CHEMICAL MEETING THE CRITERIA FOR LISTING AS CAUSING CANCER VIA THE AUTHORITATIVE BODIES MECHANISM

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Reproductive and Cancer Hazard Assessment Section
Office of Environmental Health Hazard Assessment
California Environmental Protection Agency

The chemical listed in the table below meets the criteria for listing under Proposition 65 via the authoritative bodies listing mechanism. The regulatory guidance for listing by this mechanism is set forth in Title 22, California Code of Regulations (CCR), Section 12306. For example, the regulations include provisions covering the criteria for evaluating the documentation and scientific findings by the authoritative body to determine whether listing under Proposition 65 is required.

The U.S. Environmental Protection Agency (U.S. EPA) is one of five institutions that have been identified as an authoritative body for the purposes of Proposition 65 (22 CCR 12306(1)). U.S. EPA has identified the chemical in the table below as causing cancer. The Office of Environmental Health Hazard Assessment (OEHHA) has found that this chemical has been "formally identified" as causing cancer according to the regulations covering this issue (22 CCR 12306(d)): The chemical below is the subject of a report published by the authoritative body which concludes that the chemical causes cancer. Also, the document specifically and accurately identifies the chemical and meets one or more of the criteria outlined in 22 CCR 12306(d)(2).

OEHHA also finds that the criteria given in regulation for "as causing cancer" (22 CCR 12306(e)) have been satisfied for the chemical in the table below. In making this evaluation, OEHHA relied upon the discussion of data by the authoritative body in making its findings that the specified chemical causes cancer. A brief discussion of the relevant carcinogenesis studies providing evidence for the finding is presented below. The statement in bold reflects data and conclusions that satisfy the criteria for the sufficiency of evidence for carcinogenicity (22 CCR 12306(e)). The full citation for the authoritative body document is given in this report.

Chemical Meeting the Criteria for Listing as Causing Cancer

Chemical	CAS No.	Chemical Use	Reference
Diuron	330-54-1	Substituted urea herbicide used against broadleaf and grass weeds and mosses.	U.S. EPA (1997)

Diuron (CAS No. 330-54-1)

Increased incidence of malignant and combined malignant and benign tumors in male and female rats and increased incidence of malignant tumors in female mice.

U.S. EPA (1997) has concluded that diuron is "known/likely" to be carcinogenic to humans by all routes of exposure based on studies in Wistar rats and in NMRI mice. The studies are briefly summarized below.

Diuron was administered to male and female Wistar rats via diet for two years. Marked increases in urinary bladder epithelial carcinomas and combined papillomas and/or carcinomas were observed in the high-dose groups of both sexes. The incidence of urinary bladder epithelial carcinomas in male rats was 1/49, 0/50, 1/49, and 35/48 (for control, low-, mid- and high-dose groups, respectively) and in female rats, 1/47, 0/49, 1/50, and 13/49. Male rats also had a significant increasing trend in kidney renal pelvis epithelial papillomas and/or carcinomas. Two kidney carcinomas, considered a rare tumor, were observed in high-dose male rats.

Male and female NMRI mice were exposed to diuron via the diet for 24 months. In females, increases in the incidence of mammary gland adenocarcinomas (2/34, 1/29, 1/44, 6/37) occurred with a significant positive trend. The incidence of mammary gland adenocarcinomas at the highest dose exceeded historical controls from the testing laboratory. Of the 16 studies in the historical control database from the testing laboratory, the highest number of female mice with malignant mammary gland tumors in any of these 16 control groups was three and was observed in three separate studies (3/48, 3/48, 3/49). No treatment related tumors were observed in male mice.

REFERENCES

U.S. Environmental Protection Agency (U.S. EPA, 1997). *Memorandum: Carcinogenicity Peer Review of Diuron.* Office of Prevention, Pesticides and Toxic Substances. May 8, 1997.