June 28, 2012

Office of Environmental Health Hazard Assessment
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Submitted Via E-Mail to: P65Public.Comments@oehha.ca.gov

Re: Notice of Proposed Rulemaking Title 27, California Code of Regulations Amendment To Section 25805 Specific Regulatory Levels: Chemicals Causing Reproductive Toxicity Chloroform

Dear Sir or Madam:

On behalf of the American Chemistry Council (ACC)[1], I submit these comments on the Office of Environmental Health Hazard Assessment (OEHHA) Notice of Proposed Rulemaking Title 27, California Code of Regulations Amendment To Section 25805 Specific Regulatory Levels: Chemicals Causing Reproductive Toxicity Chloroform. The notice proposes to adopt a maximum allowable dose level (MADL) of 660 micrograms per day for inhalation exposures to chloroform and provides an "Initial Statement of Reason: Chloroform MADL (Statement)" document that purports to offer the background and purpose for the amendment. However, neither OEHHA's Notice of the Proposed Rulemaking nor the Statement provide adequate justification for the revision of the MADL or offer sufficient detail for stakeholders to peer review the scientific evidence OEHHA used in its decision making. We highlight several specific concerns regarding the Statement as follows:

- The Statement does not provide any detailed information on the weight of evidence framework OEHHA used to select the most sensitive study. Specifically, the Statement notes that six animal studies were identified and ultimately OEHHA selected the Baeder

[1] The American Chemistry Council (ACC) represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. ACC is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing. The business of chemistry is a $674 billion enterprise and a key element of the nation's economy. It is one of the nation's largest exporters, accounting for ten cents out of every dollar in U.S. exports. Chemistry companies are among the largest investors in research and development. Safety and security have always been primary concerns of ACC members, and they have intensified their efforts, working closely with government agencies to improve security and to defend against any threat to the nation's critical infrastructure.

and Hofmann[2] 1990 study as the most sensitive study to derive the MADL. However, the Statement does not provide any citation references or details regarding the other animal studies not selected by OEHHA. The omission of this information makes it impossible for stakeholders to adequately peer review the weight of evidence justifying OEHHA's selection of the Baeder and Hofmann study as the most sensitive.

- OEHHA has calculated the MADL utilizing data and information from the Baeder and Hofmann 1990 study. This is an unpublished study that is not readily available to stakeholders for review and thus OEHHA should provide adequate justification for selection of this study.

- The Statement provides two brief sentences regarding OEHHA's review of the human data and provides no citation references or details about the human studies assessed by OEHHA.

- Review of the calculation of the MADL utilizing the Bader and Hofmann study has proved difficult without access to the study information. The Statement does not provide any information about the statistical significance of the effects seen at the 10ppm study concentration versus effects seen in the control population.

OEHHA should consider the concerns noted above and not finalize the MADL for chloroform without providing stakeholders an opportunity to adequately peer review the scientific basis of the MADL. Specifically, OEHHA should update its Statement to include detailed information on the studies OEHHA utilized to select the most sensitive study, provide the weight of evidence framework OEHHA used to justify selection of an unpublished study for selection as the most sensitive study and allow stakeholders an additional opportunity to comment prior to the MADL being finalized.

Respectfully,

Judith Nordgren

Judith Nordgren
Managing Director
Chlorine Chemistry Division
American Chemistry Council

[2] Baeder, C. and T. Hofmann (1990). Chloroform: supplementary inhalation embryotoxicity study in Wistar rats. Report No. 91.0902. Hoechst Aktiengesellschaft Pharma Development Toxicology.