

## Initial Risk-Based Prioritization of High Production Volume Chemicals

### **Chemical/Category: Hexabromocyclododecane (HBCD)**

CAS 3194-55-6 1,2,5,6,9,10 hexabromocyclododecane

CAS 25637-99-4 hexabromocyclododecane

This document is based on screening-level characterizations done by EPA on the environmental fate, hazard, and exposure of the listed chemicals. The information used by EPA includes data submitted under the HPV Challenge Program<sup>1</sup> and the 2006 Inventory Update Reporting (IUR)<sup>2</sup>, and data publicly available through other selected sources<sup>3</sup>. This screening-level prioritization presents EPA's initial thinking regarding the potential risks presented by these chemicals and future possible actions that may be needed. These initial characterization and prioritization documents do not constitute a final Agency determination as to risk, nor do they determine whether sufficient data are available to characterize risk. Rather, they are interim evaluations. Recommended actions may be considered by EPA in the future based on a relative judgment regarding this chemical in comparison with others evaluated under this program, and in light of the uncertainties presented by gaps in the available data that may be determined to exist. These evaluations contribute to meeting U.S. commitments under the chemicals cooperation work being done in North America<sup>4</sup>.

### **Human Health and Environmental Hazard Summary:**

- Available health effects data indicate repeated dose toxicity. The overall human health hazard concern is moderate based on data suggestive of thyroid effects, which could present potential concerns for developmental neurotoxicity. Potential reproductive effects were indicated only at high doses based on observation of reproductive organ effects during a repeated dose study.
- Available aquatic toxicity studies indicate high acute aquatic toxicity to algae and high chronic toxicity to daphnia.

### **Persistence and Bioaccumulation Summary:**

- HBCD is ranked low for persistence.
- HBCD is ranked high for its potential to bioaccumulate.

### **Exposure Summary:**

- Both IUR Confidential Business Information (CBI) and non-CBI information from IUR and other sources were used in developing this overall ranking.
- Production volume: There are two CAS numbers for HBCD. 1,2,5,6,9,10 hexabromocyclododecane (CAS 3194-55-6) is an HPV chemical that was manufactured or imported in the U.S. between 10 and 50 million pounds in 2005. Hexabromocyclododecane (CAS 25637-99-4) is a moderate production volume (MPV)

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<sup>1</sup> US EPA, HPV Challenge Program information: <http://www.epa.gov/hpv/>.

<sup>2</sup> US EPA, IUR Reporting information: <http://www.epa.gov/oppt/iur/index.htm>.

<sup>3</sup> US EPA, Information on additional public databases used: <http://www.epa.gov/hpvis/pubdtsum.htm>.

<sup>4</sup> US EPA, U.S. Commitments to North American Chemicals Cooperation: <http://www.epa.gov/hpv/pubs/general/sppframework.htm>.

chemical manufactured or imported between 10 thousand and 500 thousand pounds in 2005.

- Uses: The HPV submission indicates that HBCD is used as a flame retardant primarily in polystyrene insulation foam, and also in upholstery textiles and video or audio equipment housings. In addition, other public sources report that HBCD is also used in crystal and high-impact polystyrene, SAN (Styrene-AcryloNitrile) resins, adhesives, and coatings.
- General Population and Environment: HBCD is not reported on the Toxics Release Inventory (TRI). As an additive flame retardant, HBCD is not chemically bound to the matrix of the material it protects, and thus has the potential to enter the environment. Based on this use information, EPA assumes for the purpose of this risk prioritization that there is potential for exposures to the general population and the environment.
- Workers: The National Occupational Exposure Survey (NOES), a survey conducted from 1981 to 1983, has no data for the total number of workers potentially exposed to this chemical under CAS number 3194-55-6 (specifically 1,2,5,6,9,10-HBCD); however, the NOES estimated a total of 11,921 workers potentially exposed to this chemical under CAS number 25637-99-4. Based on IUR reporting, which included at least one report that worker information was not readily obtainable, the maximum total number of workers likely to be exposed to this chemical during manufacturing and industrial processing and use is between 100 and 999. (Differences between numbers of workers estimated by IUR submitters and by the NOES are attributable to many factors, including time, scope, and method of the estimates. For example, NOES estimates are for all workplaces while IUR are for industrial workplaces only, and NOES used a survey and extrapolation method while IUR submitters simply provide their best estimates based on available information for the specific reporting year.) Vapor pressure is low, so significant worker inhalation exposure from the most common handling of liquids is considered unlikely. Workers may be exposed to airborne dust containing HBCD. Based on IUR data, specifically the number of potentially exposed workers and use codes, the potential worker exposure is high.
- Commercial Workers and Consumers: The IUR information has some commercial/consumer products listed for HBCD (fabrics, textiles, apparel, rubber and plastics). Commercial workers and consumers may have potential dermal and inhalation exposure to the chemical. The IUR-based ranking for commercial workers/consumers is high.
- Children: The IUR information suggests either that HBCD will not be used in children's consumer products or that this type of information is not readily available. Because of this uncertainty and the assumption that HBCD may be present in products intended to be used by children, the IUR-based ranking for children is moderate.

#### **Assumptions and Uncertainties:**

- HBCD has two CAS numbers. One (25637-99-4; hexabromocyclododecane) describes the HBCD mixture that is the focus of the OECD SIAP. The other (3194-55-6; 1,2,5,6,9,10-hexabromocyclododecane) describes the same mixture but identifies the position of each bromine in the chemical name. For the purpose of this Initial Risk-Based Prioritization, they are treated the same.
- HBCD may have uses that were not reported under the IUR.
- Uncertainty exists regarding the significance of the thyroid effects and the suggested potential for associated developmental neurotoxicity effects.

- Although reproductive organ effects were seen only at high doses in a repeated dose study, the absence of an actual reproductive toxicity study introduces some additional uncertainty.

**Risk Characterization Summary:**

- Potential Risk to Aquatic Organisms from Environmental Releases (HIGH CONCERN): EPA assumes there is potential for exposure to aquatic organisms from environmental releases. The bioaccumulation potential and high hazard for HBCD under acute (aquatic plants) and chronic (aquatic invertebrates) conditions suggest a high concern for potential risk to aquatic organisms from environmental releases, although the low persistence may mitigate this to some degree.
- Potential Risk to the General Population from Environmental Releases (MEDIUM CONCERN): EPA assumes there is potential for exposure to the general population from environmental releases. The moderate concern for hazard to human health combined with the potential environmental exposures and low persistence suggests a medium concern for potential risk to the general population from environmental releases.
- Potential Risk to Workers (HIGH CONCERN): Data suggest that workers may be exposed to HBCD. The moderate concern for hazard to human health combined with the likely exposures that occur in the occupational setting suggests a high concern for potential risk to workers.
- Potential Risk to Commercial Workers and Consumers from Known Uses (HIGH CONCERN): IUR information suggests that commercial workers and consumers may be exposed to HBCD. Recent findings in the scientific literature also suggest the potential for consumer exposures from HBCD use, although this requires further evaluation. The moderate concern for hazard to human health combined with the likely exposures that occur in commercial worker/consumer use settings suggests a high concern for potential risk to commercial workers and consumers.
- Potential Risk to Children (HIGH CONCERN): Information suggests that HBCD will be used in consumer products. It is likely that children will be exposed to consumer products containing this chemical. The moderate concern for hazard to human health is important in the case of children's health because studies have indicated that changes in thyroid function may lead to abnormal development, particularly in the nervous system. Therefore, the overall moderate human health hazard concern (and specific concerns for developmental effects) combined with expected exposures suggests a high concern for potential risks to children.

**Rationale Leading To Prioritization Decision:**

- The high concern suggested for potential risks to aquatic organisms is driven by a combination of :
  - Assumptions about the potential for exposure based on limited data, including information concerning uses and the general absence of data on environmental releases resulting from use and disposal of treated products, noting that the low persistence is a mitigating factor;
  - The bioaccumulative properties of the chemical;
  - Reports of the presence of HBCD in biota in remote environments; and
  - High hazard concerns for both acute and chronic toxicity.

- The high concern suggested for workers, consumers, and children and the medium concern suggested for potential risk to the general population are driven by a combination of :
  - The bioaccumulative properties of the chemical;
  - Assumptions about the potential for exposure based on limited data, including IUR information, concerning uses;
  - Uncertainty concerning potential exposure of children and consumers to HBCD in household dust;
  - The general absence of environmental release data;
  - Uncertainty concerning general population exposure from release of HBCD during use and disposal of treated products; and
  - Moderate hazard concerns.
- Further information specifically addressing releases to the environment and exposures arising from release of HBCD from use and disposal of treated products could directly affect the level of concern suggested for potential risk by replacing default exposure assumptions with more accurate data. Data moderating exposure assumptions could reduce the level of concern for potential risk. Conversely, data confirming exposure assumptions could also inform appropriate actions to take in order to moderate risk.

**Prioritization Decision:**

- **HIGH PRIORITY:** Although the lack of persistence helps to mitigate some concerns, in order to further evaluate the suggested concerns for potential risk currently based on release and exposure assumptions and on limited available exposure data, particularly concerning potential exposures to consumers and children, companies are encouraged to provide available information on a voluntary and non-confidential basis. Examples of information that would assist EPA in its analysis include, but are not limited to:
  - Worker exposures to HBCD;
  - Potential exposure of consumers and children to HBCD;
  - Releases, presence and bioaccumulation of HBCD to the environment; and
  - Other information pertinent to potential exposures to HBCD.
- HBCD is currently scheduled for an Integrated Risk Information System (IRIS) assessment and will be included in future iterations of the National Health and Nutrition Examination Survey (NHANES) human biomonitoring program, to identify the levels of HBCD in the U.S. population.
- When data from the IRIS and NHANES activities become available, they will assist EPA in making further decisions on this chemical, such as whether there may be a need for additional toxicity testing and whether HBCD might be a candidate for the Voluntary Children's Chemical Evaluation Program.

**Supporting Documentation:**

**Screening-Level Risk Characterization: 3/14/2008**

**Screening-Level Hazard Characterization: OECD SIDS Initial Assessment Profile, 4/20/2007**

**Note:** OECD SIDS Initial Assessment Profiles (SIAP) and SIDS Initial Assessment Reports (SIAR) are publicly available through the United Nations Environmental Programme website. These documents are presented in an

international forum that involves review and endorsement by governmental authorities around the world. The U.S. EPA is an active participant in these meetings and accepts these documents as reliable screening-level hazard assessments for the purpose of the U.S. HPV Challenge qualitative risk characterization process.

**Screening-Level Exposure Characterization: 3/14/2008**

**Screening-Level Physical/Chemical and Environmental Fate Characterization  
2/12/08**