 65 Maximum Allowable Dose Level (MADL) for Reproductive Toxicity for N-Methylpyrrolidone for Dermal and Inhalation Exposure. OEHHA Reproductive and Cancer Hazard Assessment Section, California Environmental Protection Agency, Sacramento). The document was modified to include discussion of an additional study of N-methylpyrrolidone in rodents. This study has no impact on the calculation of the MADL.

SUMMARY AND RESPONSE TO COMMENTS RECEIVED

Two comments were received. One comment was from the N-Methylpyrrolidone Producers Group of Washington, D.C., in support of the adoption of the proposed maximum allowable dose levels (MADLs) for inhalation and dermal exposures to N-methylpyrrolidone. The comments note that the adoption of the MADLs for N-methylpyrrolidone will greatly facilitate the steps necessary for compliance with Proposition 65 with respect to the chemical. OEHHA acknowledges the comment.

The second comment was from Dr. Anne-Marie Saillenfait, of the Institut National de Recherche et de Securite in France. Dr. Saillenfait submitted two articles for consideration in the development of the MADL for N-methylpyrrolidone. The first article pertained to toxicity following oral exposures of rodents to N-methylpyrrolidone. The proposed regulation did not address oral exposures to the chemical; rather, it proposed MADLs for the inhalation and dermal exposure routes. Since there are direct data on inhalation and dermal exposures, the article does not have an impact on the development of the proposed MADLs. The second paper reports the results of an inhalation study in rats. That paper has a slightly higher no observable effect level than the study providing the basis for the MADL in the proposed regulation, but had a shorter duration of exposure. Pursuant to Title 22, California Code of Regulations, Section 12803, the NOEL is to be based on the most sensitive study deemed to be of sufficient quality. Both inhalation studies are of sufficient quality, but the study with the longer exposure duration is the more sensitive study in this context. Thus, the study originally identified as providing the basis of the proposed MADL remains the most appropriate for establishing the MADL. The supporting document cited in the Initial Statement of Reasons has been modified to include the study submitted (OEHHA, 2003, Proposition 65 Maximum Allowable Dose Level (MADL) for Reproductive Toxicity for N-Methylpyrrolidone for Dermal and Inhalation Exposure. OEHHA Reproductive and Cancer Hazard Assessment Section, California Environmental Protection Agency, Sacramento).

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 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 that represent the one one-thousandth of the no observable effect level.

The purpose of this regulation is to provide "safe harbor" levels for certain chemical exposures. This regulation establishes MADLs for four chemicals that cause reproductive toxicity. The discharge prohibition does not apply to exposures at or below these levels 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 to people involving these chemicals is subject to the warning requirement and discharge prohibition provisions of the Act (Health and Safety Code Sections 25249.6 and 25249.5 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 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. 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.