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 CHEMICAL FEBRUARY 23, 2001

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 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 Title 22, California Code of Regulations (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 nimodipine as known to the State to cause reproductive toxicity pursuant to the "formally required to be labeled or identified" mechanism provided in Health and Safety Code Section 25249.8(b).

In a public notice published in the California Regulatory Notice Register (CRNR) on September 29, 2000 (Register 00, No. 39-Z), OEHHA announced that 23 chemicals were under consideration for administrative listing based on a review of information indicating that the chemicals may meet the regulatory criteria. 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 began on September 29, 2000, and was extended to close on December 28, 2000. A public forum was held on October 26, 2000 to provide an opportunity for oral comments. No comments were received on nimodipine during the extended public comment period. OEHHA has determined that nimodipine meets the criteria for administrative listing via the "formally required to be labeled or identified" mechanism. A document providing the basis for the listing of this chemical 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 www.oehha.ca.gov. [Note to reader: Comments were received on nine of the 23 chemicals during the request for relevant information phase. The comments are currently under consideration. In a separate public notice published in the CRNR on December 29, 2000 (Register 00, No. 52-Z), a Notice of Intent to List was issued for 13 of the 23 chemicals. No comments were received during this second comment period; and thus, the 13 chemicals will be added to the Proposition 65 list effective February 27, 2001 as announced in a separate notice published elsewhere in this issue of the *CRNR*.]

Under the "formally required to be labeled or identified" mechanism, objections to the listing should be 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 nimodipine should submit written comments in <u>triplicate</u>, along with supporting documentation, by mail, fax or hand-delivery to:

Ms. Cynthia Oshita
Office of Environmental Health Hazard Assessment
Street address: 1001 I Street, 19th floor
Sacramento, California 95814
Mailing address: P.O. Box 4010
Sacramento, California 95812-4010

Fax no.: (916) 323-8803 Telephone no.: (9160 445-6900

In order to be considered, comments must by postmarked (if sent by mail) or received at OEHHA (if hand-delivered or sent by fax) by 5:00 p.m. on Monday, March 26, 2001.

Chemical which meets the criteria set forth in 22 CCR Section 12902 for listing as known to cause reproductive toxicity via the formally required to be labeled or identified mechanism:

Chemical	CAS No.	Toxicological Endpoint	Reference
Nimodipine	66085-59-4	Developmental toxicity	FDA (1996)

Reference:

Food and Drug Administration (FDA, 1996). Final printed labeling for the drug nimodipine. FDA approved 1996.