

**EVIDENCE ON THE DEVELOPMENTAL AND
REPRODUCTIVE TOXICITY OF**

Perchlorate

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**Reproductive and Cancer Hazard Assessment Section
Office of Environmental Health Hazard Assessment
California Environmental Protection Agency**

PREFACE

The Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65, California Health and Safety Code 25249.5 *et seq.*) requires that the Governor cause to be published a list of those chemicals “known to the state” to cause cancer or reproductive toxicity. The Act specifies that one of the mechanisms by which “a chemical is known to the state to cause cancer or reproductive toxicity ... if in the opinion of the state’s qualified experts the chemical has been clearly shown through scientifically valid testing according to generally accepted principles to cause cancer or reproductive toxicity” (Health and Safety Code Section 25249.8(b)). The lead agency for implementing Proposition 65 is the Office of Environmental Health Hazard Assessment (OEHHA) of the California Environmental Protection Agency. The “state’s qualified experts” regarding findings of reproductive toxicity are identified as members of the Developmental and Reproductive Toxicant (DART) Identification Committee of the Office of Environmental Health Hazard Assessment’s Science Advisory Board (Title 22, California Code of Regulations, Section 12301).

At a meeting of the Developmental and Reproductive Toxicant (DART) Identification Committee held on [December 4, 2002](#), after considering a petition from several interested parties, the Committee asked OEHHA to take perchlorate out of the usual prioritization process order and to prepare a draft hazard identification document (HID) as resources were available. A public request for information relevant to the assessment of the evidence on the reproductive toxicity of this chemical was announced on April 11, 2003, in the *California Regulatory Notice Register*. Four sets of comments were received as a result of this request. These hazard identification materials were compiled to provide the Committee with the available scientific evidence on the reproductive toxicity potential of this chemical, and were released on May 20, 2005 for a 60-day public comment period.

At its August 11, 2005 meeting, following discussion and deliberation, the Committee, by a vote of five against and one abstention, did not find that perchlorate had been “clearly shown through scientifically valid testing according to generally accepted principles to cause reproductive toxicity.” Accordingly, perchlorate was not placed on the Proposition 65 list of chemicals known to the state to cause reproductive toxicity.

The following are the hazard identification materials that were discussed by the Committee at its August 2005 meeting.

SUMMARY OF AVAILABLE INFORMATION

Ammonium perchlorate has been and continues to be used as an oxidizer in solid rocket propellant. Sodium perchlorate is used in slurry explosive, and potassium perchlorate is used in road flares and air bag inflation systems. Large volumes of perchlorate have been disposed of since the 1950's. Some of this has leached into soil, and into aquifers used as drinking water sources. Perchlorate is highly mobile in aqueous systems and can persist for many decades under typical ground and surface water conditions. As discussed in more detail in the Attachments, perchlorate blocks uptake of iodine by the thyroid gland that may lead to decreased synthesis of the thyroid hormones, T₃ and T₄. These thyroid hormones are critical determinants of growth and development in fetuses, infants and young children. Among the sensitive subpopulations identified are pregnant women and their fetuses, lactating women, and infants.

ATTACHMENTS

In order to provide the DART Identification Committee with the scientific evidence on the potential for perchlorate to cause developmental and reproductive toxicity, attached are:

Attachment I. Public Health Goals for Chemicals In Drinking Water: Perchlorate (2005) prepared by OEHHA.

Attachment II. Health Implications of Perchlorate Ingestion (2005). Committee to Assess the Health Implications of Perchlorate Ingestion. National Research Council of the National Academies.

Attachment III. Greer MA, Goodman G, Pleus RC, and Greer SE (2002). Health effects assessment for environmental perchlorate contamination: The dose-response for inhibition of thyroidal radioiodine uptake in humans. *Environ Health Perspect* (110) 9; 927-937. This study, based on human trials of the effects of perchlorate exposure on iodine uptake by the thyroid, was used by OEHHA as the basis for the PHG for perchlorate, and by the NAS as the basis for estimating the Reference Dose (RfD) for perchlorate.

Attachment IV. Baldrige MG, Stahl RL, Gerstenberger SL, Tripoli V, Hutz RJ. (2004) In utero and lactational exposure of Long-Evans rats to ammonium perchlorate (AP) disrupts ovarian follicle maturation. *Reprod Toxicol.* 19(2):155-161. This study was not reviewed by the NAS committee, presumably because it was published after the last meeting of the committee.

Attachment Va. Report of a study conducted by Argus Laboratories entitled, *A neurobehavioral developmental study of ammonium perchlorate administered orally*

in drinking water to rats [report amendment: July 27]. Protocol no. 1613-002. Argus Research Laboratories, Inc., Horsham, PA. (1998a).

Attachment Vb. Report of a study conducted by Argus Research Laboratories entitled, *Hormone, thyroid and neurohistological effects of oral (drinking water) exposure to ammonium perchlorate in pregnant and lactating rats and in fetuses and nursing pups exposed to ammonium perchlorate during gestation or via maternal milk*. Protocol no. 1416-003. Argus Research Laboratories, Inc., Horsham, PA. (2001).

Attachment Vc. Seven addenda items submitted by the authors and/or pathologist of these studies to the U.S. EPA providing supplemental materials to the original reports.

Additional materials that may aid in the review of the reproductive toxicity of perchlorate including the Draft U.S. EPA [Perchlorate Environmental Contamination: Toxicological Review and Risk Characterization \(2002\)](#) are electronically available and may be downloaded/accessed at the websites below.

<http://cfpub2.epa.gov/ncea/cfm/recordisplay.cfm?deid=24002>

<http://www.epa.gov/ncea/perchlorate/references2/>