

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 CHEMICALS
FEBRUARY 7, 1997

The Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65) provides two mechanisms for administratively listing chemicals which are known to the State to cause cancer or reproductive toxicity [Health and Safety Code Section 25249.8(b)]. One mechanism by which a chemical is 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 have been identified as authoritative bodies for purposes of the Act: the United States Environmental Protection Agency (USEPA), the International Agency for Research on Cancer (IARC), the National Toxicology Program (NTP), the United States 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.

The Act also provides another mechanism for the administrative listing of a chemical, that is if a state or federal agency has formally required that the chemical be labeled or identified as causing cancer or reproductive toxicity. The criteria for listing of chemicals through this mechanism are set forth in 22 CCR, Section 12902.

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 chemicals identified below as known to the State to cause cancer or reproductive toxicity, pursuant to the two administrative mechanisms provided in Health and Safety Code Section 25249.8(b).

In a notice dated September 27, 1996, OEHHA announced that these chemicals were under consideration for listing based on a review of information indicating that the chemicals may meet the criteria set forth in 22 CCR, Section 12306 or Section 12902. OEHHA solicited comments and information relevant to the evaluation of these chemicals in the context of the regulatory criteria for administrative listing under Proposition 65. The public comment period commenced on September 27, 1996, and closed on, November 26, 1996. A public forum was held on October 29, 1996 to provide an opportunity for oral comments. OEHHA has reviewed the information received during the public comment period, and has determined that the nine chemicals identified below meet the criteria for listing under either 22 CCR, Section 12306, or Section 12902.

Anyone objecting to the listing of the chemicals identified under *Section A* below as carcinogens on the basis that there is no substantial evidence that the criteria of sufficiency of evidence of carcinogenicity identified in 22CCR, Section 12306 have been satisfied, or to the listing of the carcinogens and reproductive toxicants identified in *Section B* below on the basis that the criteria in 22 CCR, Section 12902 have not been met, should provide written comments, along with supporting documentation, by mail or by fax to:

Ms. Cynthia Oshita
Office of Environmental Health Hazard Assessment
P. O. Box 942732
Sacramento, California 94234-7320
Fax No.: (916) 327-1097

Comments may also be hand-delivered to Ms. Oshita at the Office of Environmental Health Hazard Assessment, 601 North 7th Street, Sacramento, California.

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, March 10, 1997.

- A. The following agents have been determined by OEHHA to meet the criteria set forth in 22 CCR, Section 12306 for listing as carcinogens under the authoritative bodies mechanism:

<i>Chemical</i>	<i>CAS No.</i>	<i>Reference</i>
Nitromethane	75-52-5	NTP (1995a; 1995c)
Tetrafluoroethylene	116-14-3	NTP (1995b; 1995c)
Vinyl Fluoride	75-02-5	IARC (1995)

- B. The following agents have been determined by OEHHA to meet the criteria set forth in 22 CCR, Section 12902 for listing based on a formal requirement for labeling or identification as causing cancer or reproductive toxicity:

Carcinogens:

<i>Chemical</i>	<i>CAS No.</i>	<i>Reference</i>
Spirolactone	52-01-7	FDA, 1990
Stanozolol	10418-03-8	FDA, 1992

Reproductive toxicants:

<i>Chemical</i>	<i>CAS No.</i>	<i>Reference</i>	<i>Type of Reproductive Toxicity</i>
Clarithromycin	81103-11-9	FDA, 1995a	developmental
Dihydroergotamine mesylate	6190-39-2	FDA, 1994	developmental
Hydroxyurea	127-07-1	FDA, 1971	developmental
Oxymetholone	434-07-1	FDA, 1993	developmental

One of the chemicals which appeared in the September 27, 1996 notice is not included in this *Notice of Intent to List*. Simvastatin was under consideration for possible listing through the formally required to be labeled or identified mechanism. OEHHA is seeking clarifying information from the FDA on simvastatin before deciding whether or not to proceed with an intent to list.

Correction note: In the justification document, entitled, "Chemicals Under Consideration for Possible Listing Via the Authoritative Bodies Mechanism", dated September 27, 1996 and made available to the public, OEHHA inadvertently used the term "Teflon" in reference to the general class of fluoropolymers. Teflon[®] is a registered trademark of DuPont. In the future, when OEHHA refers to the uses of tetrafluoroethylene we will use the term "fluoropolymers".

References:

International Agency for Research on Cancer (IARC, 1995). *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans*. Volume 63. *Dry Cleaning, Some Chlorinated Solvents and Other Industrial Chemicals*. IARC, Lyon, France.

National Toxicology Program (NTP, 1995a). *Toxicology and Carcinogenesis Studies of Nitromethane (CAS No. 72-52-5) in F344/N Rats and B6C3F₁ Mice (Inhalation Studies)*. Board Draft. NTP Technical Report Series No. 461. NTIS Publication No. 95-3377. US Department of Health and Human Services, NTP, Research Triangle Park, NC.

National Toxicology Program (NTP, 1995b). *Toxicology and Carcinogenesis Studies of Tetrafluoroethylene (CAS No. 116-14-3) in F344/N Rats and B6C3F₁ Mice (Inhalation Studies)*. Board Draft. NTP Technical Report Series No. 450. NTIS Publication No. 95-3366. US Department of Health and Human Services, NTP, Research Triangle Park, NC.

National Toxicology Program (NTP, 1995c). *Summary Minutes from Peer Review of Draft Technical Reports of Long-Term Toxicology and Carcinogenesis Studies by the Technical Reports Review Subcommittee on December 5, 1995*. NTP, Research Triangle Park, NC.

Food and Drug Administration (FDA, 1990). Final printed labeling for the drug Aldactazide (spironolactone with hydrochlorothiazide). FDA approved March 1990.

Food and Drug Administration (FDA, 1992). Final printed labeling for the drug stanozolol. FDA approved February 1992.

Food and Drug Administration (FDA, 1995a). Final printed labeling for the drug clarithromycin. FDA approved February 1995.

Food and Drug Administration (FDA, 1994). Final printed labeling for the drug dihydroergotamine mesylate. FDA approved May 1994.

Food and Drug Administration (FDA, 1971). Final printed labeling for the drug hydroxyurea. FDA approved November 1971.

Food and Drug Administration (FDA, 1993). Final printed labeling for the drug oxymetholone. FDA approved July 1993.