

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

PACKAGE 19b.5

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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 International Agency for Research on Cancer (IARC) is one of five institutions which have been identified as authoritative bodies for the purposes of Proposition 65 (22 CCR 12306(m)). IARC has identified the chemical in the table below as causing cancer. The Office of Environmental Health Hazard Assessment (OEHHA) has found that the 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 that concludes that the chemical causes cancer. Also, the document specifically and accurately identifies the chemical and the document 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 citations for the authoritative body documents are given in this report.

Chemical	CAS No.	Chemical Use	Reference
Catechol	120-80-9	Used as a starting material for insecticides, perfumes, drugs and polymerization inhibitors; also as an antiseptic, in photography, dyestuffs, electroplating, specialty inks, antioxidants and light stabilizers, and in organic synthesis.	IARC (1999)

Catechol (CAS No. 120-80-9)

Increased incidences of malignant tumors in female rats, and of malignant and combined malignant and benign tumors in male rats of multiple strains.

IARC (1999) has concluded that there is sufficient evidence for the carcinogenicity of catechol in experimental animals and has classified catechol in Group 2B, possibly carcinogenic to humans. The relevant studies evaluated by IARC are summarized below.

Hirose *et al.* (1990; 1993) treated Fischer 344 rats (30 rats/group/sex) with 0 or 0.8% catechol in the diet for 104 weeks. In the glandular stomach, adenocarcinomas were observed in 15/28 treated males and 12/28 treated females ($p < 0.001$) compared with none in control animals.

Tanaka *et al.* (1995) administered catechol (0 or 0.8%) to male Wistar, WKY, Lewis and SD rats (20-30 animals/group). In treated animals, forestomach papillomas occurred in 6/30 SD rats, 2/30 Wistar rats and 1/30 WKY rats. Forestomach carcinomas were observed in 1/30 SD rats and 1/30 Wistar rats. No tumors were observed in control animals. In the glandular stomach, the incidence of adenomas was 97-100% in treated groups in all strains, compared with none in controls. Adenocarcinomas occurred in 23/30 SD rats, 22/30 Lewis rats, 20/30 Wistar rats and 3/30 WKY rats, compared to none in controls.

REFERENCES

Hirose M, Fukushima S, Shirai T, Hasegawa R, Kato T, Tanaka H, Asakawa E, Ito N (1990). Stomach carcinogenicity of caffeic acid, sesamol and catechol in rats and mice. *Jpn J Cancer Res* **81**: 207-212.

Hirose M, Fukushima S, Tanaka H, Asakawa E, Takahashi S, Ito N (1993). Carcinogenicity of catechol in F344 rats and B6C3F₁ mice. *Carcinogenesis* **14**: 525-529.

International Agency for Research on Cancer (IARC, 1999). *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans*. Volume 71: 433-452. *Re-evaluation of Some Organic Chemicals, Hydrazine and Hydrogen Peroxide (Part Two)*. IARC, Lyon France.

Tanaka H, Hirose M, Hagiwara A, Imaida K, Shirai T, Ito N (1995). Rat strain differences in catechol carcinogenicity to the stomach. *Food Chem Toxicol* **33**: 93-98.