Candidate 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 July, 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. As described below, OEHHA has determined that scientific criteria for "as causing reproductive toxicity" given in regulation (22 CCR 12306(g)) were not satisfied for **sulprofos** (CAS No. 035400-43-2), which was added by U.S. EPA in 1994 to the TRI list on the basis of developmental toxicity.

Sulprofos (CAS No. 035400-43-2)

U.S. EPA (*Federal Register* 59(8):1813, 1994) based its finding of developmental toxicity on a single rat developmental toxicity study (Bayer AG., 1981, *Project T 3000995*), reporting increased unossified sternebrae in offspring of animals receiving a dose of 10 mg/kg/day. Although there was an increase in incompletely ossified Vth sternebrae at 10 mg/kg (32.5% vs control 22.5%) there was a corresponding decrease in completely unossified Vth sternebrae (2.5% vs 10.6%) and thus no overall difference in reduced ossification (35.0% vs control 33.1%). Reduced ossification was not indicated for any other sternebrae at the 10 mg/kg dose. Apparent effects at the high dose tested (30 mg/kg/day) could not be appropriately interpreted because of excessive maternal mortality, with 12/25 treated animals dying. Thus, there is no clear evidence of a treatment-related developmental effect from this study.