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
DECEMBER 29, 2000

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 United States Environmental Protection Agency (U.S. EPA), 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) 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 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 public notice published on September 29, 2000, OEHHA announced 23 chemicals were under consideration for administrative 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 began on September 29, 2000, and closed on November 28, 2000. [Except for famciclovir which was granted a comment period extension until December 8, 2000 and atorvastatin calcium, fluvastatin sodium, and nimodipine which were granted a comment period extension until December 28, 2000.] A public forum was held on October 26, 2000 to provide an opportunity for oral comments. Written comments have been received on DEF, catechol, naphthalene, strong inorganic acid mists containing sulfuric acid, albuterol, famciclovir, and felodipine and are under review by OEHHA staff. No comments were received on 13 of the
chemicals during the public comment period. OEHHA has determined that these 13 chemicals meet the criteria for administrative listing: five chemicals meet the criteria for listing under the authoritative bodies mechanism (Table A), and eight chemicals meet the criteria for listing via the ‘formally required to be labeled’ mechanism (Table B). Documents providing the basis for the listing of these chemicals 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. Any one wishing to object to the listing of chemicals in the tables below should submit written comments in triplicate, 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
Sacramento, California 95814
Mailing address: P.O. Box 4010
Sacramento, California 95812-4010
Fax No.: (916) 327-1097
Telephone: (916) 445-6900

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, January 29, 2001.

Table A1. Chemicals determined by OEHHA to meet the criteria set forth in 22 CCR, Section 12306 for listing as causing cancer under the authoritative bodies mechanism:

<table>
<thead>
<tr>
<th>Chemical</th>
<th>CAS No.</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethoprop</td>
<td>13194-48-4</td>
<td>U.S. EPA (1997a)</td>
</tr>
<tr>
<td>Indium phosphide</td>
<td>22398-80-7</td>
<td>NTP (2000a; 2000b)</td>
</tr>
<tr>
<td>Lynestrenol</td>
<td>52-76-6</td>
<td>IARC (1999)</td>
</tr>
<tr>
<td>Norethynodrel</td>
<td>68-23-5</td>
<td>IARC (1999)</td>
</tr>
<tr>
<td>Propachlor</td>
<td>1918-16-7</td>
<td>U.S. EPA (1997b)</td>
</tr>
</tbody>
</table>
Table B. Chemicals which meet the criteria set forth in 22 CCR Section 12902 for listing as known to cause cancer and/or reproductive toxicity via the “formally required to be labeled or identified” mechanism:

<table>
<thead>
<tr>
<th>Chemical</th>
<th>CAS No.</th>
<th>Toxicological Endpoints</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amantadine hydrochloride</td>
<td>665-66-7</td>
<td>Developmental toxicity</td>
<td>FDA (1993a)</td>
</tr>
<tr>
<td>Diazoxide</td>
<td>364-98-7</td>
<td>Developmental toxicity</td>
<td>FDA (1994a)</td>
</tr>
<tr>
<td>Dichlorphenamide</td>
<td>120-97-8</td>
<td>Developmental toxicity</td>
<td>FDA (1994b)</td>
</tr>
<tr>
<td>Diltiazem hydrochloride</td>
<td>42399-41-7</td>
<td>Developmental toxicity</td>
<td>FDA (1996)</td>
</tr>
<tr>
<td>Filgrastim</td>
<td>121181-53-1</td>
<td>Developmental toxicity</td>
<td>FDA (1992)</td>
</tr>
<tr>
<td>Ribavirin*</td>
<td>36791-04-5</td>
<td>Male reproductive toxicity</td>
<td>FDA (1993b)</td>
</tr>
<tr>
<td>Rifampin</td>
<td>13292-46-1</td>
<td>Developmental toxicity Female reproductive toxicity</td>
<td>FDA (1997)</td>
</tr>
<tr>
<td>Trientine hydrochloride</td>
<td>38260-01-4</td>
<td>Developmental toxicity</td>
<td>FDA (1988)</td>
</tr>
</tbody>
</table>

* Ribavirin was added to the list of chemicals known to cause reproductive toxicity on the basis of a developmental toxicity endpoint on April 1, 1990.
References:


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


Food and Drug Administration (FDA, 1997). Final printed labeling for the drug rifampin. FDA approved 1997.


National Toxicology Program (NTP, 2000b). *Summary Minutes from Peer Review of Draft Technical Reports of Long-Term Toxicology and Carcinogenesis Studies by the Technical Reports Review Subcommittee on May 18, 2000.* NTP, Research Triangle Park, NC.


