

**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 TRIPHENYLTIN HYDROXIDE
January 18, 2002**

The Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65) provides two mechanisms for administratively listing chemicals that are known to the State to cause cancer or reproductive toxicity (Health and Safety Code Section 25249.8(b)). One such mechanism by which a chemical may be listed is if a body considered to be authoritative by the state's qualified experts has formally identified it as causing cancer or reproductive toxicity. The following are identified as authoritative bodies for purposes of Proposition 65 as it pertains to chemicals known to cause reproductive toxicity: the U.S. Environmental Protection Agency (U.S. EPA), the International Agency for Research on Cancer (IARC) (for transplacental carcinogenicity only), the U.S. Food and Drug Administration (FDA), and the National Institute for Occupational Safety and Health (NIOSH). The criteria for listing chemicals through the authoritative bodies mechanism are set forth in Title 22, California Code of Regulations (22 CCR), Section 12306.

As the lead agency for the implementation of Proposition 65, the Office of Environmental Health Hazard Assessment (OEHHA) of the California Environmental Protection Agency intends to list the chemical triphenyltin hydroxide (CAS No. 76-87-9) as known to the State to cause reproductive toxicity, pursuant to this administrative mechanism as provided in Health and Safety Code Section 25249.8(b) and 22 CCR, Section 12306.

This is the second notice of intent to list issued for triphenyltin hydroxide. As a matter of clarification a brief historical account of triphenyltin hydroxide and Proposition 65 listing via the authoritative bodies mechanism is provided. The possibility that triphenyltin hydroxide, a pesticide not registered for use in California, may meet the criteria for listing under Proposition 65 via the authoritative bodies mechanism was announced in a public notice published in the *California Regulatory Notice Register* (CRNR) on October 9, 1998 (Register 98, No. 41-Z) requesting relevant information. A public forum was held on November 20, 1998. No oral or written public comments were received. On January 29, 1999, OEHHA issued in the CRNR a notice of intent to list triphenyltin hydroxide. The authoritative body, U.S. EPA, described one study in its identification of triphenyltin hydroxide as a chemical causing developmental toxicity, and referred to supporting data in the U.S. EPA "Tox One-Liner" database. Until recently, OEHHA did not have possession of the Tox One-Liner entry for triphenyltin hydroxide. The Proposition 65 notice of intent to list was therefore not based on data described in the U.S. EPA Tox One-Liner database but on the one study on which OEHHA had adequate documentation for the review of the scientific evidence. Subsequent to that notice,

OEHHA determined that the evidence in the study providing the basis for the listing was indicative of female reproductive toxicity, not developmental toxicity, the endpoint identified by the authoritative body. OEHHA then announced in the CRNR, on May 21, 1999, that the evidence was insufficient for listing triphenyltin hydroxide under Proposition 65. In that notice OEHHA also announced that the chemical would be referred to the Developmental and Reproductive Toxicant (DART) Identification Committee, the state's qualified experts for reproductive toxicity pursuant to Proposition 65. The referral was in accordance with 22 CCR, Section 12306(i) which states that after the issuance of a notice of intent to list OEHHA finds that the regulatory criteria for listing have not been satisfied, OEHHA shall refer the chemical to the appropriate Committee, in this case the DART Identification Committee, for its opinion as to whether the chemical has been clearly shown to cause reproductive toxicity.

Most recently, the U.S. EPA Tox One-Liner database entry for triphenyltin hydroxide has become available to OEHHA. This document describes several additional studies which provide evidence for developmental toxicity, the endpoint identified by the authoritative body. With the inclusion of this additional information, OEHHA has determined that triphenyltin hydroxide meets the criteria for listing as causing reproductive toxicity under 22 CCR, Section 12306. OEHHA is therefore issuing this notice of intent to list triphenyltin hydroxide. Accordingly, triphenyltin hydroxide will not at this time be referred to the DART Identification Committee.

A document providing more detail on the basis for the listing can be obtained from OEHHA's Proposition 65 Implementation Office at the address and telephone number indicated below, or from the OEHHA Web site at: <http://www.oehha.ca.gov>. Anyone objecting to the listing of triphenyltin hydroxide as causing reproductive toxicity on the basis that there is no substantial evidence that the criteria of sufficiency of evidence of reproductive toxicity identified in 22 CCR, Section 12306 have been satisfied should provide written comments in triplicate, along with supporting documentation, by mail or by fax to:

Ms. Cynthia Oshita
Office of Environmental Health Hazard Assessment
P.O. Box 4010
Sacramento, California 95812-4010
Fax No.: (916) 323-8803
Telephone: (916) 445-6900

Comments may also be hand-delivered to Ms. Oshita at the Office of Environmental Health Hazard Assessment at the same address.

In order to be considered, comments must be postmarked (if sent by mail) or received at OEHHA (if hand-delivered or sent by fax) by 5:00 p.m. on Monday, February 18, 2002.

The following chemical has been determined by OEHHA to meet the criteria set forth in 22 CCR, Section 12306 for listing as causing reproductive toxicity under the authoritative bodies mechanism:

Chemical	CAS No.	Toxicological Endpoint	Reference^a
Triphenyltin hydroxide	76-87-9	Developmental toxicity	U.S. EPA (1994a,b)

^a Formal identification by US EPA of chemicals causing reproductive toxicity is provided in US EPA (1994b) below, while additional information on the basis for such identification is provided in US EPA (1994a).

References

U.S. Environmental Protection Agency (U.S. EPA, 1994a). Proposed Rule: Addition of Certain Chemicals; Toxic Chemical Release Reporting; Community Right to Know. *Federal Register* (**59** FR 1788).

U.S. Environmental Protection Agency (U.S. EPA, 1994b). Final Rule: Addition of Certain Chemicals; Toxic Chemical Release Reporting; Community Right to Know. *Federal Register* (**59** FR 61432).