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## Scope of the Risk Evaluation for 1-Bromopropane

CASRN: 106-94-5



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### **Docket**

Supporting information can be found in public docket (Docket: [EPA-HQ-OPPT-2016-0741](#)).

### **Disclaimer**

Reference herein to any specific commercial products, process or service by trade name, trademark, manufacturer or otherwise does not constitute or imply its endorsement, recommendation or favoring by the United States Government.

## ABBREVIATIONS

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°C	Degrees Celsius
ACGIH	American Conference of Government Industrial Hygienists
atm	Atmosphere(s)
ATSDR	Agency for Toxic Substances and Disease Registry
BAF	Bioaccumulation Factor
BCF	Bioconcentration Factor
BMD	Benchmark Dose Modeling
1-BP	1-Bromopropane
CAA	Clean Air Act
CASRN	Chemical Abstracts Service Registry Number
CBI	Confidential Business Information
CDR	Chemical Data Reporting
CEHD	Chemical Exposure Health Data
CFC	Chlorofluorocarbon
COC	Concentration of Concern
CoCAM	Cooperative Chemicals Assessment Meeting
CPCat	Chemical and Product Categories
CSAC	Chemical Safety and Advisory Council
CSCL	Chemical Substances Control Law
DOE	Department of Energy
DNA	Deoxyribonucleic Acid
ECHA	European Chemicals Agency
EPA	Environmental Protection Agency
EPCRA	Emergency Planning and Community Right-to-Know Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
g	Gram(s)
HAP	Hazardous Air Pollutant
HCFC	Hydrochlorofluorocarbon
HPV	High Production Volume
IMAP	Inventory Multi-Tiered Assessment and Prioritisation
IRIS	Integrated Risk Information System
ISHA	Industrial Safety and Health Act
IUR	Inhalation Unit Risk
kPa	Kilopascal(s)
L	Liter(s)
lb	Pound(s)
Log K <sub>oc</sub>	Logarithmic Soil Organic Carbon:Water Partitioning Coefficient
Log K <sub>ow</sub>	Logarithmic Octanol:Water Partition Coefficient
m <sup>3</sup>	Cubic Meter(s)
mmHg	Millimeter(s) of Mercury
mPa·s	Millipascal(s)-Second
MSDS	Material Safety Data Sheet
NAAQS	National Ambient Air Quality Standards
NAICS	North American Industry Classification System
NEI	National Emissions Inventory

NESHAP	National Emission Standards for Hazardous Air Pollutants
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
NIH	National Institute of Health
NIOSH	National Institute of Occupational Safety and Health
NTP	National Toxicology Program
OCSPP	Office of Chemical Safety and Pollution Prevention
OECD	Organisation for Economic Co-operation and Development
OPPT	Office of Pollution Prevention and Toxics
OSHA	Occupational Safety and Health Administration
OTVD	Open Top Vapor Degreaser
PBPK	Physiologically Based Pharmacokinetic
PEL	Permissible Exposure Limit
PERC	Perchloroethylene
POD	Point of Departure
POTW	Publicly Owned Treatment Works
ppm	Part(s) per Million
QC	Quality Control
RA	Risk Assessment
RCRA	Resource Conservation and Recovery Act
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SDS	Safety Data Sheet
SIDS	Screening Information Data Set
SNAP	Significant New Alternatives Policy
SVHC	Substance of Very High Concern
TCCR	Transparent, Clear, Consistent, and Reasonable
TCE	Trichloroethylene
TLV	Threshold Limit Value
TRI	Toxics Release Inventory
TSCA	Toxic Substances Control Act
TWA	Time-Weighted Average
VOC	Volatile Organic Compound
U.S.	United States

## EXECUTIVE SUMMARY

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TSCA § 6(b)(4) requires the U.S. Environmental Protection Agency (EPA) to establish a risk evaluation process. In performing risk evaluations for existing chemicals, EPA is directed to “determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator under the conditions of use.” In December of 2016, EPA published a list of 10 chemical substances that are the subject of the Agency’s initial chemical risk evaluations ([81 FR 91927](#)), as required by TSCA § 6(b)(2)(A). 1-Bromopropane (1-BP) was one of these chemicals.

TSCA § 6(b)(4)(D) requires that EPA publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use and potentially exposed or susceptible subpopulations that the Administrator expects to consider. This document fulfills the TSCA § 6(b)(4)(D) requirement for 1-BP.

This document presents the scope of the risk evaluation to be conducted for 1-BP. If a hazard, exposure, condition of use or potentially exposed or susceptible subpopulation has not been discussed, EPA, at this point in time, is not intending to include it in the scope of the risk evaluation. As per the rulemaking, *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act (TSCA)*, with respect to conditions of use in conducting a risk evaluation under TSCA, EPA will first identify “circumstances” that constitute “conditions of use” for each chemical. While EPA interprets this as largely a factual determination—i.e., EPA is to determine whether a chemical substance is actually involved in one or more of the activities listed in the definition—the determination will inevitably involve the exercise of some discretion.

To the extent practicable, EPA has aligned this scope document with the approach set forth in the risk evaluation process rule; however, the scope documents for the first 10 chemicals in the risk evaluation process differ from the scope documents that EPA anticipates publishing in the future. Time constraints have resulted in scope documents for the first 10 chemicals that are not as refined or specific as future scope documents are anticipated to be.

Because there was insufficient time for EPA to provide an opportunity for comment on a draft of this scope document, as it intends to do for future scope documents, EPA will publish and take public comment on a Problem Formulation document which will refine the current scope, as an additional interim step, prior to publication of the draft risk evaluation for 1-BP. This problem formulation is expected to be released within approximately 6 months of publication of the scope.

1-BP is primarily used as a solvent cleaner in vapor and immersion degreasing operations to clean optics, electronics and metals, but it has also been reported to be used as an alternative to ozone-depleting substances and chlorinated solvents, as a solvent vehicle in industries using spray adhesives such as foam cushion manufacturing. In the past, 1-BP was used as a solvent for fats, waxes or resins and as an intermediate in pharmaceutical, insecticide, quaternary ammonium compound, flavor and fragrance synthesis. Information from the 2016 Chemical Data Reporting (CDR) for 1-BP indicates the reported production volume is 25.9 million lbs/year (manufacture and import).

The initial conceptual models presented in Section 2 identify conditions of use; exposure pathways (e.g., media); exposure routes (e.g., inhalation, dermal, oral); potentially exposed populations, including potentially exposed or susceptible subpopulations; and hazards EPA expects to evaluate based on the inherent hazards of 1-BP. It is expected that inhalation will be the primary route of exposure to all populations.

This document presents the occupational scenarios in which workers and occupational non-users may be exposed to 1-BP during a variety of conditions of use, such as spray adhesives, dry cleaning (including spot cleaning) and degreasing (vapor, cold cleaning, and aerosol). It also presents the consumer model which indicates exposures occurring from consumer uses for 1-BP such as aerosol and spray adhesives, aerosol spot removers and aerosol cleaning and degreasing products. For 1-BP, EPA believes that workers, consumers, and bystanders as well as certain other groups of individuals may experience greater exposures than the general population. EPA will evaluate whether other groups of individuals within the general population may be exposed via pathways that are distinct from the general population due to unique characteristics (e.g., life stage, behaviors, activities, duration) or have greater susceptibility than the general population, and should therefore be considered relevant potentially exposed or susceptible subpopulations for purposes of this risk evaluation.

Exposures to the general population may occur from industrial releases. The manufacturing, processing, distribution and use of 1-BP can result in releases to air, water, and soil. EPA expects to consider exposures to the general population and the environment via inhalation of air emitted from manufacturing, processing, distribution, use facilities and from water, sediments, soils that may receive releases or wastes and disposal from such facilities.

A [2016 Draft Risk Assessment \(U.S. EPA, 2016b\)](#) on 1-BP was previously released for public comment (on March 2, 2016) and for a Chemical Safety and Advisory Council (CSAC) Peer Review (May 24-25, 2016)<sup>1</sup>. 1-BP was recently listed on the Toxics Release Inventory (TRI/80 FR 72906). Data on the environmental releases of 1-BP to air, landfills or water are likely to become available in the near term through TRI. EPA also published a draft notice (January 9, 2017) on the rationale for granting the petitions to add 1-BP to the list of hazardous air pollutants (HAPs).

1-BP has been the subject of numerous health hazard reviews including EPA's [2016 Draft Risk Assessment \(U.S. EPA, 2016b\)](#), the Agency for Toxic Substances and Disease Registry's (ATSDR's) Toxicological Profile, and the National Institute for Occupational Safety and Health's (NIOSH's) Criteria Document. Any existing assessments will be a starting point as EPA will conduct a systematic review of the literature, including new literature since the existing assessments, as available in *1-Bromopropane (CASRN 106-94-5) Bibliography: Supplemental File for the TSCA Scope Document*, [EPA-HQ-OPPT-2016-0741](#)). In the [2016 Draft Risk Assessment](#), EPA reviewed the evidence for 1-BP toxicity and selected liver toxicity, kidney toxicity, reproductive/developmental toxicity, neurotoxicity and cancer as the most robust, sensitive and consistent adverse human health effects for risk characterization. In addition, EPA did not assess environmental exposures from the selected uses of 1-BP in the [2016 Draft Risk Assessment](#) due to 1-BP's low persistence, low bioaccumulation and low hazard for aquatic toxicity, as well as the expectation that low levels of 1-BP would be present in surface water. These hazards will be evaluated based on the specific exposure scenarios identified.

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<sup>1</sup> The full February 2016 Draft Risk Assessment can be found at: [https://www.epa.gov/sites/production/files/2016-03/documents/1-BP\\_report\\_and\\_appendices\\_final.pdf](https://www.epa.gov/sites/production/files/2016-03/documents/1-BP_report_and_appendices_final.pdf).

The initial analysis plan describes EPA's plan for conducting systematic review of readily available information and identification of assessment approaches to be used in conducting the risk evaluation for 1-BP. The initial analysis plan will be used to develop the problem formulation and final analysis plan for the risk evaluation of 1-BP.

# 1 INTRODUCTION

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This document presents the scope of the risk evaluation to be conducted for 1-Bromopropane (1-BP). If a condition of use has not been discussed, EPA, at this point in time, is not intending to include that condition of use in the scope of the risk evaluation. Moreover, during problem formulation EPA may determine that not all conditions of use mentioned in this scope will be included in the risk evaluation. Any condition of use that will not be evaluated will be clearly described in the problem formulation document.

On June 22, 2016, the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which amended the Toxic Substances Control Act (TSCA), the nation's primary chemicals management law, was signed into law. The new law includes statutory requirements and deadlines for actions related to conducting risk evaluations of existing chemicals.

TSCA § 6(b)(4) requires the U.S. Environmental Protection Agency (EPA) to establish a risk evaluation process. In performing risk evaluations for existing chemicals, EPA is directed to “determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator under the conditions of use.”

In December of 2016, EPA published a list of 10 chemical substances that are the subject of the Agency's initial chemical risk evaluations (81 FR 91927), as required by TSCA § 6(b)(2)(A). These 10 chemical substances were drawn from the 2014 update of EPA's TSCA Work Plan for Chemical Assessments, a list of chemicals that EPA identified in 2012 and updated in 2014 (currently totaling 90 chemicals) for further assessment under TSCA. EPA's designation of the first 10 chemical substances constituted the initiation of the risk evaluation process for each of these chemical substances, pursuant to the requirements of TSCA § 6(b)(4).

TSCA § 6(b)(4)(D) requires that EPA publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use and potentially exposed or susceptible subpopulations that the Administrator expects to consider. On February 14, 2017, EPA convened a public meeting to receive input and information to assist the Agency in its efforts to establish the scope of the risk evaluations under development for the ten chemical substances designated in December 2016 for risk evaluations pursuant to TSCA. EPA provided the public an opportunity to identify information, via oral comment or by submission to a public docket, specifically related to the conditions of use for the ten chemical substances. EPA used this information in developing this scope document, which fulfills the TSCA § 6(b)(4)(D) requirement for 1-BP.

As per the rulemaking, *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act (TSCA)*, in conducting a risk evaluation under TSCA EPA will first identify “circumstances” that constitute “conditions of use” for each chemical. While EPA interprets this as largely a factual determination—i.e., EPA is to determine whether a chemical substance is actually involved in one or more of the activities listed in the definition—the determination will inevitably involve the exercise of some discretion. Based on legislative history, statutory structure and other evidence of Congressional intent, EPA has determined that certain activities may not generally be considered to be conditions of use. In exercising its discretion, for example, EPA would not generally consider that a single

unsubstantiated or anecdotal statement (or even a few isolated statements) on the internet that a chemical can be used for a particular purpose would necessitate concluding that this represented part of the chemical substance's "conditions of use." As a further example, although the definition could be read literally to include all intentional misuses (e.g., inhalant abuse), as a "known" or "reasonably foreseen" activity in some circumstances, EPA does not generally intend to include such activities in either a chemical substance's prioritization or risk evaluation. In addition, EPA interprets the mandates under section 6(a)-(b) to conduct risk evaluations and any corresponding risk management to focus on uses for which manufacture, processing, or distribution in commerce is intended, known to be occurring, or reasonably foreseen (i.e., is prospective or on-going), rather than reaching back to evaluate the risks associated with legacy uses, associated disposal, and legacy disposal, and interprets the definition of "conditions of use" in that context. For instance, the conditions of use for purposes of section 6 might reasonably include the use of a chemical substance in insulation where the manufacture, processing or distribution in commerce for that use is prospective or on-going, but would not include the use of the chemical substance in previously installed insulation, if the manufacture, processing or distribution for that use is not prospective or on-going. In other words, EPA interprets the risk evaluation process of section 6 to focus on the continuing flow of chemical substances from manufacture, processing and distribution in commerce into the use and disposal stages of their lifecycle. That said, in a particular risk evaluation, EPA may consider background exposures from legacy use, associated disposal, and legacy disposal as part of an assessment of aggregate exposure or as a tool to evaluate the risk of exposures resulting from non-legacy uses.

Furthermore, in exercising its discretion under section 6(b)(4)(D) to identify the conditions of use that EPA expects to consider in a risk evaluation, EPA believes it is important for the Agency to have the discretion to make reasonable, technically sound scoping decisions in light of the overall objective of determining whether chemical substances in commerce present an unreasonable risk. Consequently, EPA may, on a case-by case basis, exclude certain activities that EPA has determined to be conditions of use in order to focus its analytical efforts on those exposures that are likely to present the greatest concern meriting an unreasonable risk consideration. For example, EPA intends to exercise discretion in addressing circumstances where the chemical substance subject to scoping is unintentionally present as an impurity in another chemical substance that is not the subject of the pertinent scoping, in order to determine which risk evaluation the potential risks from the chemical substance should be addressed in. As an additional example, EPA may, on a case-by-case basis, exclude uses that EPA has sufficient basis to conclude would present only "de minimis" exposures. This could include uses that occur in a closed system that effectively precludes exposure, or use as an intermediate. During the scoping phase, EPA may also exclude a condition of use that has been adequately assessed by another regulatory agency, particularly where the other agency has effectively managed the risks.

The situations identified above are examples of the kinds of discretion that EPA will exercise in determining what activities constitute conditions of use, and what conditions of use are to be included in the scope of any given risk evaluation. See the preamble to *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act (TSCA)* for further discussion of these issues.

To the extent practicable, EPA has aligned this scope document with the approach set forth in the risk evaluation process rule; however, the scope documents for the first 10 chemicals in the risk evaluation process differ from the scope documents that EPA anticipates publishing in the future. The first 10 chemical substances were not subject to the prioritization process that will be used in the future in

accordance with amendments to TSCA. EPA expects to collect and screen much of the relevant information about chemical substances that will be subject to the risk evaluation process during and before prioritization. The volume of data and information about the first 10 chemicals that is available to EPA is extremely large and EPA is still in the process of reviewing it, since the Agency had limited ability to process the information gathered before issuing the scope documents for the first 10 chemicals. As a result of the statutory timeframes, EPA had limited time to process all of the information gathered during scoping for the first 10 chemicals within the time provided in the statute for publication of the scopes after initiation of the risk evaluation process. For these reasons, EPA's initial screenings and designations with regard to applicability of data (e.g., on-topic vs. off-topic information and data) may change as EPA progresses through the risk evaluation process. Likewise, the Conceptual Models and Analysis Plans provided in the first 10 chemical scopes are designated as "Initial" to indicate that EPA expects to further refine them during problem formulation.

The aforementioned time constraints have resulted in scope documents for the first 10 chemicals that are not as refined or specific as future scope documents are anticipated to be. In addition, there was insufficient time for EPA to provide an opportunity for comment on a draft of this scope document, as it intends to do for future scope documents. For these reasons, EPA will publish and take public comment on a problem formulation document which will refine the current scope, as an additional interim step, prior to publication of the draft risk evaluations for the first 10 chemicals. This problem formulation is expected to be released within approximately 6 months of publication of the scope.

## **1.1 Regulatory History**

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EPA conducted a search of existing domestic and international laws, regulations and assessments pertaining to 1-Bromopropane (1-BP). EPA compiled this summary from data available from federal, state, international and other government sources, as cited in Appendix A. During risk evaluation, EPA will evaluate and consider the impact of these existing laws and regulations in the problem formulation step to determine what, if any further analysis might be necessary as part of the risk evaluation.

### ***Federal Laws and Regulations***

1-BP is subject to federal statutes or regulations, other than TSCA, that are implemented by other offices within EPA and/or other federal agencies/departments. A summary of federal laws, regulations and implementing authorities is provided in Appendix A.1.

### ***State Laws and Regulations***

1-BP is subject to state statutes or regulations implemented by state agencies or departments. A summary of state laws, regulations and implementing authorities is provided in Appendix A.2.

### ***Laws and Regulations in Other Countries and International Treaties or Agreements***

1-BP is subject to statutes or regulations in countries other than the United States and/or international treaties and/or agreements. A summary of these laws, regulations, treaties and/or agreements is provided in Appendix A.3.

## 1.2 Assessment History

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EPA has identified assessments conducted by other EPA Programs and other organizations (see Table 1-1). Depending on the source, these assessments may include information on conditions of use, hazards, exposures and potentially exposed or susceptible subpopulations—information useful to EPA in preparing this scope for risk evaluation. Table 1-1 shows the assessments that have been conducted. In addition to using this information, EPA intends to conduct a full review of the data collected (see *1-Bromopropane (CASRN 106-94-5) Bibliography: Supplemental File for the TSCA Scope Document*, [EPA-HQ-OPPT-2016-0741](#)) using the literature search strategy (see *Strategy for Conducting Literature Searches for 1-Bromopropane: Supplemental File for the TSCA Scope Document* [EPA-HQ-OPPT-2016-0741](#)) to ensure that EPA is considering information that has been made available since these assessments were conducted.

A [2016 Draft Risk Assessment \(U.S. EPA, 2016b\)](#) on 1-BP was previously released for public comment<sup>2</sup>. During scoping and problem formulation for the [2016 Draft Risk Assessment](#) on 1-BP, EPA considered all known TSCA uses, and focused on those that involved products with high 1-BP content, and those that were emissive, exhibiting high potential for worker and/or consumer exposure. Occupational uses of concern identified for 1-BP included its use in spray adhesives, dry cleaning (including spot cleaning) and degreasing (vapor, cold cleaning and aerosol). Consumer uses identified for 1-BP included aerosol spray adhesives, aerosol spot removers and aerosol cleaning and degreasing products, many of which were identified to contain 60-100% 1-BP. EPA expects to consider all these uses identified in the [2016 Draft Risk Assessment](#). In addition, in the [2016 Draft Risk Assessment](#), EPA reviewed the evidence for 1-BP toxicity and selected liver toxicity, kidney toxicity, reproductive/developmental toxicity, neurotoxicity and cancer as the most robust, sensitive and consistent adverse human health effects for risk characterization. EPA expects to use these previous analyses and also expects to consider other studies (e.g., more recently published, alternative test data) that have been published since the [2016 Draft Risk Assessment](#), as identified in the literature search conducted by the Agency for 1-BP (*1-Bromopropane (CASRN 106-94-5) Bibliography: Supplemental File for the TSCA Scope Document* ([EPA-HQ-OPPT-2016-0741](#))). Furthermore, the identified activities/uses, exposure pathways, routes of exposures, receptors, hazards and dose-response analyses conducted in the [2016 Draft Risk Assessment](#) were recently released for public comment (March 2016) and then subsequently peer reviewed by the Chemical Safety and Advisory Council (CSAC) Peer Review (May 24-25, 2016; [EPA-HQ-OPPT-2015-0805-0028](#)). EPA also expects to consider the comments received by the public as well as the recommendations made by the CSAC peer reviewers to incorporate a life cycle approach that includes manufacturing, processing, distribution and use activities/scenarios; exposures via dermal and oral exposures; and additional receptors, for example, the general population and those populations co-located with dry cleaning facilities that use 1-BP.

EPA also published a draft notice (January 9, 2017) on the rationale for granting the petitions to add 1-BP to the list of hazardous air pollutants (HAPs), which included a review of both the exposure potential and hazard characterization for 1-BP (<https://www.regulations.gov/document?D=EPA-HQ-OAR-2014-0471-0062>).

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<sup>2</sup> The full February 2016 Draft Risk Assessment can be found at: [https://www.epa.gov/sites/production/files/2016-03/documents/1-BP\\_report\\_and\\_appendices\\_final.pdf](https://www.epa.gov/sites/production/files/2016-03/documents/1-BP_report_and_appendices_final.pdf).

**Table 1-1. Assessment History of 1-BP**

Authoring Organization	Assessment
<b>EPA Assessments</b>	
Office of Chemical Safety and Pollution Prevention (OCSP)/Office of Pollution Prevention and Toxics (OPPT)	<a href="#">TSCA work plan chemical risk assessment: Peer review draft 1-bromopropane: (n-Propyl bromide) spray adhesives, dry cleaning, and degreasing uses CASRN: 106-94-5 (2016b)</a>
Office of Air Quality Planning and Standards (OAQPS)	Draft notice to grant the petition to add 1-BP to the list of HAPs ( <a href="https://www.regulations.gov/document?D=EPA-HQ-OAR-2014-0471-0062">https://www.regulations.gov/document?D=EPA-HQ-OAR-2014-0471-0062</a> )
<b>Other U.S.-Based Organizations</b>	
National Institute for Occupational Safety and Health (NIOSH)	<a href="#">Criteria for a Recommended Standard: Occupational Exposure to 1-Bromopropane (2016)</a>
Agency for Toxic Substances and Disease Registry (ATSDR)	<a href="#">Toxicological Profile for 1-Bromopropane (2016)</a>

### 1.3 Data and Information Collection

EPA/OPPT generally applies a process and workflow that includes: (1) data collection; (2) data evaluation; and (3) data integration of the scientific data used in risk assessments developed under TSCA. Scientific analysis is often iterative in nature as new knowledge is obtained. Hence, EPA/OPPT expects that multiple refinements regarding data collection will occur during the process of risk evaluation.

#### **Data Collection: Data Search**

EPA/OPPT conducted chemical-specific searches for data and information on: physical and chemical properties; environmental fate and transport; conditions of use information; environmental exposures, human exposures, including potentially exposed or susceptible subpopulations; ecological hazard, human health hazard, including potentially exposed or susceptible subpopulations.

EPA/OPPT designed its initial data search to be broad enough to capture a comprehensive set of sources containing data and/or information potentially relevant to the risk evaluation. Generally, the search was not limited by date and was conducted on a wide range of data sources, including but not limited to: peer-reviewed literature and gray literature (e.g., publicly-available industry reports, trade association resources, government reports). When available, EPA/OPPT relied on the search strategies from recent assessments, such as EPA Integrated Risk Information System (IRIS) assessments and the National Toxicology Program’s (NTP) *Report on Carcinogens* ([NTP, 2013](#)), to identify relevant references and supplemented these searches to identify relevant information published after the end date of the previous search to capture more recent literature. *Strategy for Conducting Literature Searches for 1-Bromopropane: Supplemental File for the TSCA Scope Document* ([EPA-HQ-OPPT-2016-0741](#)) provides details about the data sources and search terms that were used in the initial search.

### **Data Collection: Data Screening**

Following the data search, references were screened and categorized using selection criteria outlined in the *Strategy for Conducting Literature Searches for 1-Bromopropane: Supplemental File for the TSCA Scope Document* ([EPA-HQ-OPPT-2016-0741](#)). Titles and abstracts were screened against the criteria as a first step with the goal of identifying a smaller subset of the relevant data to move into the subsequent data extraction and data evaluation steps. Prior to full-text review, EPA/OPPT anticipates refinements to the search and screening strategies, as informed by an evaluation of the performance of the initial title/abstract screening and categorization process.

The categorization scheme (or tagging structure) used for data screening varies by scientific discipline (i.e., physical and chemical properties; environmental fate and transport; chemical use/conditions of use information; human and environmental exposures, including potentially exposed or susceptible subpopulations identified by virtue of greater exposure; human health hazard, including potentially exposed or susceptible subpopulations identified by virtue of greater susceptibility; and ecological hazard), but within each data set, there are two broad categories or data tags: (1) *on-topic* references or (2) *off-topic* references. *On-topic* references are those that may contain data and/or information relevant to the risk evaluation. *Off-topic* references are those that do not appear to contain data or information relevant to the risk evaluation. The *Strategy for Conducting Literature Searches for 1-Bromopropane: Supplemental File for the TSCA Scope Document* ([EPA-HQ-OPPT-2016-0741](#)) discusses the inclusion and exclusion criteria that EPA/OPPT used to categorize references as *on-topic* or *off-topic*.

Additional data screening using sub-categories (or sub-tags) was also performed to facilitate further sorting of data/information for example, identifying references by source type (e.g., published peer-reviewed journal article, government report); data type (e.g., primary data, review article); human health hazard (e.g., liver toxicity, cancer, reproductive toxicity); or chemical-specific and use-specific data or information. These sub-categories are described in *Strategy for Conducting Literature Searches for 1-Bromopropane: Supplemental File for the TSCA Scope Document* ([EPA-HQ-OPPT-2016-0741](#)) and will be used to organize the different streams of data during the stages of data evaluation and data integration steps of systematic review.

Results of the initial search and categorization results can be found in the *1-Bromopropane (CASRN 106-94-5) Bibliography: Supplemental File for the TSCA Scope Document* ([EPA-HQ-OPPT-2016-0741](#)). This document provides a comprehensive list (bibliography) of the sources of data identified by the initial search and the initial categorization for *on-topic* and *off-topic* references. Because systematic review is an iterative process, EPA/OPPT expects that some references may move from the *on-topic* to the *off-topic* categories, and vice versa. Moreover, targeted supplemental searches may also be conducted to address specific needs for the analysis phase (e.g., to locate specific data needed for modeling); hence, additional *on-topic* references not initially identified in the initial search may be identified as the systematic review process proceeds.

## 2 SCOPE OF THE EVALUATION

As required by TSCA, the scope of the risk evaluation identifies the conditions of use, hazards, exposures and potentially exposed or susceptible subpopulations that the Administrator expects to consider. To communicate and visually convey the relationships between these components, EPA is including an initial life cycle diagram and initial conceptual models that describe the actual or potential relationships between 1-BP and human and ecological receptors. An initial analysis plan is also included which identifies, to the extent feasible, the approaches and methods that EPA may use to assess exposures, effects (hazards) and risks under the conditions of use of 1-BP. As noted previously, EPA intends to refine this analysis plan during the problem formulation phase of risk evaluation.

### 2.1 Physical and Chemical Properties

Physical-chemical properties influence the environmental behavior and the toxic properties of a chemical, thereby informing the potential conditions of use, exposure pathways and routes and hazards that EPA intends to consider. For scope development, EPA considered the measured or estimated physical-chemical properties set forth in Table 2-1.

**Table 2-1. Physical and Chemical Properties of 1-BP**

Property	Value <sup>a</sup>	References
Molecular formula	C <sub>3</sub> H <sub>7</sub> Br	<a href="#">O'Neil (2013)</a>
Molecular weight	122.99	<a href="#">O'Neil (2013)</a>
Physical form	Colorless liquid; sweet hydrocarbon odor	<a href="#">O'Neil (2013)</a>
Melting point	-110°C	<a href="#">O'Neil (2013)</a>
Boiling point	71°C at 760 mmHg	<a href="#">O'Neil (2013)</a>
Density	1.353 g/cm <sup>3</sup> at 20°C	<a href="#">O'Neil (2013)</a>
Vapor pressure	146.26 mmHg (19.5 kPa) at 20°C	<a href="#">Boublík et al. (1984)</a>
Vapor density	4.25 (relative to air)	<a href="#">Patty et al. (1963)</a>
Water solubility	2.450 g/L at 20°C	<a href="#">Yalkowsky et al. (2010)</a>
Octanol/water partition coefficient (Log K <sub>ow</sub> )	2.10	<a href="#">Hansch (1995)</a>
Henry's Law constant	7.3x10 <sup>-3</sup> atm·m <sup>3</sup> /mole (estimated)	<a href="#">U.S. EPA (2012a)</a>
Flash point	22°C	<a href="#">O'Neil (2013)</a>
Autoflammability	490°C	<a href="#">NFPA (2010)</a>
Viscosity	5.241 mPa · s at 20°C	<a href="#">Haynes and Lide (2010)</a>
Refractive index	1.4341	<a href="#">O'Neil (2013)</a>
Dielectric constant	8.09 at 20°C	<a href="#">Haynes and Lide (2010)</a>

<sup>a</sup> Measured unless otherwise noted.

## 2.2 Conditions of Use

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TSCA § 3(4) defines the conditions of use as “the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.”

### 2.2.1 Data and Information Sources

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As the first step in preparing these scope documents, EPA identified, based on reasonably available information, the conditions of use for the subject chemicals. As further described in this document, EPA searched a number of available data sources (e.g., *Use and Market Profile for 1-Bromopropane*, [EPA-HQ-OPPT-2016-0741](#)). Based on this search, EPA published a preliminary list of information and sources related to chemical conditions of use (see *Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: 1-Bromopropane*, [EPA-HQ-OPPT-2016-0741-0003](#)) prior to a February 2017 public meeting on scoping efforts for risk evaluation convened to solicit comment and input from the public. EPA also convened meetings with companies, industry groups, chemical users and other stakeholders to aid in identifying conditions of use and verifying conditions of use identified by EPA. The information and input received from the public and stakeholder meetings has been incorporated into this scope document to the extent appropriate, as indicated in Table 2-3. Thus, EPA believes the manufacture, processing, distribution, use and disposal activities identified in these documents constitute the intended, known, and reasonably foreseen activities associated with the subject chemicals, based on reasonably available information. The documents do not, in most cases, specify whether activity under discussion is intended, known, or reasonably foreseen, in part due to the time constraints in preparing these documents.

### 2.2.2 Identification of Conditions of Use

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As part of the scope, an initial life cycle diagram is provided (Figure 2-1) depicting the conditions of use that are within the scope of the risk evaluation during various life cycle stages including manufacturing, processing, use (industrial, commercial, consumer; when distinguishable), distribution and disposal. The information is grouped according to Chemical Data Reporting (CDR) processing codes and use categories (including functional use codes for industrial uses and product categories for industrial, commercial and consumer uses), in combination with other data sources (e.g., published literature and consultation with stakeholders), to provide an overview of conditions of use. EPA notes that some subcategories of use may be grouped under multiple CDR categories.

For the purposes of this scope, CDR definitions were used. CDR use categories include the following: “industrial use” means use at a site at which one or more chemicals or mixtures are manufactured (including imported) or processed. “Commercial use” means the use of a chemical or a mixture containing a chemical (including as part of an article) in a commercial enterprise providing saleable goods or services. “Consumer use” means the use of a chemical or a mixture containing a chemical (including as part of an article, such as furniture or clothing) when sold to or made available to consumers for their use ([U.S. EPA, 2016a](#)).

To understand conditions of use relative to one another and associated potential exposures under those conditions of use, the life cycle diagram includes the production volume associated with each stage of the life cycle, as reported in the 2016 CDR reporting ([U.S. EPA, 2016a](#)), when the volume was not claimed confidential business information (CBI). The 2016 CDR reporting data for 1-BP are provided in Table 2-2 for 1-BP from EPA’s CDR database ([U.S. EPA, 2016a](#)).

**Table 2-2. Production Volume of 1-BP in CDR Reporting Period (2012 to 2015) <sup>a</sup>**

Reporting Year	2012	2013	2014	2015
Total Aggregate Production Volume (lbs)	18,800,000	24,000,000	18,500,000	25,900,000

<sup>a</sup> The CDR data for the 2016 reporting period is available via ChemView (<https://java.epa.gov/chemview>) (U.S. EPA, 2016a). Because of an ongoing CBI substantiation process required by amended TSCA, the CDR data available in the scope document is more specific than currently in ChemView.

According to data collected in EPA's [2016 Chemical Data Reporting \(CDR\)](#) Rule, 25.9 million pounds of 1-BP were produced or imported in the United States in 2015 (U.S. EPA, 2016a). Data reported indicate that there are two manufacturers and six importers of 1-BP in the United States. Additional companies manufacturing or importing 1-BP are claimed as CBI.

Total production volume (manufacture plus import) of 1-BP has increased from 2012 to 2015, as can be seen in Table 2-2 (U.S. EPA, 2016a). 1-BP's use has increased because it has been an alternative to ozone-depleting substances and chlorinated solvents. Import volumes for 1-BP reported to the [2016 CDR](#) are between 10 million and 25 million pounds per year (U.S. EPA, 2016a). In past years, import data from 1-BP were claimed as CBI, but import data from other sources indicate that import volumes of brominated derivatives of acyclic hydrocarbons (which includes 1-BP as well as other chemicals) were 10.9 million pounds in 2007, which dropped to 10.3 million pounds in 2011 (NTP, 2013).

Figure 2-1 depicts the initial life cycle diagram for 1-BP from manufacture to the point of disposal. This diagram does not distinguish between industrial, commercial and consumer uses; EPA will further investigate and define the differences between these uses during problem formulation. Based on market information from other sources, EPA expects degreasing and spray adhesive to be the primary uses of 1-BP; however, the exact use volumes associated with these categories are claimed CBI in the [2016 CDR](#) and are therefore not shown in the diagram (U.S. EPA, 2016a). Activities related to distribution (e.g., loading, unloading) will be considered throughout the 1-BP life cycle, rather than using a single distribution scenario. EPA expects that some commercial products containing 1-BP are also available for purchase by consumers, such that many products are used in both commercial and consumer applications/scenarios. EPA will further investigate 1-BP use in these products during the risk evaluation process.

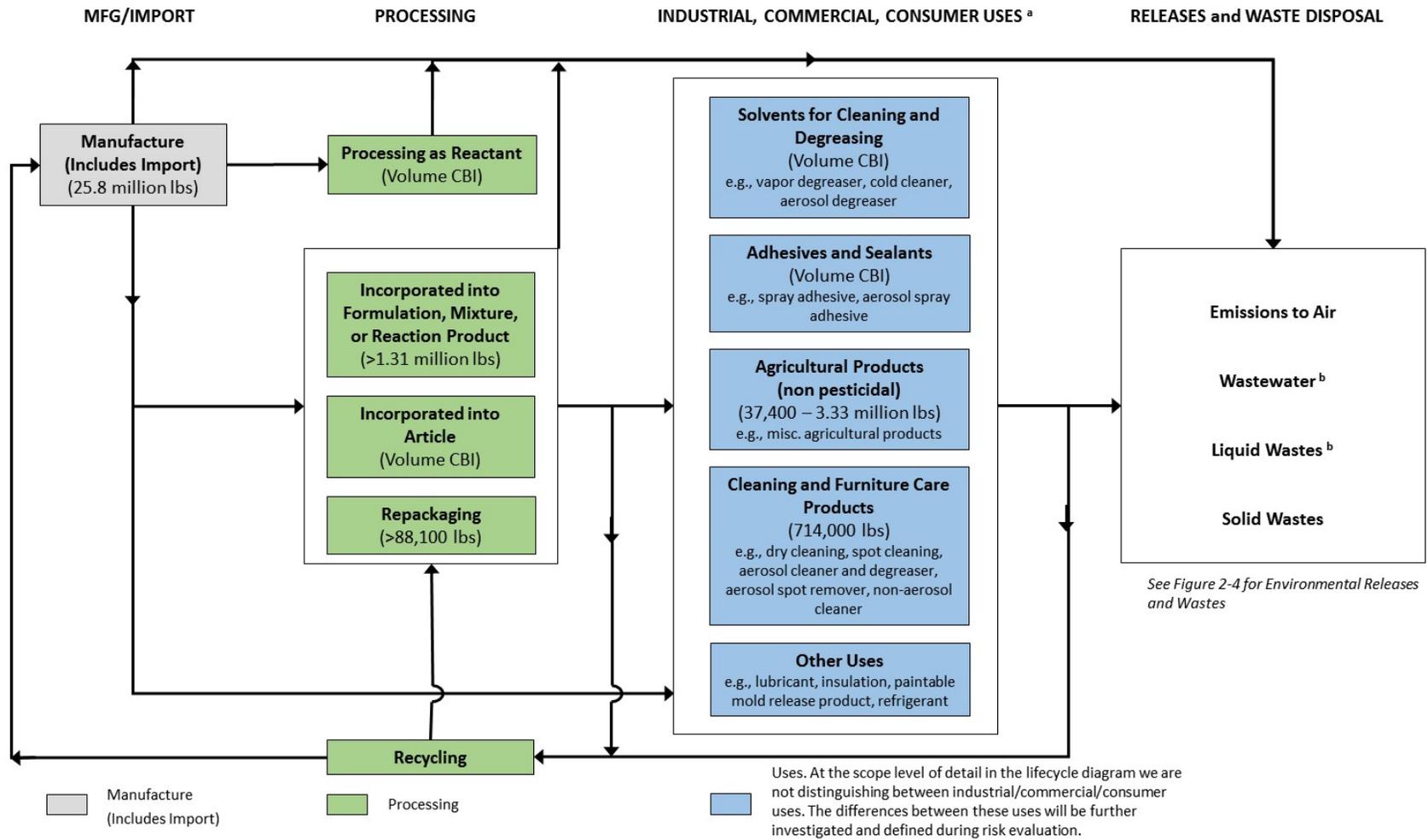
Descriptions of the industrial, commercial and consumer use categories identified from the [2016 CDR](#) and included in the life cycle diagram are summarized below (U.S. EPA, 2016a). The descriptions provide a brief overview of the use category; Appendix B contains more detailed descriptions (e.g., process descriptions, worker activities, process flow diagrams, equipment illustrations) for each manufacture, processing, distribution, use and disposal category. The descriptions provided below are primarily based on the corresponding industrial function category and/or commercial and consumer product category descriptions from the [2016 CDR](#) and can be found in EPA's [Instructions for Reporting 2016 TSCA Chemical Data Reporting \(U.S. EPA 2016\)](#) (U.S. EPA, 2016a).

The "***Solvents for Cleaning and Degreasing***" category encompasses chemical substances used to dissolve oils, greases and similar materials from a variety of substrates, including metal surfaces,

glassware and textile. This category includes the use of 1-BP in vapor degreasing, cold cleaning and in industrial and commercial aerosol degreasing products.

The “**Adhesives and Sealants**” category encompasses chemical substances contained in adhesive and sealant products used to fasten other materials together. EPA anticipates that a subcategory within the Adhesives and Sealants category is the use of 1-BP as a solvent in spray adhesive for foam cushion manufacturing. This category also covers uses of 1-BP in other adhesive products.

The “**Cleaning and Furniture Care Products**” category encompasses chemical substances contained in products that are used to remove dirt, grease, stains and foreign matter from furniture and furnishings, or to cleanse, sanitize, bleach, scour, polish, protect or improve the appearance of surfaces. This category includes a wide variety of 1-BP uses, including, but not limited to, the use of 1-BP as dry cleaning solvent, in spot cleaning formulations and in aerosol and non-aerosol type cleaners.



**Figure 2-1. Initial 1-BP Life Cycle Diagram**

The initial life cycle diagram depicts the conditions of use that are within the scope of the risk evaluation during various life cycle stages including manufacturing, processing, use (industrial, commercial, consumer), distribution and disposal. The production volumes shown are for reporting year 2015 from the 2016 CDR reporting period ([U.S. EPA, 2016a](#)). Activities related to distribution (e.g., loading, unloading) will be considered throughout the 1-BP life cycle, rather than using a single distribution scenario.

<sup>a</sup> See Table 2-3 for additional uses not mentioned specifically in this diagram.

<sup>b</sup> Wastewater: combination of water and organic liquid, where the organic content is <50%. Liquid wastes: combination of water and organic liquid, where the organic content is >50%.

Table 2-3 summarizes each life cycle stage and the corresponding categories and subcategories of conditions of use for 1-BP that EPA expects to consider in the risk evaluation. Using the [2016 CDR](#), EPA identified industrial processing or use activities, industrial function categories and commercial and consumer use product categories. EPA identified the subcategories by supplementing CDR data with other published literature and information obtained through stakeholder consultations. For risk evaluations, EPA intends to consider each life cycle stage (and corresponding use categories and subcategories) and assess relevant potential sources of release and human exposure associated with that life cycle stage.

**Table 2-3. Categories and Subcategories of Conditions of Use for 1-BP**

Life Cycle Stage	Category <sup>a</sup>	Subcategory <sup>b</sup>	References
Manufacture	Domestic manufacture	Domestic manufacture	<a href="#">U.S. EPA (2016a)</a>
	Import	Import	<a href="#">U.S. EPA (2016a)</a>
Processing	Processing as a reactant	Intermediate in all other basic inorganic chemical manufacturing, all other basic organic chemical manufacturing, and pesticide, fertilizer and other agricultural chemical manufacturing	<a href="#">U.S. EPA (2016a)</a>
	Processing - incorporating into formulation, mixture or reaction product	Solvents for cleaning or degreasing in manufacturing of: <ul style="list-style-type: none"> <li>- all other chemical product and preparation</li> <li>- computer and electronic product</li> <li>- electrical equipment, appliance and component</li> <li>- soap, cleaning compound and toilet preparation</li> <li>- services</li> </ul>	<a href="#">U.S. EPA (2016a)</a>
	Processing - incorporating into articles	Solvents (which become part of product formulation or mixture) in construction	<a href="#">U.S. EPA (2016a)</a> ; Public Comment, <a href="#">EPA-HQ-OPPT-2016-0741-0017</a>
	Repackaging	Solvent for cleaning or degreasing in all other basic organic chemical manufacturing	<a href="#">U.S. EPA (2016a)</a>
	Recycling	Recycling	<a href="#">U.S. EPA (2016a)</a> ; Use Document, <a href="#">EPA-HQ-OPPT-2016-0741-0003</a>

Life Cycle Stage	Category <sup>a</sup>	Subcategory <sup>b</sup>	References
Distribution in commerce	Distribution	Distribution	<a href="#">U.S. EPA (2016a)</a> ; Use Document, <a href="#">EPA-HQ-OPPT-2016-0741-0003</a>
Industrial/ commercial/ consumer use	Solvent (for cleaning or degreasing)	Batch vapor degreaser (e.g., open-top, closed-loop)	<a href="#">U.S. EPA (2016b)</a> ; Public Comment, <a href="#">EPA-HQ-OPPT-2016-0741-0014</a> ; Public Comment, <a href="#">EPA-HQ-OPPT-2016-0741-0015</a> ; Public Comment, <a href="#">EPA-HQ-OPPT-2016-0741-0016</a>
		In-line vapor degreaser (e.g., conveyORIZED, web cleaner)	<a href="#">Kanegsberg and Kanegsberg (2011)</a> ; Public Comment, <a href="#">EPA-HQ-OPPT-2016-0741-0014</a> ; Public Comment, <a href="#">EPA-HQ-OPPT-2016-0741-0016</a>
		Cold cleaner	<a href="#">U.S. EPA (2016b)</a> ; Public Comment, <a href="#">EPA-HQ-OPPT-2016-0741-0016</a>
		Aerosol spray degreaser/cleaner	<a href="#">U.S. EPA (2016b)</a> ; Public Comment, <a href="#">EPA-HQ-OPPT-2016-0741-0016</a> ; Public Comment, <a href="#">EPA-HQ-OPPT-2016-0741-0018</a> ; Public Comment, <a href="#">EPA-HQ-OPPT-2016-0741-0020</a>
		Adhesives and sealants	<a href="#">U.S. EPA (2016b)</a> ; Public Comment, <a href="#">EPA-HQ-OPPT-2016-0741-0016</a>
		Agricultural products (non-pesticidal)	Miscellaneous agricultural products

Life Cycle Stage	Category <sup>a</sup>	Subcategory <sup>b</sup>	References
Industrial/ commercial/ consumer use (continued)	Cleaning and furniture care products	Dry cleaning solvent	<a href="#">U.S. EPA (2016b)</a> ; Public Comment, <a href="#">EPA-HQ-OPPT-2016-0741-0005</a> ; Public Comment, <a href="#">EPA-HQ-OPPT-2016-0741-0016</a>
		Spot cleaner, stain remover	<a href="#">U.S. EPA (2016b)</a> ; Public Comment, <a href="#">EPA-HQ-OPPT-2016-0741-0016</a> ; Public Comment, <a href="#">EPA-HQ-OPPT-2016-0741-0022</a>
		Liquid cleaner (e.g., coin and scissor cleaner)	Use Document, <a href="#">EPA-HQ-OPPT-2016-0741-0003</a>
		Liquid spray/aerosol cleaner	Use Document, <a href="#">EPA-HQ-OPPT-2016-0741-0003</a>
	Other uses	Arts, crafts and hobby materials - adhesive accelerant	<a href="#">U.S. EPA (2016b)</a>
		Automotive care products - engine degreaser, brake cleaner	Use Document, <a href="#">EPA-HQ-OPPT-2016-0741-0003</a>
		Anti-adhesive agents - mold cleaning and release product	<a href="#">U.S. EPA (2016b)</a> ; Public Comment, <a href="#">EPA-HQ-OPPT-2016-0741-0014</a> ; Public Comment, <a href="#">EPA-HQ-OPPT-2016-0741-0015</a> ; Public Comment, <a href="#">EPA-HQ-OPPT-2016-0741-0016</a> ; Public Comment, <a href="#">EPA-HQ-OPPT-2016-0741-0018</a>
		Building/construction materials not covered elsewhere - insulation	Use Document, <a href="#">EPA-HQ-OPPT-2016-0741-0003</a> ; Public Comment, <a href="#">EPA-HQ-OPPT-2016-0741-0027</a>

Life Cycle Stage	Category <sup>a</sup>	Subcategory <sup>b</sup>	References
Industrial/ commercial/ consumer use (continued)	Other uses	Electronic and electronic products and metal products	<a href="#">U.S. EPA (2016a)</a> ; Public Comment, <a href="#">EPA-HQ-OPPT-2016-0741-0016</a> ; Public Comment, <a href="#">EPA-HQ-OPPT-2016-0741-0024</a>
		Functional fluids (closed systems) - refrigerant	Use Document, <a href="#">EPA-HQ-OPPT-2016-0741-0003</a>
		Functional fluids (open system) - cutting oils	Use Document, <a href="#">EPA-HQ-OPPT-2016-0741-0003</a> ; Public Comment, <a href="#">EPA-HQ-OPPT-2016-0741-0014</a>
		Other - asphalt extraction	Use Document, <a href="#">EPA-HQ-OPPT-2016-0741-0003</a> ; Public Comment, <a href="#">EPA-HQ-OPPT-2016-0741-0016</a>
		Temperature Indicator – Laboratory chemicals	Use Document, <a href="#">EPA-HQ-OPPT-2016-0741-0003</a>
		Temperature Indicator – Coatings	Use Document, <a href="#">EPA-HQ-OPPT-2016-0741-0003</a> ; Public Comment, <a href="#">EPA-HQ-OPPT-2016-0741-0014</a> ; Public Comment, <a href="#">EPA-HQ-OPPT-2016-0741-0016</a>

Life Cycle Stage	Category <sup>a</sup>	Subcategory <sup>b</sup>	References	
Disposal	Emissions to air	Air	<a href="#">U.S. EPA (2017b)</a> ; based on Toxic Release Inventory (TRI) information of other work plan chemicals including trichloroethylene (TCE) and perchloroethylene (PERC)	
	Wastewater	Industrial pre-treatment		
		Industrial wastewater treatment		
		Publicly owned treatment works (POTW)		
		Underground injection		
	Liquid and solid wastes	Municipal landfill		
		Hazardous landfill		
		Other land disposal		
		Municipal waste incinerator		
		Hazardous waste incinerator		
		Off-site waste transfer		
<sup>a</sup> These categories of conditions of use appear in the Life Cycle Diagram, reflect CDR codes and broadly represent conditions of use of 1-BP in industrial and/or commercial settings. <sup>b</sup> These subcategories reflect more specific uses of 1-BP.				

## 2.3 Exposures

For TSCA exposure assessments, EPA expects to evaluate exposures and releases to the environment resulting from the conditions of use applicable to 1-BP. Post-release pathways and routes will be described to characterize the relationship or connection between the conditions of use of 1-BP and the exposure to human receptors, including potentially exposed or susceptible subpopulations and ecological receptors. EPA will take into account, where relevant, the duration, intensity (concentration), frequency and number of exposures in characterizing exposures to 1-BP.

### 2.3.1 Fate and Transport

Environmental fate includes both transport and transformation processes. Environmental transport is the movement of the chemical within and between environmental media. Transformation occurs through the degradation or reaction of the chemical with other species in the environment. Hence, knowledge of the environmental fate of the chemical informs the determination of the specific exposure pathways and potential human and environmental receptors EPA expects to consider in the risk evaluation. Table 2-4 provides environmental fate data that EPA has identified and considered in developing the scope for 1-BP.

**Table 2-4. Environmental Fate Characteristics of 1-BP**

Property or Endpoint	Value <sup>a</sup>	References
Indirect photodegradation	9-12 days (estimated for atmospheric degradation)	<a href="#">U.S. EPA (2016b)</a>
Hydrolysis half-life	26 days	<a href="#">U.S. EPA (2016b)</a>
Biodegradation	70% in 28 days (OECD 301C) 19.2% in 28 days (OECD 301D)	<a href="#">U.S. EPA (2016b)</a>
Bioconcentration factor (BCF)	11 (estimated)	<a href="#">U.S. EPA (2012a)</a>
Bioaccumulation factor (BAF)	12 (estimated)	<a href="#">U.S. EPA (2016b)</a>
Organic carbon:water partition coefficient (Log K <sub>oc</sub> )	1.6 (estimated)	<a href="#">U.S. EPA (2016b)</a>
<sup>a</sup> Measured unless otherwise noted		

1-BP is a water soluble, volatile liquid and mobile in soil. Adsorption to soils is not expected; therefore, 1-BP can migrate through soil to ground water. 1-BP is degraded by sunlight and reactants when released to the atmosphere with a half-life of 9-12 days. Based on this estimated half-life in air, long-range transport via the atmosphere is possible. Volatilization and microbial degradation influence the fate of 1-BP when released to water, sediment or soil. Biotic and abiotic degradation rates ranging from days to months have been reported.

Biotic and abiotic degradation studies have not shown this substance to be persistent (overall environmental half-life of <2 months). No measured bioconcentration studies for 1-BP are available. An estimated BCF of 11 and an estimated BAF of 12 suggest that bioconcentration and bioaccumulation potential in aquatic organisms is low (BCF/BAF <1,000).

### **2.3.2 Releases to the Environment**

Releases to the environment from conditions of use (e.g., industrial and commercial processes, commercial or consumer uses resulting in down-the-drain releases) are one component of potential exposure and may be derived from reported data that are obtained through direct measurement, calculations based on empirical data and/or assumptions and models.

Based on its high volatility (vapor pressure of 146.26 mmHg at 20°C), 1-BP is expected to be released to air during manufacturing, processing, distribution and use.

Wastes containing 1-BP may be present in either liquid form (e.g., spent solvent) or solid form (e.g., rags, wipe materials, transport containers with 1-BP residue). Industrial wastes containing 1-BP may be incinerated. While 1-BP does not meet the definition of hazardous waste under the Resource Conservation and Recovery Act (RCRA), it may be present in or co-mingled with solvent mixtures that do meet the definition of hazardous waste under RCRA. Consumer wastes containing 1-BP may be disposed with general municipal wastes, which may be incinerated or landfilled. Depending on the incinerator destruction efficiency, the incineration of 1-BP may result in subsequent releases to air. Landfilling wastes containing 1-BP may result in subsequent fugitive emissions to air or migration to groundwater.

In general, EPA expects that releases of 1-BP to wastewater are unlikely. However, TRI data for similar solvents such as trichloroethylene suggest that water releases are possible. Therefore, this pathway is included in the conceptual model for completeness.

A source of information that EPA expects to consider in evaluating releases to the environment are data reported under the TRI program. EPA published a final rule on November 23, 2015 (80 FR 72906) to add 1-BP to the TRI chemical list, as 1-BP meets the Emergency Planning and Community Right-to-Know Act (EPCRA) Section 313(d)(2)(B) statutory listing criteria. Under this rule, 1-BP is reportable beginning with the 2016 calendar year with the first reporting forms from facilities due by July 1, 2017. For the 2016 reporting year, EPA expects that 140 facilities will file TRI reporting forms containing release and waste management data for 1-BP. Facilities are required to report if they manufacture (including import) or process more than 25,000 pounds of 1-BP, or if they otherwise use more than 10,000 pounds of 1-BP. EPA expects to consider these data in conducting the exposure assessment component of the risk evaluation for 1-BP.

### **2.3.3 Presence in the Environment and Biota**

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Monitoring studies or a collection of relevant and reliable monitoring studies provide(s) information that can be used in an exposure assessment. Monitoring studies that measure environmental concentrations or concentrations of chemical substances in biota provide evidence of exposure.

Environmental monitoring data were not identified in the [2016 Draft Risk Assessment \(U.S. EPA, 2016b\)](#); however, EPA expects to consider any environmental monitoring data that may result from the updated literature search. Biomonitoring data were identified in the [2016 Draft Risk Assessment](#). Several human and laboratory animal studies have investigated the utility of both urine and serum bromide ion levels, as well as urinary metabolites, as biomarkers of human exposure to 1-BP. EPA expects to consider the utility of this information in the risk evaluation.

### **2.3.4 Environmental Exposures**

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As shown in Figure 2-4, the manufacturing, processing, distribution, use and disposal of 1-BP can result in releases to water, air, and soil. EPA expects to consider exposures to the environment and ecological receptors that occur via these exposure pathways or media in conducting the risk evaluation for 1-BP.

### **2.3.5 Human Exposures**

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EPA expects to consider three broad categories of human exposures: occupational exposures, consumer exposures and general population exposures. Subpopulations within these exposure categories will also be considered as described herein.

#### **2.3.5.1 Occupational Exposures**

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EPA expects to consider worker activities where there is a potential for exposure under the various conditions of use described in Section 2.2. In addition, EPA expects to consider exposure to occupational non-users, who do not directly handle the chemical but perform work in an area where the chemical is present. When data and information are available to support the analysis, EPA also expects to consider the effect(s) that engineering controls and/or personal protective equipment have on occupational exposure levels.

In the [2016 Draft Risk Assessment \(U.S. EPA, 2016b\)](#), EPA evaluated inhalation exposures to 1-BP for occupational use in spray adhesives, dry cleaning (including spot cleaning) and degreasing (vapor, cold cleaning and aerosol). Based on information identified during this scoping, as described in Section 2.2, additional conditions of use resulting in occupational exposures will be considered during the risk evaluation.

Workers and occupational non-users may be exposed to 1-BP when performing activities associated with the conditions of use described in Section 2.2, including, but not limited to:

- Unloading and transferring 1-BP to and from storage containers and to process vessels;
- Handling, transporting and disposing waste containing 1-BP;
- Using 1-BP in process equipment (e.g., vapor degreasing machine);
- Cleaning and maintaining equipment;
- Sampling chemicals, formulations or products containing 1-BP for quality control (QC);
- Applying formulations and products containing 1-BP onto substrates (e.g., spray applying adhesive containing 1-BP onto furniture pieces);
- Performing other work activities in or near areas where 1-BP is used.

Based on these activities, EPA expects to consider inhalation exposure to vapor and mists and dermal exposure, including skin contact with liquids and vapors for workers and occupational non-users. EPA also expects to consider potential worker exposure through mists that deposit in the upper respiratory tract and are swallowed.

The Occupational Safety and Health Administration (OSHA) has not set permissible exposure limits (PELs) and the NIOSH has not recommended worker exposure limits (RELs) for 1-BP; however, NIOSH recently proposed a REL of 0.3 ppm ([Criteria for a Recommended Standard: Occupational Exposure to 1-Bromopropane \(2016\)](#); 81 FR 7122, February 10, 2016). A revised document was released for comment in January of 2017. The American Conference of Government Industrial Hygienists (ACGIH) has recommended a Threshold Limit Value (TLV) of 0.1 ppm 8-hour time-weighted average (TWA) 1-BP for workers ([ATSDR, 2016](#)). Also, ACGIH classifies 1-BP as a “confirmed animal carcinogen with unknown relevance in humans” and the Department of Health and Human Services classifies 1-BP as “reasonably anticipated to be a human carcinogen” based on NTPs *Report on Carcinogens* ([NTP, 2013](#)).

Key data that inform occupational exposure assessment and which EPA expects to consider include: the OSHA Chemical Exposure Health Data (CEHD) and NIOSH Health Hazard Evaluation (HHE) program data. OSHA data are workplace monitoring data from OSHA inspections. The inspections can be random or targeted, or can be the result of a worker complaint. OSHA data can be obtained through the OSHA Integrated Management Information System (IMIS) at <https://www.osha.gov/oshstats/index.html>. Table\_Apx B-1 in Appendix B provides a summary of industry sectors with 1-BP personal monitoring air samples obtained from OSHA inspections conducted between 2013 and 2016. NIOSH HHEs are conducted at the request of employees, union officials, or employers and help inform potential hazards at the workplace. HHEs can be downloaded at <https://www.cdc.gov/niosh/hhe/>. During the problem formulation, EPA will review these data and evaluate their utility in the risk evaluation.

### **2.3.5.2 Consumer Exposures**

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1-BP can be found in consumer products and/or commercial products that are readily available for public purchase at common retailers [[EPA-HQ-OPPT-2016-0741-0003](#), Sections 3 and 4 ([U.S. EPA, 2017a](#))] and can therefore result in exposures to consumers.

Exposures routes for consumers using products containing 1-BP may include inhalation of vapors and mists (e.g., aerosol spray applications), dermal exposure to products, and oral exposure through mists that deposit in the upper respiratory tract and are swallowed. Although less likely given the physical-chemical properties, oral exposure may also include ingestion of 1-BP residue on hand/body.

The previous [2016 Draft Risk Assessment \(U.S. EPA, 2016b\)](#) characterized inhalation exposures to 1-BP from the following uses:

1. Aerosol spray adhesives
2. Aerosol spot removers
3. Aerosol cleaners and degreasers (including engine degreasing, brake cleaning and electronics cleaning)

Acute inhalation exposures to consumers (such as residential users) and bystanders (those who may not be actively engaged in the use of the product, but may be in the room of use) in residential settings were assessed for the consumer uses identified in the [2016 Draft Risk Assessment \(U.S. EPA, 2016b\)](#). While it is anticipated that inhalation serves as the primary route of 1-BP exposure to consumers, additional exposure pathways will be considered, including dermal exposure from skin contact with liquids and vapor.

### **2.3.5.3 General Population Exposures**

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Wastewater/liquid wastes, solid wastes or air emissions of 1-BP could result in potential pathways for oral, dermal, or inhalation exposure to the general population. EPA will consider each media, route, and pathway to estimate general population exposures.

#### ***Inhalation***

The volatility of 1-BP makes inhalation exposures a likely exposure pathway when 1-BP is released (via air or as a result of waste disposal) during industrial/commercial use (see Figure 2-4). Inhalation of 1-BP may also occur in indoor settings as a result of co-location with dry cleaning facilities that use 1-BP.

Based on these potential sources and pathways of exposure, EPA expects to consider inhalation exposures to the general population that may result from the conditions of use of 1-BP.

#### ***Oral***

There is the potential for oral exposure to 1-BP by ingestion of water from contaminated surface water or ground water sources. Although incidental hand-to-mouth ingestion of soil may occur, adsorption to soils is not expected since 1-BP is volatile and mobile in soil (see Section 2.3.1); therefore, ingestion of soil is not expected to be a significant route of exposure and EPA is not expected to consider this route of exposure in the risk evaluation.

Based on these potential sources and pathways of exposure, EPA expects to consider oral exposures to the general population that may result from the conditions of use of 1-BP identified.

## ***Dermal***

Dermal exposure via water could occur through contact with contaminated surface or ground waters. Dermal exposure may also occur by contact with contaminated air in indoor settings (co-location with dry cleaners), however based on the physical and chemical properties of 1-BP, this is not expected to be the primary route of exposure.

Based on these potential sources and pathways of exposure, EPA does expect to consider dermal exposures to the general population that may result from the conditions of use of 1-BP.

### **2.3.5.4 Potentially Exposed or Susceptible Subpopulations**

TSCA requires that the determination of whether a chemical substance presents an unreasonable risk include consideration of unreasonable risk to “a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation” by EPA. TSCA § 3(12) states that “the term ‘potentially exposed or susceptible subpopulation’ means a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly.”

In this section, EPA addresses the potentially exposed or susceptible subpopulations identified as relevant based on greater exposure. EPA will address the subpopulations identified as relevant based on greater susceptibility in the hazard section.

Of the human receptors identified in the previous sections, EPA identifies the following as potentially exposed or susceptible subpopulations due to their *greater exposure* that EPA expects to consider in the risk evaluation:

- Workers and occupational non-users.
- Consumers and bystanders associated with consumer use. 1-BP has been identified as being used in products available to consumers; however, only some individuals within the general population may use these products. Therefore, those who do use these products are a potentially exposed or susceptible subpopulation due to greater exposure.
- Other groups of individuals within the general population who may experience greater exposures due to their proximity to conditions of use identified in Section 2.2 that result in releases to the environment and subsequent exposures (e.g., individuals who live or work near manufacturing, processing, distribution, use or disposal sites).

In developing scenarios, EPA will evaluate available data to ascertain whether some human receptor groups may be exposed via exposure pathways that may be distinct to a particular subpopulation or lifestage (e.g., children’s crawling, mouthing or hand-to-mouth behaviors) and whether some human receptor groups may have higher exposure via identified pathways of exposure due to unique characteristics (e.g., activities, duration or location of exposure) when compared with the general population ([U.S. EPA, 2006a](#)).

In summary, in the risk evaluation for 1-BP, EPA expects to consider the following potentially exposed groups of human receptors: workers, occupational non-users, consumers, bystanders associated with consumer use. As described above, EPA may also identify additional potentially exposed or susceptible subpopulations that will be considered based on greater exposure.

## 2.4 Hazards (Effects)

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For scoping, EPA conducted comprehensive searches for data on hazards of 1-BP, as described in *Strategy for Conducting Scoping-Level Literature Searches for 1-Bromopropane: Supplemental File for the TSCA Scope Document* ([EPA-HQ-OPPT-2016-0741](#)). Based on initial screening, EPA expects to consider the hazards of 1-BP identified in this scope document. However, when conducting the risk evaluation, the relevance of each hazard within the context of a specific exposure scenario will be judged for appropriateness. For example, hazards that occur only as a result of chronic exposures may not be applicable for acute exposure scenarios. This means that it is unlikely that every hazard identified in the scope will be considered for every exposure scenario.

### 2.4.1 Environmental Hazards

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For scoping purposes, EPA consulted the following sources of environmental hazard data for 1-BP: [European Chemicals Agency \(ECHA\)](#) ([ECHA, 2017](#)). However, EPA also expects to consider other studies (e.g., more recently published, alternative test data) that have been published since these reviews, as identified in the literature search conducted by the Agency for 1-BP (*1-Bromopropane (CASRN 106-94-5) Bibliography: Supplemental File for the TSCA Scope Document*, [EPA-HQ-OPPT-2016-0741](#)).

EPA expects to consider the hazards of 1-BP to aquatic organisms including fish, aquatic invertebrates and algae potentially exposed under acute and chronic exposure conditions.

For the [2016 Draft Risk Assessment](#) ([U.S. EPA, 2016b](#)), EPA reviewed and summarized available published studies on ecotoxicity ([U.S. EPA, 2012b, 1999](#)) to understand the potential effects of 1-BP releases on ecological receptors, including toxicity to fish, invertebrates, plants and birds. Based on that review, EPA concluded that the acute toxicity of 1-BP to aquatic organisms was low based on available data. The hazard of 1-BP was expected to be low for chronic aquatic organisms, sediment and terrestrial species based on physical and chemical properties of 1-BP. The [2016 Draft Risk Assessment](#) contains a summary of the aquatic toxicity studies considered during the initial ecological hazard evaluation for 1-BP.

### 2.4.2 Human Health Hazards

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1-BP does not have an existing EPA IRIS Assessment; however, EPA has previously reviewed data/information on health effects endpoints, identified hazards and conducted dose-response analysis in the [2016 Draft Risk Assessment](#) ([U.S. EPA, 2016b](#)); these hazard identification and dose-response analyses on 1-BP have been recently peer reviewed ([EPA-HQ-OPPT-2015-0805-0028](#)). EPA expects to use these previous analyses. EPA also expects to consider other studies (e.g., more recently published, alternative test data) that have been published since the [2016 Draft Risk Assessment](#), as identified in the literature search conducted by the Agency for 1-BP (*1-Bromopropane (CASRN 106-94-5) Bibliography: Supplemental File for the TSCA Scope Document* [EPA-HQ-OPPT-2016-0741](#)). EPA expects to consider all potential hazards associated with 1-BP. Based on reasonably available information, the following are the hazards that have been identified in previous government documents and that EPA currently expects will likely be the focus of its analysis.

#### 2.4.2.1 Non-Cancer Hazards

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For the [2016 Draft Risk Assessment](#) ([U.S. EPA, 2016b](#)) on 1-BP, EPA evaluated studies for the following non-cancer hazards: acute toxicity (acute lethality at high concentrations only), blood toxicity, immunotoxicity, cardiovascular toxicity, liver toxicity, kidney toxicity, reproductive toxicity, developmental toxicity, and neurotoxicity. A comprehensive summary of all endpoints considered can

be found in the [2016 Draft Risk Assessment](#). The following five health hazards were used for quantitative risk characterization:

### ***Liver Toxicity***

Reported effects include liver histopathology (e.g., hepatocellular vacuolation, swelling, degeneration and necrosis), increased liver weight and clinical chemistry changes indicative of hepatotoxicity [[2016 Draft Risk Assessment](#) (U.S. EPA, 2016b)].

### ***Kidney Toxicity***

Laboratory animal studies have provided evidence of kidney toxicity following 1-BP exposure. Reported kidney effects include increased organ weight, histopathology (pelvic mineralization, tubular casts) and associated clinical chemistry changes (e.g., increased blood urea nitrogen) [[2016 Draft Risk Assessment](#) (U.S. EPA, 2016b)]. Other kidney endpoints include increased incidence of pelvic mineralization in male and female rats from a subchronic duration inhalation study.

### ***Reproductive/Developmental Toxicity***

A two-generation reproduction study in rats reported a variety of adverse effects on male and female reproductive parameters (U.S. EPA, 2016b; [WIL Research, 2001](#)), including significant increases in the number of implantation sites, decreases in mating indices, increased estrous cycle length, increased numbers of females with evidence of mating without delivery, decreased absolute prostate and epididymal weights, decreased sperm motility and decreased mating and fertility indices. These findings are supported by similar reports of reproductive toxicity from other laboratory studies with rats and mice, including spermatogenic effects (decreased sperm count, altered sperm morphology and decreased sperm motility), organ weight changes in males (decreased epididymis, prostate and seminal vesicle weights), estrous cycle alterations and decreased numbers of antral follicles in females.

Developmental effects of 1-BP exposure have been evaluated on the basis of standard prenatal developmental toxicity studies, and a two-generation reproductive toxicity study in rats exposed via inhalation. Evidence for 1-BP-induced developmental toxicity includes dose-related adverse effects on live litter size, postnatal survival, pup body weight, brain weight and skeletal development.

### ***Neurotoxicity***

Data from studies in humans and animals demonstrate that the nervous system is a sensitive target of 1-BP exposure. Both the central and peripheral nervous systems are affected. Most inhalation studies using concentrations  $\geq 1,000$  ppm reported ataxia progressing to severely altered gait, hindlimb weakness to loss of hindlimb control, convulsions and death [[2016 Draft Risk Assessment](#) (U.S. EPA, 2016b)]. Other effects include neuropathological changes such as peripheral nerve degeneration, myelin sheath abnormalities and spinal cord axonal swelling. Brain pathology has also been reported in several studies, including white and gray matter vacuolization, degeneration of Purkinje cells in the cerebellum and decreased noradrenergic but not serotonergic axonal density in frontal cortex and amygdala. Decreased brain weight has been reported in adult and developmental studies. In a two-generation study, decreased brain weight in F1-generation males was reported.

Human studies (case-control studies, industrial surveys and case reports) corroborate that the nervous system is a sensitive target of 1-BP exposure in humans. Clinical signs of neurotoxicity (including headache, dizziness, weakness, numbness in lower extremities, ataxia, paresthesias and changes in

mood) and motor and sensory impairments were noted in the case reports of workers occupationally exposed to 1-BP for 2 weeks to 3 years, and in industrial surveys ranging from 2 weeks to 9 years [[2016 Draft Risk Assessment \(U.S. EPA, 2016b\)](#)].

#### **2.4.2.2 Genotoxicity and Cancer Hazards**

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There is some evidence for mutagenicity and deoxyribonucleic acid (DNA) damage associated with exposure to 1-BP in vitro, but the results are not conclusive as to whether and to what extent such effects may occur in mammals in vivo. 1-BP was mutagenic with or without metabolic activation, but other tests in bacteria for mutagenicity were negative. In vitro mammalian cell assays showed increased mutation frequency, and DNA damage was significantly increased in human leukocytes; however, tests conducted in vivo were mostly negative, including assays for dominant lethal mutations and micronuclei induction. An evaluation of leukocytes in workers exposed to 1-BP showed no definitive evidence of DNA damage. Positive results have been observed in several genotoxicity tests using known or postulated metabolites of 1-BP.

In the [2016 Draft Risk Assessment \(U.S. EPA, 2016b\)](#) on 1-BP, EPA evaluated cancer hazards from studies in laboratory animals and humans following chronic ( $\geq 10\%$  of a lifetime ([U.S. EPA, 2011](#))) inhalation exposures. Repeated exposures (e.g.,  $\geq 5$  consecutive days) are anticipated during chronic exposure. 1BP has been shown to be a multi-target carcinogen in rats and mice. The exact mechanism/mode of action of 1-BP carcinogenesis is not clearly understood, however, the weight-of-evidence analysis for the cancer endpoint is sufficient to support a probable mutagenic mode of action for 1-BP carcinogenesis. In the [2016 Draft Risk Assessment](#), EPA derived an inhalation unit risk (IUR) based on lung tumors in female mice.

#### **2.4.2.3 Potentially Exposed or Susceptible Subpopulations**

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TSCA requires that the determination of whether a chemical substance presents an unreasonable risk include consideration of unreasonable risk to “a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation” by EPA. TSCA § 3(12) states that “the term ‘potentially exposed or susceptible subpopulation’ means a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly.” In developing the hazard assessment, EPA will evaluate available data to ascertain whether some human receptor groups may have greater susceptibility than the general population to 1-BP’s hazard(s).

In the [2016 Draft Risk Assessment \(U.S. EPA, 2016b\)](#) on 1-BP, the evaluation of non-cancer risks associated with acute exposures was based on developmental toxicity in a rodent study ([WIL Research, 2001](#)), which is representative of a sensitive subpopulation (i.e., adult women of child-bearing age and their offspring). EPA consulted EPA’s [Guidelines for Developmental Toxicity Risk Assessment](#) when making the decision to use a developmental endpoint (i.e., decreased live litter size) as the basis of the dose-response analysis for acute exposures. More detailed information on this conclusion can be found in the [2016 Draft Risk Assessment](#).

## **2.5 Initial Conceptual Models**

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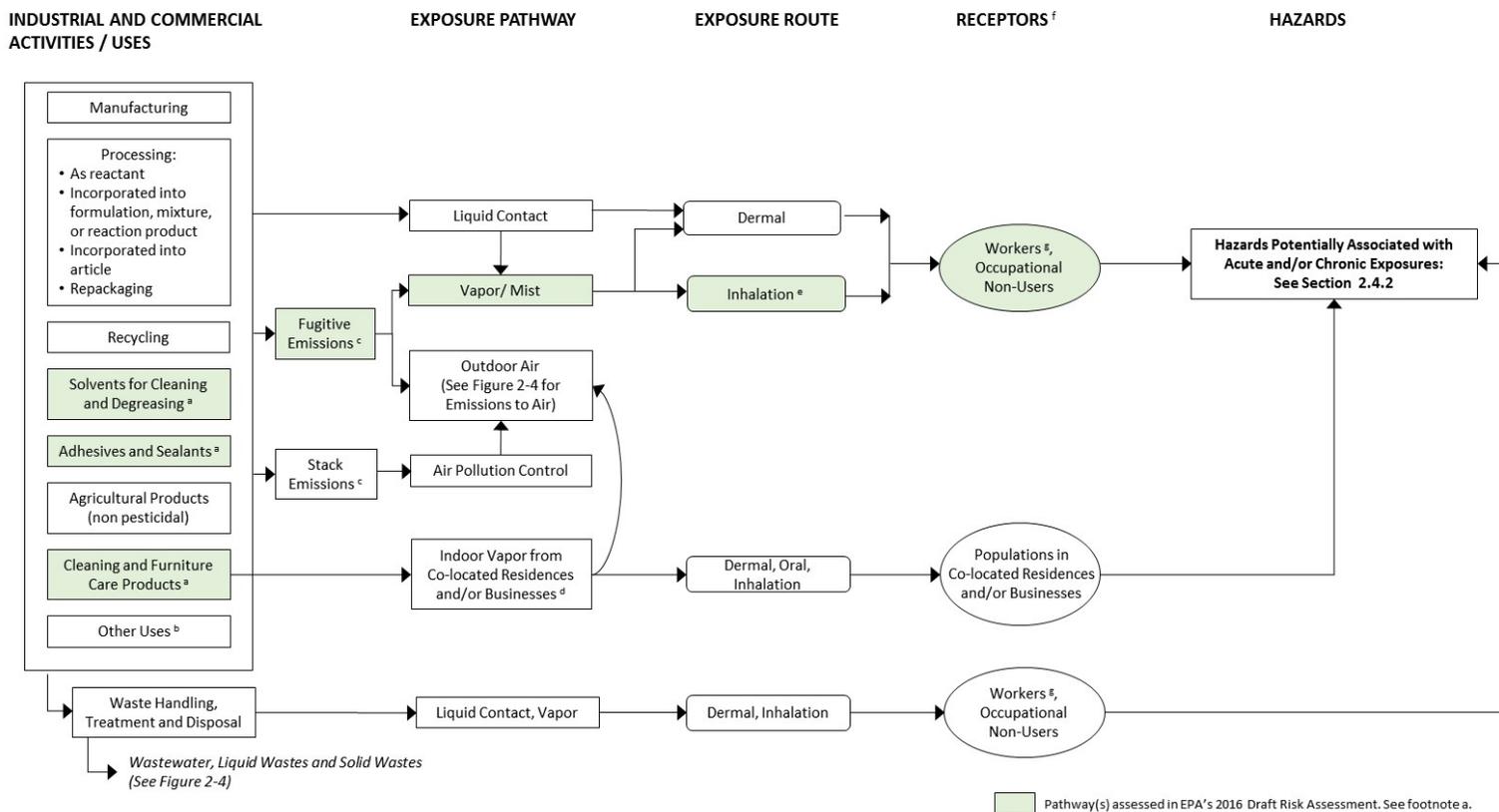
A conceptual model describes the actual or predicted relationships between the chemical substance and receptors, either human or environmental. These conceptual models are integrated depictions of

the conditions of use, exposures (pathways and routes), hazards and receptors. As part of the scope for 1-BP, EPA developed three conceptual models, presented here.

### **2.5.1 Initial Conceptual Model for Industrial and Commercial Activities and Uses: Potential Exposures and Hazards**

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Figure 2-2 presents the initial conceptual model for human receptors from industrial and commercial activities and uses of 1-BP. EPA anticipates that workers and occupational non-users may be exposed to 1-BP via inhalation and dermal routes. EPA anticipates inhalation of vapor and mist as being the most likely exposure routes. Certain conditions of use, such as maintenance of industrial degreasing tanks, can also result in dermal exposure. EPA expects to consider potential exposure to mists that deposit in the upper respiratory tract and are swallowed.



**Figure 2-2. Initial 1-BP Conceptual Model for Industrial and Commercial Activities and Uses: Potential Exposures and Hazards**

The conceptual model presents the exposure pathways, exposure routes and hazards to human receptors from industrial and commercial activities and uses of 1-BP.

<sup>a</sup> 2016 Risk Assessment of 1-BP ([U.S. EPA, 2016b](#)) assessed vapor degreasing, cold cleaning and aerosol degreasing in industrial settings and dry cleaning and spot cleaning in commercial settings (pathways shaded green).

<sup>b</sup> Some products are used in both commercial and consumer applications. Additional uses of 1-BP are included in Table 2-3.

<sup>c</sup> Stack air emissions are emissions that occur through stacks, confined vents, ducts, pipes or other confined air streams. Fugitive air emissions are those that are not stack emissions and include fugitive equipment leaks from valves, pump seals, flanges, compressors, sampling connections, open-ended lines; evaporative losses from surface impoundment and spills; and releases from building ventilation systems.

<sup>d</sup> Infiltration or re-uptake of outdoor air to indoor air from co-located residences and/or businesses.

<sup>e</sup> Exposure may occur through mists that deposit in the upper respiratory tract and are swallowed.

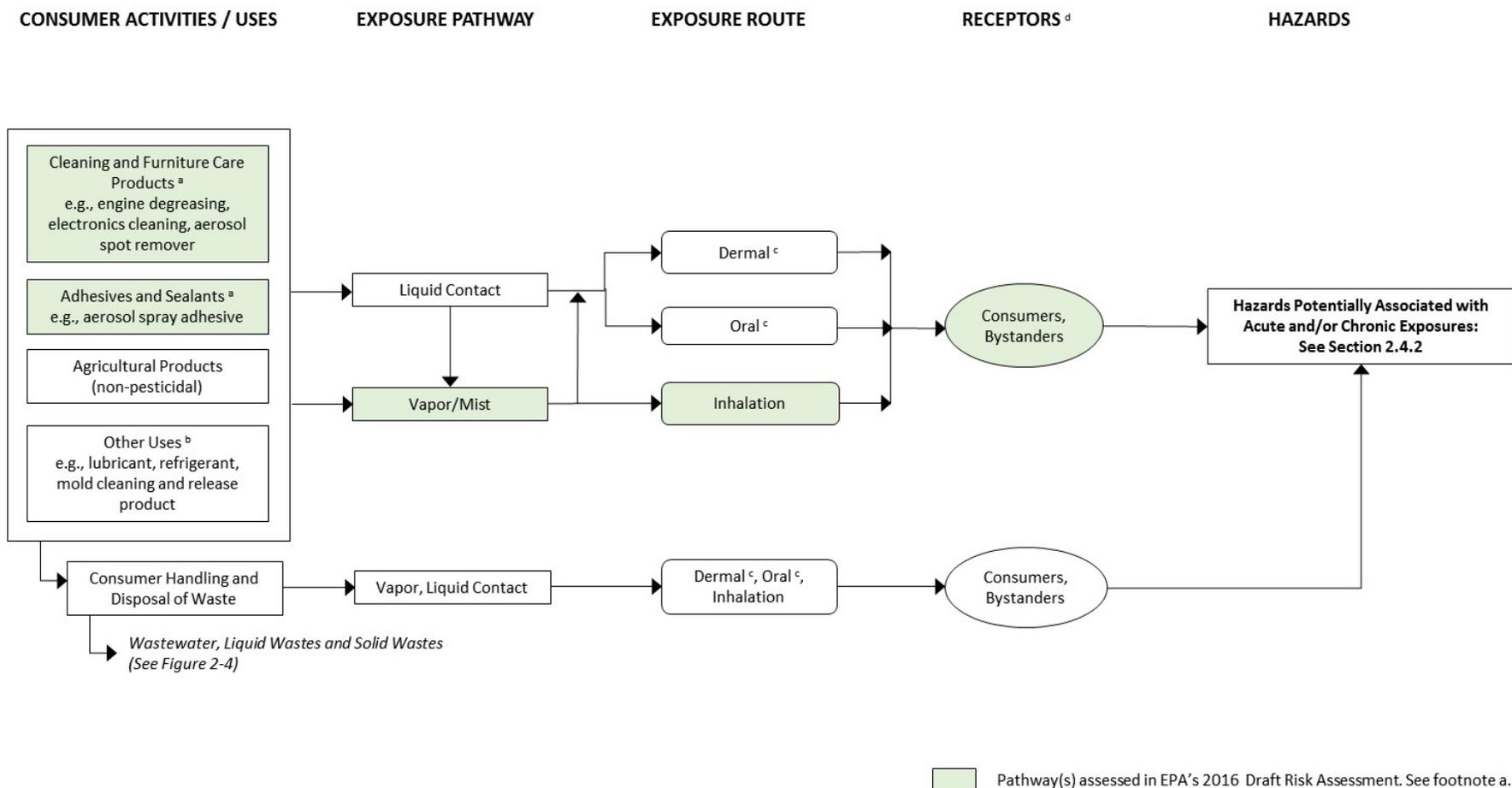
<sup>f</sup> Receptors include potentially exposed or susceptible subpopulations.

<sup>g</sup> When data and information are available to support the analysis, EPA also considers the effect that engineering controls and/or personal protective equipment have on occupational exposure levels.

## **2.5.2 Initial Conceptual Model for Consumer Activities and Uses: Potential Exposures and Hazards**

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Figure 2-3 presents the conceptual model for human receptors from consumer uses of 1-BP. Similar to Figure 2-2, EPA expects that consumers and bystanders may be exposed via inhalation, dermal and oral routes, with inhalation of vapor and mist being the most likely exposure route. Figure 2-3 also shows emissions of 1-BP to vapor/mist, as well as liquid wastes containing 1-BP. It should be noted that some consumers may purchase and use products primarily intended for commercial use. Dermal exposure from skin contact with liquids and vapor may also occur when performing certain activities associated with use of some consumer products. Oral exposure may occur through mists that deposit in the upper respiratory tract and are swallowed. Although less likely given the physical-chemical properties, oral exposure may also occur from incidental ingestion of 1-BP residue on hand/body.



**Figure 2-3. Initial 1-BP Conceptual Model for Consumer Activities and Uses: Potential Exposures and Hazards**

The conceptual model presents the exposure pathways, exposure routes and hazards to human receptors from consumer activities and uses of 1-BP.

<sup>a</sup> 2016 Risk Assessment of 1-BP ([U.S. EPA, 2016b](#)) assessed vapor degreasing, cold cleaning and aerosol degreasing in industrial settings and dry cleaning and spot cleaning in commercial settings (pathways shaded green).

<sup>b</sup> Some products are used in both commercial and consumer applications. Additional uses of 1-BP are included in Table 2-3.

<sup>c</sup> Dermal exposure may occur through skin contact with liquids and vapors; oral exposure may occur through mists that deposit in the upper respiratory tract and are swallowed. Although less likely given the physical-chemical properties, oral exposure may also occur from incidental ingestion of residue on hand/body.

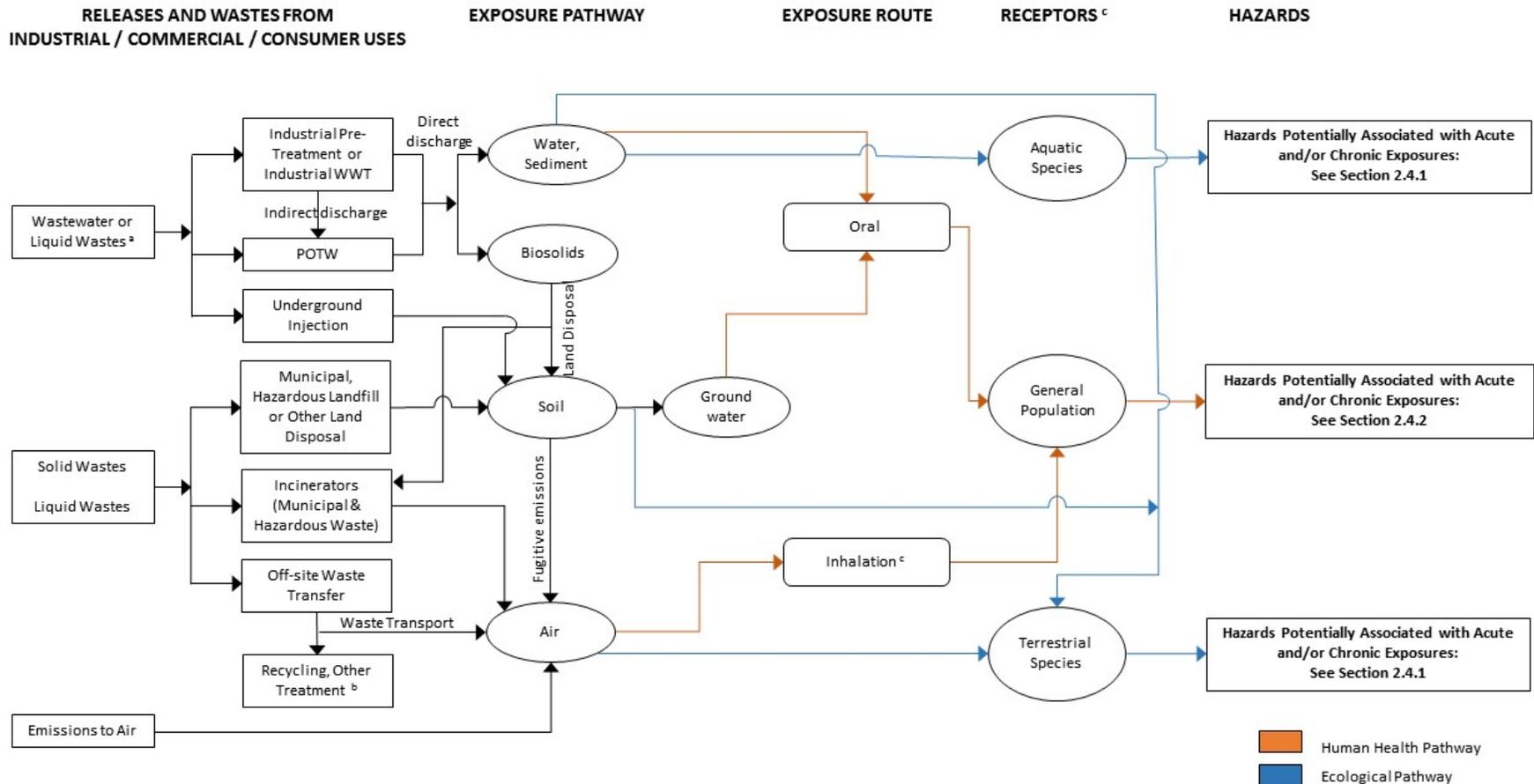
<sup>d</sup> Receptors include potentially exposed or susceptible subpopulations.

### **2.5.3 Initial Conceptual Model for Environmental Releases and Wastes: Potential Exposures and Hazards**

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Figure 2-4 illustrates exposure pathways for human and environmental receptors from environmental releases and waste disposal activities.

EPA anticipates that general populations living near industrial and commercial facilities using 1-BP may be exposed via inhalation of outdoor air. In addition, aquatic and terrestrial life may be exposed to 1-BP contaminated water, sediment, and soil.



**Figure 2-4. Initial 1-BP Conceptual Model for Environmental Releases and Wastes: Potential Exposures and Hazards**

The conceptual model presents the exposure pathways, exposure routes and hazards to human and environmental receptors from environmental releases and wastes of 1-BP.

<sup>a</sup> Additional releases may occur from recycling and other waste treatment and disposal activities

<sup>b</sup> Presence of mist is not expected. Dermal and oral exposure are expected to be low.

<sup>c</sup> Receptors include potentially exposed or susceptible subpopulations.

## 2.6 Initial Analysis Plan

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The initial analysis plan will be used to develop the eventual problem formulation and final analysis plan for the risk evaluation. While EPA has conducted a search for readily available data and information from public sources (1-Bromopropane (CASRN 106-94-5) *Bibliography: Supplemental File for the TSCA Scope Document* ([EPA-HQ-OPPT-2016-0741](#))) as described in Section 1.3, EPA encourages submission of additional existing data, such as full study reports or workplace monitoring from industry sources, that may be relevant for refining conditions of use, exposures, hazards and potentially exposed or susceptible subpopulations.

The analysis plan outlined here is based on the conditions of use of 1-BP, as described in Section 2.2 of this scope. The analysis plan may be refined as EPA proceeds with the systematic review of the information in the 1-Bromopropane (CASRN 106-94-5) *Bibliography: Supplemental File for the TSCA Scope Document* ([EPA-HQ-OPPT-2016-0741](#)). EPA will be evaluating the weight of the scientific evidence for both hazard and exposure. Consistent with this approach, EPA will also use a systematic review approach. As such, EPA will use explicit, pre-specified criteria and approaches to identify, select, assess, and summarize the findings of studies. This approach will help to ensure that the review is complete, unbiased, reproducible, and transparent.

### 2.6.1 Exposure

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#### 2.6.1.1 Environmental Releases

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EPA expects to consider and analyze releases to environmental media as follows:

- 1) Review reasonably available published literature or information on processes and activities associated with the conditions of use to evaluate the types of releases and wastes generated.
- 2) Review reasonably available chemical-specific release data, including measured or estimated release data (e.g., data collected under the TRI and National Emissions Inventory [NEI] programs).
- 3) Review reasonably available measured or estimated release data for surrogate chemicals that have similar uses, volatility, chemical and physical properties.
- 4) Understand and consider regulatory limits that may inform estimation of environmental releases.
- 5) Review and determine applicability of Organization for Economic Co-operation and Development (OECD) Emission Scenario Documents and EPA Generic Scenarios to estimation of environmental releases.
- 6) Evaluate the weight of the evidence of environmental release data.
- 7) Map or group each condition(s) of use to a release assessment scenario.

#### 2.6.1.2 Environmental Fate

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EPA expects to consider and analyze fate and transport in environmental media as follows:

- 1) Review reasonably available measured or estimated environmental fate endpoint data collected through the literature search.
- 2) Using measured data and/or modeling, determine the influence of environmental fate endpoints (e.g., persistence, bioaccumulation, partitioning, transport) on exposure pathways and routes of exposure to human and environmental receptors.
- 3) Evaluate the weight of the evidence of environmental fate data.

### **2.6.1.3 Environmental Exposures**

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EPA expects to consider the following in developing its environmental exposure assessment of 1-BP:

- 1) Review reasonably available environmental and biological monitoring data for all media relevant to environmental exposure.
- 2) Review reasonably available information on releases to determine how modeled estimates of concentrations near industrial point sources compare with available monitoring data. Available exposure models will be evaluated and considered alongside available monitoring data to characterize environmental exposures. Modeling approaches to estimate surface water concentrations, sediment concentrations and soil concentrations generally consider the following inputs: release into the media of interest, fate and transport and characteristics of the environment.
- 3) Review reasonably available biomonitoring data. Consider whether these monitoring data could be used to compare with species or taxa-specific toxicological benchmarks.
- 4) Determine applicability of existing additional contextualizing information for any monitored data or modeled estimates during risk evaluation. Review and characterize the spatial and temporal variability, to the extent that data are available, and characterize exposed aquatic and terrestrial populations.
- 5) Evaluate the weight of evidence of environmental occurrence data and modeled estimates.
- 6) Map or group each condition(s) of use to environmental assessment scenario(s).

### **2.6.1.4 Occupational Exposures**

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EPA expects to consider and analyze both worker and occupational non-user exposures as follows:

- 1) Review reasonably available exposure monitoring data for specific condition(s) of use. Exposure data to be reviewed may include workplace monitoring data collected by government agencies such as OSHA and the National Institute of Occupational Safety and Health (NIOSH), and monitoring data found in published literature (e.g., personal exposure monitoring data (direct measurements) and area monitoring data (indirect measurements)).
- 2) Review reasonably available exposure data for surrogate chemicals that have uses, volatility and chemical and physical properties similar to 1-BP.
- 3) For conditions of use where data are limited or not available, review existing exposure models that may be applicable in estimating exposure levels.
- 4) Review reasonably available data that may be used in developing, adapting or applying exposure models to the particular risk evaluation.
- 5) Consider and incorporate applicable engineering controls and/or personal protective equipment into exposure scenarios.
- 6) Evaluate the weight of evidence of occupational exposure data.
- 7) Map or group each condition of use to occupational exposure assessment scenario(s).

### **2.6.1.5 Consumer Exposures**

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EPA expects to consider and analyze both consumers using a consumer product and bystanders associated with the consumer using the product as follows:

- 1) Review reasonably available consumer product-specific exposure data related to consumer uses/exposures.
- 2) Evaluate the weight of the evidence of consumer exposure data.
- 3) For exposure pathways where data are not available, review existing exposure models that may be applicable in estimating exposure levels.

- 4) Review reasonably available data that may be used in developing, adapting or applying exposure models to the particular risk evaluation. For example, existing models developed for a chemical assessment may be applicable to another chemical assessment if model parameter data are available.
- 5) Review reasonably available consumer product-specific sources to determine how those exposure estimates compare with those reported in monitoring data.
- 6) Review reasonably available population- or subpopulation-specific exposure factors and activity patterns to determine if potentially exposed or susceptible subpopulations need be further refined.
- 7) Map or group each condition of use to consumer exposure assessment scenario(s).

#### **2.6.1.6 General Population**

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EPA expects to consider and analyze general population exposures as follows:

- 1) Review reasonably available environmental and biological monitoring data for media to which general population exposures are expected. For exposure pathways where data are not available, review existing exposure models that may be applicable in estimating exposure levels.
- 2) Consider and incorporate applicable media-specific regulations into exposure scenarios or modeling.
- 3) Review reasonably available data that may be used in developing, adapting or applying exposure models to the particular risk evaluation. For example, existing models developed for a chemical assessment may be applicable to another chemical assessment if model parameter data are available.
- 4) Review reasonably available information on releases to determine how modeled estimates of concentrations near industrial point sources compare with available monitoring data.
- 5) Review reasonably available population- or subpopulation-specific exposure factors and activity patterns to determine if potentially exposed or susceptible subpopulations need be further defined.
- 6) Evaluate the weight of the evidence of general population exposure data.
- 7) Map or group each condition of use to general population exposure assessment scenario(s).

#### **2.6.2 Hazards (Effects)**

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##### **2.6.2.1 Environmental Hazards**

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EPA expects to consider and analyze environmental hazards as follows:

- 1) Review reasonably available environmental hazard data, including data from alternative test methods (e.g., computational toxicology and bioinformatics; high-throughput screening methods; data on categories and read-across; *in vitro* studies).
- 2) Conduct hazard identification (the qualitative process of identifying acute and chronic endpoints) and concentration-response assessment (the quantitative relationship between hazard and exposure) for all identified environmental hazard endpoints.
- 3) Derive concentrations of concern (COC) for all identified endpoints.
- 4) Evaluate the weight of the evidence of environmental hazard data.
- 5) Consider the route(s) of exposure, available biomonitoring data and available approaches to integrate exposure and hazard assessments.

### 2.6.2.2 Human Health Hazards

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EPA expects to consider and analyze human health hazards as follows:

- 1) Review reasonably available human health hazard data, including data from alternative test methods (e.g., computational toxicology and bioinformatics; high-throughput screening methods; data on categories and read-across; *in vitro* studies; systems biology).
- 2) In evaluating reasonably available data, determine whether particular human receptor groups may have greater susceptibility to the chemical's hazard(s) than the general population.
- 3) Conduct hazard identification (the qualitative process of identifying non-cancer and cancer endpoints) and dose-response assessment (the quantitative relationship between hazard and exposure) for all identified human health hazard endpoints.
- 4) Derive points of departure (PODs) where appropriate; conduct benchmark dose modeling (BMD) depending on the available data. Adjust the PODs as appropriate to conform (e.g., adjust for duration of exposure) to the specific exposure scenarios evaluated.
- 5) Evaluate the weight of the evidence of human health hazard data.
- 6) Consider the route(s) of exposure (oral, inhalation, dermal), available route-to-route extrapolation approaches, available biomonitoring data and available approaches to correlate internal and external exposures to integrate exposure and hazard assessment.

### 2.6.3 Risk Characterization

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Risk characterization is an integral component of the risk assessment process for both ecological and human health risks. EPA will derive the risk characterization in accordance with EPA's *Risk Characterization Handbook* ([U.S. EPA, 2000](#)). As defined in EPA's *Risk Characterization Policy*, "the risk characterization integrates information from the preceding components of the risk evaluation and synthesizes an overall conclusion about risk that is complete, informative and useful for decision makers." Risk characterization is considered to be a conscious and deliberate process to bring all important considerations about risk, not only the likelihood of the risk but also the strengths and limitations of the assessment, and a description of how others have assessed the risk into an integrated picture.

Risk characterization at EPA assumes different levels of complexity depending on the nature of the risk assessment being characterized. The level of information contained in each risk characterization varies according to the type of assessment for which the characterization is written. Regardless of the level of complexity or information, the risk characterization for TSCA risk evaluations will be prepared in a manner that is transparent, clear, consistent, and reasonable (TCCR) ([U.S. EPA, 2000](#)). EPA will also present information in this section consistent with approaches described in the Risk Evaluation Framework Rule.

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# APPENDICES

## Appendix A REGULATORY HISTORY

### A.1 Federal Laws and Regulations

Table\_Apx A-1. Federal Laws and Regulations

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
<b>US EPA Regulations</b>		
Toxic Substances Control Act (TSCA) – Section 6(b)	EPA is directed to identify and begin risk evaluations on 10 chemical substances drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments.	1-BP is on the initial list of chemicals to be evaluated for unreasonable risk under TSCA (81 FR 91927, December 19, 2016)
Toxic Substances Control Act (TSCA) – Section 8(a)	The TSCA section 8(a) Chemical Data Reporting (CDR) Rule requires manufacturers (including importers) to give EPA basic exposure-related information on the types, quantities and uses of chemical substances produced domestically and imported into the US.	1-BP manufacturing, importing, processing, and use information is reported under the Chemical Data Reporting (CDR) rule (76 FR 50816, August 16, 2011).
Toxic Substances Control Act (TSCA) – Section 8(b)	EPA must compile, keep current, and publish a list (the TSCA Inventory) of each chemical substance manufactured, processed, or imported in the United States.	1-BP was on the initial TSCA Inventory and therefore was not subject to EPA’s new chemicals review process (60 FR 16309, March 29, 1995).
Toxic Substances Control Act (TSCA) – Section 8(e)	Manufacturers (including importers), processors, and distributors must immediately notify EPA if they obtain information that supports the conclusion that a chemical substance or mixture presents a substantial risk of injury to health or the environment.	Eleven notifications of substantial risk (Section 8(e)) received before 2001 (US EPA, ChemView. Accessed April 13, 2017).
Toxic Substances Control Act (TSCA) – Section 4	Provides EPA with authority to issue rules and orders requiring manufacturers (including importers) and processors to test chemical substances and mixtures.	One submission from a test rule (Section 4) received in 1981 (US EPA, ChemView. Accessed April 13, 2017).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
Emergency Planning and Community Right-To-Know Act (EPCRA) – Section 313	Requires annual reporting from facilities in specific industry sectors that employ 10 or more full time equivalent employees and that manufacture, process, or otherwise use a Toxics Release Inventory (TRI)-listed chemical in quantities above threshold levels.	1-BP is a listed substance subject to reporting requirements under 40 CFR 372.65 effective as of January 1, 2016, with reporting due July 1, 2017 (80 FR 72906, November 23, 2015).
Clean Air Act (CAA) – Section 112(b)	This section lists 189 Hazardous Air Pollutants (HAPs) that must be addressed by EPA and includes authority for EPA to add or delete pollutants. EPA may, by rule, add pollutants that present, or may present, a threat of adverse human health effects or adverse environmental effects.	EPA received petitions from the Halogenated Solvent Industry Alliance and the New York State Department of Environmental Conservation to list 1-BP as a <i>hazardous air pollutant</i> (HAP) under section 112(b)(1) of the Clean Air Act (80 FR 6676, February 6, 2015). On January 9, 2017, EPA published a draft notice on the rational for granting the petitions to add 1-BP to the list of hazardous air pollutants. Comments are due June 8, 2017 (82 FR 2354, January 9, 2017). Since 1-BP is not a HAP, currently, there are no National Emissions Standards for Hazardous Air Pollutants (NESHAPs) that apply to the life cycle.
Clean Air Act (CAA) – Section 183(e)	Section 183(e) requires EPA to list the categories of consumer and commercial products that account for at least 80 percent of all VOC emissions in areas that violate the National Ambient Air Quality Standards (NAAQS) for ozone and to issue standards for these categories that require “best available controls.” In lieu of regulations, EPA may issue control techniques guidelines if the guidelines are determined to be	1-BP is listed under the National Volatile Organic Compound Emission Standards for Aerosol Coatings (40 CFR part 59, subpart E). 1-BP has a reactivity factor of 0.35 g O <sub>3</sub> /g VOC.

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	substantially as effective as regulations.	
Clean Air Act (CAA) – Section 612	Under Section 612 of the Clean Air Act (CAA), EPA’s Significant New Alternatives Policy (SNAP) program reviews substitutes for ozone depleting substances within a comparative risk framework. EPA publishes lists of acceptable and unacceptable alternatives. A determination that an alternative is unacceptable, or acceptable only with conditions, is made through rulemaking.	Under EPA’s SNAP program, EPA evaluated 1-BP as an acceptable substitute for ozone-depleting substances. In 2007, EPA listed 1-BP as an acceptable substitute for chlorofluorocarbon (CFC)-113 and methyl chloroform in the solvent and cleaning sector for metals cleaning, electronics cleaning, and precision cleaning. EPA recommended the use of personal protective equipment, including chemical goggles, flexible laminate protective gloves and chemical-resistant clothing (72 FR 30142, May 30, 2007). In 2007, the Agency also proposed to list 1-BP as an unacceptable substitute for CFC-113, hydrochlorofluorocarbon (HCFC)- 114b and methyl chloroform when used in adhesives or in aerosol solvents; and in the coatings end use (subject to use conditions) (72 FR 30168, May 30, 2007). The proposed rule has not been finalized by the Agency. The rule identifies 1-BP as acceptable and unacceptable substitute for ozone-depleting

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
		substances in several sectors.
<b>Other Federal Regulations</b>		
Occupational Safety and Health Act (OSHA)	<p>Requires employers to provide their workers with a place of employment free from recognized hazards to safety and health, such as exposure to toxic chemicals, excessive noise levels, mechanical dangers, heat or cold stress, or unsanitary conditions.</p> <p>Under the Act, OSHA can issue occupational safety and health standards including such provisions as Permissible Exposure Limits (PELs), exposure monitoring, engineering and administrative control measures, and respiratory protection.</p>	<p>OSHA has not issued a PEL for 1-BP.</p> <p>OSHA and the National Institute for Occupational Safety and Health (NIOSH) issued a Hazard Alert regarding 1-BP (OSHA-NIOSH, 2013) providing information regarding health effects, how workers are exposed, how to control the exposures and how OSHA and NIOSH can help.</p>
Department of Energy (DOE)	The Atomic Energy Act authorizes DOE to regulate the health and safety of its contractor employees.	10 CFR 851.23, Worker Safety and Health Program, requires the use of the 2005 ACGIH TLVs if they are more protective than the OSHA PEL. The 2005 TLV for 1-BP is 10 ppm (8hr Time Weighted Average).

## A.2 State Laws and Regulations

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**Table\_Apx A-2. State Laws and Regulations**

State Actions	Description of Action
State Air Regulations	<p>Allowable Ambient Levels</p> <ul style="list-style-type: none"> <li>• Rhode Island (Air Pollution Regulation No. 22)</li> <li>• New Hampshire (Env-A 1400: Regulated Toxic Air Pollutants)</li> </ul>
Chemicals of High Concern	Massachusetts designated 1-BP as a higher hazard substance requiring reporting starting in 2016 (301 CMR 41.00).

State Actions	Description of Action
	Minnesota listed 1-BP as chemical of high concern to children (Minnesota Statutes 116.9401 to 116.9407).
State Permissible Exposure Limits	California PEL: 5 ppm as an 8-hr-time-weighted average (TWA) (California Code of Regulations, title 8, section 5155).
State Right-to-Know Acts	New Jersey (42 N.J.R. 1709(a)), Pennsylvania (Chapter 323. Hazardous Substance List).
Other	<p>In California, 1-BP was added to proposition 65 list in December 2004 due to developmental, female and male, toxicity; and in 2016 due to cancer. (Cal. Code Regs. title 27, section 27001).</p> <p>1-BP is listed as a Candidate Chemical under California's Safer Consumer Products Program (Health and Safety Code sections 25252 and 25253).</p> <p>California also issued a Health Hazard Alert for 1-BP (Hazard Evaluation System and Information Service, 2016).</p>

### A.3 International Laws and Regulations

Table\_Apx A-3. Regulatory Actions by other Governments and Tribes

Country /Organization	Requirements and Restrictions
European Union	<p>In 2012, 1-BP was listed on the Candidate list as a Substance of Very High Concern (SVHC) under regulation (EC) No 1907/2006 - REACH (Registration, Evaluation, Authorization and Restriction of Chemicals due to its reproductive toxicity (category 1B).</p> <p>In July 2015, 1-BP was recommended for inclusion in Annex XIV of REACH (Authorisation List) (European Chemicals Agency (ECHA) database. Accessed April 18, 2017).</p>
Australia	<p>1-BP was assessed under Environment Tier II of the Inventory Multi-tiered Assessment and Prioritisation (IMAP) (National Industrial Chemicals Notification and Assessment Scheme, 2017, <i>Human Health Tier II Assessment for Propane, 1-bromo-</i>. Accessed April, 18 2017).</p>
Japan	<p>1-BP is regulated in Japan under the following legislation:</p> <ul style="list-style-type: none"> <li>• Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Chemical Substances Control Law; CSCL)</li> <li>• Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof</li> <li>• Industrial Safety and Health Act (ISHA)</li> <li>• Air Pollution Control Law</li> </ul>

Country /Organization	Requirements and Restrictions
	(National Institute of Technology and Evaluation (NITE) Chemical Risk Information Platform (CHIRP). Accessed April 13, 2017).
Belgium, Canada, Finland, Japan, Poland, South Korea and Spain	Occupational exposure limits for 1-BP. (GESTIS International limit values for chemical agents (Occupational exposure limits, OELs) database. Accessed April 18, 2017).
Basel Convention	Halogenated organic solvents (Y41) are listed as a category of waste under the Basel Convention_– Annex I. Although the United States is not currently a party to the Basel Convention, this treaty still affects U.S. importers and exporters.
OECD Control of Transboundary Movements of Wastes Destined for Recovery Operations	Halogenated organic solvents (A3150) are listed as a category of waste subject to The Amber Control Procedure under Council Decision C (2001) 107/Final.

## **Appendix B PROCESS, RELEASE AND OCCUPATIONAL EXPOSURE INFORMATION**

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This appendix provides information and data found in preliminary data gathering for 1-BP.

### **B.1 Process Information**

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Process-related information potentially relevant to the risk evaluation may include process diagrams, descriptions and equipment. Such information may inform potential release sources and worker exposure activities. EPA will consider this information in combination with available monitoring data and estimation methods and models, as appropriate, to quantify occupational exposure and releases for the various conditions of use in the risk evaluation. Most of the process-related information provided below, especially descriptions pertaining to 1BP use in degreasing (vapor, cold and aerosol), spray adhesive, dry cleaning and spot cleaning, has been previously compiled, described and peer reviewed in EPA's [2016 Draft Risk Assessment \(U.S. EPA, 2016b\)](#).

#### **B.1.1 Manufacture (Including Import)**

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##### **B.1.1.1 Domestic Manufacture**

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1-BP is produced by reacting n-propyl alcohol with hydrogen bromide and then removing the excess water that forms in the process ([NTP, 2013](#)). The reaction product may then be distilled, neutralized with sodium hydrogen carbonate, packaged and stored ([Ichihara et al., 2004](#)).

##### **B.1.1.2 Import**

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EPA expects that imported chemicals are often stored in warehouses prior to distribution for further processing and use. In some cases, the chemicals may be repackaged into differently sized containers, depending on customer demand, and QC samples may be taken for analyses.

#### **B.1.2 Processing and Distribution**

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Based on the reported industrial processing operations in the [2016 CDR](#), 1-BP may be incorporated into a variety of formulations, products and articles, or used industrially as a chemical intermediate ([U.S. EPA, 2016a](#)). Some industrial or commercial products may also be repackaged into appropriately-sized containers to meet specific customer demands ([U.S. EPA, 2016a](#)).

##### **B.1.2.1 Processing as a Reactant**

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Processing as a reactant or intermediate is the use of 1-BP as a feedstock in the production of another chemical via a chemical reaction in which 1-BP is consumed to form the product. EPA has not identified specific information for the processing of 1-BP as a reactant.

##### **B.1.2.2 Incorporated into Formulation, Mixture or Reaction Product**

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Incorporation into a formulation, mixture or reaction product refers to the process of mixing or blending of several raw materials to obtain a product or mixture (e.g., adhesives and sealants). EPA has not identified 1-BP specific formulation processes.

##### **B.1.2.3 Incorporated into Article**

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Incorporation into an article typically refers to a process in which a chemical becomes an integral

component of an article that is distributed for industrial, trade, or consumer use. Exact process operations involved in the incorporation of 1-BP are dependent on the article. EPA will further investigate the potential use of 1-BP in this type of process during the risk evaluation.

#### **B.1.2.4 Repackaging**

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Typically, repackaging sites receive the chemical in bulk containers and transfer the chemical from the bulk container into another smaller container in preparation for distribution in commerce. Based on EPA's knowledge of the chemical industry, worker activities at repackaging sites may involve manually unloading 1-BP from bulk containers into the smaller containers for distribution or connecting/disconnecting transfer lines used to transfer 1-BP product between containers and analyzing QC samples. EPA will further investigate the potential use of 1-BP in this type of process during the risk evaluation.

#### **B.1.2.5 Recycling**

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A general description of waste solvent recovery processes was identified. Waste solvents are generated when it becomes contaminated with suspended and dissolved solids, organics, water, or other substance ([U.S. EPA, 1980](#)). Waste solvents can be restored to a condition that permits reuse via solvent reclamation/recycling ([U.S. EPA, 1980](#)). The recovery process involves an initial vapor recovery (e.g., condensation, adsorption and absorption) or mechanical separation (e.g., decanting, filtering, draining, setline and centrifuging) step followed by distillation, purification and final packaging ([U.S. EPA, 1980](#)).

### **B.1.3 Uses**

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In this scope document, EPA has grouped uses based on CDR categories and identified examples within these categories as subcategories of use. Note that some subcategories of use may be grouped under multiple CDR categories. The differences between these uses will be further investigated during risk evaluation.

#### **B.1.3.1 Solvents for Cleaning and Degreasing**

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Solvents for Cleaning and Degreasing category encompasses chemical substances used to dissolve oils, greases and similar materials from a variety of substrates including metal surfaces, glassware and textiles. This category includes the use of 1-BP in vapor degreasing, cold cleaning and in industrial and commercial aerosol degreasing products.

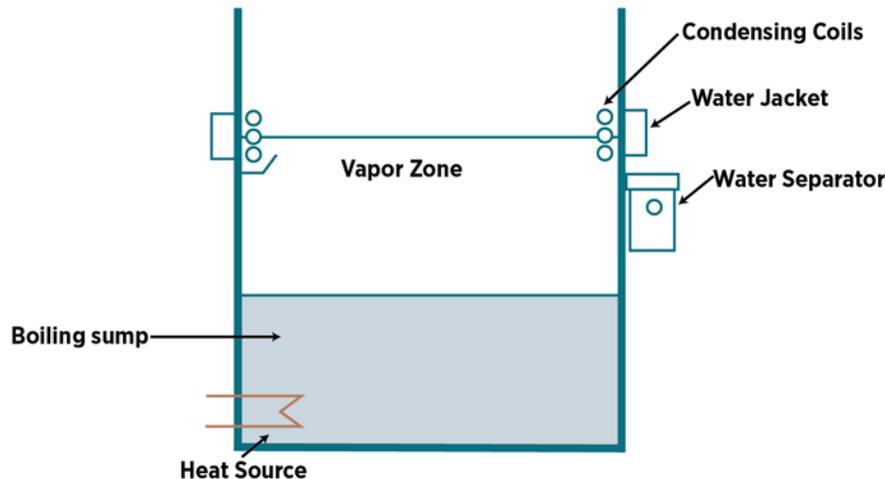
##### ***Vapor Degreasing***

Vapor degreasing is a process used to remove dirt, grease and surface contaminants in a variety of metal cleaning industries. 1-BP is often used to replace chlorinated solvents in vapor degreasing applications. Vapor degreasing may take place in batches or as part of an in-line (i.e., continuous) system. In batch machines, each load (parts or baskets of parts) is loaded into the machine after the previous load is completed. With in-line systems, parts are continuously loaded into and through the vapor degreasing equipment as well as the subsequent drying steps. Vapor degreasing equipment can generally be categorized into one of the three categories: (1) batch vapor degreasers, (2) conveyORIZED vapor degreasers and (3) web vapor degreasers.

Each category of vapor degreaser is described below.

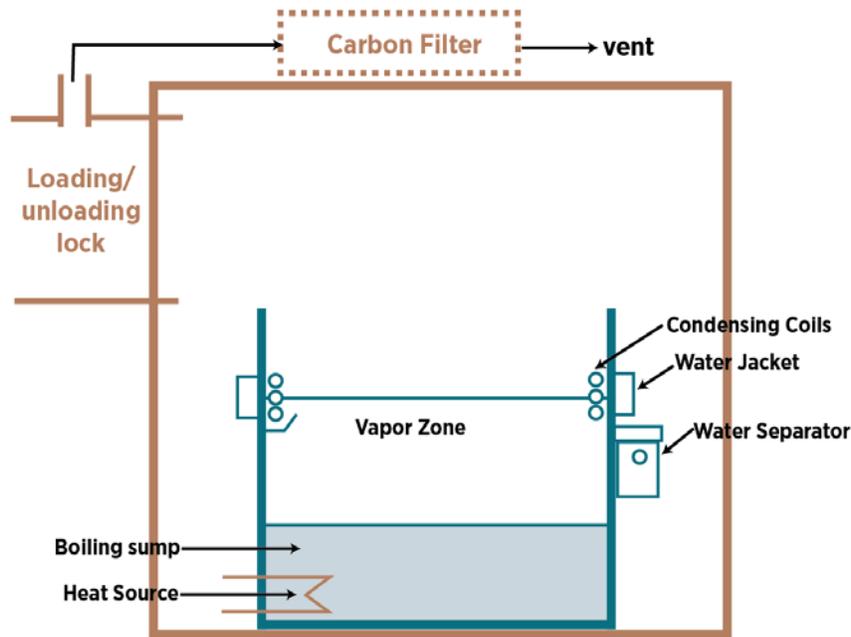
## Batch Vapor Degreasers

- *Open top vapor degreasers (OTVD)*: In OTVDs, a vapor cleaning zone is created by heating the liquid solvent in the OTVD causing it to volatilize. Workers manually load or unload fabricated parts directly into or out of the vapor cleaning zone. The tank usually has chillers along the side of the tank to prevent losses of the solvent to the air. However, these chillers are not able to eliminate emissions, and throughout the degreasing process, significant air emissions of the solvent can occur. These air emissions can cause issues with both worker health and safety as well as environmental issues. Additionally, the cost of replacing solvent lost to emissions can be expensive ([NEWMOA, 2001](#)). Figure\_Apx B-1 illustrates a standard OTVD. The use of 1-BP in OTVD has been previously described in EPA's [2016 Draft Risk Assessment \(U.S. EPA, 2016b\)](#).



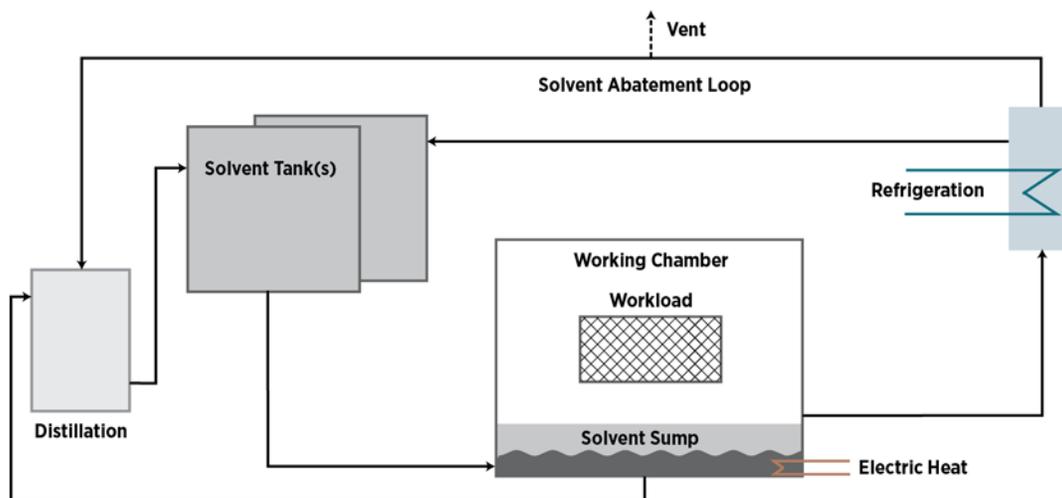
Figure\_Apx B-1. Open Top Vapor Degreaser

- *OTVD with enclosure*: OTVDs with enclosures operate the same as standard OTVDs except that the OTVD is enclosed on all sides during degreasing. The enclosure is opened and closed to add or remove parts to/from the machine, and solvent is exposed to the air when the cover is open. Enclosed OTVDs may be vented directly to the atmosphere or first vented to an external carbon filter and then to the atmosphere ([U.S. EPA, 2004](#)). Figure\_Apx B-2 illustrates an OTVD with an enclosure. The dotted lines in Figure\_Apx B-2 represent the optional carbon filter that may or may not be used with an enclosed OTVD.



Figure\_Apx B-2. Open Top Vapor Degreaser with Enclosure

- *Closed-loop degreasing system (airtight):* In closed-loop degreasers, parts are placed into a basket, which is then placed into an airtight work chamber. The door is closed and solvent vapors are sprayed onto the parts. Solvent can also be introduced to the parts as a liquid spray or liquid immersion. When cleaning is complete, vapors are exhausted from the chamber and circulated over a cooling coil where the vapors are condensed and recovered. The parts are dried by forced hot air. Air is circulated through the chamber and residual solvent vapors are captured by carbon adsorption. The door is opened when the residual solvent vapor concentration has reached a specified level ([Kanegsberg and Kanegsberg, 2011](#)). Figure\_Apx B-3 illustrates a standard closed-loop vapor degreasing system.



Figure\_Apx B-3. Closed-Loop/Vacuum Vapor Degreaser

- *Airless degreasing system (vacuum drying):* Airless degreasing systems are also sealed, closed-loop systems, but remove air at some point of the degreasing process. Removing air typically takes the form of drawing vacuum, but could also include purging air with nitrogen at some point of the process (in contrast to drawing vacuum, a nitrogen purge operates at a slightly positive pressure). In airless degreasing systems with vacuum drying only, the cleaning stage works similarly as with the airtight closed-loop degreaser. However, a vacuum is generated during the drying stage, typically below 5 torr (5 mmHg). The vacuum dries the parts and a vapor recovery system captures the vapors ([Kanegsberg and Kanegsberg, 2011](#); [NEWMOA, 2001](#); [U.S. EPA, 2001](#)).
- *Airless vacuum-to-vacuum degreasing system:* Airless vacuum-to-vacuum degreasers are true “airless” systems because the entire cycle is operated under vacuum. Typically, parts are placed into the chamber, the chamber sealed, and then vacuum drawn within the chamber. The typical solvent cleaning process is a hot solvent vapor spray. The introduction of vapors in the vacuum chamber raises the pressure in the chamber. The parts are dried by again drawing vacuum in the chamber. Solvent vapors are recovered through compression and cooling. An air purge then purges residual vapors over an optional carbon adsorber and through a vent. Air is then introduced in the chamber to return the chamber to atmospheric pressure before the chamber is opened ([Durkee, 2014](#); [NEWMOA, 2001](#)).

The general design of vacuum vapor degreasers and airless vacuum degreasers is similar as illustrated in Figure\_Apx B-3 for closed-loop systems except that the work chamber is under vacuum during various stages of the cleaning process.

### **Conveyorized Vapor Degreasers**

Conveyorized vapor degreasing systems are solvent cleaning machines that use an automated parts handling system, typically a conveyor, to automatically provide a continuous supply of parts to be cleaned. Conveyorized degreasing systems are usually fully enclosed except for the conveyor inlet and outlet portals. Conveyorized degreasers are likely used in similar shop types as batch vapor degreasers except for repair shops, where the number of parts being cleaned is likely not large enough to warrant the use of a conveyorized system.

There are seven major types of conveyorized degreasers ([U.S. EPA, 1977](#)):

- *Monorail degreasers:* Monorail degreasing systems are typically used when parts are already being transported throughout the manufacturing areas by a conveyor conveyor ([U.S. EPA, 1977](#)). They use a straight-line conveyor to transport parts into and out of the cleaning zone. The parts may enter one side and exit and the other or may make a 180° turn and exit through a tunnel parallel to the entrance ([U.S. EPA, 1977](#)).
- *Cross-rod degreasers:* Cross-rod degreasing systems utilize two parallel chains connected by a rod that support the parts throughout the cleaning process. The parts are usually loaded into perforated baskets or cylinders and then transported through the machine by the chain support system. The baskets and cylinders are typically manually loaded and unloaded ([U.S. EPA, 1977](#)). Cylinders are used for small parts or parts that need enhanced solvent drainage because of crevices and cavities. The cylinders allow the parts to be tumbled during cleaning and drying and thus increase cleaning and drying efficiency.

- *Vibra degreasers*: In vibra degreasing systems, parts are fed by conveyor through a chute that leads to a pan flooded with solvent in the cleaning zone. The pan and the connected spiral elevator are continuously vibrated throughout the process, causing the parts to move from the pan and up a spiral elevator to the exit chute. As the parts travel up the elevator, the solvent condenses and the parts are dried before exiting the machine ([U.S. EPA, 1977](#)).
- *Ferris wheel degreasers*: Ferris wheel degreasing systems are generally the smallest of all the conveyORIZED degreasers ([U.S. EPA, 1977](#)). In these systems, parts are manually loaded into perforated baskets or cylinders and then rotated vertically through the cleaning zone and back out.
- *Belt degreasers*: Belt degreasing systems (similar to strip degreasers; see next bullet) are used when simple and rapid loading and unloading of parts is desired ([U.S. EPA, 1977](#)). Parts are loaded onto a mesh conveyor belt that transports them through the cleaning zone and out the other side.
- *Strip degreasers*: Strip degreasing systems operate similar to belt degreasers except that the belt itself is being cleaned rather than parts being loaded onto the belt for cleaning.
- *Circuit board cleaners*: Circuit board degreasers use any of the conveyORIZED designs. However, in circuit board degreasing, parts are cleaned in three different steps due to the manufacturing processes involved in circuit board production ([U.S. EPA, 1977](#)).

### **Continuous Web Vapor Degreasers**

Continuous web cleaning machines differ from typical conveyORIZED degreasers in that they are specifically designed for cleaning parts that are coiled or on spools such as films, wires and metal strips ([Kanegsberg and Kanegsberg, 2011](#); [U.S. EPA, 2006b](#)). In continuous web degreasers, parts are uncoiled and loaded onto rollers that transport the parts through the cleaning and drying zones at speeds >11 feet/minute ([U.S. EPA, 2006b](#)). The parts are then recoiled or cut after exiting the cleaning machine ([Kanegsberg and Kanegsberg, 2011](#); [U.S. EPA, 2006b](#)).

### **Cold Cleaning**

1-BP can also be used as a solvent in cold cleaners, which are non-boiling solvent degreasing units. Cold cleaning operations include spraying, brushing, flushing and immersion. In a typical batch-loaded, maintenance cold cleaner, dirty parts are cleaned manually by spraying and then soaking in the tank. After cleaning, the parts are either suspended over the tank to drain or are placed on an external rack that routes the drained solvent back into the cleaner. Batch manufacturing cold cleaners could vary widely, but have two basic equipment designs: the simple spray sink and the dip tank. The dip tank design typically provides better cleaning through immersion, and often involves an immersion tank equipped with agitation ([U.S. EPA, 1981](#)). Emissions from batch cold cleaning machines typically result from (1) evaporation of the solvent from the solvent-to-air interface, (2) “carry out” of excess solvent on cleaned parts and (3) evaporative losses of the solvent during filling and draining of the machine ([U.S. EPA, 2006b](#)).

### **Aerosol Degreasing**

Aerosol degreasing is a process that uses an aerosolized solvent spray, typically applied from a pressurized can, to remove residual contaminants from fabricated parts. The aerosol droplets bead up on the fabricated part and then drip off, carrying away any contaminants and leaving behind a clean surface. One example of commercial setting that uses aerosol degreasing operation is repair shops, where service items are cleaned to remove any contaminants that would otherwise compromise the

service item's operation. Internal components may be cleaned in place or removed from the service item, cleaned, and then re-installed once dry ([U.S. EPA, 2014](#)).

### **B.1.3.2 Adhesives and Sealants**

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1-BP is a component of spray adhesive. In foam cushion manufacturing, workers use a spray gun to spray-apply adhesive containing 1-BP onto flexible foam surfaces. Adhesive spraying typically occurs either on an open top workbench with side panels that may have some local ventilation, or in an open workspace with general room ventilation. After the adhesive is applied, workers hand-press the flexible foam pieces together to assemble the cushions.

### **B.1.3.3 Agricultural Products (Non-pesticidal)**

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This CDR category includes chemicals used to improve crop productivity and quality, including fertilizers, additives, colorants, application aids, pH adjusters, moisture retention agents, soil conditioners and seed coatings ([U.S. EPA, 2016a](#)). The product category does not include any chemical that is manufactured, processed, or distributed in commerce for use as a pesticide as defined by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) ([U.S. EPA, 2016a](#)). The company reported that the determination of whether this product was for commercial or consumer uses was “not known or reasonably ascertainable.” EPA has not identified further process information specific to use of 1BP in agricultural products.

### **B.1.3.4 Cleaning and Furniture Care Products**

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1-BP can be used as a solvent in dry cleaning machines and 1-BP formulations such as DrySolv® are often marketed as “drop-in” replacements for PERC, which indicates that they can be used in third-generation or higher PERC equipment ([TURI, 2012](#)). Dry cleaners who opt to use 1-BP can either convert existing PERC machines or purchase a new dry cleaning machine specifically designed for 1-BP. To convert existing PERC machines to use 1-BP, machine settings and components must be changed to prevent machine overheating and solvent leaks ([Blando et al., 2010](#)). 1-BP is known to damage rubber gaskets and seals. It can also degrade cast aluminum, which is sometimes used on equipment doors and other dry cleaning machine components. In addition, 1-BP is not compatible with polyurethane and silicone ([TURI, 2012](#)).

In addition, 1-BP is found in products used to spot clean garments. Spot cleaning products can be applied to the garment either before or after the garment is dry cleaned. Spot cleaning occurs on a spotting board and spotting agent can be applied from squeeze bottles, hand-held spray bottles or even from spray guns connected to pressurized tanks. Once applied, the dry cleaner may come into further contact with the 1-BP if using a brush, spatula, pressurized air or steam or their fingers to scrape or flush away the stain ([Young, 2012](#); [NIOSH, 1997](#)).

### **B.1.3.5 Other Uses**

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Based on products identified in EPA's preliminary data gathering and information received in public comments, a variety of other uses may exist for 1-BP including in lubricants, insulation, mold release products, refrigerants, adhesive accelerants, asphalt extraction, and temperature indicators for laboratory applications [see *Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: 1-Bromopropane*, [EPA-HQ-OPPT-2016-0741-0003](#) ([U.S. EPA, 2017a](#))]. EPA has not identified any process-specific information to further refine the use of 1-BP in these applications at this time and more information on these uses will be gathered through expanded literature searches during risk evaluation.

### **B.1.4 Disposal**

Disposal of a chemical should take into consideration the chemical’s potential impact on air quality, migration to groundwater, effect on biological species, and disposal regulations (if any) ([ATSDR, 2016](#)). Due to the high volatility of 1-BP, releases to the atmosphere are expected to be the primary release route of 1-BP ([ATSDR, 2016](#)). Currently, 1-BP is not regulated under federal regulations as a hazardous waste ([U.S. EPA, 2017a](#)). However, 1-BP may be disposed of as a hazardous waste if it is present in or co-mingled with solvent mixtures that are RCRA regulated substances. EPA has not identified further process information specific to disposal of 1-BP at this time, but will review TRI data submitted for 1-BP, as it becomes available, for information on how wastes containing 1-BP are disposed.

## **B.2 Occupational Exposure Data**

EPA presents below an example of occupational exposure-related information from the preliminary data gathering. EPA will consider this information and data in combination with other data and methods for use in the risk evaluation.

Table\_Apx B-1 summarizes the industry sectors with 1-BP OSHA CEHD data ([OSHA, 2017](#)).

**Table\_Apx B-1. Summary of Industry Sectors with 1-BP Personal Monitoring Air Samples Obtained from OSHA Inspections Conducted Between 2013 and 2016**

<b>North American Industry Classification System (NAICS)</b>	<b>NAICS Description</b>
336412	Aircraft engine and engine parts manufacturing
448190	Other clothing stores
333517	Machine tool manufacturing
334418	Printed circuit assembly
331210	Iron and steel pipe and tube manufacturing from purchased steel
336413	Other aircraft parts and auxiliary equipment manufacturing
332813	Electroplating, plating, polishing, anodizing and coloring
323113	Commercial screen printing
332913	Plumbing fixture fitting and trim manufacturing
332721	Precision turned product manufacturing
333911	Pump and pumping equipment manufacturing