The Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65 or the Act) requires the Governor to publish, and update at least annually, a list of chemicals known to the State to cause cancer or reproductive toxicity. The Act provides two mechanisms for administratively listing chemicals as 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. 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 second mechanism for the administrative listing of a chemical applies if an agency of state or federal government 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 is investigating the possible listing of the chemicals identified below, based upon information in the references cited. Documentation summarizing the rationale for considering the evaluation of these chemicals for possible administrative listing is available from OEHHA’s Proposition 65 Implementation Office at the address and telephone number indicated below, or from the Internet at the following address: http://www.oehha.ca.gov/.

OEHHA is committed to public participation and external scientific peer review in its implementation of Proposition 65, and welcomes public input on this listing process. As part of its efforts to ensure that regulatory decisions are based upon a thorough consideration of all relevant information, OEHHA is soliciting information which may be relevant to the evaluation of these chemicals in the context of the Proposition 65 administrative listing regulatory criteria (22 CCR Section 12306 or Section 12902, as appropriate).
A public forum will be held on **Thursday, October 26, 2000**, to provide an opportunity for interested parties to present oral comments and to discuss the scientific data and other information relevant to a determination as to whether these chemicals meet the criteria for listing set forth in 22 CCR Section 12306 or Section 12902. The public forum will begin at 10:00 a.m. at 1515 Clay Street, Elihu Harris State Building, Conference Room A, Oakland, California and will last until all business has been conducted or until 5:00 p.m.

Written comments provided in **triplicate**, along with supporting information, may also be submitted to:

Cynthia Oshita  
Office of Environmental Health Hazard Assessment  
301 Capitol Mall, 2nd Floor  
Sacramento, California 95814  
FAX: (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. Tuesday, November 28, 2000.**

Following the review of all comments received, OEHHA will announce its intention to proceed with the listing of those candidate chemicals that meet the regulatory criteria for administrative listing in a *Notice of Intent to List Chemicals*.

A. Chemicals which may meet the criteria set forth in 22 CCR Section 12306 for listing as known to cause **carcinogenicity** via the “authoritative bodies” mechanism:

<table>
<thead>
<tr>
<th>Chemical</th>
<th>CAS No.</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catechol</td>
<td>120-80-9</td>
<td>IARC (1999a)</td>
</tr>
<tr>
<td>DEF (S,S,S-tributyl phosphorotrithioate; Tribufos)</td>
<td>78-48-8</td>
<td>U.S. EPA (1997c)</td>
</tr>
<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; 2000c)</td>
</tr>
<tr>
<td>Lynestrenol</td>
<td>52-76-6</td>
<td>IARC (1999b)</td>
</tr>
<tr>
<td>Naphthalene</td>
<td>91-20-3</td>
<td>NTP (2000b; 2000c)</td>
</tr>
<tr>
<td>Norethynodrel</td>
<td>68-23-5</td>
<td>IARC (1999b)</td>
</tr>
<tr>
<td>Propachlor</td>
<td>1918-16-7</td>
<td>U.S. EPA (1997b)</td>
</tr>
<tr>
<td>Strong inorganic acid mists containing sulfuric acid</td>
<td>7664-93-9</td>
<td>NTP (2000d)</td>
</tr>
</tbody>
</table>
B. Chemicals which may meet 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:

<table>
<thead>
<tr>
<th>Chemical</th>
<th>CAS No.</th>
<th>Toxicological Endpoints</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albuterol</td>
<td>18559-94-9</td>
<td>Developmental toxicity</td>
<td>FDA (1986)</td>
</tr>
<tr>
<td>Amantadine hydrochloride</td>
<td>665-66-7</td>
<td>Developmental toxicity</td>
<td>FDA (1993a)</td>
</tr>
<tr>
<td>Atorvastatin calcium</td>
<td>134523-03-8</td>
<td>Developmental toxicity</td>
<td>FDA (1998a)</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 (1996b)</td>
</tr>
<tr>
<td>Famciclovir</td>
<td>104227-87-4</td>
<td>Male reproductive toxicity</td>
<td>FDA (1997a)</td>
</tr>
<tr>
<td>Felodipine</td>
<td>72509-76-3</td>
<td>Developmental toxicity Male reproductive toxicity</td>
<td>FDA (1998b)</td>
</tr>
<tr>
<td>Filgrastim</td>
<td>121181-53-1</td>
<td>Developmental toxicity</td>
<td>FDA (1992)</td>
</tr>
<tr>
<td>Fluvastatin sodium</td>
<td>93957-55-0</td>
<td>Developmental toxicity Male reproductive toxicity</td>
<td>FDA (1999)</td>
</tr>
<tr>
<td>Nimodipine</td>
<td>66085-59-4</td>
<td>Developmental toxicity</td>
<td>FDA (1996c)</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 Male reproductive toxicity</td>
<td>FDA (1997b)</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, 1996b). Final printed labeling for the drug diltiazem hydrochloride. FDA approved 1996.


Food and Drug Administration (FDA, 1999). Final printed labeling for the drug fluvastatin sodium. FDA approved 1999.

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

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


