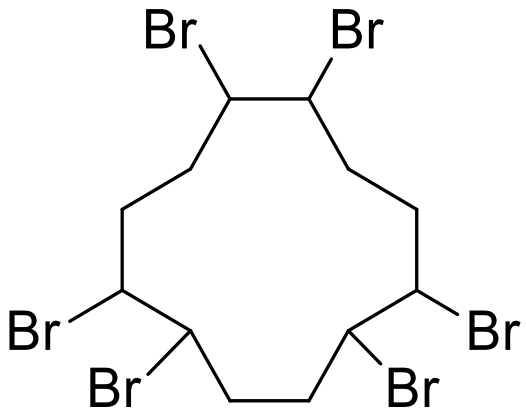
United States
Environmental Protection Agency

EPA Document #740-R1-8006
September 2020
Office of Chemical Safety and
Pollution Prevention

Nontechnical Summary of the Risk Evaluation for

Cyclic Aliphatic Bromide Cluster (HBCD)

CASRN: 25637-99-4
CASRN: 3194-55-6
CASRN: 3194-57-8



September 2020

BACKGROUND

- The primary use for cyclic aliphatic bromide cluster chemicals, including hexabromocyclododecane (HBCD), has been as a flame retardant in expanded polystyrene and extruded polystyrene in insulation foam used for construction; however, EPA identified other uses including use as a component of solder and use in automobile replacement parts.
- The manufacturing (including import) and use of HBCD has rapidly declined in the United States and globally over the past 10 years due to international regulation and the availability of substitutes. Annual production volumes were consistently 10-50 million lbs. from 2007 to 2011. From 2012 to 2015, production fell to 1-10 million lbs/year. Additional communications with industry representatives indicate that, as of 2018, domestic manufacture of HBCD had ceased and there are currently no U.S. manufacturers of the chemical.

ACTION

- EPA is releasing a final risk evaluation on HBCD after evaluating 12 conditions of use of HBCD. EPA has determined that HBCD presents an unreasonable risk for six conditions of use. For this chemical, commercial and consumer conditions of use were combined.
- This final risk evaluation is conducted pursuant to the Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which requires EPA to prioritize and evaluate the safety of existing chemicals to determine whether a chemical presents an unreasonable risk of injury to health or the environment under the conditions of use. If a chemical is determined to present an unreasonable risk, then EPA must regulate the substance to address the unreasonable risk.
- The final risk evaluation and supplemental materials can be found in docket EPA-HQ-OPPT-2019-0237 on www.regulations.gov.
- HBCD was selected in 2016 as one of the first 10 chemicals for risk evaluation under Section 6 of TSCA.
- Public comments and external scientific peer review informed the development of the HBCD final risk evaluation. EPA published the HBCD draft risk evaluation in June 2019, the HBCD problem formulation document in May 2018, and the scope document in June 2017.

KEY POINTS

- Risk conclusions for the environment are based upon both aquatic and terrestrial organisms of numerous species from different families. Adverse effects on aquatic species included reduced growth of aquatic plants (algae), reduced growth and delayed embryo development in fish, reduced growth and survival for pelagic (water flea) and benthic (California blackworm) invertebrates. Adverse effects in terrestrial soil organisms included effects on reproduction and mortality in earthworms chronically exposed to HBCD.
- Risk conclusions for human health effects were based on the most robust and sensitive acute (offspring loss) and chronic (thyroid hormone effects) endpoints. Thyroid hormone changes (both acute and chronic) are considered the primary effect resulting from HBCD exposure, as they are associated with all of the other observed downstream endpoints.
- After evaluating 12 conditions of use of HBCD, EPA determined that HBCD presents an unreasonable risk of injury for six conditions of use.
- Unreasonable risks were determined for the environment for six conditions of use: import, processing the chemical as a formulation, mixture, or reaction product; processing the

chemical into articles; recycling; commercial installation of building/construction materials; and disposal (demolition).
    - EPA made unreasonable risk determinations to the environment by assessing effects to aquatic (water or sediment dwelling) and terrestrial (land dwelling) species due to HBCD exposures. For aquatic species, risks include delayed hatching and reduced growth of juvenile organisms due to acute and chronic exposures to HBCD. For sediment dwelling organisms, the unreasonable risk determinations are due to chronic exposure to HBCD resulting in reduced reproduction and survival. Unreasonable risks were not found for terrestrial organisms.
    - For workers and occupational non-users (ONUs)[1], there is unreasonable risk to health for two conditions of use (commercial installation of building/construction materials, and disposal (demolition)). EPA determined there is unreasonable risk to workers from acute and chronic inhalation exposure resulting in potential thyroid hormone disruption affecting offspring and developmental toxicity. These same conditions of use also had unreasonable risk for the environmental receptors.
- The conditions of use that EPA determined do not present an unreasonable risk include: processing: recycling (of electronics waste containing high impact polystyrene (HIPS) that contains HBCD); distribution; commercial/consumer use: other – replacement automobile parts; commercial/consumer use: other – plastic and other articles; commercial/consumer use: other – formulated products and articles; and disposal of formulated products and articles.
- HBCD does not pose an unreasonable risk for use of consumer articles and products or where these items were distributed in commerce.
- EPA found no unreasonable risk for the general population from any of the conditions of use via exposures from ambient air, surface water, biosolids, or sediments. Similarly, EPA determined that the evaluation does not support an unreasonable risk determination to the general population via drinking water based on an assessment of the physical chemical properties and fate of HBCD in the environment as well as the absence of any HBCD measured in water samples.
- This risk evaluation includes uses of HBCD that are no longer manufactured, processed, or distributed for use in products and the disposal of those products, otherwise known as "legacy uses" and "associated disposal," respectively. Because of the Ninth Circuit Court of Appeals ruling in *Safer Chemicals Healthy Families v. U.S. Environmental Protection,* that found such uses within the statutory definition of "conditions of use" as well as public and peer review comments, EPA made additional assessments on these uses: general population exposure to HBCD in dust and indoor air released from HBCD-containing products, and articles that are still in use but for which the manufacture, processing, and distribution for such use has ceased.
- EPA released the draft risk evaluation for HBCD in June 2019 for a 60-day public comment period. Additionally, EPA held a peer review meeting of the Science Advisory Committee on Chemicals (SACC) on the draft risk evaluation of HBCD on July 29-August 2, 2019. The report of the SACC on HBCD is in the docket (EPA-HQ-OPPT-2019-0237). Along with the final risk evaluation, EPA is releasing a document that provides a response to public and peer review comments.

[1] ONUs are workers that are in the vicinity of, but are not actively working with, the chemical substance.

NEXT STEPS

- EPA has issued the final risk evaluation for HBCD, meeting the requirements set forth in TSCA Section 6(b) for chemical risk evaluations. EPA is now initiating the process to address the unreasonable risks identified. EPA has two years following the issuance of the final risk evaluation to address, by rule, the unreasonable risks identified.

SUMMARY OF UNREASONABLE RISK DETERMINATIONS

EPA has determined that the following conditions of use of HBCD do not present an unreasonable risk of injury to health or the environment. These determinations are considered final agency action and is being issued by order pursuant to TSCA Section 6(i)(1).

Conditions of Use that Do Not Present an Unreasonable Risk
• Processing: Recycling (of electronics waste containing high impact polystyrene (HIPS) that contains HBCD) • Distribution • Commercial/Consumer use: Other – Replacement automobile parts • Commercial/Consumer use: Other – Plastic and other articles • Commercial/Consumer use: Other – Formulated products and articles • Disposal of Formulated products and articles

EPA has determined that the following conditions of use of HBCD present an unreasonable risk of injury to health and/or the environment. There is unreasonable risk of injury to the environment for the six conditions of use listed below as well as unreasonable risk of injury to the health of workers for commercial/use through installation of building/construction materials and for disposal (demolition). EPA will initiate TSCA Section 6(a) risk management actions on these conditions of use as required under TSCA Section 6(c)(1). Pursuant to TSCA Section 6(i)(2), the unreasonable risk determinations for these conditions of use are not considered final agency action.

Manufacturing That Presents an Unreasonable Risk to the Environment
• Import

Processing that Presents an Unreasonable Risk to the Environment
• Processing: Incorporation into a formulation, mixture, or reaction products • Processing: Incorporation into article • Processing: Recycling (of XPS and EPS foam, resin, and panels containing HBCD)

Commercial/Consumer Use* that Presents an Unreasonable Risk to Human Health and the Environment
• Commercial/Consumer Use: Building/construction materials (Installation)

*Note: While commercial and consumer use was assessed as part of the same exposure scenario, risks were quantified separately and **no** unreasonable risks to consumers were identified.

Disposal that Presents an Unreasonable Risk to Human Health and the Environment
• Disposal (Demolition)