

**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
October 29, 1999**

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. For carcinogenicity, the U.S. Environmental Protection Agency (U.S. EPA), the International Agency for Research on Cancer (IARC), the National Toxicology Program (NTP), the U.S. Food and Drug Administration (FDA), and the National Institute for Occupational Safety and Health (NIOSH) have been identified as authoritative bodies for purposes of the Act. For reproductive toxicity, U.S. EPA, IARC (for transplacental carcinogenicity only), FDA, and NIOSH have been identified as authoritative bodies for purposes of the Act. The criteria for listing chemicals through the authoritative bodies mechanism are set forth in Title 22, California Code of Regulations (22 CCR), Section 12306.

Under the second mechanism for the administrative listing, a chemical is listed when 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 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 in Tables A and B 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). Simvastatin was announced in a public notice published on September 27, 1996 requesting relevant information. Carbon black and pravastatin sodium were announced in a public notice published on August 22, 1997 requesting relevant information. Palygorskite fibers (> 5µm in length) was announced in a public notice published on February 5, 1999. Public forums were held on October 29, 1996, October 1, 1997, and March 2, 1999, respectively. Public comments were received on all but one of these chemicals. OEHHA has completed its review of the comments and has determined that the chemicals meet the criteria for listing under 22 CCR, Section 12306 or Section 12902. Documents providing more detail on the basis for the listing of carbon black and palygorskite fibers (>5µm in length) via the authoritative bodies mechanism and for the listing of simvastatin and pravastatin sodium via the formally required to be labeled or identified mechanism can be obtained from OEHHA's Proposition 65 Implementation Office at the address and telephone number indicated below, or from the OEHHA Home Page at www.oehha.ca.gov.

Under the authoritative bodies mechanism, objections to the listing shall be made on the basis that there is no substantial evidence that the criteria of sufficiency of evidence of carcinogenicity or reproductive toxicity identified in 22 CCR, Section 12306 have been satisfied. Objections to listings via the second mechanism are made on the basis that the criteria and definitions in 22 CCR, Section 12902 have not been met. Anyone wishing to object to the listing of chemicals in the tables below should submit written comments in triplicate, along with supporting documentation, by mail or by fax to:

Ms. Cynthia Oshita
Office of Environmental Health Hazard Assessment
301 Capitol Mall, 2nd Floor, Room 205
Sacramento, California 95814
Fax No.: (916) 327-1097
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, November 29, 1999.

Table A. Chemicals determined by OEHHA to meet the criteria for listing as causing cancer under the authoritative bodies mechanism:

Chemical	CAS No.	Reference
Carbon black (airborne particles of respirable size)	1333-86-4	IARC (1996)
Palygorskite fibers (>5µm in length)	12174-11-7	IARC (1997)

Table B. Chemicals determined by OEHHA to meet the criteria for listing based on a formal requirement for labeling or identification as causing reproductive toxicity

Chemical	CAS No.	Reproductive Endpoint	Reference
Pravastatin sodium	81131-70-6	Developmental toxicity	FDA (1998)
Simvastatin	79902-63-9	Developmental toxicity	FDA (1998)

References

Food and Drug Administration (FDA, 1998). FDA approved labeling changes for the drug pravastatin sodium. FDA approved 1998. <http://www.fda.gov/medwatch/safety/1998/aug98.htm>.

Food and Drug Administration (FDA, 1998). Final printed labeling for the drug simvastatin. FDA approved 1998.

International Agency for Research on Cancer (IARC, 1996). *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans*. Volume 65. Printing Processes and Printing Inks, Carbon Black and Some Nitro Compounds. IARC, Lyon, France.

International Agency for Research on Cancer (IARC, 1997). *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans*. Volume 68. *Silica, Some Silicates, Coal Dust and Para-aramid Fibrils*. IARC, Lyon, France.