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 National Toxicology Program (NTP) is one of five institutions which have been identified as authoritative bodies for the purposes of Proposition 65 (22 CCR 12306(l)). The NTP has identified the chemical in the table below as causing cancer. The Office of Environmental Health Hazard Assessment (OEHHA) has found that this chemical is "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 findings 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	CAS No.	Chemical Use	Reference
Pyridine	110-86-1	Industrial and laboratory solvent; denaturant in alcohol and antifreeze mixtures; intermediate in insecticide, herbicide, and fungicide manufacture; intermediate and solvent in preparation of vitamins, drugs, dyes, textile water repellents and flavoring agents in food.	NTP (2000)

Pyridine (CAS No. 110-86-1)

Increased incidence of malignant tumors in male and female mice.

NTP (2000) has concluded that there is clear evidence of carcinogenic activity of pyridine in male and female B6C3F₁ mice.

NTP (2000) exposed male and female F344/N rats, male Wistar rats and male and female $B6C3F_1$ mice to pyridine in drinking water for two years. In both male and female mice, increased incidences of hepatocellular neoplasms were observed. Pyridine exposure of mice resulted in statistically significant increases in hepatocellular carcinoma (males: 15/50, 35/50, 41/49, 40/50 for control, low-, mid- and high-dose animals, respectively; females: 13/49, 23/50, 33/50, 41/50) and in uncommon hepatoblastoma (males: 2/50, 18/50, 22/49, 15/50; females: 1/49, 2/50, 9/50, 16/50).

In male F344/N rats, an increase in renal tubule neoplasms, which exceeded historical control ranges, was observed in high-dose animals. Incidences in standard (simple sections) and extended (step sections) evaluations combined were 2/50, 3/48, 6/50, 10/49 (adenoma) and 2/50, 4/48, 6/50, 10/49 (adenoma or carcinoma). NTP (2000) concluded that there was some evidence of the carcinogenicity of pyridine in male F344/N rats based on increased incidences of renal tubule neoplasms.

NTP (2000) also concluded that there was equivocal evidence of carcinogenicity of pyridine in female F344/N rats based on an increased incidence of mononuclear cell leukemia (12/50; 16/50; 22/50; 23/50). NTP (2000) concluded that there was equivocal evidence of carcinogenicity of pyridine in male Wistar rats based on an increased incidence of interstitial cell adenoma of the testis.

REFERENCE

National Toxicology Program (NTP, 2000). *Toxicology and Carcinogenesis Studies of Pyridine (CAS No. 110-86-1) in F344/N Rats, Wistar Rats and B6C3F₁ Mice (Drinking Water Studies)*. NTP Technical Report Series No. 470. NIH Publication No. 97-3960. U.S. Department of Health and Human Services, NTP, Research Triangle Park, NC.