

## **Candidates for Proposition 65 Listing via the Authoritative Bodies Mechanism Found Not to Meet the Scientific Criteria (22 CCR 12306(g))**

### **Office of Environmental Health Hazard Assessment June, 1999**

The U.S. Environmental Protection Agency (U.S. EPA), an authoritative body for purposes of Proposition 65 (22 CCR Section 12306(l)), identifies chemicals as causing developmental or reproductive toxicity in implementing its Toxic Release Inventory (TRI) program (*i.e.*, Section 313 of the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA)). On this basis the U.S. EPA, in 1994, added a number of chemicals to the TRI list and published its findings in the *Federal Register* (59:1788-1859, 1994 and 59:61432-61485, 1994). The Office of Environmental Health Hazard Assessment (OEHHA) has reviewed the bases for these TRI chemical additions in the context of the regulatory criteria governing Proposition 65 listing via the authoritative bodies mechanism (Title 22, California Code of Regulations, Section 12306 (22 CCR 12306)).

OEHHA determined for several TRI chemicals that the 22 CCR 12306 regulatory criteria were met and is in the process of placing these chemicals on the Proposition 65 list of chemicals known to cause reproductive toxicity. OEHHA has determined that these criteria have not been met for some of the chemicals added by U.S. EPA in 1994 to the TRI list on the basis of reproductive or developmental toxicity. These chemicals are listed in Table 1. In each case the scientific criteria for “as causing reproductive toxicity” given in regulation (22 CCR 12306(g)) were not satisfied, as described below.

In accordance with 22 CCR 12306(i), the two chemicals in Table 1, 2,4-D 2-ethylhexyl ester, and 2,4-D 2-ethyl-4-methylpentyl ester, will be referred to the Developmental and Reproductive Toxicant Identification Committee of the OEHHA Science Advisory Board because this determination was made subsequent to the issuance of a notice of intent to list (*California Regulatory Notice Register (CRNR)*, April 16, 1999 for 2,4-D 2-ethylhexyl ester and 2,4-D 2-ethyl-4-methylpentyl ester). Therefore, at a future meeting, the Committee will opine whether these chemicals have been “clearly shown through scientifically valid testing according to generally accepted principles” to cause reproductive toxicity.

**Table 1: TRI chemicals not meeting the scientific criteria (22 CCR 12306(g))  
for authoritative bodies listing as causing reproductive toxicity under Proposition 65**

2,4-D 2-ethylhexyl ester (001928-43-4)  
2,4-D 2-ethyl-4-methylpentyl ester (053404-37-8)

2,4-D 2-ethylhexyl ester (CAS No. 001928-43-4)

2,4-D 2-ethylhexyl ester was added to the TRI list on the basis of developmental toxicity identified in studies using isooctyl esters. Although 2,4-D 2-ethylhexyl ester is an isooctyl ester, the two studies cited by U.S. EPA in its TRI listing do not specify the test material used in the cited experiments by either CAS number or pesticide active ingredient category, and do not specify the nature or amount of isooctyl esters contained in the test material. Thus, within the context of 22 CCR 12306, there are not sufficient data on this specific isomer to support Proposition 65 listing via the authoritative bodies mechanism.

2,4-D 2-ethyl-4-methylpentyl ester (CAS No. 053404-37-8)

2,4-D 2-ethyl-4-methylpentyl ester was added to the TRI list on the basis of developmental toxicity identified in studies using isooctyl esters. Although 2,4-D 2-ethyl-4-methylpentyl ester is an isooctyl ester, the two studies cited by U.S. EPA in its TRI listing do not specify the test material used in the cited experiments by either CAS number or pesticide active ingredient category, and do not specify the nature or amount of isooctyl esters contained in the test material. Thus, within the context of 22 CCR 12306, there are not sufficient data on this specific isomer to support Proposition 65 listing via the authoritative bodies mechanism.