

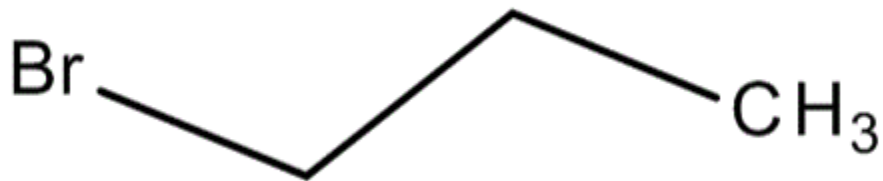


United States
Environmental Protection Agency

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Office of Chemical Safety and
Pollution Prevention

**Non-Technical Summary of the Risk Evaluation for
1-Bromopropane
(*n*-Propyl Bromide)**

CASRN: 106-94-5



December 2022

BACKGROUND

- The TSCA risk evaluation for 1-bromopropane (1-BP) was issued in August 2020.
- Uses for 1-BP include use as a reactant in the manufacturing of other chemical substances, as a solvent in vapor degreasing and aerosol degreasing operations, in spray adhesives and dry cleaning, and in laboratory uses. Consumer and commercial uses of 1-BP include several applications including aerosol degreaser, spot cleaner and stain removers, and in insulation for building and construction materials.
- The total annual aggregate production volume reported for 1-BP under the Chemical Data Reporting (CDR) rule ranged from 31 million to 170 million pounds between 2016 and 2019.

ACTION

- EPA is releasing a final revision to the risk determination on 1-BP with an order withdrawing the TSCA section 6(i)(1) order previously included in the August 2020 risk evaluation. This action follows issuance of a draft revised risk determination that EPA issued for comment in July 2022 (87 FR 43265). EPA has determined that 1-BP presents an unreasonable risk of injury to health under its conditions of use.
- This final risk evaluation, which includes the 2020 risk evaluation and a 2022 final revised unreasonable risk determination, 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 risk of existing chemicals to determine whether a chemical presents an unreasonable risk of injury to health or the environment under the conditions of use. Under TSCA, if a chemical is determined to present an unreasonable risk, then EPA will propose risk management regulatory action to the extent necessary so that the chemical substance no longer presents an unreasonable risk.
- The 2020 risk evaluation, supplemental materials, 2022 revised unreasonable risk determination and corresponding response to public comments can be found in dockets EPA-HQ-OPPT-2019-0235 and EPA-HQ-OPPT-2016-0741 on www.regulations.gov.
- 1-BP was selected in 2016 as one of the first 10 chemicals for risk evaluation under section 6 of TSCA.

KEY POINTS

- EPA has identified risks for non-cancer adverse effects from acute and chronic inhalation and dermal exposures to 1-BP, and for cancer from chronic inhalation and dermal exposures to 1-BP. In the 1-BP risk characterization, developmental toxicity (i.e., post-implantation loss) was identified as the most sensitive endpoint for non-cancer adverse effects from acute and chronic inhalation and dermal exposures for all conditions of use.
- Additional risks associated with other adverse effects (e.g., additional developmental toxicity, reproductive toxicity, liver toxicity, kidney toxicity, and neurotoxicity) were identified for acute and chronic inhalation and dermal exposures.
- Public comments and external scientific peer review informed the development of the 1-BP final risk evaluation. EPA published the 1-BP final revised unreasonable risk determination in December 2022, the 1-BP draft revised unreasonable risk determination in July 2022, the 1-BP risk evaluation in August 2020, the 1-BP draft risk evaluation in August 2019 (for a 60-day public comment period), the 1-BP problem formulation document in May 2018, and the scope document in June 2017.

- Additionally, EPA held a peer review meeting of the Science Advisory Committee on Chemicals (SACC) on the draft risk evaluation of 1-BP on September 10-12, 2019.
- In the revised unreasonable risk determination for 1-BP, EPA is making an unreasonable risk determination for 1-BP as a whole chemical substance, rather than taking a condition of use-specific approach. The whole chemical approach is appropriate for 1-BP because there are benchmark exceedances for a substantial number of conditions of use for human health and there are irreversible health effects (e.g., cancer) associated with 1-BP exposures.
- After evaluating 25 conditions of use, EPA determined that 1-BP presents an unreasonable risk to human health under its conditions of use based on risk of injury to health of workers, occupational non-users (ONUs), consumers, and bystanders.
- In addition, EPA is revising the assumption that workers always and properly use personal protective equipment (PPE), although EPA does not question public comments received regarding the occupational safety practices often followed by industry. Information on the use of PPE as a means of mitigating risk will be considered during the risk management phase. Removing the assumption that workers wear PPE in making the whole chemical risk determination for 1-BP means that: seven conditions of use in addition to the original 16 conditions of use drive the unreasonable risk for 1-BP; additional risks of cancer from dermal exposures is also identified as driving the unreasonable risk to workers in six conditions of use; additional risks for acute and chronic non-cancer effects from inhalation exposures drive the unreasonable risk to workers in two conditions of use; and additional risks for acute and chronic non-cancer effects and cancer from inhalation and dermal exposures to workers drive the unreasonable risk in one condition of use (where previously this condition of use was identified as presenting unreasonable risk only to ONUs).
- Overall, 23 of the 25 conditions of use evaluated drive the 1-BP whole chemical unreasonable risk determination due to risks identified for human health. These conditions of use include but are not limited to: processing the chemical into formulation; use as solvent in industrial and commercial cleaning and degreasing, including vapor degreasing, cold cleaning and spray and aerosol degreasers; use in adhesives and sealants; use in dry cleaning and spot cleaning for clothing; use in several specialty spray/aerosol applications. Additionally, the conditions of use found to drive unreasonable risk to consumers include: solvent in aerosol spray degreasers/cleaners, spot cleaners and stain removers, liquid cleaner used for coins or scissors, liquid spray/aerosol cleaners, adhesive accelerants used in arts, crafts, and hobby materials, automotive care products such as refrigerant flush, and anti-adhesive agents used in mold cleaning and release products.
- The conditions of use that do not drive EPA's unreasonable risk determination for 1-BP are distribution in commerce and commercial and consumer use in insulation.
- For 1-BP, the air exposure pathway was not fully assessed in the final risk evaluation (see Sections 1.4.2 and 4.5.2.3 of the August 2020 1-BP risk evaluation). EPA is conducting a screening approach to assess risks from the air and water pathways for several of the first 10 chemicals, including 1-BP. The goal of the recently-developed screening approach is to remedy this exclusion and to determine if there may be risks that were unaccounted for in the 1-BP risk evaluation. EPA expects to describe its findings regarding the chemical-specific application of this screening-level approach in the forthcoming proposed rule under TSCA section 6(a) for 1-BP.
- EPA did not identify risks of injury to the environment that drive the unreasonable risk determination for 1-BP.

- As noted above, EPA is releasing a final revision to the unreasonable risk determination with an order withdrawing the TSCA section 6(i)(1) order previously included in the August 2020 risk evaluation. EPA is also releasing a document with responses to public comments received on the draft revised risk determination for 1-BP published in July 2022.

NEXT STEPS

- EPA has issued the final risk evaluation (2020 risk evaluation and 2022 revised risk determination) for 1-BP, meeting the requirements set forth in TSCA section 6(b) for chemical risk evaluations. EPA is now initiating the process to address the unreasonable risk identified. Following the issuance of the final risk evaluation, EPA will address, by rule, the unreasonable risk identified. The public will have an opportunity to comment on a proposed rule before EPA issues a final rule.

SUMMARY OF UNREASONABLE RISK DETERMINATION

EPA has determined that 1-BP presents an unreasonable risk of injury to human health under the conditions of use.

EPA's unreasonable risk determination for 1-BP is driven by risks associated with the following conditions of use, considered singularly or in combination with other exposures:

- Manufacture (domestic manufacturing);
- Manufacture (import);
- Processing: as a reactant;
- Processing: incorporation into formulation, mixture or reaction product;
- Processing: incorporation into articles;
- Processing: repackaging;
- Processing: recycling;
- Industrial and commercial use as solvent for cleaning and degreasing in vapor degreaser (batch vapor degreaser – open-top, inline vapor degreaser);
- Industrial and commercial use as solvent for cleaning and degreasing in vapor degreaser (batch vapor degreaser – closed-loop);
- Industrial and commercial use as solvent for cleaning and degreasing in cold cleaners;
- Industrial and commercial use as solvent in aerosol spray degreaser/cleaner;
- Industrial and commercial use in adhesives and sealants;
- Industrial and commercial use in dry cleaning solvents, spot cleaners and stain removers;
- Industrial and commercial use in liquid cleaners (e.g., coin and scissor cleaner) and liquid spray/aerosol cleaners;
- Other industrial and commercial uses: arts, crafts, hobby materials (adhesives accelerant); automotive care products (engine degrease, brake cleaner, refrigerant flush); anti-adhesive agents (mold cleaning and release product); electronic and electronic products and metal products; functional fluids (close/open-systems) – refrigerant/cutting oils; asphalt extraction; laboratory chemicals; and temperature indicator – coatings;
- Consumer use as solvent in aerosol spray degreasers/cleaners;
- Consumer use in spot cleaners and stain removers;

- Consumer use in liquid cleaners (e.g., coin and scissor cleaners);
- Consumer use in liquid spray/aerosol cleaners;
- Consumer use in arts, crafts, hobby materials (adhesive accelerant);
- Consumer use in automotive care products (refrigerant flush);
- Consumer use in anti-adhesives agents (mold cleaning and release product); and
- Disposal.

The following conditions of use do not drive EPA's unreasonable risk determination for 1-BP:

- Distribution in commerce; and
- Commercial and consumer uses of building/construction materials (insulation).

EPA is not making condition of use-specific risk determinations for these conditions of use, is not issuing a final order under TSCA section 6(i)(1) for these conditions of use, and does not consider the revised risk determination for 1-BP to constitute a final agency action at this point in time.

Consistent with the statutory requirements of TSCA section 6(a), EPA will propose risk management regulatory action to the extent necessary so that 1-BP no longer presents an unreasonable risk. EPA expects to focus its risk management action on the conditions of use that drive the unreasonable risk. However, it should be noted that, under TSCA section 6(a), EPA is not limited to regulating the specific activities found to drive unreasonable risk and may select from among a suite of risk management requirements in section 6(a) related to manufacture (including import), processing, distribution in commerce, commercial use, and disposal as part of its regulatory options to address the unreasonable risk. As a general example, EPA may regulate upstream activities (e.g., processing, distribution in commerce) to address downstream activities (e.g., consumer uses) driving unreasonable risk, even if the upstream activities do not drive the unreasonable risk.