

**Candidate for Proposition 65 Listing via the Authoritative Bodies
Mechanism Found Not to Meet the Scientific Criteria
(22 CCR Section 12306(g)):
Diuron (CAS No. 330-54-1)**

**Office of Environmental Health Hazard Assessment
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The U.S. Environmental Protection Agency (U.S. EPA), an authoritative body for purposes of Proposition 65 (Title 22, California Code of Regulations, Section 12306(l) (22 CCR §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 (22 CCR §12306).

OEHHA determined for many TRI chemicals that the 22 CCR §12306 regulatory criteria were met and has placed these chemicals on the Proposition 65 list of chemicals known to cause reproductive toxicity. A number of other TRI chemicals were found not to meet the 22 CCR §12306 criteria and have been removed from listing consideration at this time. As described below, OEHHA has determined that scientific criteria for “as causing reproductive toxicity” specified in regulation (22 CCR §12306(g)) were not satisfied for diuron (CAS No. 330-54-1). This chemical was added by U.S. EPA in 1994 to the TRI list on the basis of developmental toxicity.

Subdivision (i) of section 12306 requires that chemicals which have reached the Notice of Intent to List phase, but are later determined not to meet the technical criteria in 22 CCR §12306 must be sent to the appropriate committee. Accordingly, diuron will be referred to the Developmental and Reproductive Toxicant Identification Committee of the OEHHA Science Advisory Board since this chemical was the subject of a notice of intent to list (*California Regulatory Notice Register (CRNR)*, May 21, 1999, Register 99, No. 21-Z). Therefore, at a future meeting, the Committee will opine whether “the chemical has been clearly shown through scientifically valid testing according to generally accepted principles” to cause reproductive toxicity.

Diuron (CAS No. 330-54-1)

U.S. EPA (*Federal Register* 59(8):1813, 1994) based its finding of developmental toxicity on a developmental toxicity study in rats by Khera et al. (1979) and a three generation reproduction study in rats by Hodge et al. (1967). In the Hodge et al. study, neither the fertility index nor the average number of pups per litter was altered by exposure to diuron. There was some evidence for adverse effects on postnatal growth of the F_{2b} and F_{3a} generations, but this finding was not repeated when the study was replicated and may be attributable to postnatal exposures. Khera et al. reported decreased fetal weight at the highest dose tested, and increased incidences of wavy ribs and delayed ossification of the calvarium at some doses tested. This study is not, in itself, fully adequate for identification of developmental toxicity under Proposition 65 in the absence of other data. No single factor led to this determination. Rather, the conclusion was based on a combination of factors, including the lack of details provided on the maternal response to treatment, and the failure to report litter incidences for specific skeletal variations. Thus, although the study is suggestive of developmental effects for diuron, OEHHA has determined that the scientific criteria (22 CCR §12306(g)) for listing diuron for developmental toxicity via the authoritative bodies listing mechanism have not been met.

References

Hodge HC, Downs WL, Panner BS, Smith DW and Maynard EA (1967). Oral toxicity and metabolism of diuron (N-(3,4)-dichlorophenyl-N',N'-dimethylurea) in rats and dogs. *Food Cosmet. Toxicol.* 5:513-531.

Khera KS, Whalen C, Trivett G and Angers G (1979). Teratogenicity studies on pesticide formulations of dimethoate, diuron and lindane in rats. *Bull. Env. Contam. Toxicol.* 22:522-529.