

EPA Draft Risk Evaluation for 1-BP Finds Unreasonable Risks to Workers, Occupational Non-Users, Consumers, and Bystanders under Certain Specific Uses



Article By
[TCSA Blog at Bergeson Campbell
Bergeson & Campbell, P.C.
Toxic Substances Control Act Blog](#)

- [Biotech, Food, Drug](#)
- [Environmental, Energy & Resources](#)
- [Consumer Protection](#)
- [Labor & Employment](#)

- [All Federal](#)

Monday, August 12, 2019

The U.S. Environmental Protection Agency (EPA) released on August 9, 2019, the [draft risk evaluation for 1-bromopropane \(1-BP\)](#), the fourth of the first ten chemicals undergoing risk evaluation under the amended Toxic Substances Control Act (TSCA). The draft risk evaluation states that there could be unreasonable risks to workers, occupational non-users, consumers, and bystanders under certain conditions of use. EPA did not find unreasonable risk to the environment under any of the conditions of use. Because the TSCA Science Advisory Committee on

Chemicals (SACC) will be peer reviewing the draft risk evaluation at its **September 10-12, 2019**, meeting, EPA requests comments on the draft risk evaluation by **August 30, 2019**. EPA will continue to accept comments on the draft risk evaluations until **October 11, 2019**.

EPA's [fact sheet](#) on the draft risk evaluation for 1-BP provides the following chemical description:

- 1-BP is used as a solvent, including in degreasing operations, spray adhesives, and dry cleaning, in several industries. 1-BP is also used as a reactant in the manufacturing of other chemical substances;
- Consumer uses of 1-BP include several applications, including aerosol degreasers, spot cleaners, and stain removers, and in insulation for building and construction materials; and
- 2016 Chemical Data Reporting data show the total manufactured volume, including imports, was nearly 26 million pounds of 1-BP in the U.S in 2015.

According to the fact sheet, EPA made draft risk determinations on 25 conditions of use associated with the manufacturing (including import), processing, distribution, use, and disposal of 1-BP. These uses include the following:

- Processing for incorporation into a formulation, mixture, or reaction product;
- Processing as a reactant;
- Industrial and commercial uses as solvents for cleaning or degreasing;
- Industrial and commercial uses in adhesives and sealants;
- Industrial and commercial uses in cleaning and furniture care products;
- Other industrial and commercial uses, such as:
 - Adhesive accelerant;
 - Automotive care products;
 - Mold cleaning and release products; and
 - Electronic products; and
- Consumer uses, such as aerosol spray degreasers, spot cleaners, liquid cleaners, adhesive accelerant, refrigerant flush, mold cleaning, and insulation for building and construction materials.

EPA notes that 1-BP's production volume increased during the period 2012-2015 due to its use as an alternative to ozone-depleting substances and chlorinated solvents.

In the August 2019 draft 1-BP risk evaluation, EPA made the following initial determinations on risk. EPA notes that these initial determinations are not its final determinations on whether 1-BP presents unreasonable or no unreasonable risks

under the conditions of use and states that these initial determinations may change as its evaluation becomes more refined through the public- and peer-review processes. EPA's initial determinations of unreasonable risks include the following:

- **Unreasonable risks to workers and occupational non-users (others in the general area of 1-BP use) under specific industrial and commercial conditions of use;** and
- **Unreasonable risks to consumers and bystanders under specific consumer conditions of use.**

The conditions of use identified as presenting an unreasonable risk in the two bullets above include:

- Processing: Incorporation into formulation, mixture, or reaction products;
- Industrial and commercial use as a solvent for cleaning and degreasing, including vapor degreasers (*e.g.*, open-top and closed-loop batch vapor degreasers and inline vapor degreasers), cold cleaners and aerosol spray degreasers and cleaners;
- Industrial and commercial use in adhesives and sealants;
- Industrial and commercial use as cleaning and furniture care products, including dry cleaning, spot cleaner, and other liquid, spray, and aerosol cleaners;
- Other industrial and commercial uses: Arts, crafts, and hobby materials (adhesive accelerant); automotive care products (engine degreaser, brake cleaner, refrigerant flush); anti-adhesive agents (mold cleaning and release product); building/construction materials not covered elsewhere (insulation); electronic and electronic products and metal products; functional fluids (close/open-systems) -- refrigerant/cutting oils; asphalt extraction; laboratory chemicals; and temperature indicator -- coatings; and
- Other consumer uses: As a solvent (for cleaning or degreasing) in the form of aerosol spray degreaser or cleaner; as a cleaning and furniture care product in the form of: spot cleaner or stain remover, liquid cleaner (*e.g.*, coin and scissor cleaner), and liquid spray or aerosol cleaner; as arts, crafts, and hobby materials in the form of adhesive accelerant; as automotive care products in the form of refrigerant flush; and as anti-adhesive agents in the form of mold cleaning and release product.

EPA's initial findings of no unreasonable risk include the following:

- **No unreasonable risk to workers, occupational non-users (others in the general area of 1-BP use), consumers, and bystanders under other specific conditions of use, including:**
 - Manufacturing (Domestic Manufacturing and Import);

- Processing: as a reactant/intermediate;
 - Processing: Incorporation into articles;
 - Repackaging;
 - Recycling;
 - Distribution in commerce;
 - Disposal; and
 - Consumer uses of insulation; and
- **No unreasonable risk to the environment for all the conditions of use included in the draft risk evaluation.**

EPA makes clear that the draft risk evaluation, including initial risk determinations as to whether the chemical under the conditions of use presents an unreasonable risk to human health or the environment, is not final. If unreasonable risk is found for one or more conditions of use in a final risk evaluation, EPA states that it will propose actions to address those risks within the time frame required by TSCA.

Peer Review and Comment Deadlines

The SACC will [peer review the draft risk evaluation](#) at a **September 10-12, 2019**, meeting. EPA will hold a preparatory virtual meeting on **August 21, 2019**, to discuss the scope and clarity of the [draft charge questions to SACC](#). EPA requests comments on the draft risk evaluation by **August 30, 2019**, to allow SACC time to review and consider them before the peer review meeting. Comments received after **August 30, 2019**, and prior to the end of the oral public comment period during the meeting will still be provided to the SACC for their consideration. EPA will continue to accept comments on the draft risk evaluation until **October 11, 2019**. EPA will consider all comments received on the draft risk evaluation by the **October 11, 2019**, deadline when developing the final risk evaluation.

Commentary

A careful review of the hazard and exposure assessments underlying EPA's risk evaluation is pending, and interested stakeholders and the SACC will have to dig deep into EPA's hazard and exposure assessments. Absent errors or material scientific disagreements with EPA's approach, it seems that EPA's final risk evaluation may support unreasonable risk to workers, occupational non-workers, bystanders, and consumers from inhalation (and in some limited cases, dermal) exposure to 1-BP across a variety of uses. In numerous cases, EPA has calculated margins of exposure (MOE) well below the benchmark MOE of 100. Many of the scenarios that EPA evaluated lead to potential risk from inhalation exposure to end users. In some cases, EPA calculated unreasonable risk for scenarios in which workers use respirators with an assigned protection factor (APF) of 50 (full-face respirators with organic vapor cartridge). The relatively low point of departure for developmental toxicity (human-equivalent concentration (HEC) of 17 ppm for

developmental effects) and the high vapor pressure seem to be contributing to the large number of circumstances of potential unreasonable risk to health.

There are some confusing values in EPA's exposure estimates as, in some cases, "low-intensity" users have higher exposures than "high-intensity" users. A careful examination of EPA's assumptions is needed to evaluate whether the data support a higher exposure for less intense use. Given the wide range of uses and conditions of use for which EPA identified potential unreasonable risk, however, any discrepancies or scientific differences will have to be both large and systematic for EPA ultimately to conclude that 1-BP does not present unreasonable risk to health.

We recognize the seriousness of the human hazard and exposure potential associated with 1-BP and commend EPA for its efforts to address these issues comprehensively. Perhaps the only bright spot in the risk evaluation is that EPA did not find unreasonable risk to aquatic species.

Stakeholders should monitor carefully the 1-BP action. EPA's risk assessment and (it seems) likely risk management actions that may follow will provide better insight into EPA's plan and policies for both risk evaluation and risk management of chemical substances under Section 6 of TSCA.

©2019 Bergeson & Campbell, P.C.

Source URL: <https://www.natlawreview.com/article/epa-draft-risk-evaluation-1-bp-finds-unreasonable-risks-to-workers-occupational-non>