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: p-CHLORO- α , α , α -TRIFLUOROTOLUENE (pARA-CHLOROBENZOTRIFLUORIDE, pCBTF)

November 23, 2018

The California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA) intends to list *p-chloro-a,a,a-trifluorotoluene* (also known as para-chlorobenzotrifluoride, or PCBTF) 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
p-Chloro-α,α,α-trifluorotoluene (para-Chlorobenzotrifluoride, PCBTF)	NTP (2018)	Solvent used in paints, inks and coatings and as an industrial intermediate in the production of other chemicals (e.g. herbicides, dyes, pharmaceuticals).

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 which were not considered by the authoritative body clearly establish that the sufficiency of evidence criteria were not met (Section 25306(f)).

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

OEHHA is the lead agency for Proposition 65 implementation. 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.

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.

OEHHA's determination: p-Chloro- α , α , α -trifluorotoluene meets the criteria for listing as known to the state to cause cancer under Proposition 65, based on findings of the NTP (2018).

Formal identification and sufficiency of evidence for

p-chloro-α,α,α-trifluorotoluene: In 2018, NTP published a report, entitled *Toxicology* and *Carcinogenesis Studies of p*-Chloro-α,α,α-Trifluorotoluene *in Sprague Dawley Rats* (Hsd:Sprague Dawley SD) and B6C3F1/N Mice (Inhalation Studies), that concludes that the chemical causes cancer (NTP, 2018). 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 *p-chloro-α*,*α*,*α-trifluorotoluene* causes cancer. NTP (2018) states in the Conclusion section of the report's Summary (page 6):

"We conclude that inhalation exposure to p-chloro- α , α , α -trifluorotoluene caused tumors...in the liver of male and female mice, and in the Harderian gland in female mice..."

The NTP (2018) report states in the Conclusion section of the report's Abstract and main body of the report (pages 10 and 78, respectively):

"Under the conditions of these 2-year inhalation studies... There was *clear* evidence of carcinogenic activity of *p*-chloro-α,α,α-trifluorotoluene in male B6C3F1/N mice based on increased incidences of hepatocellular carcinoma and hepatoblastoma in the liver."

"There was *clear evidence of carcinogenic activity* of p-chloro- α , α , α -trifluorotoluene in female B6C3F1/N mice based on increased incidences of hepatocellular adenoma, hepatocellular carcinoma, and hepatoblastoma in the liver. The combined incidences of adenoma or adenocarcinoma in the Harderian gland of female mice were also considered to be related to treatment." (Emphasis in original)

Thus, NTP (2018) found that *p-chloro-a*, *a*, *a-trifluorotoluene* causes increased incidences of two types of malignant liver tumors in male and female mice, and of combined malignant and benign Harderian gland tumors in female mice.

Request for comments: OEHHA is requesting comments as to whether *p-chloro-α,α,α-trifluorotoluene* meets the criteria set forth in the Proposition 65 regulations for authoritative bodies listings. In order to be considered, **OEHHA must receive comments by 5:00 p.m. on December 24, 2018.** 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. By sending us your comments you are waiving any right to privacy you may have in the information you provide. Individual commenters should advise OEHHA when submitting documents to request redaction of home address or personal telephone numbers. Electronic files submitted should not have any form of encryption.

If you have any questions, please contact Mr. Leichty at <u>Julian.Leichty@oehha.ca.gov</u> or at (916) 445-6900.

References

National Toxicology Program (NTP, 2018). *Toxicology and Carcinogenesis Studies of p-Chloro-α,α,α-Trifluorotoluene in Sprague Dawley Rats (Hsd:Sprague Dawley SD) and B6C3F1/N Mice (Inhalation Studies)*. Technical Report Series No. 594. US Department of Health and Human Services, NTP, Research Triangle Park, NC. Available at https://ntp.niehs.nih.gov/ntp/htdocs/lt_rpts/tr594_508.pdf