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: BROMODICHLOROACETIC ACID

May 27, 2016

The California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA) intends to list the chemical *bromodichloroacetic acid* as known to the state to cause cancer under the Safe Drinking Water and Toxic Enforcement Act of 1986[1]. This action is being proposed under the authoritative bodies listing mechanism[2].

Chemical (CAS No.)	Reference	Occurrence
Bromodichloroacetic acid (71133-14-7)	NTP (2015)	Bromodichloroacetic acid can form when water containing natural organic matter and bromide is disinfected with chlorine-containing oxidizing compounds.

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 pursuant to Title 27, Cal. Code of Regs., section 25306(d)[3].
2) The evidence considered by the authoritative body meets the sufficiency criteria contained in 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)).

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.

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[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 further references are to sections of Title 27 of the Cal. Code of Regulations, unless otherwise stated.

OEHHA's determination: *Bromodichloroacetic acid* meets the criteria for listing as known to the state to cause cancer under Proposition 65, based on findings of the NTP (NTP, 2015).

Formal identification and sufficiency of evidence for *bromodichloroacetic acid*: In 2015, the NTP published a report on bromodichloroacetic acid entitled *Toxicology Studies of Bromodichloroacetic Acid (CAS No. 71133-14-7) in F344/N Rats and B6C3F1/N Mice and Toxicology and Carcinogenesis Studies of Bromodichloroacetic Acid in F344/NTac Rats and B6C3F1/N Mice (Drinking Water Studies)*. The NTP report concludes that the chemical causes cancer (NTP, 2015) and 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 bromodichloroacetic acid causes cancer. NTP (2015) states in the Conclusion section of the report's Summary (page 6):

"We conclude that bromodichloroacetic acid in the drinking water caused malignant mesothelioma and skin tumors in male rats and fibroadenomas and carcinomas of the mammary gland in female rats. Brain tumors in male and female rats and tumors of the oral cavity, large intestine, and mammary gland in male rats may also have been related to bromodichloroacetic acid exposure. We conclude that bromodichloroacetic acid caused liver cancer in male and female mice and Harderian gland cancer in male mice."

The NTP (2015) report states in the Conclusion section of the report's Abstract and main body of the report (pages 10 and 94):

> "Under the conditions of this 2-year inhalation study, there was *clear evidence of carcinogenic activity* of bromodichloroacetic acid in male F344/NTac rats based on increased incidences of malignant mesothelioma and the combined incidences of epithelial tumors of the skin. Occurrences of subcutaneous fibromas were also related to exposure to bromodichloroacetic acid. Occurrences of glioma or oligodendroglioma (combined) of the brain, squamous cell papilloma and squamous cell carcinoma of the oral cavity (oral mucosa or tongue), adenoma of the large intestine, and fibroadenoma of the mammary gland may have been related to exposure to bromodichloroacetic acid."
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> "There was *clear evidence of carcinogenic activity* of bromodichloroacetic acid in female F344/NTac rats based on increased incidences of fibroadenoma and carcinoma of the mammary gland. The occurrences of glioma or oligodendroglioma (combined) of the brain may have been related to bromodichloroacetic acid exposure."
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> "There was *clear evidence of carcinogenic activity* of bromodichloroacetic acid in male B6C3F1/N mice based on increased incidences of

hepatocellular carcinoma and hepatoblastoma and increased incidences of adenoma or carcinoma (combined) of the Harderian gland."

"There was *clear evidence of carcinogenic activity* of bromodichloroacetic acid in female B6C3F1/N mice based on increased incidences of hepatocellular adenoma, hepatocellular carcinoma, and hepatoblastoma." (Emphasis in original)

Thus, NTP (2015) has found that bromodichloroacetic acid causes increased incidences of malignant and combined malignant and benign tumors in male and female rats and male and female mice.

Request for comments: OEHHA is requesting comments as to whether bromodichloroacetic acid 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 June 27, 2016.** We encourage you to submit comments via e-mail, rather than in paper form. Comments transmitted by e-mail should be addressed to P65Public.Comments@oehha.ca.gov with "NOIL-bromodichloroacetic acid" in the subject line. Comments submitted in paper form may be mailed, faxed, or delivered in person to the addresses below:

Mailing Address:	Michelle Robinson Office of Environmental Health Hazard Assessment P.O. Box 4010, MS-12B Sacramento, California 95812-4010
Fax:	(916) 323-2265
Street Address:	1001 I Street Sacramento, California 95814

Comments received during the public comment period will be posted on the OEHHA web site 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. Robinson at Michelle.Robinson@oehha.ca.gov or at (916) 445-6900.

References

National Toxicology Program (NTP, 2015). *Toxicology Studies of Bromodichloroacetic Acid (CAS No. 71133-14-7) in F344/N Rats and B6C3F1 Mice and Toxicology and Carcinogenesis Studies of Bromodichloroacetic Acid in F344/NTac Rats and B6C3F1/N Mice (Drinking Water Studies).* NTP Technical Report Series No. 583. US Department of Health and Human Services, NTP, Research Triangle Park, NC. Available at http://ntp.niehs.nih.gov/ntp/htdocs/lt_rpts/tr583_508.pdf.