

**CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT
SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986
(PROPOSITION 65)**

**NOTICE OF INTENT TO LIST:
PENTABROMODIPHENYL ETHER MIXTURE [DE-71 (TECHNICAL GRADE)]**

MAY 5, 2017

The California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA) intends to list *pentabromodiphenyl ether mixture [DE-71 (technical grade)]* as known to the State to cause cancer under the Safe Drinking Water and Toxic Enforcement Act of 1986¹. This action is being proposed under the authoritative bodies listing mechanism².

Chemical	Reference	Occurrence and Uses
<i>Pentabromodiphenyl ether mixture [DE-71 (technical grade)]</i>	NTP (2016)	Used in the past as an additive flame retardant, especially for polyester foam commonly used in furniture. US production and use of pentabromodiphenyl ether mixtures was voluntarily phased out around 2004.

Background on listing via the authoritative bodies mechanism: A chemical must be listed under the Proposition 65 regulations when two conditions are met:

- 1) An authoritative body formally identifies the chemical as causing cancer (Section 25306(d)³).
- 2) The evidence considered by the authoritative body meets the sufficiency criteria contained in the regulations (Section 25306(e)).

However, the chemical is not listed if scientifically valid data that were not considered by the authoritative body clearly establish that the sufficiency of evidence criteria were not met (Section 25306(f)).

¹ Commonly known as Proposition 65, the Safe Drinking Water and Toxic Enforcement Act of 1986 is codified in Health and Safety Code section 25249.5 *et seq.*

² See Health and Safety Code section 25249.8(b) and Title 27, Cal. Code of Regs., section 25306.

³ All referenced sections are from Title 27 of the Cal. Code of Regulations.

The National Toxicology Program (NTP) is one of several institutions designated as authoritative for the identification of chemicals as causing cancer for purposes of Proposition 65 (Section 25306(m)).

OEHHA is the lead agency for Proposition 65 implementation⁴. After an authoritative body has made a determination about a chemical, OEHHA evaluates whether listing under Proposition 65 is required using the criteria contained in the regulations.

OEHHA's determination: *Pentabromodiphenyl ether mixture [DE-71 (technical grade)]* meets the criteria for listing as known to the state to cause cancer under Proposition 65, based on findings of the NTP (2016).

Formal identification and sufficiency of evidence for *Pentabromodiphenyl ether mixture [DE-71 (technical grade)]*: In 2016, NTP published a report on pentabromodiphenyl ether mixture [DE-71 (technical grade)], entitled *Toxicology Studies of a Pentabromodiphenyl Ether Mixture [DE-71 (Technical Grade)] (CASRN 32534-81-9) in F344/N Rats and B6C3F1/N Mice and Toxicology and Carcinogenesis Studies of a Pentabromodiphenyl Ether Mixture [DE-71 (Technical Grade)] in Wistar Han [CrI:WI(Han)] Rats and B6C3F1/N Mice (Gavage Studies)*, that concludes that the chemical causes cancer (NTP, 2016). This report satisfies the formal identification and sufficiency of evidence criteria in the Proposition 65 regulations.

OEHHA is relying on the NTP's discussion of data and conclusions in the report that pentabromodiphenyl ether mixture [DE-71 (technical grade)] causes cancer. The NTP (2016) states in the Conclusion section of the report's Summary (page 6):

"We conclude that DE-71 caused liver cancers in male and female rats and mice. Occurrences of thyroid gland and pituitary gland tumors in male rats were also considered to be related to treatment. Occurrences of uterine tumors in female rats may also have been related to exposure to DE-71."

The NTP (2016) report states in the Conclusion section of the report's Abstract and main body of the report (pages 11 and 113):

"Under the conditions of these 2-year oral gavage studies, there was *clear evidence of carcinogenic activity* of DE-71 in male Wistar Han rats based on increased incidences of hepatocholangioma, hepatocellular adenoma, or hepatocellular carcinoma (combined). Increased incidences of thyroid gland

⁴ Health and Safety Code section 25249.12, Title 27 Cal. Code of Regs., section 25102(o)

follicular cell adenoma and increased incidences of pituitary gland (pars distalis) adenoma were also considered to be related to exposure.”

There was *clear evidence of carcinogenic activity* of DE-71 in female Wistar Han rats based on increased incidences of hepatocholangioma, hepatocellular adenoma, and hepatocellular carcinoma. The occurrence of cholangiocarcinoma of the liver was also considered related to treatment. The incidences of stromal polyp or stromal sarcoma (combined) of the uterus may have been related to treatment.”

“There was *clear evidence of carcinogenic activity* of DE-71 in male B6C3F1/N mice based on increased incidences of hepatocellular adenoma, hepatocellular carcinoma, and hepatoblastoma.”

“There was *clear evidence of carcinogenic activity* of DE-71 in female B6C3F1/N mice based on increased incidences of hepatocellular adenoma and hepatocellular carcinoma.” (Emphasis in the original.)

Thus, NTP (2016) found that pentabromodiphenyl ether mixture [DE-71 (technical grade)] causes increased incidences of combined malignant and benign tumors in male rats, and malignant and combined malignant and benign tumors in female rats and in male and female mice.

Request for comments: OEHHA is requesting comments as to whether *pentabromodiphenyl ether mixture [DE-71 (technical grade)]* meets the criteria set forth in the Proposition 65 regulations for authoritative bodies listings. To be considered, **OEHHA must receive comments by 5:00 p.m. on Monday, June 5, 2017.** We encourage you to submit comments in electronic form, rather than in paper form. Comments may be submitted electronically through our website at <https://oehha.ca.gov/comments>. Comments submitted in paper form can be mailed, faxed, or delivered in person to the address below.

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Comments received during the public comment period will be posted on the OEHHA website after the close of the comment period. Electronic files submitted should not have any form of encryption.

If you have any questions, please contact Ms. Ramirez at Michelle.Ramirez@oehha.ca.gov or at (916) 445-6900.

References

National Toxicology Program (NTP, 2016). *Toxicology Studies of a Pentabromodiphenyl Ether Mixture [DE-71 (Technical Grade)] (CASRN 32534-81-9) in F344/N Rats and B6C3F1/N Mice and Toxicology and Carcinogenesis Studies of a Pentabromodiphenyl Ether Mixture [DE-71 (Technical Grade)] in Wistar Han [CrI:WI(Han)] Rats and B6C3F1/N Mice (Gavage Studies)*. Technical Report Series No. 589. U.S. Department of Health and Human Services, NTP, Research Triangle Park, NC. Available at URL: http://ntp.niehs.nih.gov/ntp/htdocs/lt_rpts/tr589_508.pdf