

**CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY  
OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT**

**SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986  
(PROPOSITION 65)**

**NOTICE OF INTENT TO LIST ACRYLAMIDE**

**February 26, 2010**

The California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA) has found that acrylamide meets the criteria for listing as a reproductive toxicant under the Safe Drinking Water and Toxic Enforcement Act of 1986.<sup>1</sup> It is therefore issuing this notice of intent to list this chemical under Proposition 65. This action is being taken under the authoritative bodies listing mechanism.<sup>2</sup>

**Background on listing via the authoritative bodies mechanism:** A chemical must be listed under the Proposition 65 regulations when two conditions are met:

- 1) An authoritative body formally identifies the chemical as causing reproductive toxicity (Section 25306(d)<sup>3</sup>).
- 2) The evidence considered by the authoritative body meets the sufficiency criteria contained in the regulations (Section 25306(g)).

However, the chemical is not listed if scientifically valid data which were not considered by the authoritative body clearly establish that the sufficiency of evidence criteria were not met (Section 25306 (h)).

The National Institute for Occupational Safety and Health (NIOSH) and the National Toxicology Program (NTP) are two of several institutions designated as authoritative for the identification of chemicals as causing reproductive toxicity (Section 25306(l)). The NTP designation applies solely as to final reports of the NTP's Center for the Evaluation of Risks to Human Reproduction (CERHR).

OEHHA is the lead agency for implementation of Proposition 65. After an authoritative body has made a determination about a chemical, OEHHA evaluates whether listing under Proposition 65 is required using the criteria contained in the regulations.

**OEHHA's determination:** Acrylamide meets the criteria for listing as known to the State to cause reproductive toxicity under Proposition 65, based on findings of NIOSH and NTP-CERHR in their documents, as indicated in the table below.

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<sup>1</sup> Commonly known as Proposition 65, the Safe Drinking Water and Toxic Enforcement Act of 1986 is codified in Health and Safety Code section 25249.5 *et seq.*

<sup>2</sup> See Health and Safety Code section 25249.8(b) and Title 27, Cal. Code of Regs., section 25306.

<sup>3</sup> All referenced sections are from Title 27 of the Cal. Code of Regulations.

Chemical	CAS No.	Endpoint	Reference	Chemical Use
Acrylamide	79-06-1	Developmental, male reproductive	NIOSH (1991) and 1992) NTP-CERHR (2005)	Used in the formation of plastics and grouting agents, formed in certain foods that have been cooked at high-temperature, present in cigarette smoke

**Formal identification and sufficiency of evidence:**

In 1991 and 1992, NIOSH published reports on occupational health standards for acrylamide that identified developmental and male reproductive toxicity (NIOSH 1991, 1992). These reports satisfy the formal identification and sufficiency of evidence criteria in the Proposition 65 regulations.

NIOSH (1991) concluded that:

“...acrylamide monomer may be neurotoxic, carcinogenic, genotoxic, and hazardous to reproduction. Recent studies confirm that acrylamide exposures cause cancer and reproductive effects in animals, but epidemiologic studies have not demonstrated these effects in humans.”

“Acrylamide exposure affected both fetal and postnatal development in mouse and rat offspring when dams were orally dosed during pregnancy.”

NIOSH (1992) stated that:

“Acrylamide is an irritant, a potent neurotoxin that affects both the central and peripheral nervous systems, a reproductive toxin, and a carcinogen.”

Adverse effects on male reproduction cited in NIOSH (1991, 1992) consisted of testicular degeneration, decreased testosterone levels, decreased fertility, and dominant lethal effects in exposed experimental animals. Developmental effects included nerve degeneration, decreased birth weight and decreased weight gain in the offspring of animals exposed to acrylamide during pregnancy.

In 2005, the NTP-CERHR published a report on acrylamide (NTP-CERHR, 2005). This report concludes that the chemical causes developmental and male reproductive toxicity, and satisfies the formal identification and sufficiency of evidence criteria in the Proposition 65 regulations.

OEHHA is relying on the NTP-CERHR’s conclusions in the report that acrylamide causes reproductive toxicity. The NTP-CERHR report concludes that there is:

Clear evidence of adverse effects for developmental toxicity in laboratory animals.

Clear evidence of adverse effects for reproductive toxicity in laboratory animals (male mice and rats).

Developmental effects included reduced fetal and pup body weights in mice and rats. Male reproductive effects included adverse effects on sperm production, impaired mating ability and genetic damage in sperm that results in death of the embryo or fetus.

Based on the NTP-CERHR and NIOSH reports and the references cited in the reports, the evidence is sufficient for listing acrylamide as known to cause reproductive toxicity by the authoritative bodies mechanism.

**Proposed safe harbor:** Because of the significant public interest in this chemical, a Notice of Proposed Rulemaking identifying a proposed Maximum Allowable Dose Level (MADL) is being published concurrently with this notice of intent to list. OEHHA is proposing a MADL for acrylamide to assist stakeholders and the general public in assessing the potential impact of the listing. In the event the chemical is not listed for those endpoints, OEHHA will not proceed with the adoption of the proposed MADL.

**History of consideration of acrylamide listing for reproductive toxicity endpoints:** Relevant information related to the possible listing of this chemical was requested in a notice published in the *California Regulatory Notice Register* on August 22, 1997 (Register 97, No. 34-Z). A public forum was held on October 1, 1997. Written comments were received and responses provided. In 1998, the Developmental and Reproductive Toxicant Identification Committee, the state's qualified experts for reproductive toxicity, removed NTP as an authoritative body for purposes of reproductive toxicity under Proposition 65. In 2003 the Committee reinstated NTP as an authoritative body for reproductive toxicity, solely as to final reports of the CERHR. In 2005, the NTP-CERHR finalized its assessment of acrylamide. OEHHA reviewed this assessment and determined that the criteria for listing as known to cause reproductive toxicity under Section 25306 are met for acrylamide. Accordingly, formal identification by NTP is now based on the NTP-CERHR monograph, and not the reports referenced in the August 1997 request for information.

OEHHA has determined that acrylamide meets the criteria for listing under Title 27, Cal. Code of Regs., section 25306, and therefore OEHHA is issuing this notice of intent to list it under Proposition 65.

**Opportunity for Public Comment:** OEHHA is committed to public participation in its implementation of Proposition 65. OEHHA wants to ensure that its regulatory decisions are based on a thorough consideration of all relevant information. If you wish to comment on whether this chemical meets the criteria for listing provided in Section 25306, please **submit your comments to OEHHA by 5:00 p.m. on Tuesday, April 27, 2010.** We encourage you to submit comments in electronic form, rather than in paper form. Comments transmitted by e-mail should be addressed to

[coshita@oehha.ca.gov](mailto:coshita@oehha.ca.gov). Comments submitted in paper form may be mailed, faxed, or delivered in person to the addresses below:

Mailing Address: Ms. Cynthia Oshita  
Office of Environmental Health Hazard Assessment  
P.O. Box 4010, MS-19B  
Sacramento, California 95812-4010

Fax: (916) 323-8803

Street Address: 1001 I Street  
Sacramento, California 95814

If you have any questions, please contact Ms. Oshita at [coshita@oehha.ca.gov](mailto:coshita@oehha.ca.gov) or at (916) 445-6900.

### References

National Institute for Occupational Safety and Health (NIOSH, 1991). *NIOH and NIOSH basis for an occupational health standard - Acrylamide: A review of the literature*. Centers for Disease Control, Public Health Service, US Department of Health and Human Services in cooperation with the National Institute of Occupational Health, Solna, Sweden. DHHS/PUB/NIOSH-91-115.

National Institute for Occupational Safety and Health (NIOSH, 1992). *Occupational Safety and Health Guideline for Acrylamide*. US Department of Health and Human Services, Public Health Service, Centers for Disease Control, NIOSH, Division of Standards Development and Technology Transfer.

National Toxicology Program – Center for the Evaluation of Risks to Human Reproduction (NTP-CERHR, 2005). *NTP-CERHR Monograph on the Potential Human Reproductive and Developmental Effects of Acrylamide*. NIH Publication No. 05-4472.