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Problem Formulation of the Risk Evaluation for 1-Bromopropane

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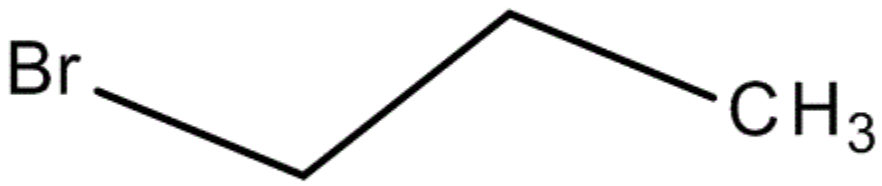

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Disclaimer

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ABBREVIATIONS

°C	Degrees Celsius
ACGIH	American Conference of Government Industrial Hygienists
ACR	Acute-to-Chronic Ratio
atm	Atmosphere(s)
ATCM	Airborne Toxic Control Measure
ATSDR	Agency for Toxic Substances and Disease Registry
AF	Assessment Factor
BAF	Bioaccumulation Factor
BCF	Bioconcentration Factor
BMD	Benchmark Dose Modeling
1-BP	1-Bromopropane
CAA	Clean Air Act
CARB	California Air Resources Board
CASRN	Chemical Abstracts Service Registry Number
CBI	Confidential Business Information
CCL	Contaminant Candidate List
CDR	Chemical Data Reporting
CEHD	Chemical Exposure Health Data
CEM	Consumer Exposure Model
CFC	Chlorofluorocarbon
CFR	Code of Federal Regulations
ChV	Chronic Value (MATC)
COC	Concentration of Concern
COU	Conditions of Use
CSCL	Chemical Substances Control Law
CWA	Clean Water Act
DIY	Do It Yourself
DOE	Department of Energy
DNA	Deoxyribonucleic Acid
DRE	Destruction Removal Efficiencies
EC_{50}	Effective Concentration with 50% immobilized test organisms
ECHA	European Chemicals Agency
EPA	Environmental Protection Agency
EPCRA	Emergency Planning and Community Right-to-Know Act
ESD	Emissions Scenario Document
g/L	Gram(s) per Liter
GS	Generic Scenario
HAP	Hazardous Air Pollutant
HCFC	Hydrochlorofluorocarbon
HHE	Health Hazard Evaluation
Hr	Hour
IMAP	Inventory Multi-Tiered Assessment and Prioritisation (Australia)
IRIS	Integrated Risk Information System
ISHA	Industrial Safety and Health Act

ISOR	Initial Statement of Reasons
IUR	Inhalation Unit Risk
kg	Kilogram(s)
kPa	Kilopascal(s)
L	Liter(s)
LOAEL	Lowest Observed Adverse Effect Level
lb	Pound(s)
LC_{50}	Lethal Concentration of 50% test organisms
LOEC	Lowest Observed Effect Concentration
Log K_{oc}	Logarithmic Soil Organic Carbon:Water Partitioning Coefficient
Log K_{ow}	Logarithmic Octanol:Water Partition Coefficient
m^3	Cubic Meter(s)
mg/L	Milligram(s) per Liter
mmHg	Millimeter(s) of Mercury
mPa·s	Millipascal(s)-Second
MACT	Maximum Achievable Control Technology
MATC	Maximum Acceptable Toxicant Concentration
MSWLFs	Municipal Solid Waste Landfills
NAAQS	National Ambient Air Quality Standards
NAICS	North American Industry Classification System
NEI	National Emissions Inventory
NESHAP	National Emission Standards for Hazardous Air Pollutants
NF/FF	Near Field/Far Field
NICNAS	National Industrial Chemicals Notification and Assessment Scheme (Australia)
NIOSH	National Institute for Occupational Safety and Health
NOAEL	No Observed Adverse Effect Level
NOEC	No Observed Effect Concentration
NTP	National Toxicology Program
OAQPS	Office of Air Quality Planning and Standards
OCSPP	Office of Chemical Safety and Pollution Prevention
OECD	Organisation for Economic Co-operation and Development
ONU	Occupational Non-User
OPPT	Office of Pollution Prevention and Toxics
OSHA	Occupational Safety and Health Administration
OTVD	Open Top Vapor Degreaser
PECO	Populations, Exposures, Comparisons, Outcomes
PESS	Potentially Exposed or Susceptible Subpopulations
PBPK	Physiologically Based Pharmacokinetic
PBZ	Personal Breathing Zone
PEL	Permissible Exposure Limit
PERC	Perchloroethylene
POD	Point of Departure
POTW	Publicly Owned Treatment Works
PPE	Personal Protective Equipment
ppm	Part(s) per Million
PSD	Particle Size Distribution

PV	Production Volume
QC	Quality Control
RCRA	Resource Conservation and Recovery Act
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals (European Union)
REL	Recommended Exposure Limit
SDS	Safety Data Sheet
SDWA	Safe Drinking Water Act
SNAP	Significant New Alternatives Policy
STP	Sewage Treatment Plant
SVHC	Substance of Very High Concern (European Union)
t ½	Half-Life
TCE	Trichloroethylene
TLV	Threshold Limit Value
TRI	Toxics Release Inventory
TSCA	Toxic Substances Control Act
TWA	Time-Weighted Average
VP	Vapor Pressure
VOC	Volatile Organic Compound
U.S.	United States
WTP	Wastewater Treatment Plant
WWT	Wastewater Treatment
Yr	Year

EXECUTIVE SUMMARY

TSCA § 6(b)(4) requires the U.S. Environmental Protection Agency (U.S. 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. In June, 2017, EPA published the Scope of the Risk Evaluation for 1-BP (Scope Document; EPA-HQ-OPPT-2016-0741-0049). As explained in the Scope Document, because there was insufficient time for EPA to provide an opportunity for comment on a draft of the scope, as EPA intends to do for future scope documents, EPA is publishing and taking public comment on a problem formulation document to refine the current scope, as an additional interim step prior to publication of the draft risk evaluation for 1-BP. Comments received on this problem formulation document will inform development of the draft risk evaluation.

This problem formulation document refines the conditions of use, exposures and hazards presented in the scope of the risk evaluation for 1-BP and presents refined conceptual models and analysis plans that describe how EPA expects to evaluate risk for 1-BP.

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 and in the dry cleaning industry. 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).

This document presents the potential exposures that may result from the conditions of use of 1-BP. Exposures to workers, consumers, and/or the general population may occur from industrial, commercial, consumer uses of 1-BP and industrial releases to air, water or land. Workers and occupational non-users (i.e., workers who do not directly handle the chemical but perform work in an area where the chemical is used) may be exposed to 1-BP during a variety of conditions of use such as manufacturing, processing, distribution, repackaging, spray adhesives, dry cleaning (including spot cleaning) and degreasing (vapor, cold cleaning, and aerosol). Consumers and bystanders may be exposed to 1-BP from various consumer uses such as aerosol and spray adhesives, aerosol spot removers and aerosol cleaning and degreasing products. For 1-BP, EPA considers workers, occupational non-users, consumers, bystanders, and certain other groups of individuals who may experience greater exposures than the general population due to proximity to conditions of use to be potentially exposed or susceptible subpopulations. Exposures to the general population may occur from industrial and/or commercial uses; industrial releases to air, water, or land; and other conditions of use. EPA will evaluate whether 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, or duration) that increase exposure and whether groups of individuals have heightened susceptibility, and should therefore be considered potentially exposed or susceptible subpopulations for purposes of the risk evaluation. EPA plans to further analyze inhalation exposures to vapors and mists for workers and occupational non-users (workers who do not

directly handle the chemical but perform work in an area where the chemical is present) and dermal exposures for skin contact with liquids in occluded situations for workers in the risk evaluation. EPA plans to further analyze inhalation exposures to vapors and mists for consumers and bystanders and dermal exposures for skin contact with liquids in the risk evaluation. For environmental release pathways, EPA does not plan to further analyze surface water exposure to aquatic invertebrates and aquatic plants in the risk evaluation.

1-BP has been the subject of numerous health hazard reviews including 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, in addition to the 2016 Draft Risk Assessment (U.S. EPA, 2016b). Any existing assessments will be a starting point as EPA conducts 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-2016-0741-0047). If additional hazard concerns are identified during the systematic review of the literature, these will also be considered. These hazards will be evaluated based on the specific exposure scenarios identified.

The revised conceptual models presented in this problem formulation identify conditions of use; exposure pathways (e.g., media); exposure routes (e.g., inhalation, dermal, oral); potentially exposed or susceptible subpopulations; and hazards EPA expects to consider in the risk evaluation. The initial conceptual models provided in the scope document were revised during problem formulation based on evaluation of reasonably available information for physical and chemical properties, fate, exposures, hazards, and conditions of use and based upon consideration of other statutory and regulatory authorities. In each problem formulation document for the first 10 chemical substances, EPA also refined the activities, hazards, and exposure pathways that will be included in and excluded from the risk evaluation.

EPA's overall objectives in the risk evaluation process are to conduct timely, relevant, high-quality, and scientifically credible risk evaluations within the statutory deadlines, and to evaluate the conditions of use that raise greatest potential for risk. 82 FR 33726, 33728 (July 20, 2017).

1 INTRODUCTION

This document presents for comment the problem formulation of the risk evaluation to be conducted for 1-Bromopropane (1-BP) under the Frank R. Lautenberg Chemical Safety for the 21st Century Act. The Frank R. Lautenberg Chemical Safety for the 21st Century Act amended the Toxic Substances Control Act (TSCA), the Nation's primary chemicals management law, on June 22, 2016. The new law includes statutory requirements and deadlines for actions related to conducting risk evaluations of existing chemicals.

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 (COU) and potentially exposed or susceptible subpopulations (PESS) that the Administrator expects to consider, within 6 months after the initiation of a risk evaluation. The scope documents for all first 10 chemical substances were issued on June 22, 2017. The first 10 problem formulation documents are a refinement of what was presented in the first 10 scope documents. TSCA § 6(b)(4)(D) does not distinguish between scoping and problem formulation, and requires EPA to issue scope documents that include information about the chemical substance, including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations that the Administrator expects to consider in the risk evaluation. In the future, EPA expects scoping and problem formulation to be completed prior to the issuance of scope documents and intends to issue scope documents that include problem formulation.

As explained in the scope document, because there was insufficient time for EPA to provide an opportunity for comment on a draft of the scope, as EPA intends to do for future scope documents, EPA is publishing and taking public comment on a problem formulation document to refine the current scope, as an additional interim step prior to publication of the draft risk evaluation for 1-BP. Comments received on this problem formulation document will inform development of the draft risk evaluation.

The Agency defines problem formulation as the analytical phase of the risk assessment in which "the purpose for the assessment is articulated, the problem is defined and a plan for analyzing and characterizing risk is determined" [see Section 2.2 of the Framework for Human Health Risk Assessment to Inform Decision Making; (U.S. EPA, 2014b)]. The outcome of problem formulation is a conceptual model(s) and an analysis plan. The conceptual model describes the linkages between stressors and adverse human health effects, including the stressor(s), exposure pathway(s), exposed life stage(s) and population(s), and endpoint(s) that will be addressed in the risk evaluation (U.S. EPA, 2014b). The analysis plan follows the development of the conceptual model(s) and is intended to describe the approach for conducting the risk evaluation, including its design, methods and key inputs and intended outputs as described in (U.S. EPA, 2014b). The problem formulation documents refine the initial conceptual models and analysis plans that were provided in the scope documents.

First, EPA has removed from the risk evaluation any activities and exposure pathways that EPA has concluded do not warrant inclusion in the risk evaluation. For example, for some activities that were

listed as "conditions of use" in the scope document, EPA has insufficient information following the further investigations during problem formulation to find they are circumstances under which the chemical is actually "intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of."

Second, EPA also identified certain exposure pathways that are under the jurisdiction of regulatory programs and associated analytical processes carried out under other EPA-administered environmental statutes – namely, the Safe Drinking Water Act (SDWA), the Clean Water Act (CWA), and the Resource Conservation and Recovery Act (RCRA) – and which EPA does not expect to include in the risk evaluation.

As a general matter, EPA believes that certain programs under other Federal environmental laws adequately assess and effectively manage the risks for the covered exposure pathways. To use Agency resources efficiently under the TSCA program, to avoid duplicating efforts taken pursuant to other Agency programs, to maximize scientific and analytical efforts, and to meet the three-year statutory deadline, EPA is planning to exercise its discretion under TSCA 6(b)(4)(D) to focus its analytical efforts on exposures that are likely to present the greatest concern and consequently merit a risk evaluation under TSCA, by excluding, on a case-by-case basis, certain exposure pathways that fall under the jurisdiction of other EPA-administered statutes.[1] EPA does not expect to include any such excluded pathways as further explained below in the risk evaluation. The provisions of various EPA-administered environmental statutes and their implementing regulations represent the judgment of Congress and the Administrator, respectively, as to the degree of health and environmental risk reduction that is sufficient under the various environmental statutes.

Third, EPA identified any conditions of use, hazards, or exposure pathways which were included in the scope document and that EPA expects to include in the risk evaluation but which EPA does not plan to further analyze in the risk evaluation. EPA expects to be able to reach conclusions about particular conditions of use, hazards or exposure pathways without further analysis and therefore plans to conduct no further analysis on those conditions of use, hazards or exposure pathways in order to focus the Agency's resources on more extensive or quantitative analyses. Each risk evaluation will be "fit-for-purpose," meaning not all conditions of use will warrant the same level of evaluation and the Agency may be able to reach some conclusions without comprehensive or quantitative risk evaluations. 82 FR 33726, 33734, 33739 (July 20, 2017).

EPA received comments on the published scope document for 1-BP and has considered the comments specific to 1-BP in this problem formulation document. EPA is soliciting public comment on this problem formulation document and when the draft risk evaluation is issued the Agency intends to respond to comments that are submitted. In its draft risk evaluation, EPA may revise the conclusions and approaches contained in this problem formulation, including the conditions of use and pathways covered and the conceptual models and analysis plans, based on comments received.

1.1 Regulatory History

EPA conducted a search of existing domestic and international laws, regulations and assessments pertaining to 1-BP. EPA compiled this summary from data available from federal, state, international

[1] As explained in the final rule for chemical risk evaluation procedures, "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, and consequently merit an unreasonable risk determination [82 FR 33726 (July 20 2017)].

and other government sources, as cited in Appendix A. EPA evaluated and considered the impact of existing laws and regulations (e.g., regulations on landfill disposal, design, and operations) in the problem formulation step to determine what, if any further analysis might be necessary as part of the risk evaluation. Consideration of the nexus between these existing regulations and TSCA conditions of use may additionally be made as detailed/specific conditions of use and exposure scenarios are developed in conducting the analysis phase 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

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. Table 1-1 shows the assessments that have been conducted. EPA found no additional assessments beyond those listed in the Scope Document (Scope Document; EPA-HQ-OPPT-2016-0741-0049).

In addition to using this information, EPA intends to conduct a full review of the relevant data and information collected in the initial comprehensive search (see *1-Bromopropane (CASRN 106-94-5) Bibliography: Supplemental File for the TSCA Scope Document*, EPA-HQ-OPPT-2016-0741-0048) using the literature search and screening strategies documented in the *Strategy for Conducting Literature Searches for 1-Bromopropane: Supplemental File for the TSCA Scope Document*, (EPA-HQ-OPPT-2016-0741-0048). This will ensure that EPA considers data and information that has been made available since these assessments were conducted.

Table 1-1. Assessment History of 1-BP

Authoring Organization	Assessment
EPA Assessments	
Office of Chemical Safety and Pollution Prevention (OCSPP)/Office of Pollution Prevention and Toxics (OPPT)	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) [2016 Draft Risk Assessment (U.S. EPA, 2016b)]

Table 1-1. Assessment History of 1-BP

Authoring Organization	Assessment
Office of Air Quality Planning and Standards (OAQPS)	Draft notice to grant the petition to add 1-BP to the list of HAPs (https://www.regulations.gov/document?D=EPA-HQ-OAR-2014-0471-0062)
Other U.S.-Based Organizations	
National Institute for Occupational Safety and Health (NIOSH)	Criteria for a Recommended Standard: Occupational Exposure to 1-Bromopropane (2016)
Agency for Toxic Substances and Disease Registry (ATSDR)	Toxicological Profile for 1-Bromopropane (2017)

1.3 Data and Information Collection

EPA/OPPT generally applies a systematic review process and workflow that includes: (1) data collection; (2) data evaluation; and (3) data integration of the scientific data used in risk evaluations 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 may occur during the process of risk evaluation. Additional information that may be considered and was not part of the initial comprehensive bibliographies will be documented in the Draft Risk Evaluation for 1-BP.

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 information potentially relevant to the risk evaluation. For most disciplines, 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). For human health hazard, EPA/OPPT relied on the search strategies from recent assessments, such as the National Toxicology Program's (NTP) *Report on Carcinogens* (NTP, 2013), to identify relevant information published after the end date of the previous search to capture more recent literature. The *Strategy for Conducting Literature Searches for 1-Bromopropane: Supplemental File for the TSCA Scope Document,* (EPA-HQ-OPPT-2016-0741-0048) provides details about the data sources and search terms that were used in the literature 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-2016-0741-0048). 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. However, within each data set, there are two broad categories or data tags: (1) o*n-topic* references or (2) *off-topic* references. *On-topic* references are those that may contain data and/or information relevant to the risk evaluation. O*ff-topic* references are those that do not appear to contain data or information relevant to the risk evaluation. The supplemental document, *Strategy for Conducting Literature Searches for 1-Bromopropane: Supplemental File for the TSCA Scope Document*, (EPA-HQ-OPPT-2016-0741-0048) 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 the supplemental document, *Strategy for Conducting Literature Searches for 1-Bromopropane: Supplemental File for the TSCA Scope Document*, (EPA-HQ-OPPT-2016-0741-0048) 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 can be found in the *1-Bromopropane (CASRN 106-94-5) Bibliography: Supplemental File for the TSCA Scope Document*, EPA-HQ-OPPT-2016-0741-0047). 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.

1.4 Data Screening During Problem Formulation

EPA/OPPT is in the process of completing the full text screening of the on-topic references identified in the *1-Bromopropane (CASRN 106-94-5) Bibliography: Supplemental File for the TSCA Scope Document*, EPA-HQ-OPPT-2016-0741-0047). The screening process at the full-text level is described in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018). Appendix F provides the inclusion and exclusion criteria applied at the full text screening. The eligibility criteria are guided by the analytical considerations in the revised conceptual models and analysis plans, as discussed in the problem formulation document. Thus, it is expected that the number of data/information sources entering evaluation is reduced to those that are relevant to address the technical approach and issues described in the analysis plan of this document.

Following the screening process, the quality of the included data/information sources will be assessed using the evaluation strategies that are described in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018).

2 PROBLEM FORMULATION

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 included in the scope document (Scope Document; EPA-HQ-OPPT-2016-0741-0049) a life cycle diagram and conceptual models that describe the actual or potential relationships between 1-BP and human and ecological receptors. During the problem formulation, EPA revised the conceptual models based on further data gathering and analysis as presented in this Problem Formulation document. An updated 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.

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 and EPA found no additional information during problem formulation that would change these values.

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

Property	Value [a]	References
Molecular formula	C_3H_7Br	O'Neil (2013)
Molecular weight	122.99	O'Neil (2013)
Physical form	Colorless liquid; sweet hydrocarbon odor	O'Neil (2013)
Melting point	-110°C	O'Neil (2013)
Boiling point	71°C at 760 mmHg	O'Neil (2013)
Density	1.353 g/cm^3 at 20°C	O'Neil (2013)
Vapor pressure	146.26 mmHg (19.5 kPa) at 20°C	Boublík et al. (1984)
Vapor density	4.25 (relative to air)	Patty et al. (1963)
Water solubility	2.450 g/L at 20°C	Yalkowsky et al. (2010)

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

Octanol/water partition coefficient (Log K_{ow})	2.10	Hansch (1995)
Henry's Law constant	$7.3x10^{-3}$ atm-m^3/mole (estimated)	U.S. EPA (2012b)
Flash point	22°C	O'Neil (2013)
Autoflammability	490°C	NFPA (2010)
Viscosity	5.241 mPa·s at 20°C	Haynes and Lide (2010)
Refractive index	1.4341	O'Neil (2013)
Dielectric constant	8.09 at 20°C	Haynes and Lide (2010)

[a] Measured unless otherwise noted.

2.2 Conditions of Use

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

In the scope documents, EPA identified, based on reasonably available information, the conditions of use for the subject chemicals. EPA searched a number of available data sources (e.g., *Use and Market Profile for 1-Bromopropane;* EPA-HQ-OPPT-2016-0741-0050). 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 was incorporated into the problem formulation document to the extent appropriate. Thus, EPA believes the manufacture, processing, distribution, use and disposal activities identified in these documents constitute the intended, known, or reasonably foreseeable activities associated with the subject chemicals, based on reasonably available information.

2.2.2 Identification of Conditions of Use

To determine the current conditions of use of 1-BP and inversely, activities that do not qualify as conditions of use, EPA conducted extensive research and outreach. This included EPA's review of published literature and online databases including the most recent data available from EPA's Chemical Data Reporting program (CDR) and Safety Data Sheets (SDSs). EPA also conducted online research by reviewing company websites of potential manufacturers, importers, distributors, retailers, or other users of 1-BP and queried government and commercial trade databases. EPA also received comments on the Scope of the Risk Evaluation for 1-BP (Scope Document; EPA-HQ-OPPT-2016-0741-0049) that were

used to determine the conditions of use. Some of the comments received were more relevant to the risk evaluation process. In addition, EPA convened meetings with companies, industry groups, chemical users, states, environmental groups, and other stakeholders to aid in identifying conditions of use and verifying conditions of use identified by EPA. Those meetings included a February 14, 2017 public meeting with such entities and an October 25, 2017 site visit to CRC Industries (EPA-HQ-OPPT-2016-0741).

EPA has removed from the risk evaluation any activities that EPA has concluded do not constitute conditions of use – for example, because EPA has insufficient information to find certain activities are circumstances under which the chemical is actually "intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." EPA has also identified any conditions of use that EPA does not expect to include in the risk evaluation. As explained in the final rule for Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, TSCA section 6(b)(4)(D) requires EPA to identify "the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider in a risk evaluation," suggesting that EPA may exclude certain activities that EPA has determined to be conditions of use on a case-by-case basis (82 FR 33736, 33729; July 20, 2017). For example, EPA may exclude conditions of use that the Agency has sufficient basis to conclude would present only de minimis exposures or otherwise insignificant risks (such as use in a closed system that effectively precludes exposure or use as an intermediate).

The activities that EPA no longer believes are conditions of use or that were otherwise excluded during problem formulation are described in Section 2.2.2.1. The conditions of use included in the scope of the risk evaluation are summarized in Section 2.2.2.2.

2.2.2.1 Categories and Subcategories Determined Not to be Conditions of Use During Problem Formulation

EPA has conducted public outreach and literature searches to collect information about 1-BP's conditions of use and has reviewed reasonably available information obtained or possessed by EPA concerning activities associated with 1-BP. As a result of that analysis during problem formulation, EPA determined there is insufficient information to support a finding that certain activities which were listed as conditions of use in the Scope Document (Scope Document; EPA-HQ-OPPT-2016-0741-0049) for 1-BP actually constitute "circumstances…under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." Consequently, EPA intends to exclude these activities not considered conditions of use from the scope of the evaluation. These activities are shown in Table 2-2, and consist of agricultural non-pesticidal industrial/commercial/consumer use and the consumer use of: adhesives (except as an adhesive accelerant for arts and crafts), engine degreasing, and brake cleaning.

Based on information available to EPA, EPA determined that 1-BP is not used in agricultural products (non-pesticidal), only in the processing of such products.

A review of the use of 1-BP as a solvent in adhesives, engine degreasers, and in brake cleaners showed that these uses of 1-BP are not consumer uses, except as an adhesive accelerant in arts and crafts. In all other uses of 1-BP as an adhesive, 1-BP-containing adhesives are sold through wholesale channels for commercial and industrial uses, and usually in amounts larger than consumers could use. 1-BP has never been advertised (or used) as a consumer brake cleaner or engine degreaser. Instead, 1-BP has been advertised and used as a specialized general duty industrial or commercial degreaser. 1-BP is sometimes used by industrial and commercial users to degrease engines when these users want a nonflammable

degreaser, or are concerned about disposal of chlorinated solvents in the waste. In practice, this is only a consideration for industrial and commercial users, and not for consumers. Some industrial and commercial users use 1-BP as a general degreaser because chlorinated solvents are listed hazardous wastes under RCRA, whereas 1-BP is not, and therefore waste containing 1-BP may not be hazardous depending on the characteristics of the overall waste stream.

Also, consumers will avoid the use of 1-BP as an engine degreaser or brake cleaner because 1-BP is expensive. In general, heavy duty degreasers containing 1-BP are twice the cost of other heavy duty degreasers and five times the cost of other available consumer brake cleaners.

Table 2-2. Categories and Subcategories Determined Not to be Conditions of Use During Problem Formulation

Life Cycle Stage	Category	Subcategory	References
Industrial/Commercial/ Consumer Use	Agricultural products (non pesticidal)	Miscellaneous agricultural products	U.S. EPA (2016a)
Consumer Use	Adhesives and Sealants	Adhesive chemicals – spray adhesive for foam cushion manufacturing and other uses	U.S. EPA (2016b); Public Comment, EPA-HQ-OPPT-2016-0741-0016
	Other Uses	Automotive care products – engine degreaser, brake cleaner	Use Document, EPA-HQ-OPPT-2016-0741-0003

2.2.2.2 Categories and Subcategories of Conditions of Use Included in the Scope of the Risk Evaluation

EPA has conducted public outreach and literature searches to collect information about 1-BP's conditions of use and has reviewed reasonably available information obtained or possessed by EPA concerning activities associated with 1-BP. Based on this research and outreach, other than the category and subcategory described above in Section 2.2.2.1. EPA does not have reason to believe that any conditions of use identified in the 1-BP scope should be excluded from risk evaluation. Therefore, all of the remaining conditions of use for 1-BP will be included in the risk evaluation.

EPA currently believes that few dry cleaners use 1-BP as a dry cleaning solvent. In the 2016 Draft Risk Assessment (U.S. EPA, 2016b), EPA estimated that about 267 (1.1% of all) dry cleaning establishments used 1-BP. Recent (March 2017) public comments (EPA-HQ-OPPT-2016-0741-0016) on the 1-BP Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal of 1-BP (EPA-HQ-OPPT-2016-0741-0003) suggest than only 23 machines used 1-BP in 2016, only about 30,000 pounds of 1-BP would be used in dry cleaning machines in 2017, and that almost no dry cleaning machines would use 1-BP by 2020. However, the use of 1-BP in the dry cleaning industry remains a reasonably foreseen condition of use. EPA is currently evaluating tetrachloroethylene (perc) under TSCA, and if EPA were to restrict the use of perc in dry cleaning, many dry cleaners might use 1-BP in their machines absent regulatory restrictions from doing so. For many dry cleaners, it is less expensive to convert perc machines to use 1-BP than it is to purchase new machines that use alternative solvents. This is especially true because many dry cleaners are small, capital-constrained, family-owned and operated businesses. Most use of 1-BP in dry cleaning has been from converted machines; very few machines designed to use 1-BP as a solvent have been sold. In addition, based on monitoring data and

the low ACGIH TLV-TWA, EPA expects that the use of 1-BP in dry cleaning results in unreasonable risks to workers, as presented in the 2016 Draft Risk Assessment (U.S. EPA, 2016b).

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. In addition, activities related to distribution (e.g., loading and unloading) will be considered throughout the life cycle rather than using a single distribution scenario.

Beyond the uses identified in the Scope Document (Scope Document; EPA-HQ-OPPT-2016-0741-0049), EPA has received no additional information identifying confirming additional current conditions of use for 1-BP from public comment and stakeholder meetings.

Table 2-3. Categories and Subcategories of Conditions of Use Included in the Scope of the Risk Evaluation

Life Cycle Stage	Category [a]	Subcategory [b]	References
Manufacture	Domestic manufacture	Domestic manufacture	U.S. EPA (2016a)
	Import	Import	U.S. EPA (2016a)
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	U.S. EPA (2016a)

Table 2-3. Categories and Subcategories of Conditions of Use Included in the Scope of the Risk Evaluation

Life Cycle Stage	Category [a]	Subcategory [b]	References
Processing	Processing - incorporating into formulation, mixture or reaction product	Solvents for cleaning or degreasing in manufacturing of: - all other chemical product and preparation - computer and electronic product - electrical equipment, appliance and component - soap, cleaning compound and toilet preparation - services	U.S. EPA (2016a)
	Processing - incorporating into articles	Solvents (which become part of product formulation or mixture) in construction	U.S. EPA (2016a); Public Comment, EPA-HQ-OPPT-2016-0741-0017
	Repackaging	Solvent for cleaning or degreasing in all other basic organic chemical manufacturing	U.S. EPA (2016a)
	Recycling	Recycling	U.S. EPA (2016a); Use Document, EPA-HQ-OPPT-2016-0741-0003
Distribution in commerce	Distribution	Distribution	U.S. EPA (2016a); Use Document, EPA-HQ-OPPT-2016-0741-0003

Table 2-3. Categories and Subcategories of Conditions of Use Included in the Scope of the Risk Evaluation

Life Cycle Stage	Category [a]	Subcategory [b]	References
Industrial/ commercial/ use	Solvent (for cleaning or degreasing)	Batch vapor degreaser (e.g., open-top, closed-loop)	U.S. EPA (2016b); Public Comment, EPA-HQ-OPPT-2016-0741-0014; Public Comment, EPA-HQ-OPPT-2016-0741-0015; Public Comment, EPA-HQ-OPPT-2016-0741-0016
		In-line vapor degreaser (e.g., conveyorized, web cleaner)	Kanegsberg and Kanegsberg (2011); Public Comment, EPA-HQ-OPPT-2016-0741-0014; Public Comment, EPA-HQ-OPPT-2016-0741-0016
		Cold cleaner	U.S. EPA (2016b); Public Comment, EPA-HQ-OPPT-2016-0741-0016
		Aerosol spray degreaser/cleaner	U.S. EPA (2016b); Public Comment, EPA-HQ-OPPT-2016-0741-0016; Public Comment, EPA-HQ-OPPT-2016-0741-0018; Public Comment, EPA-HQ-OPPT-2016-0741-0020
	Adhesives and sealants	Adhesive chemicals - spray adhesive for foam cushion manufacturing and other uses	U.S. EPA (2016b); Public Comment, EPA-HQ-OPPT-2016-0741-0016

Table 2-3. Categories and Subcategories of Conditions of Use Included in the Scope of the Risk Evaluation

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

Table 2-3. Categories and Subcategories of Conditions of Use Included in the Scope of the Risk Evaluation

Life Cycle Stage	Category [a]	Subcategory [b]	References
Industrial/ commercial/use (continued)	Other uses	Electronic and electronic products and metal products	U.S. EPA (2016a); Public Comment, EPA-HQ-OPPT-2016-0741-0016; Public Comment, EPA-HQ-OPPT-2016-0741-0024
		Functional fluids (closed systems) - refrigerant	Use Document, EPA-HQ-OPPT-2016-0741-0003
		Functional fluids (open system) - cutting oils	Use Document, EPA-HQ-OPPT-2016-0741-0003; Public Comment, EPA-HQ-OPPT-2016-0741-0014
		Other - asphalt extraction	Use Document, EPA-HQ-OPPT-2016-0741-0003; Public Comment, EPA-HQ-OPPT-2016-0741-0016
		Temperature Indicator – Laboratory chemicals	Use Document, EPA-HQ-OPPT-2016-0741-0003
		Temperature Indicator – Coatings	Use Document, EPA-HQ-OPPT-2016-0741-0003; Public Comment, EPA-HQ-OPPT-2016-0741-0014; Public Comment, EPA-HQ-OPPT-2016-0741-0016
Consumer uses	Solvent (for cleaning or degreasing)	Aerosol spray degreaser/cleaner	U.S. EPA (2016b);
	Cleaning and furniture care products	Spot cleaner, stain remover	U.S. EPA (2016b); Public Comment, EPA-HQ-OPPT-2016-0741-0022
		Liquid cleaner (e.g., coin and scissor cleaner)	Use Document, EPA-HQ-OPPT-2016-0741-0003
		Liquid spray/aerosol cleaner	Use Document, EPA-HQ-OPPT-2016-0741-0003
	Other uses	Arts, crafts and hobby materials - adhesive accelerant	U.S. EPA (2016b)

Table 2-3. Categories and Subcategories of Conditions of Use Included in the Scope of the Risk Evaluation

Life Cycle Stage	Category [a]	Subcategory [b]	References
		Automotive care products – refrigerant flush	U.S. EPA (2016b)
		Anti-adhesive agents - mold cleaning and release product	U.S. EPA (2016b)
		Building/construction materials not covered elsewhere - insulation	Use Document, EPA-HQ-OPPT-2016-0741-0003; Public Comment, EPA-HQ-OPPT-2016-0741-0027
Disposal (Manufacturing, Processing, Use)	Disposal	Municipal waste incinerator Off-site transfer	2016 TRI Data (updated October 2017) U.S. EPA (2017c)
		Municipal waste incinerator	
		Off-site waste transfer	

[a]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.
[b]These subcategories reflect more specific uses of 1-BP.

Although EPA indicated in the 1-BP Scope Document (Scope Document; EPA-HQ-OPPT-2016-0741-0049) that EPA did not expect to evaluate the uses assessed in the 2016 Draft Risk Assessment (U.S. EPA, 2016b) in the 1-BP risk evaluation, EPA has decided to evaluate these conditions of use in the risk evaluation as described in this problem formulation. EPA is including these conditions of use so that they are part of EPA's determination of whether 1-BP presents an unreasonable risk "under the conditions of use," TSCA 6(b)(4)(A). EPA has concluded that the Agency's assessment of the potential risks from this widely used chemical will be more robust if the potential risks from these conditions of use are evaluated by applying standards and guidance under amended TSCA. In particular, this includes ensuring the evaluation is consistent with the scientific standards in Section 26 of TSCA, the Procedures for Chemical Risk Evaluation under the Amended Toxic Substances Control Act (40 CFR Part 702) and EPA's supplemental document, *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018). EPA also expects to consider other available hazard and exposure data to ensure that all reasonably available information is taken into consideration.

2.2.2.3 Overview of Conditions of Use and Life Cycle Diagram

The life cycle diagram provided in Figure 2-1 depicts the conditions of use that are considered within the scope of the risk evaluation during various life cycle stages including manufacturing, processing, distribution, use (industrial, commercial, and consumer; when distinguishable), and disposal. Additions or changes to the conditions of use based on additional information gathered or analyzed during problem

formulation were described in Sections 2.2.2.1 and 2.2.2.2. The activities that EPA determined are out of scope during problem formulation are not included in the life cycle diagram. 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.

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).

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 (U.S. EPA, 2016a). EPA will evaluate activities resulting in exposures associated with distribution in commerce (e.g. loading, unloading) throughout the various lifecycle stages and conditions of use (e.g. manufacturing, processing, industrial use, consumer use, disposal) rather as 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.

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 2-4 for 1-BP from EPA's CDR database (U.S. EPA, 2016a). This information has not changed from that provided in the Scope Document (EPA-HQ-OPPT-2016-0741-0049).

Table 2-4. Production Volume of 1-BP in CDR Reporting Period (2012 to 2015) [a]

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

[a] 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 (EPA-HQ-OPPT-2016-0741-0049) 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 2-4 (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).

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, 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 depicts the life cycle diagram of 1-BP from manufacture to the point of disposal. Activities related to distribution (e.g., loading, unloading) will be considered throughout the 1-BP life cycle, rather than using a single distribution scenario.

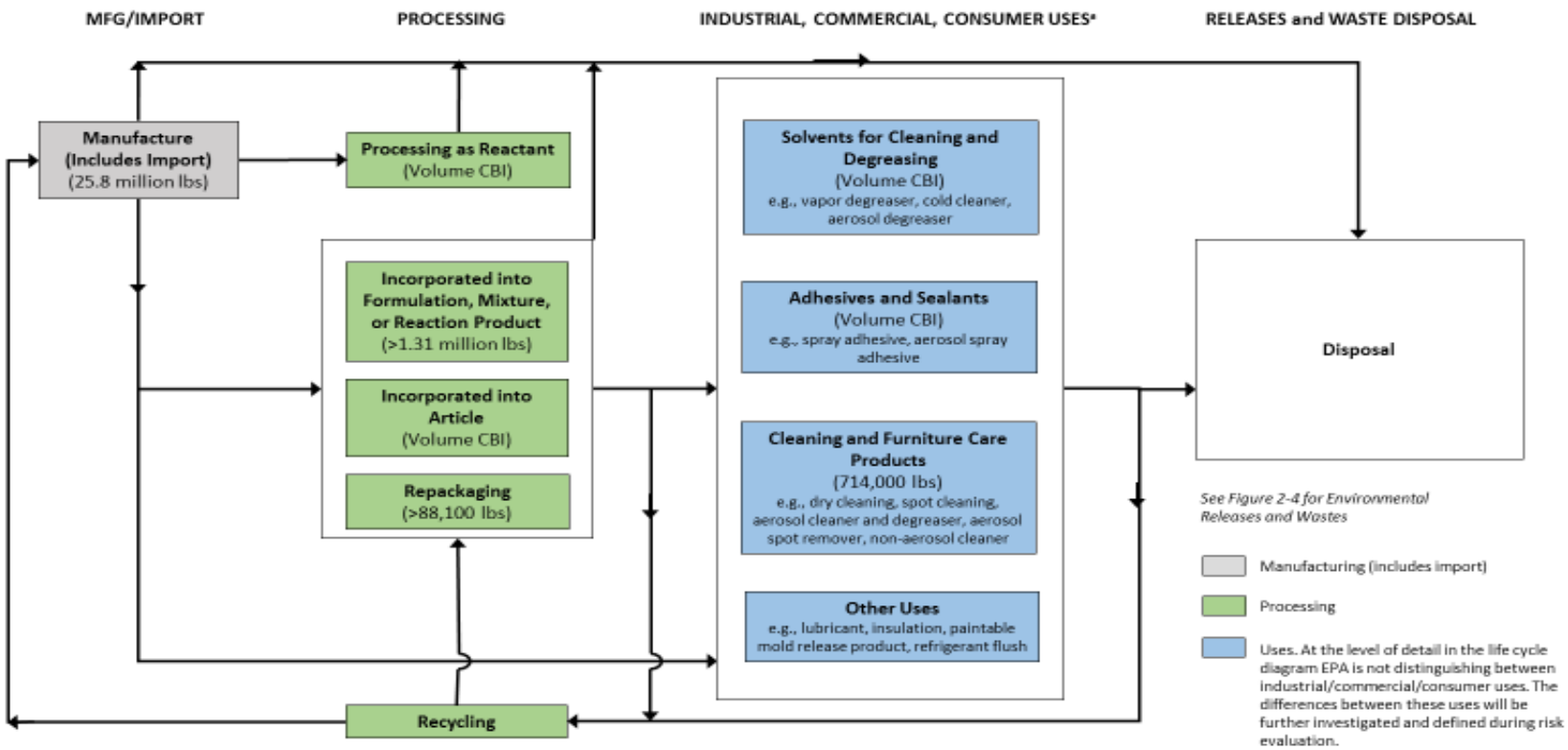

Figure 2-1. 1-BP Life Cycle Diagram

The 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). EPA will evaluate activities resulting in exposures associated with distribution in commerce (e.g. loading, unloading) throughout the various lifecycle stages and conditions of use (e.g. manufacturing, processing, industrial use, consumer use, disposal) rather as a single distribution scenario.

[a] See Table 2-3 for additional uses not mentioned specifically in this diagram.

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 for 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 2-5 provides environmental fate data that EPA identified and considered in developing the scope for 1-BP. This information has not changed from that provided in the Scope Document (EPA-HQ-OPPT-2016-0741-0049).

Fate data including volatilization during wastewater treatment, volatilization from lakes and rivers, biodegradation rates, and organic carbon:water partition coefficient (log K_{OC}) were used when considering changes to the conceptual models. Model results and basic principles were used to support the fate data used in problem formulation while the literature review is currently underway through the systematic review process.

EPI Suite™ (U.S. EPA, 2012b) modules were used to predict volatilization of 1-BP from wastewater treatment plants, lakes, and rivers and to confirm the data showing moderate to rapid biodegradation. The EPI Suite™ module that estimates chemical removal in sewage treatment plants ("STP" module) was run using default settings to evaluate the potential for 1-BP to volatilize to air or adsorb to sludge during wastewater treatment. The STP module estimates that 73% of 1-BP in wastewater will be removed by volatilization while 1% of 1-BP will be removed by adsorption.

The EPI Suite™ module that estimates volatilization from lakes and rivers ("Volatilization" module) was run using default settings to evaluate the volatilization half-life of 1-BP in surface water. The parameters required for volatilization (evaporation) rate of an organic chemical from the water body are water depth, wind and current velocity of the river or lake. The volatilization module estimates that the half-life of 1-BP in a model river will be 1.2 hours and the half-life in a model lake will be 4.4 days.

The EPI Suite™ module that predicts biodegradation rates ("BIOWIN" module) was run using default settings to estimate biodegradation rates of 1-BP under aerobic conditions. Three of the models built into the BIOWIN module (BIOWIN 2, 5 and 6) estimate that 1-BP will not rapidly biodegrade in aerobic environments, while a fourth (BIOWIN 1) estimates that 1-BP will rapidly biodegrade in aerobic environments. These results support the biodegradation data presented in the 1-BP Scope Document (EPA-HQ-OPPT-2016-0741-0049), which demonstrate a range of biodegradation rates under aerobic conditions. The model that estimates anaerobic biodegradation (BIOWIN 7) predicts that 1-BP will rapidly biodegrade under anaerobic conditions. Further, previous assessments of 1-BP found that biodegradation occurred over a range of rates from slow to rapid [Toxicological Profile for 1-Bromopropane; (ATSDR, 2017)].

The log K_{OC} reported in the 1-BP scope document was predicted using EPI Suite™. That value (1.6) is supported by the basic principles of environmental chemistry which states that the K_{OC} is typically within one order of magnitude (one log unit) of the octanol:water partition coefficient (K_{OW}). Indeed, the log K_{OW} reported for 1-BP in the Scope Document (EPA-HQ-OPPT-2016-0741-0049) was 2.1, which is within the expected range. Further, the K_{OC} could be approximately one order of magnitude larger than predicted by EPI Suite™ before sorption would be expected to significantly impact the mobility of 1-BP in groundwater. No measured K_{OC} values were found.

Table 2-5. Environmental Fate Characteristics of 1-BP

Property or Endpoint	Value [a]	References
Direct photodegradation	Not expected to undergo direct photolysis	U.S. EPA (2016b)
Indirect photodegradation	9-12 days (estimated for atmospheric degradation)	U.S. EPA (2016b)
Hydrolysis half-life	26 days	U.S. EPA (2016b)
Biodegradation	70% in 28 days (OECD 301C) 19.2% in 28 days (OECD 301D)	U.S. EPA (2016b)
Bioconcentration factor (BCF)	11 (estimated)	U.S. EPA (2012b)
Bioaccumulation factor (BAF)	12 (estimated)	U.S. EPA (2016b)
Organic carbon:water partition coefficient (Log K_{oc})	1.6 (estimated)	U.S. EPA (2016b)

[a] 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 and 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.

1-BP is expected to be released to air during manufacturing, processing, distribution and use due to its high volatility (vapor pressure of 146.26 mmHg at 20°C). 1-BP is also expected to be released to other environmental media through waste disposal (e.g., disposal of spent solvent, rags, wipe materials, and transport containers).

A source of information that EPA expects to consider in evaluating exposure are data reported under the Toxics Release Inventory (TRI) program. Under the Emergency Planning and Community Right-to-Know Act (EPCRA) Section 313 rule, 1-BP is a TRI-reportable chemical beginning with the 2016 calendar year with the first reporting forms from facilities were submitted on July 1, 2017 and on each following year. During problem formulation, EPA analyzed the TRI data reported for 2016 and examined the reported treatment and disposal methods employed to determine the level of confidence that a release would result from certain types of disposal to land (e.g., Resource Conservation and Recovery Act or RCRA Subtitle C hazardous waste landfills, Subtitle D municipal landfills, and Class I underground injection wells) and incineration.

2.3.2.1 Disposal of Wastes containing 1-BP

Industrial wastewater containing 1-BP may be subject to state or local regulations or permit limits. Solid wastes containing 1-BP may be regulated as a hazardous waste under the RCRA waste code D001 (ignitable liquids, 40 CFR 261.21). These wastes would be either incinerated in a hazardous waste incinerator or disposed to a hazardous waste landfill. 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. 1-BP migration to groundwater from RCRA Subtitle C landfills or RCRA Subtitle D municipal landfills regulated by the state / local jurisdictions to groundwater will likely be mitigated by landfill design (double liner, leachate capture for RCRA Subtitle C landfills and single liner for RCRA Subtitle D municipal landfills) and requirements to adsorb liquids onto solid adsorbent and containerize prior to disposal.

2016 TRI Data

A key source of information that EPA expects to consider in the risk evaluation 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 submitted on July 1, 2017.

Table 2-6 summarizes TRI release data for 1-BP. For the 2016 reporting year, 55 out of an estimated 140 facilities filed TRI reporting forms containing release and waste management data for 1-BP. The estimated number of facilities expected to report was derived from the Economic Analysis Report of 1-BP (https://www.regulations.gov/document?D=EPA-HQ-TRI-2015-0011-0011).[2] The difference in estimated versus actual reporting facilities could be due to several factors such as, 1) facilities could be moving away from using 1-BP; 2) some facilities may not yet be aware of the reporting requirements since this is the first year of reporting; 3) facilities could be below the threshold for reporting. Facilities

[2] Note: This estimated values of 140 facilities was derived from the Economic Analysis Report of 1-BP (https://www.regulations.gov/document?D=EPA-HQ-TRI-2015-0011-0011. Potential reporting for facilities was compiled using available US facility data and other resources such as NAICS codes, Japanese PRTR data on 1-BP, and from proxy chemical models.

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.

Table 2-6. Summary of 2016 TRI Releases for 1-BP (CASRN 106-94-5)

Waste Type	Conceptual Model Release Category	TRI Category	Volume from TRI (lbs)	Number of Reporting Sites from TRI	% of Total Production-Related Waste Managed
Wastewater or Liquid Wastes	Industrial Pre-Treatment (indirect discharge)	POTW	0	0	0%
	Industrial WWT (indirect discharge)	Off-site WWT (non-POTW)	0	0	0%
	Industrial WWT (direct discharge)	Water	5	1	<0.001%
	Underground Injection	Class I Underground Injection	10	1	<0.001%
Solid Wastes and Liquid Wastes	Hazardous and Municipal Waste Landfills	RCRA Subtitle C Landfills	57,617	1	3.7%
		Other Landfills	90,273	3	5.8%
	Waste Treatment and Management Methods	Off-site Incineration	61,301	10	3.9%
		Energy Recovery	325,752	15	20.9%
		Other Treatment and Management Methods	20,892	5	1.3%
		Transfer to Storage-Only Facility	3,307	1	<0.001%
		Transfer to Waste Broker	750	1	<0.001%
		Recycling	322,097	11	20.6%
		On-site Waste Treatment Methods[a]	53,550	2	3.4%
Emissions to Air	Emissions to Air	Fugitive Air	394,469	43	25.3%
		Stack Air	232,191	26	14.9%
Total Production Related Waste Managed			1,562,213	55	
Total One-Time Release Waste			0	0	0%
Total Waste Managed			1,562,213	55	

[a] Because sites such as treatment, storage, and disposal facilities (TSDFs) are required to report to TRI if they meet reporting thresholds, the total volumes for these categories may include volumes that were reported as transferred off-site for waste treatment purposes by other facilities, such as for off-site incineration.

Releases to Air

Table 2-6 shows air as a primary medium of environmental release. These releases include both fugitive air emissions and point source (stack) air emissions. Fugitive air emissions (totaling 394,469 pounds from 2016 TRI data) are emissions that do not occur through a confined air stream, which may include equipment leaks, releases from building ventilation systems, and evaporative losses from surface impoundments and spills. Point source (stack) air emissions (totaling 232,191 pounds from TRI 2016 data) are releases to air that occur through confined air streams, such as stacks, ducts or pipes.

Releases to Water

In the 2016 TRI, only 1 facility out of 55 reported releases to water. This facility reported 5 lbs of direct surface water discharge; assuming the release occurred over a single day, the surface water concentration in reported receiving waters is well below the COC based on EPA's preliminary calculations. No facility reported any amounts of 1-BP sent to Publicly Owned Treatment Works (POTWs).

Releases to Land

Table 2-6 shows TRI reports approximately 58,000 pounds of disposal to a single RCRA Subtitle C landfill. EPA will not further analyze releases to hazardous waste landfills because these types of landfill mitigate exposure to the wastes. TRI also reports approximately 90,000 pounds of 1-BP transferred to other off-site landfills. Further review of TRI data indicated that all reported transfers "other off-site landfills" were to facilities permitted to manage RCRA regulated waste.

Releases of Solid and Liquid Wastes to Incineration/Energy Recovery

On-site

On-site waste treatment (including incineration) and energy recovery total 275,917 lbs, which is approximately 18% of the total production waste managed. Air emissions resulting from these operations are already included in the TRI reports and will be used in the analysis of air releases.

Off-site

In Table 2-6, off-site transfers for incineration and energy recovery total 164,686 lbs, almost 10% of the total production waste managed.

Recycling

Table 2-6 shows 1-BP recycling amounts totaling 322,097 lbs in 2016, approximately 21 percent of the total production waste managed. This estimate includes all quantities of 1-BP recycled on-site and off-site, as reported in Section 8 of the Form R. EPA expects recycling to involve recovery of waste solvents containing 1-BP for re-use (e.g., using distillation, evaporation). Currently, EPA is not aware of the presence of 1-BP in recycled articles.

2.3.3 Presence in the Environment and Biota

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, any environmental monitoring data that may result from the updated literature search will be considered. Biomonitoring data were identified in the 2016 Draft Risk Assessment (U.S. EPA,

2016b). 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.

2.3.4 Environmental Exposures

The manufacturing, processing, use and disposal of 1-BP can result in releases to the environment. In this section, EPA presents exposures to aquatic and terrestrial organisms. The predominance of these exposures will be via the air pathway as releases to water are very low as described in Section 2.3.2.

Aquatic Environmental Exposures

EPA used the reported releases from EPA's Toxics Release Inventory (TRI) to predict surface water concentrations near reported facilities for this Problem Formulation. To examine whether near-facility surface water concentrations could approach 1-BP's aquatic concentrations of concern, EPA employed a first-tier approach, using readily-available modeling tools and data, as well as conservative assumptions. EPA's Exposure and Fate Assessment Screening Tool (E-FAST 2014) was used to estimate site-specific surface water concentrations based on estimated loadings of 1-BP into receiving water bodies as reported to TRI. E-FAST 2014 incorporates stream dilution using stream flow information contained within the model. E-FAST also incorporates wastewater treatment removal efficiencies. Wastewater treatment removal was assumed to be 0% for this exercise, as reported loadings/releases are assumed to account for any treatment. As days of release and operation are not reported, EPA assumed a range of possible release days (i.e., 1, 20, and 100 days/year). Refer to the E-FAST 2014 Documentation Manual for equations used in the model to estimate surface water concentrations (U.S. EPA, 2007).

Estimated surface water concentrations from all E-FAST 2014 runs ranged from 0.08 to 77.9 µg/L, with all values below the aquatic chronic concentration of concern by a factor of 3 – 3,038. For further details of this estimation approach, see Appendix C.

Terrestrial Environmental Exposures

EPA does not plan to further analyze terrestrial exposures, due to low expected toxicity (see Section 2.4.1) and low expected exposure based on the physical/chemical properties (e.g., high vapor pressure; see Section 2.1).

2.3.5 Human Exposures

In this section, EPA presents occupational, consumer, and general population exposures. Subpopulations, including potentially exposed and susceptible subpopulations within these exposure categories, are also presented.

2.3.5.1 Occupational Exposures

Exposure pathways and exposure routes are listed below for worker activities under the various conditions of use (industrial or commercial) described in Section 2.3. In addition, exposures to occupational non-users (ONU), who do not directly handle the chemical but perform work in an area where the chemical is present are listed. Engineering controls and/or personal protective equipment may affect the 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), which will be considered in the 1-BP risk evaluation. As described in Section 2.2, all the conditions of use identified which results in occupational exposures will be considered during the risk evaluation.

Worker Activities

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. Work activities with potential for exposure may include, but are 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;
- Handling and transporting 1-BP during distribution in commerce;
- 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.

Inhalation

Based on these occupational exposure scenarios, EPA expects inhalation of vapor to be the primary route of exposure for workers and occupational non-users. Where mist generation is expected (e.g. spray application), EPA will also analyze inhalation exposure to mist for workers and ONU.

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 Governmental Industrial Hygienists (ACGIH) has recommended a Threshold Limit Value (TLV) of 0.1 ppm 8-hour time-weighted average (TWA) 1-BP for workers (ACGIH, 2015).

Oral

Worker exposure via the oral route is not expected. Exposure may occur through mists that deposit in the upper respiratory tract however, based on physical chemical properties, mists of 1-BP will likely be rapidly absorbed in the respiratory tract or evaporate and will be considered as an inhalation exposure.

Dermal

For conditions of use where workers may come into contact with liquids containing 1-BP, EPA estimates the skin contact time to be less than 2 minutes due to rapid volatilization. The estimated evaporation time is based on vapor generation rate of 1-BP at ambient conditions as calculated using the EPA/OPPT Penetration Model. 1-BP is an organic chemical with vapor pressure of 111 mmHg at 20°C. At the typical skin surface temperature of 32°C, the vapor pressure is estimated to be 186 mmHg (Frasch et al., 2014). The Penetration Model estimates the release of a chemical from an open, exposed liquid surface in an indoor environment. Evaporation time can then be calculated from the vapor generation rate, and the exposure load from EPA/OPPT 2-Hand Dermal Contact with Liquid Model or the EPA/OPPT 2-Hand Dermal Immersion in Liquid Model (2.1 to 10.3 mg/cm^2), and skin surface area of two hands (1,070 cm^2) from EPA/OPPT models (U.S. EPA, 2013a). Therefore, dermal exposure to 1-BP based on a single finite exposure event is likely negligible.

EPA also expects the dermal absorbed fraction to be low (0.16 percent – see discussion under Dermal section of Section 2.3.5.2). However, there is potential for increased dermal penetration for uses where occluded exposure, repeated contact, or dermal immersion may occur. For occupational non-users, dermal exposure to liquid is generally not expected as they do not directly handle 1-BP.

Key Data

Key data that inform occupational exposure assessment 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. OSHA sampling data can be obtained through the CEHD at https://www.osha.gov/opengov/healthsamples.html. Table_Apx B-1 and Table_Apx B-2 summarize the exposure scenarios and industry sectors where 1-BP personal and area monitoring data are available from OSHA inspections conducted between 2013 and 2016.

2.3.5.2 Consumer Exposures

1-BP can be found in consumer products and/or commercial products that are readily available for public purchase at common retailers (Sections 3 and 4 of *Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: 1-Bromopropane,* EPA-HQ-OPPT-2016-0741-0003) and can therefore result in exposures to consumers and bystanders [non-product users that are incidentally exposed to the product or article, (U.S. EPA, 2017b)].

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)

During Problem Formulation, further review of consumer products and consumer uses was performed, and is discussed in Section 2.2.2. It was concluded that there is no consumer use of 1-BP for engine degreasers, brake cleaning, or aerosol spray adhesives (except as an adhesive accelerant in arts and crafts applications). Although 1-BP is sometimes used by industrial and commercial users to degrease engines when these users want a nonflammable degreaser, it is not expected to be used by consumers for the purposes of engine degreasing or brake cleaning.

Based on information summarized in Section 2.2.2, additional consumer uses that will be further analyzed include:

- Solvents (for cleaning or degreasing)
  - Aerosol spray degreaser/cleaner
- Cleaning and Furniture Care Products
  - Spot cleaner, stain remover
  - Liquid cleaner (e.g., coin and scissor cleaner)
  - Liquid spray/aerosol cleaner
- Other uses
  - Arts, crafts and hobby materials – adhesive accelerant
  - Automotive care products – refrigerant flush

- Anti-adhesive agents – mold cleaning and release product
- Building and construction materials not covered elsewhere – insulation

Use patterns and habits and practices may vary depending on the use and user. There may be higher end users (e.g., DIY) who purchase consumer products, and use these products more frequently. Examples may be small shops or businesses (e.g., art shops that routinely use a spray adhesive, small garages that frequently use degreasers) where the frequency of use is higher or where users or hobbyists may use products more than once per day on a regular basis. This may lead to chronic exposure whereas typical consumer exposures are expected to be acute in nature based on the identified consumer products/uses. Use of articles, such as insulation, may lead to exposures that occur over longer periods of time. Use patterns for the consumer products identified will be considered using available information on magnitude, frequency and duration of exposures.

Inhalation

Based on the physical-chemical properties of 1-BP and the conditions of use, inhalation is expected to be the primary route of exposure for consumer users of 1-BP containing products. The magnitude of exposure will depend upon the concentration of 1-BP in products, use patterns (including frequency, duration, amount of product used, room of use) and application methods. Several product types and scenarios were evaluated in the 2016 Draft Risk Assessment (U.S. EPA, 2016b), including spray adhesives, spray degreasers (engine cleaning and electronics cleaning), and aerosol spot removers. Information regarding use patterns and application methods will be used to build exposure scenarios. Any products which are spray applied will result in some level of inhalation exposure to the consumer user and also to a bystander in the room of use. Products used in the liquid form are also likely to result in some level of inhalation exposure to the consumer given the high vapor pressure of 1-BP. Consumer exposures are expected to be acute in nature, however, there may be a subset of consumers who use products on a frequent or regular basis resulting in sub-chronic or chronic exposures. Based on the potential for spray application of some products containing 1-BP, exposures to mists are also expected. The exposures to consumers and bystanders through mists may deposit in the upper respiratory tract and EPA assumes these are absorbed via inhalation.

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 also assessed for the consumer uses identified in the 2016 Draft Risk Assessment (U.S. EPA, 2016b).

Oral

EPA does not plan to further analyze exposure to consumers via ingestion of 1-BP. Ingestion is not expected to be a primary route of exposure. Based on the vapor pressure, 1-BP will exist as a vapor/mist during use. A fraction of 1-BP may be available for absorption in the respiratory tract however ingestion of 1-BP is anticipated to be low since 1-BP is expected to be absorbed in the lung quickly and not have appreciable ability to travel up the mucosal elevator and be swallowed.

Dermal

There is the potential for dermal exposure from consumer uses of 1-BP. Dermal exposure may occur via vapor/mist deposition onto skin or via direct liquid contact during use, particularly in occluded scenarios. As described in the NIOSH Skin Notation Profile for 1-BP (NIOSH, 2017), *in vitro* dermal penetration of 0.16% of the applied dose (13.5 mg/cm^2) was measured following transient exposure in a non-occluded environment to simulate splash scenarios; therefore, losses due to evaporation were approximately 500-fold greater than the dermal absorption flux. However, measurements of skin

penetration were one to two orders or magnitude higher in occluded environments where evaporation losses were not considered (transient 10 minute exposures, or 'infinite' 3 hour exposures). Based on this information, dermal exposure in non-occluded scenarios will be a less significant route of exposure when compared to occluded scenarios, however there may be exceptions such as situations of transient or infinite exposures (e.g., vapor trapped against skin by gloves or continued contact with a wet rag) or where there is greater potential for dermal penetration due to longer durations of exposure.

Whereas users may be exposed dermally during use of consumer products depending on the specific use, it is not expected that bystanders would be dermally exposed to 1-BP.

Exposures from Disposal

EPA does not expect exposure to consumers from disposal of consumer products. It is anticipated that most products will be disposed of in original containers, particularly those products that are purchased as aerosol cans. Liquid products may be recaptured in an alternate container following use (refrigerant flush or coin cleaning).

2.3.5.3 General Population Exposures

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.

Inhalation

Emissions to air from industrial manufacturing, processing and use are expected. TRI data in Table 2-6 show air as a primary medium of environmental release. These releases include both fugitive air emissions and point source (stack) air emissions. Based on the relatively long hydroxy radical oxidation half-life (t ½ 14 days) emissions to ambient air could results in exposures to near facility human receptors and the general population. Inhalation is expected to be the primary route of exposure for the general population and near facility populations.

Inhalation of 1-BP may also occur in indoor settings as a result of co-location with dry cleaning facilities that use 1-BP.

Oral

Recent TRI reporting indicated 0 pounds released to POTWs and 5 pounds released directly to water in 2016. EPA pretreatment regulations for industrial users discharging wastewater to POTWs are expected to limit the discharge of 1-BP to POTWs and ultimately to surface water (see Section 2.3.4). Waste disposal practices and 1-BP's rapid volatilization from water are expected to mitigate drinking water exposure potential and there is no data of 1-BP found in US drinking water.

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 and contaminated drinking water are not expected.

Dermal

Based on the physical and chemical properties of 1-BP (relatively high volatility), low expected dermal absorption, and expected media concentrations (see Section 2.3.4), dermal exposure to 1-BP via surface water or soil is not expected to be a significant route of exposure.

2.3.5.4 Potentially Exposed or Susceptible Subpopulations

TSCA requires the determination of whether a chemical substance presents an 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." General population is "the total of individuals inhabiting an area or making up a whole group" and refers here to the U.S. general population (U.S. EPA, 2011).

As part of the Problem Formulation, EPA identified potentially exposed and susceptible subpopulations for further analysis during the development and refinement of the life cycle, conceptual models, exposure scenarios, and analysis plan. 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.

EPA identifies the following as potentially exposed or susceptible subpopulations that EPA expects to consider in the risk evaluation due to their *greater exposure*:

- Workers and occupational non-users.
- Consumers and bystanders associated with consumer use. 1-BP has been identified 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, use or disposal sites).

In developing exposure scenarios, EPA will analyze 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 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 plans to analyze the following potentially exposed groups of human receptors: workers, occupational non-users, consumers, bystanders associated with consumer use, and other groups of individuals within the general population who may experience greater exposure. EPA may also identify additional potentially exposed or susceptible subpopulations that will be considered based on greater exposure.

2.4 Hazards (Effects)

For scoping, EPA conducted comprehensive searches for data on hazards of 1-BP, as described in *Strategy for Conducting Literature Searches for 1-Bromopropane: Supplemental File for the TSCA Scope Document*, (EPA-HQ-OPPT-2016-0741-0048). Based on initial screening, EPA plans to analyze the hazards of 1-BP identified in the scope document (EPA-HQ-OPPT-2016-0741-0049). 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 as a result of chronic exposures may not be applicable for acute exposure scenarios. This means that it is unlikely that every identified hazard will be analyzed for every exposure scenario.

2.4.1 Environmental Hazards

Environmental hazard data identified for 1-BP are studies described in the robust summaries in the ECHA Database (ECHA, 2015) and the Ecological Hazard Literature Search Results in the 1-Bromopropane (CASRN 106-94-5) Bibliography: *Supplemental File for the TSCA Scope Document*, (U.S. EPA, 2017a). Only the *on-topic* references listed in the Ecological Hazard Literature Search Results were considered as potentially relevant data/information sources for the risk evaluation. Inclusion criteria were used to screen the results of the ECOTOX literature search (as explained in the *Strategy for Conducting Literature Searches for 1-Bromopropane: Supplemental File for the TSCA Scope Document*, (EPA-HQ-OPPT-2016-0741-0048). Data from the screened literature are summarized below (Table 2-7). EPA expects to review these data/information sources during risk evaluation using the data quality review evaluation metrics and the rating criteria described in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018).

Toxicity to Sediment and Terrestrial Organisms

During data screening, there were no available sediment, soil, nor avian toxicity studies found in the scientific literature for 1-BP. The toxicity of 1-BP is expected to be low based on the lack of on-topic environmental hazard data for 1-BP to sediment and terrestrial organisms in the published literature and the physical/chemical/fate properties (relatively high volatility (Henry's Law constant of $7.3X10^{-3}$ atm-m^3/mole), high water solubility (2.4 g/L), and low log K_{oc} (1.6) suggesting that 1-BP will only be present at low concentrations in these environmental compartments.

Toxicity to Aquatic Organisms

During problem formulation, EPA identified aquatic (aqueous-only) data reported in the literature to assess the aquatic hazard of 1-BP. The 96-hour LC_{50} value for 1-BP with fish ranged from 24.3 to 67.3 mg/L. The acute aquatic invertebrate EC_{50} for 1-BP was 99.3 mg/L. The EC_{50} for the algae toxicity test was 52.4 mg/L (biomass) and 72.3 mg/L (growth rate). The NOEC for the algae toxicity test was 12.4 mg/L.

Toxicity to Microorganisms

The EC_{50} and NOEC for micro-organisms toxicity study for a 5-minute time period was 270 mg/L and 100 mg/L, respectively.

Table 2-7. Ecological Hazard Characterization of 1-Bromopropane

Duration	Test organism	Endpoint	Hazard value*	Units	Effect Endpoint	Citation
Acute	Fish	LC_{50}	24.3 - 67.3	mg/L	Mortality	ECHA (2015);Geiger et al. (1988)
	Aquatic invertebrates	EC_{50}	99.3	mg/L	Immobilization	ECHA (2015)
	Algae	EC_{50}	52.4 / 72.3	mg/L	Biomass / growth rate	ECHA (2015)
	Microorganism	EC_{50}	270	mg/L	Respiration	ECHA (2015)
	Acute COC		4.86	mg/L		
Chronic	Fish	ChV	2.43	mg/L	Acute to chronic ratio of 10	ECHA (2015)
	Aquatic invertebrates	ChV	9.93	mg/L	Acute to chronic ratio of 10	ECHA (2015)
	Algae	NOEC	12.4	mg/L	Growth rate	ECHA (2015)
	Microorganism	NOEC	100	mg/L	Respiration	ECHA (2015)
	Chronic COC		0.24	mg/L		

* Values in the tables are presented as reported by the study authors

Concentrations of Concern

The screening-level acute and chronic concentrations of concern (COCs) for 1-BP were derived based on the lowest or most toxic ecological toxicity values (e.g., L/EC_{50}). The information below describes how the acute and chronic COC's were calculated for environmental toxicity of 1-BP using assessment factors. The application of assessment factors is based on established EPA/OPPT methods (U.S. EPA, 2013b, 2012c) and were used in this Problem Formulation to calculate lower bound effect levels (referred to as the concentration of concern; COC) that would likely encompass more sensitive species not specifically represented by the available experimental data. Also, assessment factors are included in the COC calculation to account for differences in inter- and intra-species variability, as well as laboratory-to-field variability. It should be noted that these assessment factors are dependent upon the availability of datasets that can be used to characterize relative sensitivities across multiple species within a given taxa or species group, but are often standardized in risk evaluations conducted under TSCA, due to limited data availability.

The acute COC is derived by dividing the fish 96-hr LC_{50} of 24.3 mg/L (the lowest acute value in the dataset) by an assessment factor (AF) of 5:

- Lowest value for the 96-hr fish LC_{50} (24.3 mg/L) / AF of 5 = 4.86 mg/L or 4,860 µg/L.

The acute COC of 4,860 µg/L, derived from experimental fish endpoint, is used as a conservative hazard level in this problem formulation for 1-BP.

Since there are no long-term chronic studies for 1-BP, the fish 96-hr LC_{50} of 24.3 mg/L (the lowest acute value in the dataset) is divided by an acute-to-chronic ratio (ACR) of 10 to obtain a chronic value (ChV) for fish. The fish ChV is then divided by an assessment factor of 10 to obtain a chronic COC:

- Lowest value for the fish 96-hr LC_{50} (24.3 mg/L) / 10 (ACR) / AF of 10 = 0.243 mg/L or 243 µg/L.

The chronic COC of 243 µg/L, derived from experimental fish endpoint, is used as the lower bound hazard level in this problem formulation for 1-BP.

The derived acute COC (4,860 ppb) and chronic COC (243 ppb) are based on environmental toxicity endpoint values (e.g., LC_{50}) from ECHA. Full study reports associated with these COCs were not available and will not be available in the future. In addition, the data represent the lowest bound of all 1-BP data available, so it represents the most conservative hazard value.

2.4.2 Human Health Hazards

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 as a starting point for identifying key and supporting studies to inform the human health hazard assessment, including dose-response analyses. The relevant studies will be evaluated using the data quality criteria in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018). In addition, EPA intends to review studies published after the 2016 Draft Risk Assessment (U.S. EPA, 2016b) [see (*1-Bromopropane (CASRN 106-94-5) Bibliography: Supplemental File for the TSCA Scope Document* EPA-HQ-OPPT-2016-0741-0047], using the approaches and/or methods described in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018) to ensure that EPA is considering information that has been made available since the 2016 Draft Risk Assessment (U.S. EPA, 2016b) was conducted. Based on reasonably available information, the following sections describe the hazards EPA expects to further analyze.

2.4.2.1 Non-Cancer Hazards

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. Five health hazards were used for quantitative risk characterization and will be evaluated using our systematic review approach. These hazards include:

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 ≥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 Mutagenicity/Genotoxicity and Cancer Hazards

There is some evidence for mutagenicity and deoxyribonucleic acid (DNA) binding 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. 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.

The National Toxicology Program's (NTP) *Report on Carcinogens* (NTP, 2013) concludes 1-BP is "reasonably anticipated to be a human carcinogen. 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 [≥10% of a lifetime (U.S. EPA, 2011)] inhalation exposures. Repeated exposures (e.g., ≥5 consecutive days) are anticipated during chronic exposure. 1-BP 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 inconclusive but does not rule out a probable mutagenic mode of action for 1-BP carcinogenesis. In the 2016 Draft Risk Assessment (U.S. EPA, 2016b), EPA derived an inhalation unit risk (IUR) based on lung tumors in female mice. This health hazard was used for quantitative risk characterization and will be evaluated using our systematic review approach.

2.4.2.3 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 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 the chemical's hazard(s).

2.5 Conceptual Models

EPA risk assessment guidance (U.S. EPA, 2014b, 1998), defines Problem Formulation as the part of the risk assessment framework that identifies the major factors to be considered in the assessment. It draws from the regulatory, decision-making and policy context of the assessment and informs the assessment's technical approach.

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. The initial conceptual models describing the scope of the assessment for 1-BP (Scope Document, EPA-HQ-OPPT-2016-0741-0049), which was published in June 2017, have been refined during problem formulation. The changes to the conceptual models in this Problem Formulation are described along with the rationales.

In this section, EPA outlines those pathways that will and will not be further analyzed in the TSCA risk evaluation and the underlying rationale for these decisions.

EPA determined as part of problem formulation that it is not necessary to conduct further analysis on certain exposure pathways that were identified in the 1-BP scope document and that remain in the risk evaluation. Each risk evaluation will be "fit-for-purpose," meaning not all conditions of use will warrant the same level of evaluation and the Agency may be able to reach some conclusions without extensive or quantitative risk evaluations. 82 FR 33726, 33734, 33739 (July 20, 2017).

As part of this problem formulation, EPA also identified exposure pathways under regulatory programs of other environmental statutes, administered by EPA, which adequately assess and effectively manage

exposures and for which long-standing regulatory and analytical processes already exist, i.e., the Safe Drinking Water Act (SDWA), the Clean Water Act (CWA) and the Resource Conservation and Recovery Act (RCRA). EPA worked closely with the offices within EPA that administer and implement the regulatory programs under these statutes. In some cases, EPA has determined that chemicals present in various media pathways (i.e., water, land) fall under the jurisdiction of existing regulatory programs and associated analytical processes carried out under other EPA-administered statutes and have been assessed and effectively managed under those programs. EPA believes that the TSCA risk evaluation should generally focus on those exposure pathways associated with TSCA conditions of use that are not adequately assessed and effectively managed under the regulatory regimes discussed above because these pathways are likely to represent the greatest areas of risk concern. As a result, EPA does not expect to include in the risk evaluation certain exposure pathways identified in the 1-BP scope document.

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

The revised conceptual model (Figure 2-2) illustrates the expected exposure pathways to workers and occupational non-users from industrial and commercial activities and uses of 1-BP that EPA expects to include in the risk evaluation. For most activities and uses, EPA anticipates that workers and occupational non-users may be exposed to 1-BP via inhalation and dermal routes, with inhalation of vapor/mist being the most likely exposure route. In addition to the pathways illustrated in the figure, EPA will evaluate activities resulting in exposures associated with distribution in commerce (e.g. loading, unloading) throughout the various lifecycle stages and conditions of use (e.g. manufacturing, processing, industrial use, commercial use, disposal) rather than a single distribution scenario.

As discussed in Section 2.2.2.1, EPA will not assess the commercial use of 1-BP in non-pesticidal agricultural products during risk evaluation. Based on information available to EPA, EPA determined that 1-BP is not used in agricultural products (non-pesticidal), only in the processing of such products.

Inhalation

EPA expects to analyze inhalation exposure to workers during manufacturing, processing, use and disposal of 1-BP for all uses identified in the scope (except use in non-pesticidal agricultural products). The analysis will include worker exposure to vapor from open sources, and exposure to mist during activities and uses where mist generation is expected (e.g. spray application of 1-BP).

Where inhalation exposure is expected, EPA will also analyze inhalation exposure to vapor and mists for occupational non-users.

Dermal

For most industrial and commercial activities, EPA does not plan to further analyze dermal contact with liquid because 1-BP readily evaporates from the skin. Based on the vapor generation rate of 1-BP at ambient conditions as calculated using the EPA/OPPT Penetration Model, the contact time with skin is expected to be less than 2 minutes. Further, the fraction absorbed was measured to be small (0.16%) by NIOSH (https://www.cdc.gov/niosh/docket/review/docket057a/pdfs/057-arevisedctd-1-bpcriteriadocument_030716_corrected.pdf). This exposure pathway and route will not be further analyzed for manufacturing, processing, and several uses, e.g. insulation materials, asphalt extraction, temperature indicator.

Certain conditions of use, such as maintenance of industrial degreasing tanks or commercial dry cleaning machines, can present a potential for occluded exposure (e.g. where 1-BP is trapped within a worker's gloves) or repeated dermal contacts. EPA plans to further analyze exposures to a subset of workers where occluded/repeated contact or immersion exposure are likely.

Occupational non-users are not directly handling 1-BP; therefore, skin contact with liquid 1-BP is not expected for occupational non-users and EPA does not expect to further analyze this pathway in the risk evaluation.

Businesses Co-located with Dry Cleaners

For businesses co-located with dry cleaners, inhalation is expected to be the primary route of exposure. EPA does not plan to further analyze dermal and oral exposure to indoor vapor for co-located businesses. The potential for incidental ingestion of vapor is expected to be low, since 1-BP is absorbed quickly in the lung and does not have appreciable ability to travel up the mucosal elevator to be swallowed.

Waste Handling, Treatment and Disposal

Figure 2-2 shows that waste handling, treatment and disposal is expected to lead to the same pathways as other industrial and commercial activities and uses. The path leading from the "Waste Handling, Treatment and Disposal" box to the "Hazards Potentially Associated with Acute and/or Chronic Exposures See Section 2.4.2" box was re-routed to accurately reflect the expected exposure pathways, routes, and receptors associated with these conditions of use of 1-BP.

For each condition of use identified in Table 2-3, a determination was made as to whether or not each unique combination of exposure pathway, route, and receptor will be further analyzed in the risk evaluation. The results of that analysis along with the supporting rationale are presented in Appendix D.

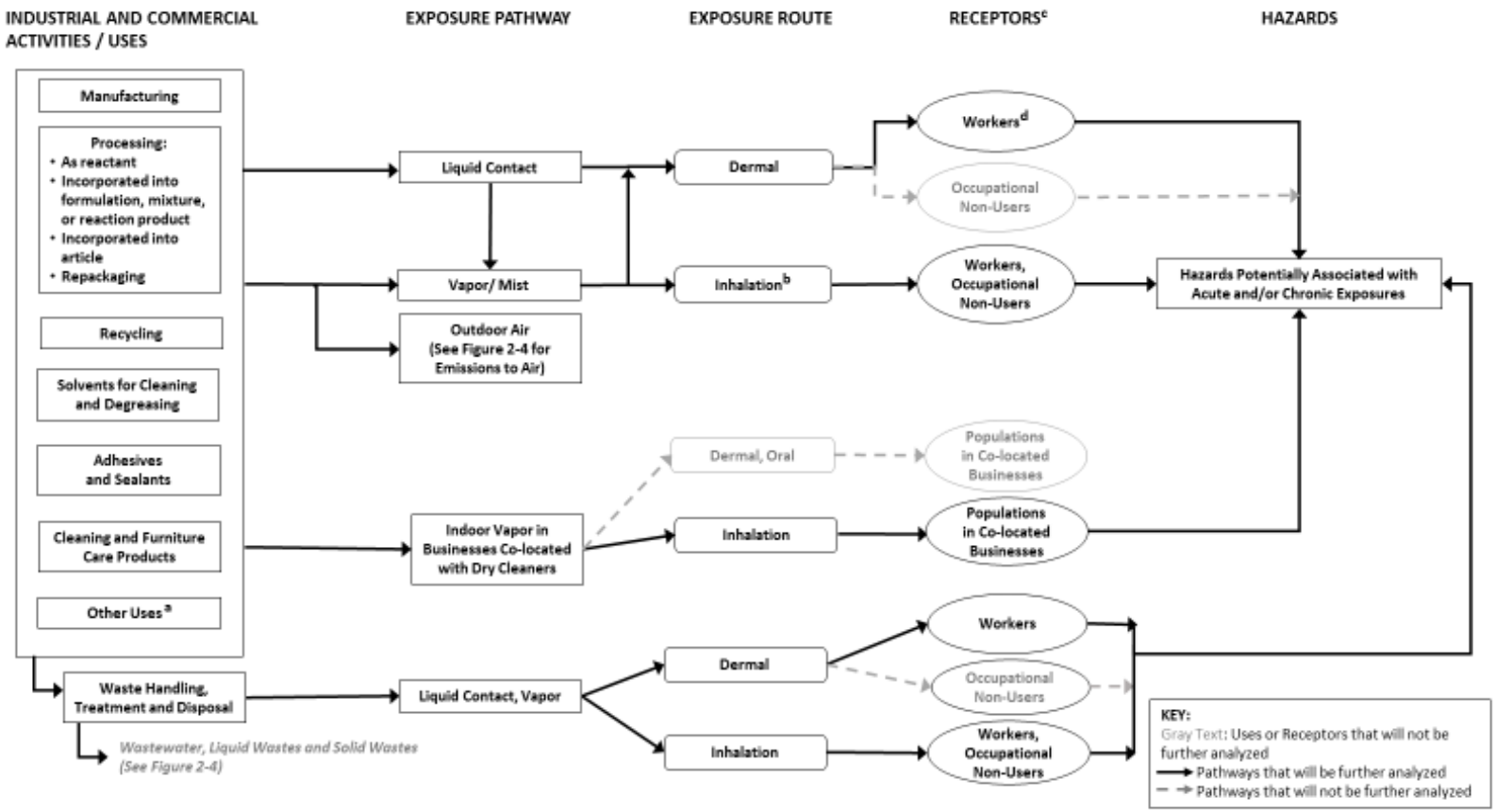

Figure 2-2. 1-BP Conceptual Model for Industrial and Commercial Activities and Uses: Potential Exposures and Hazards

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

[a]Some products are used in both commercial and consumer applications. Additional uses of 1-BP are included in Table 2-3.
[b] Exposure may occur through mists that deposit in the upper respiratory tract, however based on physical chemical properties, mists of 1-BP will likely be rapidly absorbed in the respiratory tract or evaporate and will be considered as an inhalation exposure.
[c]Receptors include potentially exposed or susceptible subpopulations.
[d] 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 Conceptual Model for Consumer Activities and Uses: Potential Exposures and Hazards

The revised conceptual model (Figure 2-3) illustrates the expected exposure pathways to human receptors from consumer uses of 1-BP that EPA expects to include in the risk evaluation. EPA expects that the primary route of exposure for consumers will be via inhalation. There may also be dermal exposure from skin contact with liquids in occluded scenarios, such as the use of a rag that has been soaked in a product containing 1-BP. For bystanders, the primary route of exposure is expected to be inhalation. Oral exposure from mists that deposit in the upper respiratory tract and are swallowed or from incidental ingestion of 1-BP residue on hand/body is not expected to be a significant route of exposure given the physical-chemical properties of 1-BP. It should be noted that some consumers may purchase and use products primarily intended for commercial use.

EPA has reviewed the uses described in the 2016 Draft Risk Assessment (U.S. EPA, 2016b) including aerosol spray degreaser/cleaners, use in adhesives and spot cleaners and has concluded that there is no consumer use of 1-BP for engine degreasers, brake cleaning, or aerosol spray adhesives (except as an adhesive accelerant in arts and crafts applications). EPA intends to continue to evaluate the uses identified in the 2016 Draft Risk Assessment (U.S. EPA, 2016b) as aerosol spray degreaser/cleaner and spot cleaners. EPA will further evaluate additional uses identified in problem formulation including: stain remover, adhesive accelerant, automotive care products, anti-adhesive agents, liquid cleaners, and building and construction materials.

Inhalation

Based on the physical-chemical properties of 1-BP and the conditions of use, inhalation exposures to 1-BP in the vapor phase from use of consumer products is expected and will be further analyzed for consumers and bystanders. This is expected to be the primary route of exposure.

Oral

EPA does not expect to further analyze exposure to consumers via ingestion of 1-BP. Ingestion is not expected to be a primary route of exposure. Based on the vapor pressure, 1-BP is likely to exist as a vapor during use. A fraction of 1-BP may be available for absorption in the respiratory tract however ingestion of 1-BP is anticipated to be low since 1-BP is expected to be absorbed in the lung quickly and not have appreciable ability to travel up the mucosal elevator and be swallowed.

Dermal

Based on the physical-chemical properties and high evaporative losses compared to dermal absorption as described in Section 2.3.5.2, non-occluded dermal exposures are not expected to be the primary route of exposure for consumers, although dermal exposures will contribute to the overall exposure. Some products may be purchased and used as a liquid. For these uses, consumers may have dermal contact from occluded exposures such as holding a rag soaked in liquid 1–BP where limited evaporation rates and penetration may be expected to be higher in these scenarios. EPA does not expect to further analyze dermal exposure to 1-BP vapor, however EPA does expect to further analyze direct dermal contact with liquid 1-BP for consumers during the risk evaluation phase.

Whereas users may be exposed dermally during use of consumer products, particularly in occluded scenarios, bystanders would generally not be expected to be dermally exposed to 1-BP in occluded or non-occluded scenarios, therefore dermal exposure to bystanders will not be further analyzed.

Disposal

EPA does not expect to further analyze exposure to consumers from disposal of consumer products. It is anticipated that most products will be disposed of in original containers, particularly those products that are purchased as aerosol cans. Liquid products may be recaptured in an alternate container following use (e.g., refrigerant flush or coin cleaning).

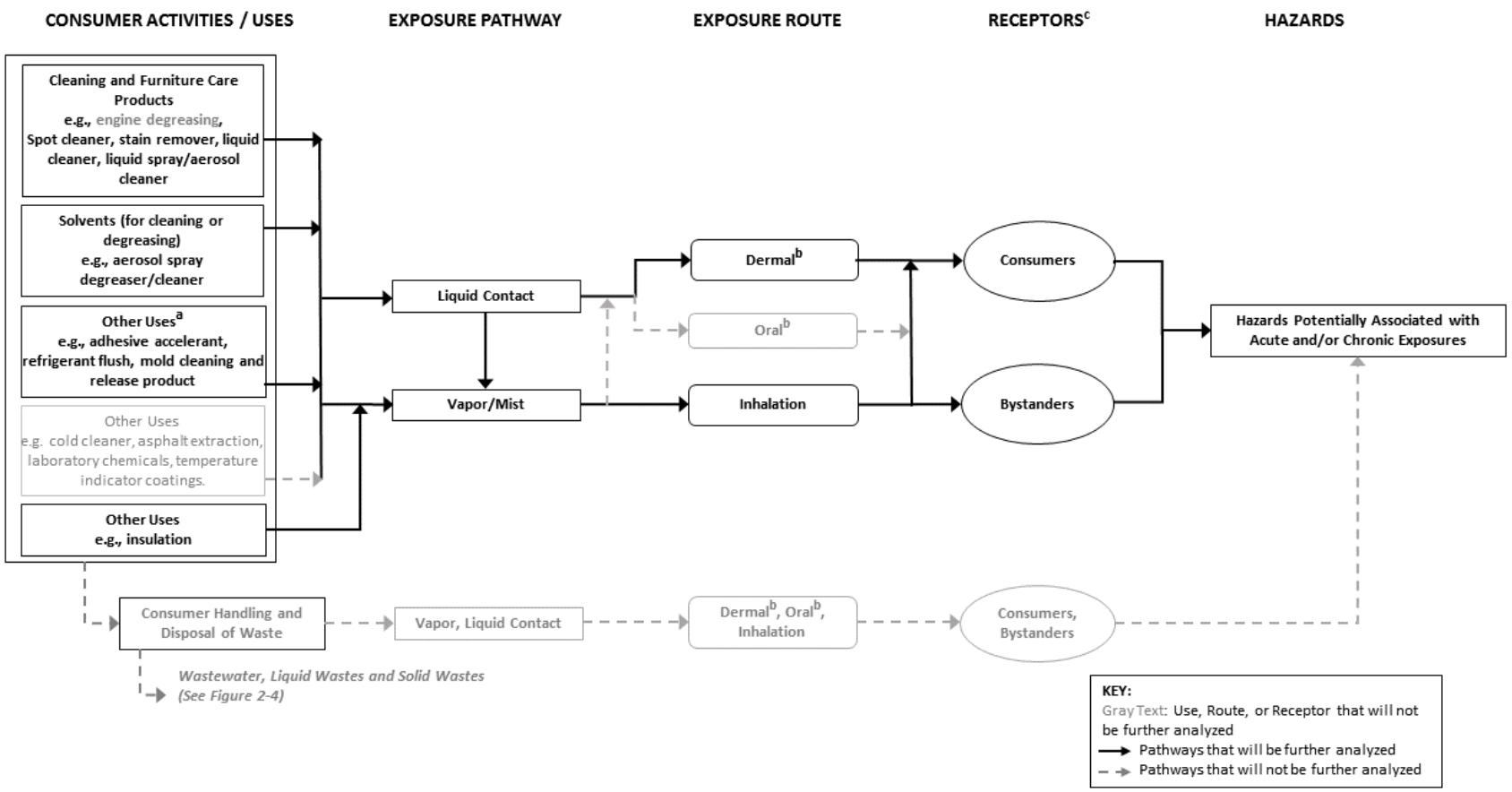

Figure 2-3. 1-BP Conceptual Model for Consumer Activities and Uses: Potential Exposures and Hazards

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

[a]Some products are used in both commercial and consumer applications. Additional uses of 1-BP are included in Table 2-3.
[b] Dermal exposure may occur through skin contact with liquids; ingestion is anticipated to be low since 1-BP is expected to be absorbed in the lung quickly and not have appreciable ability to travel up the mucosal elevator and be swallowed.
[c]Receptors include potentially exposed or susceptible subpopulations.

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

The revised conceptual model (Figure 2-4) illustrates the expected exposure pathways to ecological receptors from environmental releases and waste streams associated with industrial and commercial activities for 1-BP that EPA expects to include in the risk evaluation. The pathways that EPA expects to include and analyze further in the risk evaluation is described in Section 2.5.3.1 and shown in the conceptual model. The pathways that EPA expects to include but not further analyze in risk evaluation are described in Section 2.5.3.2 and the pathways that EPA does not expect to include in risk evaluation are described in Section 2.5.3.3.

2.5.3.1 Pathways That EPA Expects to Include and Further Analyze in the Risk Evaluation

Air Pathways

EPA expects to further analyze air emissions resulting in the general population. Emissions to air from industrial manufacturing, processing and use are expected. Based on the relatively long hydroxy radical oxidation half-life ($t_{½}$ = 14 days) emissions to ambient air could travel far enough from the release point to reach both near facility human receptors and the general population. Inhalation is expected to be the primary route of exposure for the general population and near facility populations.

During problem formulation, EPA reviewed TRI data for on-site releases to air from fugitive and point sources; these data will be used in EPA's release analysis during risk evaluation. The data also includes any air release resulting from on-site waste treatment and energy recovery.

For off-site transfer of wastes, EPA will further analyze the Destruction Removal Efficiencies (DRE's) occurring from incineration/energy recovery processes at off-site facilities, as well as the resulting air emissions. It is possible that some of these air emissions are already accounted for in the TRI data (in the on-site releases) if the off-site facility is also a TRI reporter (e.g. a TSDF facility).

These pathways include:

- The general populations living near industrial and commercial facilities using 1-BP that are exposed via inhalation of outdoor air.
- The populations co-located with dry cleaners are expected to be exposed to 1-BP via the inhalation route (recommended for assessment in peer review).
- Releases from Manufacturing, Processing, Use, Recycling to Air: land disposal, non-hazardous waste incineration and emissions to air can be expected. In the atmosphere, 1-BP is expected to occur primarily in the vapor phase and may undergo long-range transport. The 2016 TRI data reported onsite recycling and transfers to offsite for recycling.
- Releases to Air from Disposal and Recycling: TRI reports a total of 115,222 pounds of off-site releases after transfer (90,273 pounds of transfers to other landfills for disposal (3 facilities), 20,892 pounds of unknown transfers for disposal (6 facilities), 3307 pounds of transfer for disposal to a storage only facility, and 750 pounds of transfer for disposal to a waste broker.

2.5.3.2 Pathways That EPA Expects to Include in the Risk Evaluation But Not Further Analyze

Air Pathways

EPA will not further analyze inhalation exposures for ecological terrestrial species in this risk evaluation due to the physical/chemical properties associated with 1-BP (high vapor pressure; see Section 2.1) and the low expected toxicity (see Section 2.4.1), and since their inhalation exposures are expected to be short and/or of sporadic frequency due to their mobile behavior.

Water Pathways

As described in Section 2.3.5.3, there is no data of 1-BP found in US drinking water. Recent TRI reporting indicated 0 pounds released to POTWs and 5 pounds released directly to water in 2016. In addition, 1-BP is slightly soluble in water and its rapid volatilization from water are expected to mitigate exposure potential from drinking water supplied from public water systems. Therefore, EPA does not plan to further analyze drinking water pathways in the risk evaluation for 1-BP under TSCA.

EPA does not expect to further analyze releases to wastewater or surface water. As discussed in Section 2.1, 1-BP is volatile and has a relatively high Henry's law constant. 1-BP is somewhat biodegradable and is not expected to sorb to solids in wastewater. EPA's STP WTP model predicts 73% removal of 1-BP by volatilization in activated sludge treatment and 1% partitioning to biosolids. 1-BP discharged in wastewater treatment plant effluent to the aquatic environment would be subject to volatilization and biodegradation thereby reducing aquatic exposure. Although 1-BP is not a priority pollutant, EPA pretreatment regulations for industrial users discharging wastewater to POTWs for treatment prohibit the discharge of flammable substances and substances that could generate toxic vapors to POTWs. These restrictions are expected to limit the discharge of 1-BP to POTWs and ultimately to surface water. Recent TRI reporting indicated 0 pounds released to POTWs and 5 pounds released directly to water in 2016 further indicating that general population and environmental exposure via direct releases to surface waters or releases of 1-BP by POTWs is not a pathway for further exposure analysis.

In addition, EPA does not expect to further analyze hazard to aquatic organisms exposed to 1-BP in surface water. Based on 1-BP surface water concentrations estimated using TRI 2016 releases to water, EFAST modeling and the acute fish toxicity EC_{50} value 24.3 mg/L, the concentration of concern is not expected to be exceeded. For three different conservative scenarios (1, 20, and 100 days per year), the screening-level surface water concentrations were well below levels of concern for aquatic species. In addition, 1-BP is expected to be volatile from surface water based on the estimated Henry's Law Constant, mitigating exposure to aquatic life. Thus, EPA does not expect to further analyze ecological aquatic species in the risk evaluation. This conclusion is supported by the ecological risk classification derived for 1-BP by Environment and Climate Change Canada which identified a low ecological hazard and exposure for 1-BP (https://www.ec.gc.ca/ese-ees/A96E2E98-2A04-40C8-9EDC-08A6DFF235F7/CMP3%20ERC_EN.pdf). (ECCC, 2016)

Biosolids, Sediment and Soil Pathways

EPA does not expect to further analyze releases to biosolids, sediment or soils. Based on the log K_{oc} of 1.6, 1-BP is not expected to adsorb strongly to sediment or soil. If present in biosolids, 1-BP would be expected to associate with the aqueous component and volatilize to air as the biosolids are applied to soil and allowed to dry. Due to its water solubility and low sorption, some 1-BP associated with land applied sludge could migrate with water towards groundwater, however, volatilization and biodegradation may attenuate migration. Therefore, based on the characteristics of environmental fate and industrial release

information, exposure to the general population and aquatic biota via surface water, drinking water, and sediment is expected to be low. In addition, EPA does not plan to further analyze hazard to aquatic organisms exposed to 1-BP in sediment or soil environments. Based on the log K_{oc} of 1.6 and high water solubility (2.45 g/L), 1-BP is not expected to significantly partition to sediments or soils. Given low releases to water and low concentrations in the water column, low concentrations in sediments would also be expected. 1-BP released to soil is not expected to be a viable pathway of exposure for terrestrial species as 1-BP released to surface soil is expected to volatilize rapidly due to high vapor pressure (146 mmHg at 25 ºC). Thus, EPA does not expect to further analyze sediment and soil ecological species in the risk evaluation.

2.5.3.3 Pathways That EPA Does Not Expect to Include in the Risk Evaluation

Exposures to receptors (i.e., general population, terrestrial species) may occur from industrial and/or commercial uses; industrial releases to air, water or land; and other conditions of use. As described in Section 2.5, EPA does not expect to include in the risk evaluation pathways under programs of other environmental statutes, administered by EPA, which adequately assess and effectively manage exposures and for which long-standing regulatory and analytical processes already exist. These pathways are described below.

Disposal Pathways

1-BP is regulated as a hazardous waste, waste code D001 (ignitable liquids, 40CFR 261.21). The general RCRA standard in section 3004(a) for the technical (regulatory) criteria that govern the management (treatment, storage, and disposal) of hazardous waste (i.e., Subtitle C) are those "necessary to protect human health and the environment," RCRA 3004(a). The regulatory criteria for identifying "characteristic" hazardous wastes and for "listing" a waste as hazardous also relate solely to the potential risks to human health or the environment. 40 C.F.R. §§ 261.11, 261.21-261.24. RCRA statutory criteria for identifying hazardous wastes require EPA to "tak[e] into account toxicity, persistence, and degradability in nature, potential for accumulation in tissue, and other related factors such as flammability, corrosiveness, and other hazardous characteristics." Subtitle C controls cover not only hazardous wastes that are landfilled, but also hazardous wastes that are incinerated (subject to joint control under RCRA Subtitle C and the Clean Air Act (CAA) hazardous waste combustion MACT) or injected into UIC Class I hazardous waste wells (subject to joint control under Subtitle C and the Safe Drinking Water Act (SDWA)).

Emissions from hazardous waste incinerators will not be included in the risk evaluation. 40 CFR 264.345 specifies performance standards for hazardous waste incinerators. An incinerator burning hazardous waste must achieve a destruction and removal efficiency (DRE) of 99.99% for each principal organic hazardous constituent. Furthermore, RCRA provisions for site-specific risk assessments and the Hazardous Waste Combustor maximum achievable control technology (MACT) rule provisions for a Residual Risk and Technology Review together cover risks for RCRA hazardous wastes and CAA HAPs. Air emissions from municipal and industrial waste incineration and energy recovery units are regulated under the Clean Air Act. Incineration treatment of 1-BP would be subject to these regulations, as would 1-BP burned for energy recovery.

EPA does not expect to include on-site releases to land that go to underground injection in its risk evaluation. TRI reporting in 2016 only indicated 10 pounds released to underground injection to a Class I well and no releases to underground injection wells of Classes II-VI. Environmental disposal of 1-BP injected into Class I well types is managed and prevented from further environmental release by RCRA

and SDWA regulations. Therefore, disposal of 1-BP via underground injection is not likely to result in environmental and general population exposures.

EPA does not expect to include on-site releases to land that go to RCRA Subtitle C hazardous waste landfills in its risk evaluation. Based on 2016 reporting to TRI, there were 57,617 pounds of 1-BP disposal to an on-site RCRA Subtitle C landfill. Design standards for Subtitle C landfills require double liner, double leachate collection and removal systems, leak detection system, run on, runoff, and wind dispersal controls, and a construction quality assurance program. They are also subject to closure and post-closure care requirements including installing and maintaining a final cover, continuing operation of the leachate collection and removal system until leachate is no longer detected, maintaining and monitoring the leak detection and groundwater monitoring system. Bulk liquids may not be disposed in Subtitle C landfills. Subtitle C landfill operators are required to implement an analysis and testing program to ensure adequate knowledge of waste being managed, and to train personnel on routine and emergency operations at the facility. Hazardous waste being disposed in Subtitle C landfills must also meet RCRA waste treatment standards before disposal. Given these controls, general population exposure to 1-BP in groundwater from Subtitle C landfill leachate is not expected to be a significant pathway.

EPA does not expect to include on-site releases to land from RCRA Subtitle D municipal solid waste landfills (MSWLFs) or exposures of the general population (including susceptible populations) or terrestrial species from such releases in the TSCA evaluation. While permitted and managed by the individual states, municipal solid waste landfills (MSWLFs) are required by federal regulations to implement many of the same requirements as Subtitle C landfills. MSWLFs must have a liner system with leachate collection and conduct groundwater monitoring and corrective action when releases are detected. MSWLFs are also subject to closure and post-closure care requirements, as well as providing financial assurance for funding of any needed corrective actions. MSWLFs have also been designed to allow for the small amounts of hazardous waste generated by households and very small quantity waste generators (less than 100 kg per month). Bulk liquids, such as free solvent, may not be disposed of at MSWLFs.

EPA does not expect to include on-site releases to land from industrial non-hazardous and construction/demolition waste landfills. Industrial non-hazardous and construction/demolition waste landfills are primarily regulated under state regulatory programs. States must also implement limited federal regulatory requirements for siting, groundwater monitoring, and corrective action, and a prohibition on open dumping and disposal of bulk liquids. States may also establish additional requirement such as for liners, post-closure and financial assurance, but are not required to do so. Therefore, EPA does not expect to include this pathway in the risk evaluation.

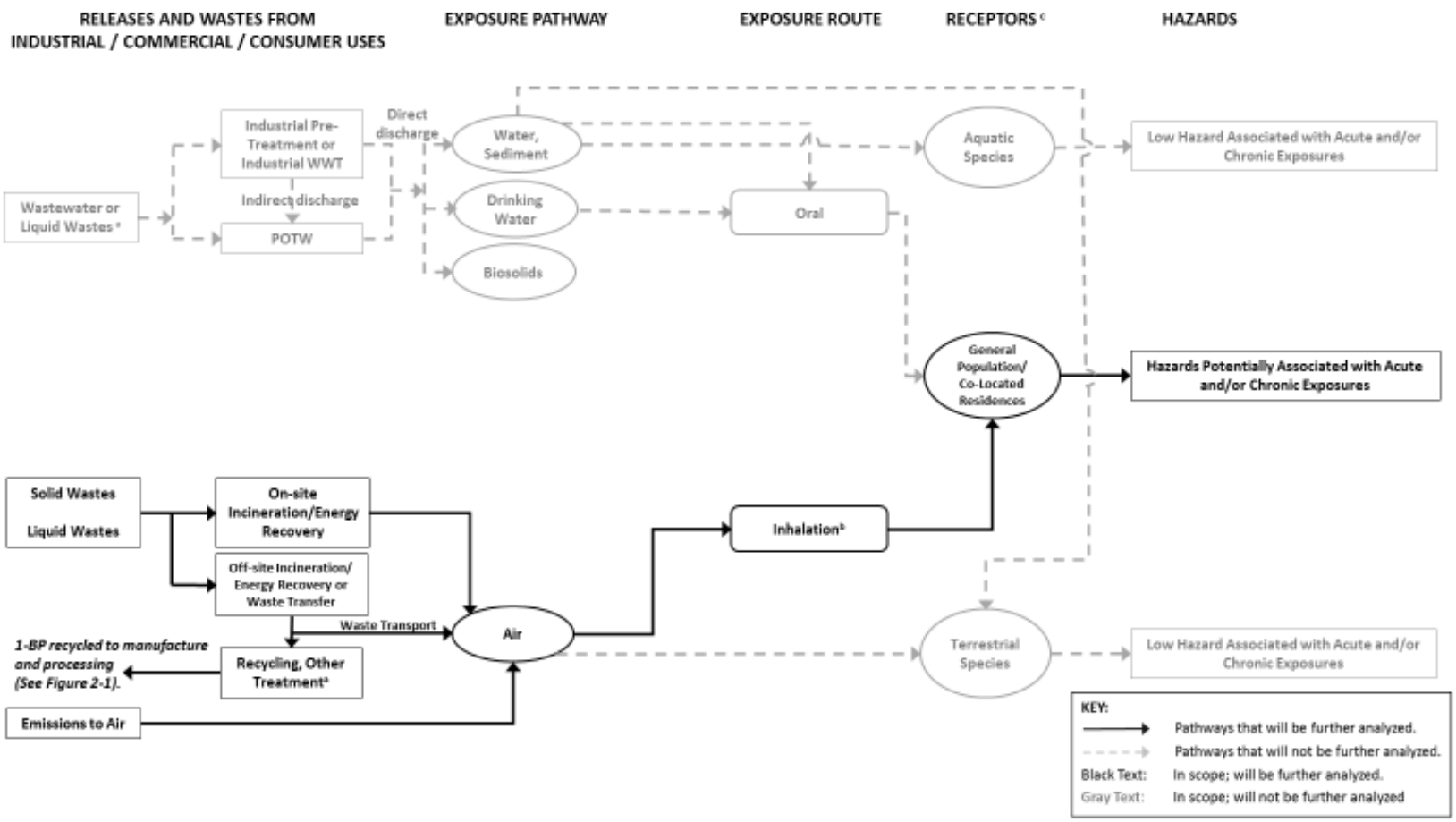

Figure 2-4. 1-BP Conceptual Model for Environmental Releases and Wastes: Potential Exposures and Hazards

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

[a]Industrial wastewater may be treated on-site and then released to surface water (direct discharge), or pre-treated and released to POTW (indirect discharge).

[b]Presence of mist is not expected. Dermal and oral exposures are expected to be low.

[c]Receptors include potentially exposed or susceptible subpopulations.

2.6 Analysis Plan

The analysis plan presented in the Problem Formulation elaborates on the initial analysis plan that was published in the Scope of the Risk Evaluation for 1-BP (Scope Document, EPA-HQ-OPPT-2016-0741-0049).

The analysis plan is based on the conditions of use of 1-BP, as described in Section 2.2 of this Problem Formulation. EPA is implementing systematic review approaches and/or methods to identify, select, assess, integrate and summarize the findings of studies supporting the TSCA risk evaluation. The analytical approaches and considerations in the analysis plan are used to frame the scope of the systematic review activities for this assessment. The supplemental document, *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018), provides additional information about criteria and methods that have been and will be applied to the first 10 chemical risk evaluations.

While EPA has conducted a comprehensive search for reasonably available data as described in the Scope of the Risk Evaluation for 1-BP (Scope Document, EPA-HQ-OPPT-2016-0741-0049), 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 during the risk evaluation. EPA will continue to consider new information submitted by the public.

During the risk evaluation, EPA will rely on the search results [*1-Bromopropane (CASRN 106-94-5) Bibliography: Supplemental File for the TSCA Scope Document* EPA-HQ-OPPT-2016-0741-0047)], or perform supplemental searches to address specific questions. Further, EPA may consider any relevant confidential business information (CBI) in the risk evaluation in a manner that protects the confidentiality of the information from public disclosure. The analysis plan is based on EPA's knowledge of 1-BP to date, which includes partial, but not complete review of identified literature. If additional data or approaches become available, EPA may refine its analysis plan based on this information.

2.6.1 Exposure

Based on their physical-chemical properties, expected sources, and transport and transformation within the outdoor and indoor environment chemical substances are more likely to be present in some media and less likely to be present in others. Media-specific levels will vary based on the chemical substance of interest. For most high-priority chemical substances level(s) can be characterized through a combination of available monitoring data and modeling approaches.

2.6.1.1 Environmental Releases

EPA expects to 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.**

   EPA has reviewed some key data sources containing information on processes and activities resulting in releases, and the information found is shown in Appendix B.1. EPA will continue to

review potentially relevant data sources identified in Table_Apx B-3 in Appendix B during risk evaluation.

EPA plans to review the following key data sources in Table 2-8 for information on processes and activities resulting in environmental releases. The evaluation strategy for engineering and occupational data sources discussed in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018) describes how studies will be reviewed. EPA has also previously compiled process information for several conditions of use in the 2016 Draft Risk Assessment (U.S. EPA, 2016b).

Table 2-8. Potential Sources of Environmental Release Data

2017 ATSDR Toxicological Profile for 1-BP: Toxicological Profile for 1-Bromopropane (2017)
U.S. EPA TRI Data (Reporting Year 2016 only)
EPA AP-42 Air Emission Factors
CARB ISOR for Proposed ATCM

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).

EPA plans to review release data to inform releases associated with the applicable conditions of use for 1-BP. For example, EPA's Toxics Release Inventory (TRI) data will be used to inform the various subcategories, such as air releases, associated with the disposal life cycle stage. According to TRI data for Reporting Year 2016, the majority of on-site releases of 1-BP were to air (fugitive and stack), followed by land disposal. Only five pounds of 1-BP were discharged to water. Of the off-site transfers, the majority went to incineration and land disposal. No off-site transfer to wastewater treatment were reported.

Additionally, for conditions of use where no measured data on releases are available, EPA may use a variety of methods including the application of default assumptions such as standard loss fractions associated with drum cleaning (3%) or single process vessel cleanout (1%), or the use of EPA Generic Scenarios and/or OECD Emission Scenario Documents to predict releases and their corresponding media.

EPA Generic Scenarios are available at the following: https://www.epa.gov/tsca-screening-tools/using-predictive-methods-assess-exposure-and-fate-under-tsca#fate.

OECD Emission Scenario Documents are available at the following: http://www.oecd.org/chemicalsafety/risk-assessment/emissionscenariodocuments.htm

EPA will also review data sources containing estimated data and identify data gaps. The 2016 Draft Risk Assessment (U.S. EPA, 2016b) contains estimates of 1-BP emission rates for several conditions of use, including dry cleaning, spot cleaning, vapor degreasing, cold cleaning, and aerosol degreasing. EPA will use existing emission factors and emission rate data to estimate environmental releases of 1-BP to air from these uses.

3) Understand and consider regulatory limits that may inform estimation of environmental releases.

Information from various EPA statutes (including, for example, regulatory limits, reporting thresholds, or disposal requirements) may be used to assess releases. EPA may determine that a condition of use is unlikely to result in release to a particular media based on existing chemical-specific regulations even though an Emission Scenario or EPA Generic Scenario document indicates a likely release to that same media.

While 1-BP is not a hazardous air pollutant (HAP) regulated under the Clean Air Act, some related rules may provide relevant information on sectors using 1-BP. For example, the NESHAP for Halogenated Solvent Cleaning (40 CFR Part 63, Subpart T) may provide useful information on industry sectors that use solvents (including 1-BP) for degreasing applications.

EPA will further consider the applicability of EPA regulations to 1-BP during the development of the risk evaluation.

4) Review and determine applicability of Organization for Economic Co-operation and Development (OECD) Emission Scenario Documents (ESDs) and EPA Generic Scenarios (GSs) to estimation of environmental releases.

EPA will analyze the conditions of use to determine which ESDs and GSs can be applied. For example, EPA may use the ESD on Industrial Use of Industrial Cleaners, the ESD on Industrial Use of Adhesives for Substrate Bonding, and the GS on Application of Agricultural Pesticides to assess potential releases to all relevant media for some conditions of use, such as the uses of 1-BP in cleaning and degreasing, adhesive, and agricultural products.

For other conditions of use, such as manufacture and import of 1-BP, use of 1-BP in insulation material, use of cutting oils, and use of 1-BP in asphalt extraction, EPA may not be able to apply generic release scenarios. In those cases, EPA may conduct industry outreach efforts, consult process technology literature sources such as the Kirk-Othmer Encyclopedia of Chemical Technology, or perform supplemental literature searches to better understand the process steps involved in that condition of use before a release assessment can be made.

5) Map or group each condition(s) of use to a release assessment scenario.

EPA has identified release/occupational exposure scenarios and mapped them to relevant conditions of use in Appendix D. As presented in the fourth column of the table in this appendix, EPA has grouped the uses into 16 representative release/exposure scenarios that will be further evaluated. EPA may further refine the mapping/grouping of these scenarios based on factors (e.g., process equipment and handling, magnitude of production volume used, and exposure/release sources) corresponding to conditions of use as additional information is identified during risk evaluation.

6) Evaluate the weight of the evidence of environmental release data.

EPA will rely on the weight of the scientific evidence when evaluating and integrating environmental release data. The data integration strategy will be designed to be fit-for-purpose in which EPA will use systematic review methods to assemble the relevant data, evaluate the data

for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence.

2.6.1.2 Environmental Fate

EPA expects to 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.**

   A general overview of persistence and bioaccumulation was presented in the 2016 Draft Risk Assessment (U.S. EPA, 2016b). Key environmental fate characteristics were included in the Scope Document (EPA-HQ-OPPT-2016-0741-0049) and in previous assessments of 1-BP, including that conducted by the US Agency for Toxic Substances and Disease Registry (ATSDR, 2017). These information sources will be used as a starting point for the environmental fate assessment. Other sources that will be consulted include those that are identified through the systematic review process. Studies will be evaluated using the evaluation strategies laid out in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018) document.

   If measured values resulting from sufficiently high-quality studies are not available (to be determined through the systematic review process), chemical properties will be estimated using EPI Suite, SPARC, and other chemical parameter estimation models. Estimated fate properties will be reviewed for applicability and quality.

2) **Using measured environmental fate data and/or environmental fate modeling, determine the influence of environmental fate endpoints (e.g., persistence, bioaccumulation, partitioning, transport) on exposure pathways and routes of exposure to human receptors.**

   Measured fate data including volatility and atmospheric photolysis rates along with physical-chemical properties and models, such as the EPI Suite™ Atmospheric Oxidation Program (which estimates rates of atmospheric oxidation), will be used to characterize the persistence of 1-BP in air and its impact on exposure.

3) **Evaluate the weight of the evidence of environmental fate data.**

   EPA will rely on the weight of the scientific evidence when evaluating and integrating environmental fate data. The data integration strategy will be designed to be fit-for-purpose in which EPA will use systematic review methods to assemble the relevant data, evaluate the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence.

2.6.1.3 Environmental Exposures

EPA does not plan to further analyze environmental exposures to 1-BP, based on the rationale described in Section 2.3.4.

2.6.1.4 General Population

EPA expects to 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.**

For 1-BP, the media of interest are expected to be ambient air and indoor air. EPA will review existing exposure models for applicability in estimating general population exposure levels associated with ongoing industrial and/or commercial releases. EPA will review reasonably available data that may be used in developing, adapting or applying exposure models. These data may include data on 1-BP or analogous chemical substances. Exposure pathways which may be modeled include air releases from point sources using air dispersion models.

Available exposure models will be evaluated and considered alongside available monitoring data to characterize environmental exposures for ambient air. Modeling approaches to estimate ambient air will generally consider the following inputs: release into air, fate and transport (partitioning within media) and characteristics of the environment (e.g., meteorological information). Some preliminary analysis may be performed to understand the impact of known releases to the overall characterization of concentrations in the environment.

Available release data (e.g. TRI data) will be used in informing releases to the environment. As data are available, EPA will estimate the air concentrations near point sources using release estimates or reported data using air dispersion models (e.g., AERMOD, AERSCREEN) incorporating what is known of incineration efficiencies (where applicable), fate and transport properties, and physical chemical properties.

2) **Consider and incorporate applicable media-specific regulations into exposure scenarios or modeling.**

1-BP is not listed on the TNSSS (Targeted National Sewage Sludge Survey), DMR (Discharge Monitoring Report), or as one of the 189 Hazardous Air Pollutants (HAPs) under Section 112(b) of the Clean Air Act. There are no specific EPA regulations regarding drinking water health advisories, ambient water quality criteria, or effluent level guidelines.

1-BP is a listed substance subject to reporting requirements under the Emergency Planning and Community Right-To-Know Act (EPCRA) – Section 313, and the TRI reporting information will be utilized for analyzing exposures to the general population via releases from manufacturing, processing and use of 1-BP. EPA may model air concentrations near facilities using air dispersion modeling applications (e.g., AERMOD or AERSCREEN).

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.**

EPA will review reasonably available data that may be used in developing, adapting or applying exposure models. These data may include modeled exposure estimates conducted by other organizations for 1-BP or analogous chemical substances. Fate and transport information will be used to inform calculations of human exposures via air. The concentrations in air will be used as inputs into exposure models to estimate general population exposures. Sources of data may

include TRI reporting for 1-BP. TRI data show air as a primary medium of environmental release. These releases include both fugitive air emissions and point source air emissions.

4) **Review reasonably available information on releases to determine how modeled estimates of concentrations near industrial point sources compare with available monitoring data.**

   General population exposure pathways expected to be relatively higher include inhalation of ambient air or inhalation in co-located buildings. EPA will review results of use specific and background exposure scenarios and select output metric relevant for exposure assessment. The metrics most likely to be relevant for 1-BP are Lifetime Average Daily Concentration (mg/m^3) and Average Daily Concentration (mg/m^3) for inhalation routes of exposure, and Lifetime Average Daily Dose (mg/kg/day) and Average Daily Dose (mg/kg/day) for dermal routes of exposure. Results within and across scenarios will be compared. For example, modeled estimates near industrial point sources can be compared with those based on 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.**

   Considerations will include:

   - Age-specific differences (exposure factors and activity patterns) for populations defined in the exposure scenario table in Appendix E;
   - Exposure factors and activities patterns will be sourced from EPA's 2011 Exposure Factors Handbook (U.S. EPA, 2011);
   - Subpopulations who may have greater exposure due to magnitude, frequency or duration of exposure as they apply a person's activity patterns or exposure factors;
   - Subpopulations who may have greater exposure or susceptibility due to spatial characteristics (e.g., those who live near point sources, those who are co-located with emission sources).

6) **Analyze the weight of the evidence of general population exposure data.**

   EPA will rely on the weight of the scientific evidence when analyzing and integrating data related to general population exposures. The weight of the evidence may include qualitative and quantitative sources of information. The data integration strategy will be designed to be fit-for-purpose in which EPA will use systematic review methods to assemble the relevant data, analyze the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence.

7) **Map or group each condition of use to general population exposure assessment scenarios.**

   EPA has identified general population exposure scenarios that include sources of exposure (i.e., releases to the environment), exposure pathways, exposure routes, and populations exposed and mapped them to relevant releases and waste streams, as shown in Appendix E. EPA may refine the mapping/grouping of general population exposures scenarios as the relationship between sources of exposure and conditions of use are further characterized.

EPA will further refine and finalize exposure scenarios for the general population with the following considerations:

- Temporal trends in uses and resulting sources/releases of 1-BP to the environment over time;
- Characterization of background levels in the environment that may or may not be generally attributable to any one use or source but from a combination of uses or sources which present exposure pathways for the general population;
- Further mapping of releases to lifecycle stages and uses/sources to environmental media;
- Consideration of spatial differences between populations located near industrial point sources and those exposed at lower background levels;
- Refined definitions of potentially exposed or susceptible subpopulations.

EPA plans to analyze a variety of data types to determine which types are most appropriate when quantifying exposure scenarios. Environmental monitoring data, biomonitoring data, modeled estimates, experimental data, epidemiological data, and survey-based data can all be used to quantify exposure scenarios. In an effort to associate exposure estimates with sources of exposure and/or conditions of use, EPA will consider source apportionment across exposure scenarios during risk evaluation. EPA anticipates that there will be a wide range in the relative exposure potential of the exposure scenarios identified in Appendix E. Source apportionment characterizes the relative contribution of any of the following: a use/source toward a total media concentration, a media concentration toward a total exposure route, or an exposure route toward a total external or internal dose. This consideration may be qualitative, semi-quantitative, or quantitative, and is dependent upon available data and approaches. For example, EPA may consider the co-location of TSCA industrial facilities with available monitoring data or modeled estimates. EPA may compare modeled estimates for discrete outdoor and indoor sources/uses that apply to unique receptor groups. If available, EPA will compare multiple scenario-specific and background exposure doses estimated from media-specific concentrations and exposure factors with available biomonitoring data. The forward-calculated and back-calculated exposures could be compared to characterize the relative contribution from defined exposure scenarios.

After refining and finalizing exposure scenarios, EPA will quantify concentrations and/or doses for these scenarios. The number of scenarios will depend on how unique combinations of uses, exposure pathways, and receptors are characterized. The number of scenarios is also dependent upon the available data and approaches to quantify scenarios. When quantifying exposure scenarios, EPA plans to use a tiered approach. First-tier analysis is based on data that is readily available without a significant number of additional inputs or assumptions, and may be qualitative, semi-quantitative, or quantitative. First-tier analyses were conducted during problem formulation and are expected to continue during risk evaluation. The results of first tier analyses inform whether scenarios require more refined analysis. Refined analyses will be iterative, and require careful consideration of variability and uncertainty. Should data become available that summarily alters the overall conclusion of a scenario through iterative tiering, EPA can refine its analysis during risk evaluation.

2.6.1.5 Occupational Exposures

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 NIOSH, and monitoring data found in published literature (e.g., personal exposure monitoring data (direct measurements) and area monitoring data (indirect measurements)). Data, information, and studies will be evaluated using the evaluation strategies laid out in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018). For some OSHA data, NAICS codes included with the data will be matched with potentially applicable conditions of use, and data gaps will be identified where no data are found for particular conditions of use. EPA will attempt to address data gaps identified as described in steps 2 and 3 below. Where possible, job descriptions may be useful in distinguishing exposures to different subpopulations within a particular condition of use. EPA has also identified additional data sources that may contain relevant monitoring data for the various conditions of use. EPA will review these sources, identified in Table 2-9 and in Table_Apx B-3 in Appendix B, and will extract relevant data for consideration and analysis during risk evaluation.

EPA will evaluate and consider applicable regulatory and non-regulatory exposure limits. Available data sources that may contain relevant monitoring data for the various conditions of use are listed in Table 2-9.

OSHA has not established any occupational exposure limits for 1-BP. However, the American Conference of Governmental Industrial Hygienists (ACGIH) has adopted a recommended Threshold Limit Value (TLV) of 0.1 ppm based on a time-weighted average (TWA) over an 8-hour workday. EPA will consider the influence of the recommended exposure limits on occupational exposures in the occupational exposure assessment.

Table 2-9. Potential Sources of Occupational Exposure Data

2017 ATSDR Toxicological Profile for 1-BP: Toxicological Profile for 1-Bromopropane (2017)
U.S. OSHA Chemical Exposure Health Data (CEHD) program data
U.S. NIOSH Health Hazard Evaluation (HHE) Program reports
2016 Draft Risk Assessment (U.S. EPA, 2016b)
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Draft NIOSH Criteria Document for a Recommended Standard for Occupational Exposure to 1-Bromopropane

2) Review reasonably available exposure data for surrogate chemicals that have uses and chemical and physical properties similar to 1-BP.

If surrogate data are identified, these data will be matched with applicable conditions of use for potentially filling data gaps. For several uses including use of adhesives, and cleaning products,

EPA believes that trichloroethylene and other similar solvents may share the same or similar conditions of use and may be considered as surrogates for 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.

EPA has identified potentially relevant OECD emissions scenario documents (ESDs) and EPA generic scenarios (GSs) corresponding to some conditions of use. For example, the ESD on Industrial Use of Adhesives for Substrate Bonding, the ESD on Metalworking Fluids, and the GS on Use of Vapor Degreasers are some of the ESDs and GSs that EPA may use to estimate occupational exposures. EPA will need to critically review these generic scenarios and ESDs to determine their applicability to the conditions of use assessed. EPA was not able to identify ESDs or GSs corresponding to several conditions of use, including recycling of 1-BP and solvent mixtures containing 1-BP, processing and formulation of 1-BP into industrial, commercial and consumer products, use of 1-BP in insulation materials, and use of 1-BP in asphalt extraction. EPA will perform additional targeted research, such as consulting Kirk-Othmer, in order to better understand those conditions of use, which may inform identification of exposure scenarios. EPA may also need to perform targeted research to identify applicable models that EPA may use to estimate exposures for certain conditions of use.

Furthermore, a mass-balance based model that has been used in addressing data gaps in some conditions of use is the Near-Field/Far-Field (NF/FF) model. This or other models, may be explored where models specific to conditions of use are not found. If any models are identified as applicable, EPA will search for appropriate model parameter data. If parameter data can be located or assumed, exposure estimates generated from these models may be used for potentially filling data gaps. EPA may perform additional targeted research to better understand conditions of use, which may inform identification of exposure scenarios. EPA may also need to perform targeted research to identify applicable models that EPA may use to estimate exposures for certain conditions of use.

4) Review reasonably available data that may be used in developing, adapting or applying exposure models to the particular risk evaluation.

If necessary, EPA will analyze relevant data to determine whether the data can be used to develop, adapt, or apply models for specific conditions of use and corresponding exposure scenarios.

In the 2016 Draft Risk Assessment (U.S. EPA, 2016b), EPA previously developed models to assess inhalation exposures to workers and occupational non-users during the use of 1-BP in dry cleaning, spot cleaning, open-top batch vapor degreasing, cold cleaning, and aerosol degreasing. The peer reviewers provided comments on EPA's modeling approach, including recommendations on specific model input parameters. During risk evaluation, EPA will further refine the exposure models for these uses based on peer reviewer feedback.

5) **Consider and incorporate applicable engineering controls and/or personal protective equipment into exposure scenarios.**

EPA will review potential data sources on engineering controls and personal protective equipment as identified in Table_Apx B-6 in Appendix B and determine their applicability and incorporation into exposure scenarios during risk evaluation.

6) **Map or group each condition of use to occupational exposure assessment scenario(s).**

EPA has identified release/occupational exposure scenarios and mapped them to relevant conditions of use in Appendix D. As presented in the fourth column of the table in this appendix, EPA has grouped the uses into 16 representative release/exposure scenarios each with 5-6 unique combinations of exposure pathway, route, and receptor that will be further analyzed. EPA may further refine the mapping/grouping of occupational exposure scenarios based on factors (e.g., process equipment and handling, magnitude of production volume used, and exposure/release sources) corresponding to conditions of use as additional information is identified during risk evaluation.

7) **Analyze the weight of evidence of occupational exposure data.**

EPA will rely on the weight of the scientific evidence when evaluating and integrating occupational exposure data. The data integration strategy will be designed to be fit-for-purpose in which EPA will use systematic review methods to assemble the relevant data, analyze the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence.

2.6.1.6 Consumer Exposures

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

1) **Refine and finalize exposure scenarios for consumers by considering sources of exposure (consumer products), exposure pathways, exposure settings, exposure routes, and populations exposed.**

Considerations for constructing exposure scenarios for consumers:

- Reasonably available data on consumer products or products available for consumer use including the content of 1-BP in products;
- Information characterizing the use patterns of consumer products containing 1-BP including how the product is used, the amount of product used, frequency and duration of use, and room of use;
- The associated exposure setting and route of exposure for consumers;
- Populations who may be exposed to products, including potentially exposed and susceptible subpopulations such as children or women of child bearing age;
- Subsets of consumers who may use commercially available products which have different concentrations of 1-BP or subsets of consumers who may use products more frequently.

2) Analyze the relative potential of exposure routes based on available data.

Indoor exposure routes expected to be relatively higher and include inhalation of vapor. The data sources associated with these respective pathways have not been comprehensively analyzed, therefore quantitative comparisons across exposure pathways or in relation to toxicity thresholds are not yet available.

3) Review existing consumer exposure models that may be applicable in estimating indoor air concentrations (near field and far field) for the user and bystander; and in estimating dermal exposure to the consumer in transient exposures and in longer term (e.g., occluded) exposure scenarios. Determine the applicability of the identified models for use in a quantitative exposure assessment.

Consumer exposure based indoor exposure models that estimate emission from spray products or liquid products into the indoor environment are available. These models generally consider overall mass transfer informed by the vapor pressure of the chemical, content of the chemical in the product and use patterns and practices. OPPT's CEM or E-FAST model and other similar models can be used to estimate indoor air concentration from use of consumer products containing 1-BP.

4) Review reasonably available empirical data that may be used in developing, adapting or applying exposure models to the exposure assessment of 1-BP. For example, existing models developed for a chemical assessment may be applicable to another chemical assessment if model parameter data are available.

To the extent other organizations have already modeled a 1-BP consumer exposure scenario that is relevant to OPPT's assessment, EPA will analyze those modeled estimates. In addition, if modeled estimates for other chemicals with similar physical chemical properties and similar uses area available, those modeled estimates will also be evaluated. The underlying parameters and assumptions of the models will also be analyzed.

5) Review reasonably available consumer product-specific sources to determine how those exposure estimates compare with each other and with any relevant existing monitoring data.

The availability of 1-BP concentrations in products will be analyzed. This data provides the source term for any subsequent consumer modeling. Source attribution and comparison of indoor air monitoring will be analyzed.

6) Review reasonably available population- or subpopulation-specific exposure factors and activity patterns to determine if potentially exposed or susceptible subpopulations need to be further refined.

Considerations will include:

- Age-specific differences (exposure factors and activity patterns) for populations defined in the exposure scenario table in Appendix E;

- Exposure factors and activities patterns will be sourced from EPA's 2011 Exposure Factors Handbook (U.S. EPA, 2011)
- The characteristics of the user of the consumer product and the bystander in the room, including for example, women of child bearing age and children;
- Subpopulations who may have greater exposure due to magnitude, frequency or duration of exposure as they apply to specific consumer products.

7) Analyze the weight of the evidence of consumer exposure estimates based on different approaches.

EPA will rely on the weight of the scientific evidence when evaluating and integrating data related to consumer exposure. The weight of the evidence may include qualitative and quantitative sources of information. The data integration strategy will be designed to be fit-for-purpose in which EPA will use systematic review methods to assemble the relevant data, analyze the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence.

2.6.2 Hazards (Effects)

2.6.2.1 Environmental Hazards

Environmental hazards will not be further analyzed because exposure analysis conducted using physical and chemical properties, fate information and TRI environmental releases for 1-BP show that ecological receptors are not significantly exposed to TSCA-related environmental releases of this chemical.

2.6.2.2 Human Health Hazards

EPA expects to 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).

Human health studies will be evaluated using the evaluation strategies laid out in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018) document. Human and animal data will be identified and included as described in the inclusions and exclusion criteria in Appendix F. EPA plans to prioritize the evaluation of mechanistic evidence. Specifically, EPA does not plan to evaluate mechanistic studies unless needed to clarify questions about associations between 1-BP and health effects and its relevance to humans. The *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018), document describes the process of how studies will be evaluated using specific data evaluation criteria and a predetermined approach. Study results will be extracted and presented in evidence tables by hazard endpoint. EPA plans to evaluate relevant studies identified in the 2016 Draft Risk Assessment (U.S. EPA, 2016b) of 1-BP as well as those that were captured in the comprehensive literature search conducted by the Agency for *1-Bromopropane (CASRN 106-94-5) Bibliography: Supplemental File for the TSCA Scope Document;* [EPA-HQ-OPPT-2016-0741-0047; (U.S. EPA, 2017a)]. EPA intends to review studies published after the 2016 Draft Risk Assessment (U.S. EPA,

2016b) to ensure that EPA is considering information that has been made available since that assessment was conducted.

2) **In analyzing reasonably available data, determine whether particular human receptor groups may have greater susceptibility to the chemical's hazard(s) than the general population.**

Reasonably available human health hazard data will be analyzed to ascertain whether some human receptor groups may have greater susceptibility than the general population to 1-BP hazard(s). Susceptibility of particular human receptor groups to 1-BP will be determined by evaluating information on factors that influence susceptibility.

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.**

Human health hazards from acute and chronic exposures will be identified by analyzing the human and animal data that meet the systematic review data quality criteria described in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018) document. Data quality evaluation will be performed on key studies identified from the 2016 Draft Risk Assessment (U.S. EPA, 2016b) of 1-BP, and studies published after 2016 that were identified in the comprehensive literature search (see *1-Bromopropane (CASRN 106-94-5) Bibliography: Supplemental File for the TSCA Scope Document* (EPA-HQ-OPPT-2016-0741-0047)). Hazards identified by studies meeting data quality criteria will be grouped by routes of exposure relevant to humans (oral, dermal, inhalation) and by cancer and noncancer endpoints.

Dose-response assessment will be performed in accordance with EPA guidance (U.S. EPA, 2012a, 2011, 1994). Dose-response analyses performed for the 2016 Draft Risk Assessment (U.S. EPA, 2016b) of 1-BP may be used if the data meet data quality criteria and if additional information on the identified hazard endpoints or additional hazard endpoints would not alter the analysis.

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.**

Hazard data will be evaluated to determine the type of dose-response modeling that is applicable. Where modeling is feasible, a set of dose-response models that are consistent with a variety of potentially underlying biological processes will be applied to empirically model the dose-response relationships in the range of the observed data consistent with the EPA *Benchmark Dose Technical Guidance Document* (U.S. EPA, 2012a). Where dose-response modeling is not feasible, NOAELs or LOAELs will be identified.

EPA will evaluate whether the available PBPK and empirical kinetic models are adequate for route-to-route and interspecies extrapolation of the POD, or for extrapolation of the POD to appropriate exposure durations for the risk evaluation.

5) **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.**

EPA believes there are sufficient health effects data to conduct dose-response analysis and/or benchmark dose modeling or NOAELs or LOAELs for inhalation route of exposure.

If sufficient dermal toxicity studies are not identified in the literature search to assess risks from dermal exposures, then a route-to-route extrapolation from the inhalation and oral toxicity studies would be needed to assess systemic risks from dermal exposures. Without an adequate PBPK model, the approaches described in the EPA guidance document *Risk Assessment Guidance for Superfund Volume I: Human Health Evaluation Manual (Part E, Supplemental Guidance for Dermal Risk Assessment)* (U.S. EPA, 2004b) could be applied. These approaches may be able to further inform the relative importance of dermal exposures compared with other routes of exposure.

6) **Evaluate the weight of the evidence of human health hazard data.**

EPA will rely on the weight of the scientific evidence when analyzing and integrating human health hazard data. The data integration strategy will be designed to be fit-for-purpose in which EPA will use systematic review methods to assemble the relevant data, evaluate the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence.

2.6.3 Risk Characterization

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 *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act* (82 FR 33726). For instance, in the risk characterization summary, EPA will further carry out the obligations under TSCA section 26; for example, by identifying and assessing uncertainty and variability in each step of the risk evaluation, discussing considerations of data quality such as the reliability, relevance and whether the methods utilized were reasonable and consistent, explaining any assumptions used, and discussing information generated from independent peer review. EPA will also be guided by EPA's Information Quality Guidelines (U.S. EPA, 2002) as it provides guidance for presenting risk information. Consistent with those guidelines, in the risk characterization, EPA will also identify: (1) Each population addressed by

an estimate of applicable risk effects; (2) the expected risk or central estimate of risk for the potentially exposed or susceptible subpopulations affected; (3) each appropriate upper-bound or lower bound estimate of risk; (4) each significant uncertainty identified in the process of the assessment of risk effects and the studies that would assist in resolving the uncertainty; and (5) peer reviewed studies known to the Agency that support, are directly relevant to, or fail to support any estimate of risk effects and the methodology used to reconcile inconsistencies in the scientific information.

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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
US EPA Regulations		
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).
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).

Table_Apx A-1. Federal Laws and Regulations

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
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 *hazardous air pollutant* (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 substantially as effective as regulations.	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 O3/g VOC.
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

Table_Apx A-1. Federal Laws and Regulations

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
		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 substances in several sectors.
Other Federal Regulations		
Occupational Safety and Health Act (OSHA)	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. 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.	OSHA has not issued a PEL for 1-BP. 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.
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

Table_Apx A-2. State Laws and Regulations

State Actions	Description of Action
State Air Regulations	Allowable Ambient Levels Rhode Island (Air Pollution Regulation No. 22) New Hampshire (Env-A 1400: Regulated Toxic Air Pollutants)
Chemicals of High Concern	Massachusetts designated 1-BP as a higher hazard substance requiring reporting starting in 2016 (301 CMR 41.00). 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	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). 1-BP is listed as a Candidate Chemical under California's Safer Consumer Products Program (Health and Safety Code sections 25252 and 25253). California also selected 1-BP as the first chemical for early warning and prevention activities under SB 193 Early Warning Authority and issued a Health Hazard Alert for 1-BP (Hazard Evaluation System and Information Service, 2016).

A.3 International Laws and Regulations

Table_Apx A-3. Regulatory Actions by other Governments and Tribes

Country /Organization	Requirements and Restrictions
European Union	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). In June 2017, 1-BP was added to Annex XIV of REACH (Authorisation List) with a sunset date of July 4, 2020 (European Chemicals Agency (ECHA) database. Accessed December 6, 2017).
Australia	1-BP was assessed under Environment Tier II of the Inventory Multi-tiered Assessment and Prioritisation (IMAP) (National Industrial Chemicals Notification and Assessment Scheme (NICNAS), 2017, *Human Health Tier II Assessment for Propane, 1-bromo-*. Accessed April, 18 2017).
Japan	1-BP is regulated in Japan under the following legislation: Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Chemical Substances Control Law; CSCL) Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof Industrial Safety and Health Act (ISHA) Air Pollution Control Law (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

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

B.1 Process Information

Process-related information for 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 quantity 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 1-BP 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)

B.1.1.1 Domestic Manufacture

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

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.1.1.3 Processing and Distribution

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.1.1.4 Processing as a Reactant

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.1.1.5 Incorporated into Formulation, Mixture or Reaction Product

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.1.1.6 Incorporated into Article

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.1.1.7 Repackaging

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.1.1.8 Recycling

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.1.2 Uses

In the Scope Document (EPA-HQ-OPPT-2016-0741-0049), 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.1.2.1 Solvents for Cleaning and Degreasing

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.

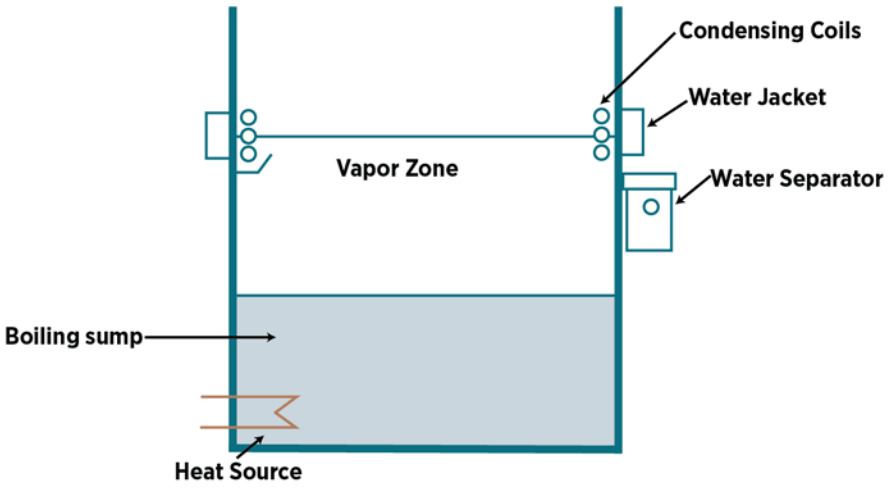
Vapor Degreasing

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.

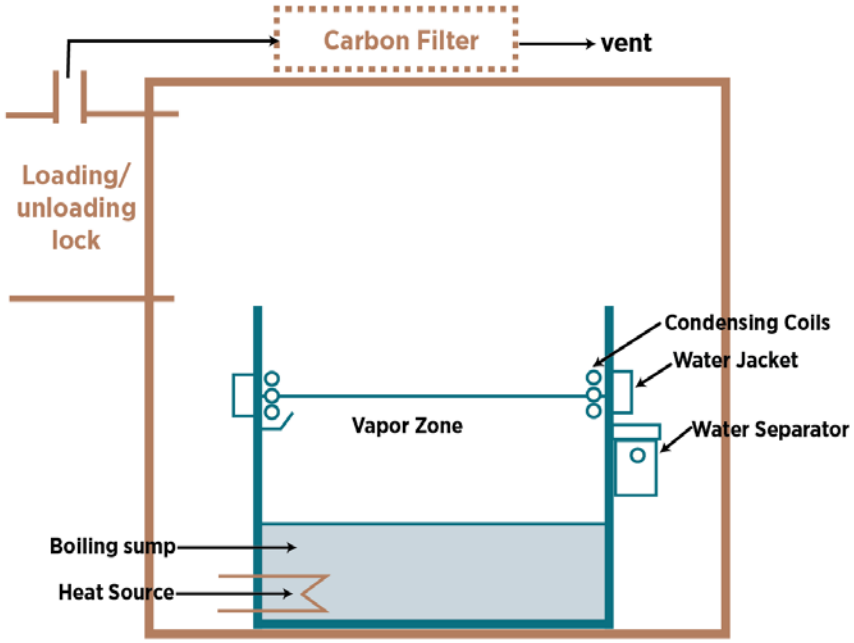
Batch Vapor Degreasers

- *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).



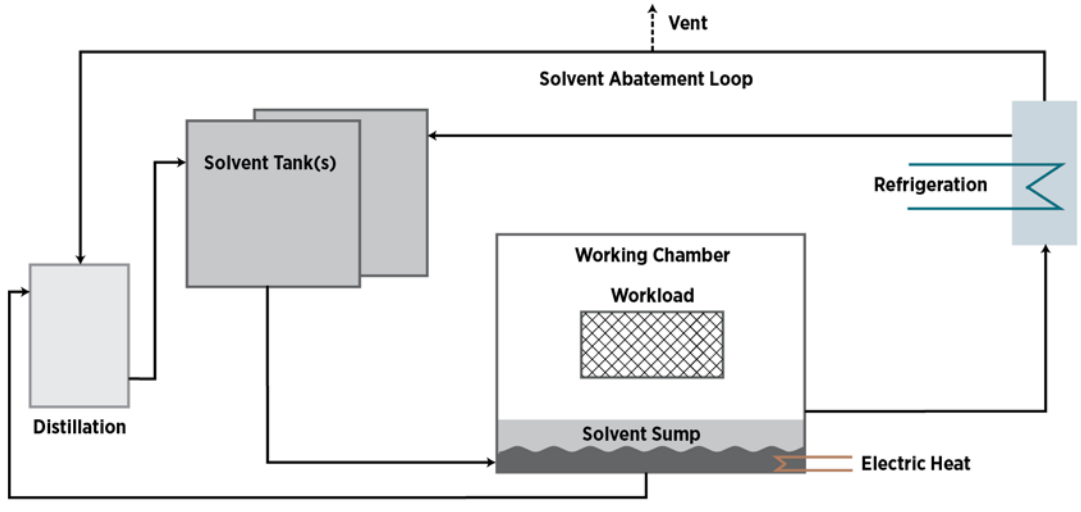
Figure_Apx B-1. Open Top Vapor Degreaser

- *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, 2004a). 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).

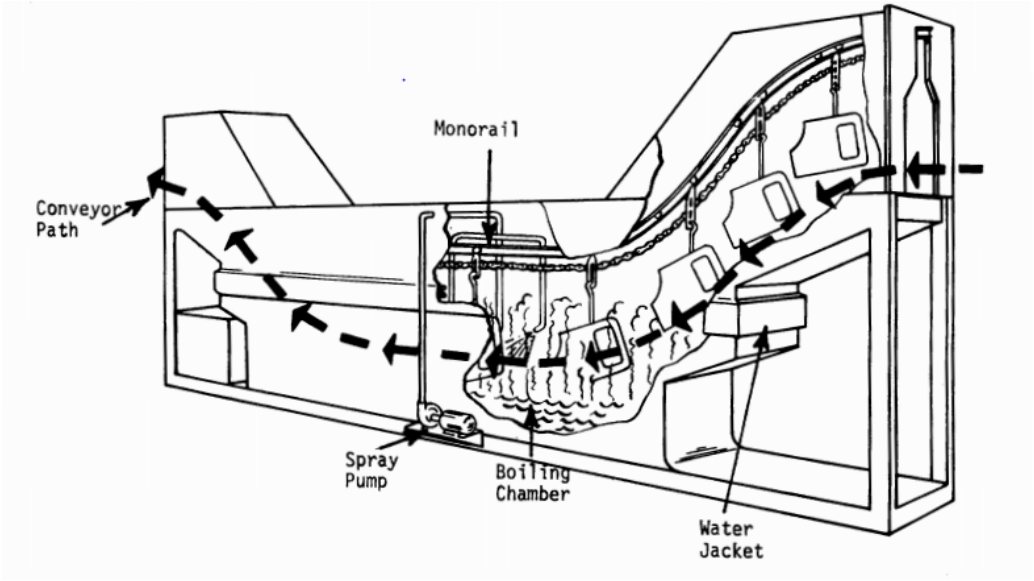
The general design of vacuum vapor degreasers and airless vacuum degreasers is similar as illustrated in Figure_Apx B-3 for closed-loop systems except that the work chamber is under vacuum during various stages of the cleaning process.

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.

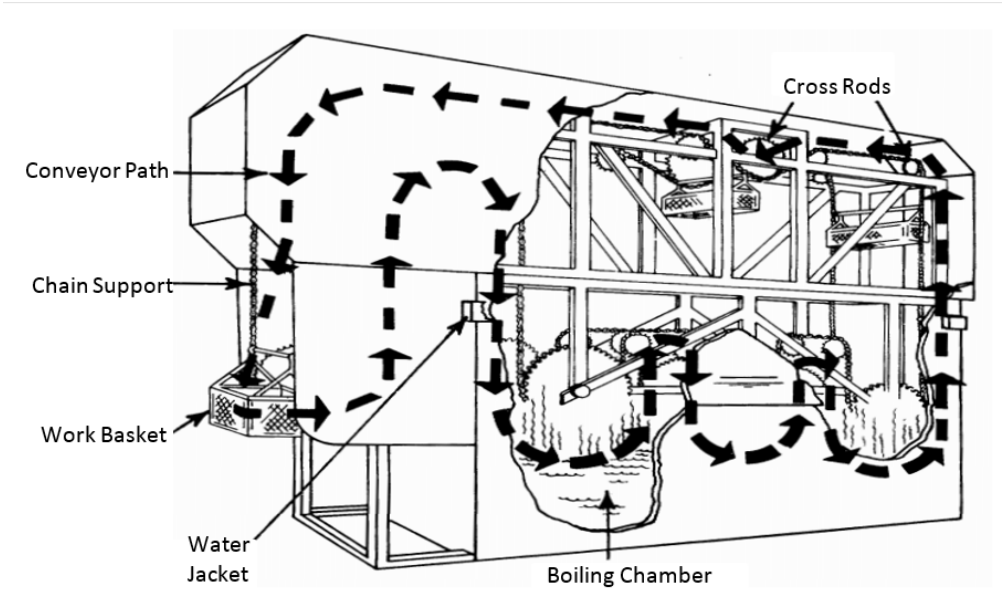
There are seven major types of conveyorized degreasers (U.S. EPA, 1977):

- *Monorail degreasers*: Monorail degreasing systems are typically used when parts are already being transported throughout the manufacturing areas by a conveyor (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). Figure_Apx B-4 illustrates a typical monorail degreaser (U.S. EPA, 1977).



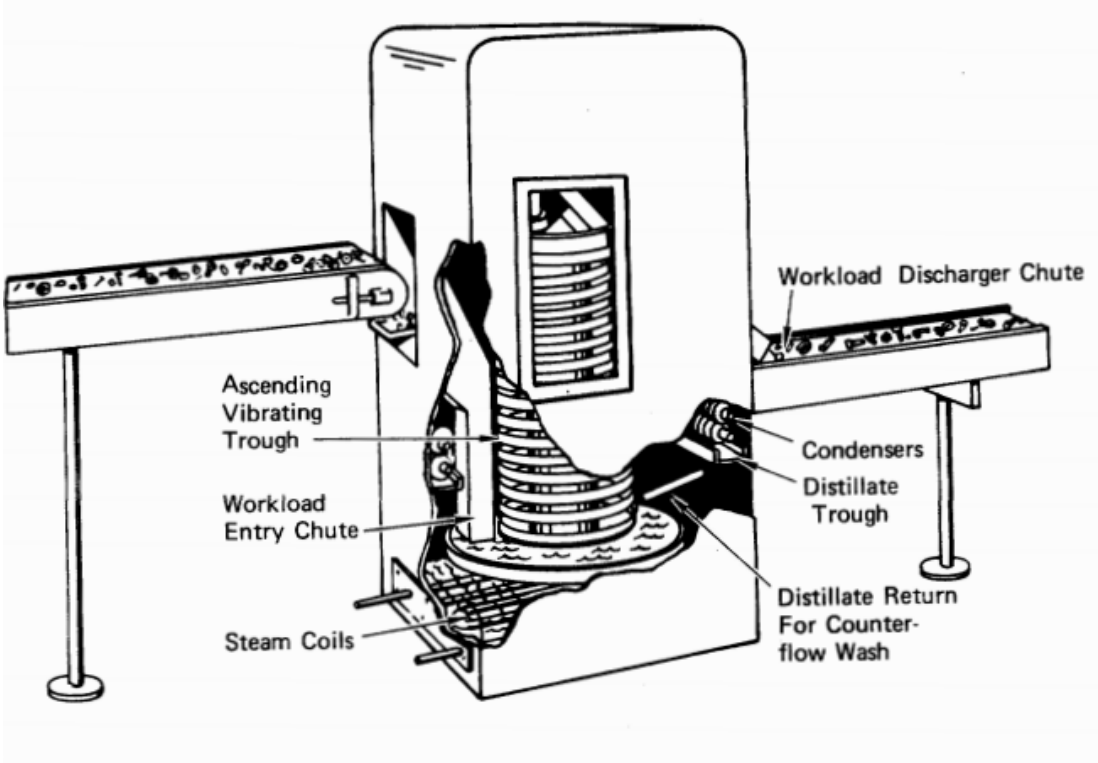
Figure_Apx B-4. Monorail Degreaser

- *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. Figure_Apx B-5 illustrates a typical cross-rod degreaser (U.S. EPA, 1977).



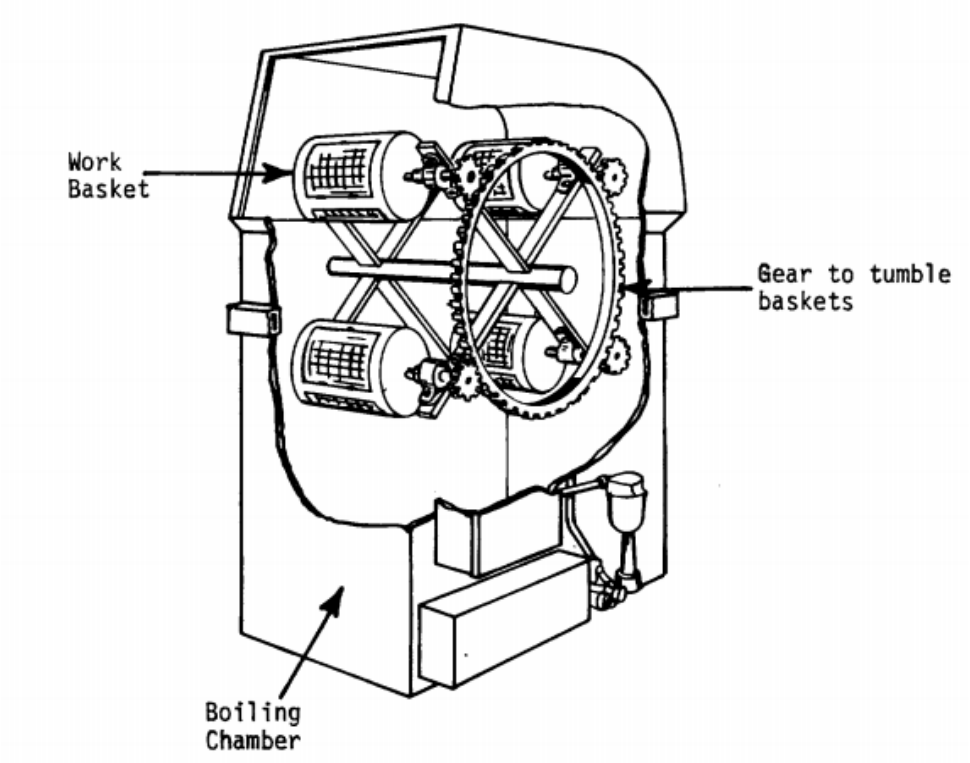
Figure_Apx B-5. Cross-Rod Degreaser

- *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).



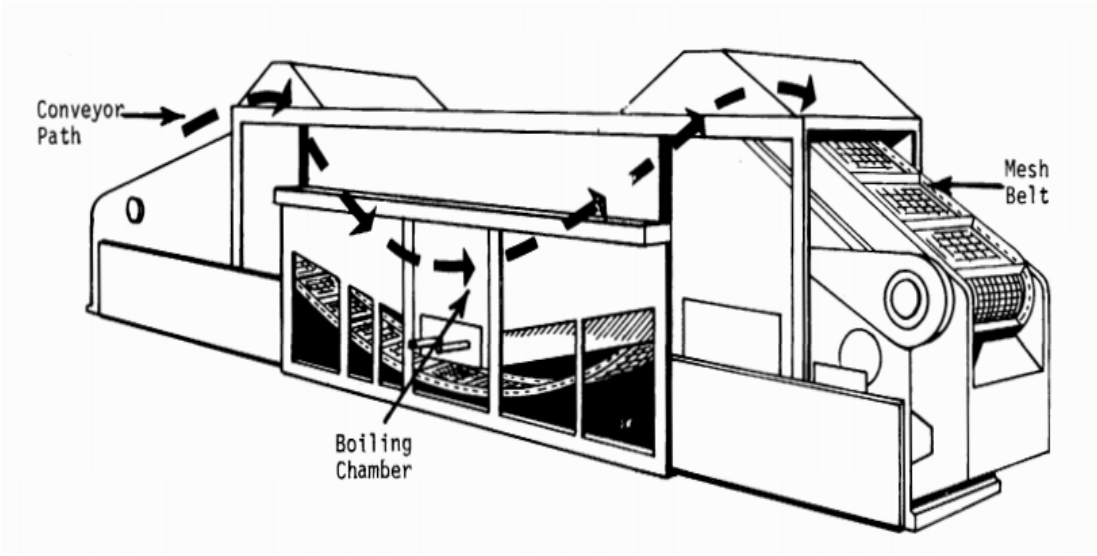
Figure_Apx B-6. Vibra Degreaser

- *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. Figure_Apx B-7 illustrates a typical ferris wheel degreaser (U.S. EPA, 1977).



Figure_Apx B-7. Ferris Wheel Conveyorized Vapor Degreasing System

- *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. Figure_Apx B-8 illustrates a typical belt or strip degreaser (U.S. EPA, 1977).

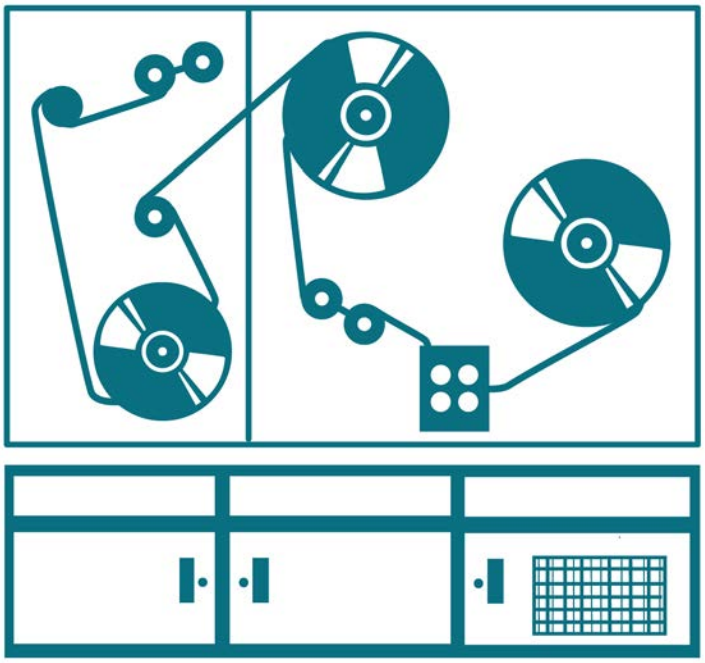


Figure_Apx B-8. Belt/Strip Conveyorized Vapor Degreasing System

- *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). Figure_Apx B-9 illustrates a typical continuous web cleaning machine.



Figure_Apx B-9. Continuous Web Vapor Degreasing System

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, 2014a). Aerosol degreasing may occur at either industrial facilities or at commercial repair shops to remove contaminants on items being serviced.

B.1.2.2 Adhesives and Sealants

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.1.2.3 Cleaning and Furniture Care Products

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). Worker who handle 1-BP at dry cleaning facilities may be exposed when 1) adding makeup solvent, typically by manually dumping it through the front hatch, 2) opening the machine door during the wash cycle, and 3) removing loads from the machines (Blando et al., 2010).

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.1.2.4 Other Uses

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, 1977)]. 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.1.3 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, 2017). Due to the high volatility of 1-BP, releases to the atmosphere are expected to be the primary release route of 1-BP (ATSDR, 2017). Currently, 1-BP is not regulated under federal regulations as a hazardous waste (U.S. EPA, 1977). 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 examples 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 release/exposure scenarios and industry sectors with available 1-BP personal monitoring data from OSHA inspections conducted between 2013 and 2016 (OSHA, 2017).

Table_Apx B-1. Summary of Release/Exposure Scenarios and Industry Sectors with 1-BP Personal Monitoring Air Samples Obtained from OSHA Inspections Conducted Between 2013 and 2016

Release/ Exposure Scenario	NAICS	NAICS Description
Solvents (for cleaning or degreasing)	336412	Aircraft Engine and Engine Parts Manufacturing
Commercial spot cleaning	448190	Other Clothing Stores
Solvents (for cleaning or degreasing)	333517	Machine Tool Manufacturing
Solvents (for cleaning or degreasing)	334418	Printed Circuit Assembly
Solvents (for cleaning or degreasing)	331210	Iron and Steel Pipe and Tube Manufacturing from Purchased Steel
Solvents (for cleaning or degreasing)	336413	Other Aircraft Parts and Auxiliary Equipment Manufacturing
Solvents (for cleaning or degreasing)	332813	Electroplating, Plating, Polishing, Anodizing, and Coloring
Other	926150	Regulation, Licensing, and Inspection of Miscellaneous Commercial Sectors
Unknown, likely commercial spot cleaning	323113	Commercial Screen Printing

Table_Apx B-1. Summary of Release/Exposure Scenarios and Industry Sectors with 1-BP Personal Monitoring Air Samples Obtained from OSHA Inspections Conducted Between 2013 and 2016

Release/ Exposure Scenario	NAICS	NAICS Description
Solvents (for cleaning or degreasing)	332913	Plumbing Fixture Fitting and Trim Manufacturing
Solvents (for cleaning or degreasing)	332721	Precision Turned Product Manufacturing
Solvents (for cleaning or degreasing)	333911	Pump and Pumping Equipment Manufacturing

Table_Apx B-2 summarizes the release/exposure scenarios and industry sectors with available area monitoring data.

Table_Apx B-2. Summary of Release/Exposure Scenarios and Industry Sectors with 1-BP Area Monitoring Air Samples Obtained from OSHA Inspections Conducted Between 2013 and 2016

Release/ Exposure Scenario	NAICS	NAICS Description
Solvents (for cleaning or degreasing)	332721	Precision Turned Product Manufacturing
Solvents (for cleaning or degreasing)	333911	Pump and Pumping Equipment Manufacturing

B.3 References related to Risk Evaluation – Environmental Release and Occupational Exposure

As part of the Systematic Review process, EPA has conducted a full-text screening of literature sources and identified sources that may be relevant for risk evaluation. This section presents a list of data sources that may contain process description, environmental release estimate, occupational exposure data, engineering control and personal protective equipment information for 1-BP. EPA will further review these data sources and determine their utility for risk evaluation.

Table_Apx B-3. Potentially Relevant Data Sources for Process Description Related Information for 1-BP [a]

Bibliography	url
NIOSH (1997). Control of health and safety hazards in commercial drycleaners: chemical exposures, fire hazards, and ergonomic risk factors. Education and Information Division. Atlanta, GA.	NIOSH (1997) https://hero.epa.gov/heronet/index.cfm/reference/download/reference_id/3044963
U.S. EPA (2016). 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. Washington, DC.	U.S. EPA (2016b) https://hero.epa.gov/heronet/index.cfm/reference/download/reference_id/3355305

Table_Apx B-3. Potentially Relevant Data Sources for Process Description Related Information for 1-BP [a]

Bibliography	url
NIOSH (2007). Workers' exposures to n-propyl bromide at a printed electronics circuit assembly manufacturer. Cincinnati, OH, NIOSH Division of Surveillance, Hazard Evaluation and Field Studies.	NIOSH (2007b) https://hero.epa.gov/heronet/index.cfm/reference/download/reference_id/3355604
NIOSH (2007). Workers' exposures to n-propyl bromide at a hydraulic power control component manufacturer. Cincinnati, OH, NIOSH Division of Surveillance, Hazard Evaluation and Field Studies.	NIOSH (2007a) https://hero.epa.gov/heronet/index.cfm/reference/download/reference_id/3355621
U.S. EPA (1995). Guidance document for the halogenated solvent cleaner NESHAP. Research Triangle Park, NC, Office of Air Quality Planning and Standards, Information Transfer and Program Integration Division, Control Technology Center, Federal Small Business Assistance Program.	U.S. EPA (1995) https://hero.epa.gov/heronet/index.cfm/reference/download/reference_id/3827323
NIOSH (2003). NIOSH Health Hazard Evaluation Report: HETA No. 99-0260-2906, Marx Industries, Inc., Sawmills, North Carolina. Hazard Evaluation and Technical Assistance Branch. Cincinnati, OH, National Institute for Occupational Health and Safety.	Harney et al. (2003) https://hero.epa.gov/heronet/index.cfm/reference/download/reference_id/3970467
U.S. EPA; ICF Consulting (2004). The U.S. solvent cleaning industry and the transition to non ozone depleting substances.	U.S. EPA; ICF Consulting (2004) https://hero.epa.gov/heronet/index.cfm/reference/download/reference_id/3982140
HSIA (2008). Chlorinated solvents - The key to surface cleaning performance.	HSIA (2008) https://hero.epa.gov/heronet/index.cfm/reference/download/reference_id/3982144

[a] The data sources identified are based on preliminary results to date of the full-text screening step of the Systematic Review process. Further screening and quality control are on-going.

Table_Apx B-4. Potentially Relevant Data Sources for Estimated or Measured Release Data for 1-BP [a]

Bibliography	url
Japanese Ministry of Environment (2017). 1-Bromopropane. Tokyo, Japan.	Japanese Ministry of Environment (2017) https://hero.epa.gov/heronet/index.cfm/reference/download/reference_id/3980936
CAMP, Inc., (2000). Final report: Beyond pollution prevention: Removal of organochlorines from industrial feedstocks and processes in the Great Lakes Basin, The Great Lakes Protection Fund, The Joyce Foundation.	CAMP (2000) https://hero.epa.gov/heronet/index.cfm/reference/download/reference_id/3981054
HSIA (2008). Chlorinated solvents - The key to surface cleaning performance.	(HSIA, 2008) https://hero.epa.gov/heronet/index.cfm/reference/download/reference_id/3982144

[a] The data sources identified are based on preliminary results to date of the full-text screening step of the Systematic Review process. Further screening and quality control are on-going.

Table_Apx B-5. Potentially Relevant Data Sources for Personal Exposure Monitoring and Area Monitoring Data for 1-BP [a]

Bibliography	url
Hanley, K. W., et al. (2006). "Urinary bromide and breathing zone concentrations of 1-bromopropane from workers exposed to flexible foam spray adhesives." Annals of Occupational Hygiene **50**(6): 599-607.	Hanley et al. (2006a) https://hero.epa.gov/heronet/index.cfm/reference/download/reference_id/607476
NIOSH (2003). NIOSH Health Hazard Evaluation Report: HETA No. 99-0260-2906, Marx Industries, Inc., Sawmills, North Carolina. Hazard Evaluation and Technical Assistance Branch. Cincinnati, OH, National Institute for Occupational Health and Safety.	Harney et al. (2003) https://hero.epa.gov/heronet/index.cfm/reference/download/reference_id/1379492

Table_Apx B-5. Potentially Relevant Data Sources for Personal Exposure Monitoring and Area Monitoring Data for 1-BP [a]

Bibliography	url
Toraason, M., et al. (2003). "Assessment of DNA strand breaks in leukocytes of workers occupationally exposed to 1-bromopropane." Toxicological Sciences **72**(S-1): 250.	Toraason et al. (2003) https://hero.epa.gov/heronet/index.cfm/reference/download/reference_id/1733747
OSHA (2013). OSHA/NIOSH hazard alert: 1-bromopropane. Washington, DC, U.S. Department of Labor.	OSHA (2013) https://hero.epa.gov/heronet/index.cfm/reference/download/reference_id/2347177
NIOSH (1997). Control of health and safety hazards in commercial drycleaners: chemical exposures, fire hazards, and ergonomic risk factors. Education and Information Division. Atlanta, GA.	NIOSH (1997) https://hero.epa.gov/heronet/index.cfm/reference/download/reference_id/3044963
NIOSH (2007). Workers' exposures to n-propyl bromide at a printed electronics circuit assembly manufacturer. Cincinnati, OH, NIOSH Division of Surveillance, Hazard Evaluation and Field Studies.	NIOSH (2007b) https://hero.epa.gov/heronet/index.cfm/reference/download/reference_id/3355604
NIOSH (2007). Workers' exposures to n-propyl bromide at a hydraulic power control component manufacturer. Cincinnati, OH, NIOSH Division of Surveillance, Hazard Evaluation and Field Studies.	NIOSH (2007a) https://hero.epa.gov/heronet/index.cfm/reference/download/reference_id/3355621
CDC (2016). Criteria for a recommended standard: Occupational exposure to 1-bromopropane. Cincinnati, OH, National Institute for Occupational Safety and Health.	CDC (2016) https://hero.epa.gov/heronet/index.cfm/reference/download/reference_id/3827326
NIOSH (2003). NIOSH Health Hazard Evaluation Report: HETA No. 99-0260-2906, Marx Industries, Inc., Sawmills, North Carolina. Hazard Evaluation and Technical Assistance Branch. Cincinnati, OH, National Institute for Occupational Health and Safety.	Harney et al. (2003) https://hero.epa.gov/heronet/index.cfm/reference/download/reference_id/3970467
Hanley, K. W., et al. (2006). "Urinary bromide and breathing zone concentrations of 1-bromopropane from workers exposed to flexible foam spray adhesives, Part3." Annals of Occupational Hygiene **6**: 599-607.	Hanley et al. (2006b) https://hero.epa.gov/heronet/index.cfm/reference/download/reference_id/3974876
OSHA (2010). Input received through web forum for identifying hazardous chemicals for which OSHA should develop exposure reduction strategies. Washington, DC, U.S. Department of Labor, Occupational Safety and Health Administration.	OSHA (2010) https://hero.epa.gov/heronet/index.cfm/reference/download/reference_id/3978176
ATSDR (2017). Toxicological profile for1-bromopropane. Atlanta, GA, Division of Toxicology and Human Health Sciences, Environmental Toxicology Branch.	ATSDR (2017) https://hero.epa.gov/heronet/index.cfm/reference/download/reference_id/3982334
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[a] The data sources identified are based on preliminary results to date of the full-text screening step of the Systematic Review process. Further screening and quality control are on-going.

Table_Apx B-6. Potentially Relevant Data Sources for Engineering Controls and Personal Protective Equipment Information for 1-BP [a]

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Table_Apx B-6. Potentially Relevant Data Sources for Engineering Controls and Personal Protective Equipment Information for 1-BP [a]

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[a] The data sources identified are based on preliminary results to date of the full-text screening step of the Systematic Review process. Further screening and quality control are on-going.

APPENDIX C ESTIMATES OF SURFACE WATER CONCENTRATION

SCENARIO 1. REPORTED RELEASES TO TRI

For 1-BP, there is one facility reporting water releases from the 2016 TRI reporting period, the Flint Hills Resources facility. This facility, located in Corpus Christi, TX, has reported 1 lb of 1-BP released to the Nueces River with 100% from stormwater on an annual basis. They also reported 4 lbs of 1-BP released to an unnamed water body with 83% from stormwater on an annual basis. These are direct releases to water and thus are presumed to be untreated at a POTW. A quick calculation of site specific surface water concentration was performed using E-FAST assuming that the total release occurs over 1 day, 20 days or 100 days. Two receiving waters were used:

a. Nueces River – the NPDES permit for Corpus Christ City POTW TX0047082 was used as a surrogate for this direct release. 0% removal was assumed since this is listed as a direct release.

b. Unnamed Waterbody – the NPDES permit for the reporting facility was available in EFAST with the receiving water body listed as the Corpus Christi Bay. Acute dilution factors were used to estimate the surface water concentration, again with 0% removal.

The resulting estimated surface water concentrations, based on the reported releases and locations, are well below the acute and chronic concentrations of concern even if the annual release amount occurs over 1 day. The maximum estimated surface water concentration is 78 µg/L for this scenario. The acute concentration of concern is 4860 ppb and the chronic concentration of concern is 243 ppb.

Table_Apx C-1. Estimated Surface Concentrations from Water Releases Reported to TRI

SCENARIO 1: REPORTED RELEASES TO TRI

Acute COC = 4860 ppb

Chronic COC = 2430 ppb

From TRI reporting: 1 reporting facility: Flint Hills Resources Corpus Christi LLC – West Plant
1 lb to Nueces River (100% from stormwater);
4 lbs to 'unnamed water body' (83% from stormwater)

Wastewater Treatment Removal= 0%; direct release
(Note: NPDES for Corpus Christi City POTW used as surrogate for Nueces River. Flint Hills Resources facility modeled directly)

	Nueces River (Corpus Christi City - TX0047082)				**Flint Hills Resources - Corpus Christi Bay, (TX0006289)**		
	7Q10 SWC µg/L				**SWC* µg/L**		
Annual Release Amount lb (kg)	1 day/yr	20 days/yr	100 days/yr		1 day/yr	20 days/yr	100 days/yr
1 (0.45)	7.86	0.39	0.08		19.4	0.97	0.19
4 (1.81)	31.60	1.58	0.31		77.90	3.90	0.77
					*Acute dilution factor for bay		

APPENDIX D SUPPORTING TABLE FOR INDUSTRIAL AND COMMERCIAL ACTIVITIES AND USES CONCEPTUAL MODEL

(Note that rows shaded in gray are not proposed for further analysis)

Table_Apx D-1. Industrial and Commercial Activities and Uses Conceptual Model Supporting Table

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Proposed for Further Analysis	Rationale for Further Analysis / No Further Analysis
Manufacture	Domestic Manufacture	Domestic Manufacture	Manufacture of 1-BP via reaction of n-propyl alcohol and hydrogen bromide	Liquid Contact	Dermal	Workers	Yes	Contact time with skin is expected to be <2 min due to rapid volatilization and the fraction absorbed was measured to be low (0.16%) by NIOSH. The number of sites mfg 1-BP is limited per CDR (3 sites).
				Vapor	Inhalation	Workers	Yes	Due to high volatility (VP = 146 torr at 20°C), inhalation pathway should be further analyzed.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical
				Vapor	Inhalation	ONU	Yes	Due to high volatility (VP = 146 torr at 20°C), inhalation pathway will be further analyzed.
				Mist	Dermal/ Inhalation	Workers, ONU	No	Mist generation is not expected during mfg and will not be further analyzed.
Manufacture	Import	Import	Repackaging of import containers	Liquid Contact	Dermal	Workers	Yes	Contact time with skin is expected to be <2 min due to rapid volatilization and the fraction absorbed was measured to be low (0.16%) by NIOSH. The number of import sites is limited (<9 sites) per CDR. Exposure will only occur in the event the imported material is repackaged.
				Vapor	Inhalation	Workers	Yes	Exposure expected only in the event the imported material is repackaged into different sized containers. Exposure frequency may be low.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical.
				Vapor	Inhalation	ONU	Yes	Exposure expected only in the event the imported material is repackaged into different sized containers. Exposure frequency may be low.

Table_Apx D-1. Industrial and Commercial Activities and Uses Conceptual Model Supporting Table

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Proposed for Further Analysis	Rationale for Further Analysis / No Further Analysis
				Mist	Dermal/ Inhalation	Workers, ONU	No	Mist generation is not expected during import and will not be further analyzed.
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	Chemical manufacture / Pesticide, fertilizer, and other agricultural chemical manufacture	Liquid Contact	Dermal	Workers	Yes	Contact time with skin is expected to be <2 min due to rapid volatilization and the fraction absorbed was measured to be low (0.16%) by NIOSH. The number of workers is expected to be low per CDR (2 submissions in CDR, 10-25 workers per submission).
				Vapor	Inhalation	Workers	Yes	Due to high volatility (VP = 146 torr at 20°C), inhalation pathway should be further analyzed. However, potential for exposure may be low in scenarios where 1-BP is consumed as a chemical intermediate.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical.
				Vapor	Inhalation	ONU		Due to high volatility (VP = 146 torr at 20°C), inhalation pathway should be further analyzed.
				Mist	Dermal/ Inhalation	Workers, ONU	No	Mist generation is not expected during processing as an intermediate and will not be further analyzed.
Processing	Incorporated into formulation, mixture or reaction product	Solvent for cleaning or degreasing in manufacturing of: - all other chemical product and preparation - computer and electronic product - electrical equipment, appliance and component - soap, cleaning compound and toilet preparation - services	Formulation of cleaning fluids	Liquid Contact	Dermal	Workers	Yes	Contact time with skin is expected to be <2 min due to rapid volatilization and the fraction absorbed was measured to be low (0.16%) by NIOSH.
				Vapor	Inhalation	Workers	Yes	Inhalation exposure is expected at processing sites that formulate products containing 1-BP. Due to high volatility (VP = 146 torr at 20°C), inhalation pathway should be further analyzed.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical.
				Vapor	Inhalation	ONU	Yes	Inhalation exposure is expected at processing sites that formulate products containing 1-BP. Due to high volatility (VP = 146 torr at 20°C), inhalation pathway should be further analyzed.
				Mist	Dermal/ Inhalation	Workers, ONU	No	Mist generation is not expected during processing/formulation operations and will not be further analyzed.

Table_Apx D-1. Industrial and Commercial Activities and Uses Conceptual Model Supporting Table

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Proposed for Further Analysis	Rationale for Further Analysis / No Further Analysis
Processing	Incorporated into articles	Solvents (which become part of product formulation or mixture) in construction	Production of insulation material	Liquid Contact	Dermal	Workers	Yes	Contact time with skin is expected to be <2 min due to rapid volatilization and the fraction absorbed was measured to be low (0.16%) by NIOSH.
				Vapor	Inhalation	Workers	Yes	Inhalation exposure is expected at processing sites. Due to high volatility (VP = 146 torr at 20°C), inhalation pathway should be further analyzed.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical.
				Vapor	Inhalation	ONU	Yes	Inhalation exposure is expected at processing sites. Due to high volatility (VP = 146 torr at 20°C), inhalation pathway should be further analyzed.
				Mist	Dermal/ Inhalation	Workers, ONU	No	Mist generation is not expected during processing operations and will not be further analyzed.
Processing	Repackaging	Solvent for cleaning or degreasing in all other basic organic chemical manufacturing	Repackaging into large and small containers	Liquid Contact	Dermal	Workers	Yes	Contact time with skin is expected to be <2 min due to rapid volatilization and the fraction absorbed was measured to be low (0.16%) by NIOSH.
				Vapor	Inhalation	Workers	Yes	Exposure frequency may be low.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical.
				Vapor	Inhalation	ONU	Yes	Exposure frequency may be low.
				Mist	Dermal/ Inhalation	Workers, ONU	No	Mist generation is not expected during repackaging and will not be further analyzed.
Processing	Recycling	Recycling	Recycling of process solvents containing 1-BP	Liquid Contact	Dermal	Workers	Yes	Contact time with skin is expected to be <2 min due to rapid volatilization and the fraction absorbed was measured to be low (0.16%) by NIOSH.
				Vapor	Inhalation	Workers	Yes	Inhalation exposure is expected at recycling sites.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical.
				Vapor	Inhalation	ONU	Yes	Inhalation exposure is expected at recycling sites.

Table_Apx D-1. Industrial and Commercial Activities and Uses Conceptual Model Supporting Table

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Proposed for Further Analysis	Rationale for Further Analysis / No Further Analysis
				Mist	Dermal/ Inhalation	Workers, ONU	No	Mist generation is not expected during recycling and will not be further analyzed.
Distribution in commerce	Distribution	Distribution	Distribution of bulk shipment of 1-BP	Liquid Contact, Vapor	Dermal/ Inhalation	Workers, ONU	Yes	EPA will further analyze activities resulting in exposures associated with distribution in commerce (e.g. loading, unloading) throughout the various lifecycle stages and conditions of use (e.g. manufacturing, processing, industrial use, consumer use, disposal) rather than as a single distribution scenario.
	Distribution	Distribution	Distribution of formulated products					
Industrial / commercial / consumer use	Solvents (for cleaning or degreasing)	Batch vapor degreaser (e.g., open-top, closed-loop) In-line vapor degreaser (e.g., conveyorized, web cleaner)	Open top vapor degreasing (OTVD) OTVD with enclosures Conveyorized vapor degreasing Cross-rod and ferris wheel vapor degreasing Web vapor degreasing Airtight closed-loop degreasing system Airless vacuum-to-vacuum degreasing system Airless vacuum drying degreasing system	Liquid Contact	Dermal	Workers	Yes	Contact time with skin is expected to be <2 min due to rapid volatilization and the fraction absorbed was measured to be low (0.16%) by NIOSH. However, repeat contact or dermal immersion may occur, especially while cleaning and maintaining degreasing equipment.
				Vapor	Inhalation	Workers	Yes	EPA has previously assessed OTVD in the 2016 RA. EPA will further refine and expand its assessment for all degreasing systems by addressing comments received from peer review, or by incorporating additional data identified through systematic review, if found. For closed-systems, EPA expects inhalation exposure to be lower than exposure associated with open systems such as OTVD.
				Vapor	Inhalation	ONU	Yes	
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical.
				Mist	Dermal/ Inhalation	Workers, ONU	No	Mist generation is not expected during this use and will not be further analyzed.
Industrial / commercial / consumer use	Solvents (for cleaning or degreasing)	Cold cleaner		Liquid Contact	Dermal	Workers	Yes	Contact time with skin is expected to be <2 min due to rapid volatilization and the fraction absorbed was measured to be low (0.16%) by NIOSH. However, repeat contact or dermal immersion may occur.

Table_Apx D-1. Industrial and Commercial Activities and Uses Conceptual Model Supporting Table

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Proposed for Further Analysis	Rationale for Further Analysis / No Further Analysis
			Spray use in cold cleaning - maintenance (manual spray; spray sink; dip tank)	Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical.
				Vapor	Inhalation	Workers	Yes	EPA has previously assessed this use in the 2016 RA. EPA will further refine its assessment by addressing comments received from peer review, or by incorporating additional data identified through systematic review, if found.
				Vapor	Inhalation	ONU	Yes	
				Mist	Dermal/ Inhalation	Workers	Yes	EPA will further analyze the potential for mist generation.
				Mist	Dermal	ONU	No	Exposure to mist is generally not expected as occupational non-users do not directly handle 1-BP. This pathway will not be further analyzed.
				Mist	Inhalation	ONU	Yes	EPA will further analyze the potential for mist generation.
Industrial / commercial / consumer use	Solvents (for cleaning or degreasing)	Aerosol spray degreaser/ cleaner	Aerosol use in degreasing/ cleaning	Liquid Contact	Dermal	Workers	Yes	Contact time with skin is expected to be <2 min due to rapid volatilization and the fraction absorbed was measured to be low (0.16%) by NIOSH. However, repeat contact may occur.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical.
				Vapor	Inhalation	Workers	Yes	EPA has previously assessed this use in the 2016 RA. EPA will further refine its assessment by addressing comments received from peer review, or by incorporating additional data identified through systematic review, if found.
				Vapor	Inhalation	ONU	Yes	
				Mist	Dermal/ Inhalation	Workers	Yes	EPA will further analyze the potential for mist generation.
				Mist	Dermal	ONU	No	Exposure to mist is generally not expected as occupational non-users do not directly handle 1-BP. This pathway will not be further analyzed.
				Mist	Inhalation	ONU	Yes	EPA will further analyze the potential for mist generation.
Industrial / commercial / consumer use	Adhesives and sealants	Adhesive chemicals - spray adhesive for foam cushion	Industrial spray adhesive application	Liquid Contact	Dermal	Workers	Yes	Contact time with skin is expected to be <2 min due to rapid volatilization and the fraction absorbed was measured to be low (0.16%) by NIOSH. However, repeat contact may occur.

Table_Apx D-1. Industrial and Commercial Activities and Uses Conceptual Model Supporting Table

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Proposed for Further Analysis	Rationale for Further Analysis / No Further Analysis
		manufacturing and other uses	Other adhesive, sealant, or coating applications (e.g. roll)	Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical.
				Vapor	Inhalation	Workers	Yes	EPA has previously assessed the use of spray adhesive in the 2016 RA. EPA will further refine its assessment by addressing comments received from peer review, or by incorporating additional data identified through systematic review, if found. For other adhesives, inhalation pathway should be analyzed due to high volatility (VP = 146 torr at 20°C).
				Vapor	Inhalation	ONU	Yes	
				Mist	Dermal/ Inhalation	Workers	Yes	Mist generation is expected for spray adhesives. EPA will further analyze to determine if mist generation is applicable for each adhesive/sealant product.
				Mist	Dermal	ONU	No	Exposure to mist is generally not expected as occupational non-users do not directly handle 1-BP. This pathway will not be further analyzed.
				Mist	Inhalation	ONU	Yes	EPA will further analyze the potential for mist generation.
Industrial / commercial / consumer use	Cleaning and furniture care products	Dry cleaning solvent Spot cleaner, stain remover	Commercial dry cleaning and spot cleaning	Liquid Contact	Dermal	Workers	Yes	Contact time with skin is expected to be <2 min due to rapid volatilization and the fraction absorbed was measured to be low (0.16%) by NIOSH. However, repeat contact may occur. Peer reviewers also indicated the potential for occluded exposure.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical.
				Vapor	Inhalation	Workers	Yes	EPA has previously assessed this use in the 2016 RA. EPA will further refine its assessment by addressing comments received from peer review, or by incorporating additional data identified through systematic review, if found.
				Vapor	Inhalation	ONU	Yes	
				Mist	Dermal/ Inhalation	Workers	Yes	EPA will further analyze the potential for mist generation.
				Mist	Dermal	ONU	No	Exposure to mist is generally not expected as occupational non-users do not directly handle 1-BP. This pathway will not be further analyzed.
				Mist	Inhalation	ONU	Yes	EPA will further analyze the potential for mist generation.
				Indoor vapor	Dermal	Co-located population	No	Exposure via dermal and oral routes may be unlikely.

Table_Apx D-1. Industrial and Commercial Activities and Uses Conceptual Model Supporting Table

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Proposed for Further Analysis	Rationale for Further Analysis / No Further Analysis
				Indoor vapor	Oral	Co-located population	No	Exposure via dermal and oral routes may be unlikely.
				Indoor vapor	Inhalation	Co-located population	Yes	EPA expects persons living in residences co-located with dry cleaners to be exposed to vapor. EPA will further analyze exposure via the inhalation route.
Industrial / commercial / consumer use	Cleaning and furniture care products	Liquid spray / aerosol cleaner	Commercial use of aerosol cleaner	Liquid Contact	Dermal	Workers	Yes	Contact time with skin is expected to be <2 min due to rapid volatilization and the fraction absorbed was measured to be low (0.16%) by NIOSH. However, repeat contact may occur.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical
				Vapor	Inhalation	Workers	Yes	Due to high volatility (VP = 146 torr at 20°C), inhalation pathway should be further analyzed.
				Vapor	Inhalation	ONU	Yes	Due to high volatility (VP = 146 torr at 20°C), inhalation pathway should be further analyzed.
				Mist	Dermal/ Inhalation	Workers	Yes	Mist generation expected for aerosol applications.
				Mist	Dermal	ONU	No	Exposure to mist is generally not expected as occupational non-users do not directly handle 1-BP. This pathway will not be further analyzed.
				Mist	Inhalation	ONU	Yes	EPA will further analyze the potential for mist generation.
Industrial / commercial / consumer use	Other uses	Other aerosol uses, e.g. automotive degreasing/brake cleaning, cutting oils	See Table 2-3 for specific scenario corresponding to the condition of use.	Liquid Contact	Dermal	Workers	Yes	Contact time with skin is expected to be <2 min due to rapid volatilization and the fraction absorbed was measured to be low (0.16%) by NIOSH. However, repeat contact may occur.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical.
				Vapor	Inhalation	Workers	Yes	Due to high volatility (VP = 146 torr at 20°C), inhalation pathway should be further analyzed.
				Vapor	Inhalation	ONU	Yes	Due to high volatility (VP = 146 torr at 20°C), inhalation pathway should be further analyzed.

Table_Apx D-1. Industrial and Commercial Activities and Uses Conceptual Model Supporting Table

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Proposed for Further Analysis	Rationale for Further Analysis / No Further Analysis
				Mist	Dermal/ Inhalation	Workers	Yes	Mist generation expected for aerosol applications.
				Mist	Dermal	ONU	No	Exposure to mist is generally not expected as occupational non-users do not directly handle 1-BP. This pathway will not be further analyzed.
				Mist	Inhalation	ONU	Yes	EPA will further analyze the potential for mist generation.
Industrial / commercial / consumer use	Other uses	Other non-aerosol uses, e.g. insulation materials, asphalt extraction, temperature indicator	See Table 2-3 for specific scenario corresponding to the condition of use.	Liquid Contact	Dermal	Workers	Yes	Contact time with skin is expected to be <2 min due to rapid volatilization and the fraction absorbed was measured to be low (0.16%) by NIOSH.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical.
				Vapor	Inhalation	Workers	Yes	Due to high volatility (VP = 146 torr at 20°C), inhalation pathway should be further analyzed. However, the potential for exposure is unknown where 1-BP is incorporated into articles.
				Vapor	Inhalation	ONU	Yes	
				Mist	Dermal/ Inhalation	Workers, ONU	No	Mist generation is not expected for non-aerosol applications and will not be further analyzed.
Disposal	Waste Handling, Treatment and Disposal	Disposal of 1-BP wastes	Worker handling of wastes	Liquid Contact	Dermal	Workers	Yes	Contact time with skin is expected to be <2 min due to rapid volatilization and the fraction absorbed was measured to be low (0.16%) by NIOSH. However, EPA will further analyze exposure where occluded exposure, repeated contact, and dermal immersion may occur.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical.
				Vapor	Inhalation	Workers	Yes	Due to high volatility (VP = 146 torr at 20°C), inhalation pathway should be further analyzed.
				Vapor	Inhalation	ONU	Yes	

APPENDIX E SUPPORTING TABLE FOR CONSUMER ACTIVITIES AND USES, GENERAL POPULATIONS, ECOLOGICAL RECEPTORS, AND ENVIRONMENTAL RELEASES AND WASTES CONCEPTUAL MODEL

(Note that rows shaded in gray are not proposed for further analysis)

Table_Apx E-1. Consumer Scenario Table

Life Cycle Stage	Category	Subcategory	Release from source	Exposure Pathway	Route	Receptor	Further Analysis	Rationale for Further Analysis / No Further Analysis
Co-Location with dry cleaners	Cleaning and Furniture Care Products		Vapor	Vapor	Inhalation	Co-located populations	Yes	Based on the VP (146 mm Hg) of 1-BP and the conditions of use, inhalation exposures to 1-BP in the vapor phase is expected.
			Vapor	Vapor	Oral Dermal	Co-located populations	No	Ingestion of 1-BP is anticipated to be low since 1-BP is expected to be absorbed in the lung quickly and not have appreciable ability to travel up the mucosal elevator and be swallowed.
Consumer Use	Solvent (for cleaning or degreasing)	Aerosol spray degreaser/cleaner	Spray	Vapor/Mist	Inhalation	Consumers Bystanders	Yes	Based on the VP (146 mm Hg) of 1-BP and the conditions of use, inhalation exposures to 1-BP in the vapor phase from use of consumer products is expected.
			Spray	Direct dermal contact; incl occluded dermal contact	Dermal	Consumers	Yes	Based on conditions of use, consumers may have direct dermal contact to 1-BP. Occluded exposures may be higher.
			Spray	Direct dermal contact; incl occluded dermal contact	Dermal	Bystanders	No	Bystanders are not expected to have direct dermal contact to 1-BP
			Spray	Vapor/Mist	Oral	Consumers Bystanders	No	Ingestion of 1-BP is anticipated to be low since 1-BP is expected to be absorbed in the lung quickly and not have appreciable ability

Table_Apx E-1. Consumer Scenario Table

Life Cycle Stage	Category	Subcategory	Release from source	Exposure Pathway	Route	Receptor	Further Analysis	Rationale for Further Analysis / No Further Analysis
								to travel up the mucosal elevator and be swallowed.
Consumer Use	Cleaning and Furniture Care Products	Spot Cleaner, Stain Remover	Spray	Vapor/Mist	Inhalation	Consumers Bystanders	Yes	Based on the VP (146 mm Hg) of 1-BP and the conditions of use, inhalation exposures to 1-BP in the vapor phase from use of consumer products is expected.
			Spray	Direct dermal contact; incl occluded dermal contact	Dermal	Consumers	Yes	Based on conditions of use, consumers may have direct dermal contact to 1-BP. Occluded exposures may be higher.
			Spray	Direct dermal contact; incl occluded dermal contact	Dermal	Bystanders	No	Bystanders are not expected to have direct dermal contact to 1-BP
			Spray	Vapor/Mist	Oral	Consumers Bystanders	No	Ingestion of 1-BP is anticipated to be low since 1-BP is expected to be absorbed in the lung quickly and not have appreciable ability to travel up the mucosal elevator and be swallowed.
Consumer Use	Cleaning and Furniture Care Products	Liquid Cleaner (e.g. coin and scissor cleaner)	Volatilization	vapor	Inhalation	Consumers Bystanders	Yes	Based on the VP (146 mm Hg) of 1-BP and the conditions of use, inhalation exposures to 1-BP in the vapor phase from use of consumer products is expected.
			Liquid	Direct dermal contact; incl occluded dermal contact	Dermal	Consumers	Yes	Based on conditions of use, consumers may have direct dermal contact to 1-BP. Occluded exposures may be higher.
			Liquid	Direct dermal contact	Dermal	Bystanders	No	Bystanders are not expected to have direct dermal contact to 1-BP
			Liquid or vapor/mist	Ingestion	Oral	Consumers Bystanders	No	Ingestion of 1-BP is anticipated to be low since 1-BP is expected to be absorbed in the lung quickly and not have appreciable ability

Table_Apx E-1. Consumer Scenario Table

Life Cycle Stage	Category	Subcategory	Release from source	Exposure Pathway	Route	Receptor	Further Analysis	Rationale for Further Analysis / No Further Analysis
								to travel up the mucosal elevator and be swallowed.
Consumer Use	Cleaning and Furniture Care Products	Liquid Spray/aerosol Cleaner	Spray	Vapor/mist	Inhalation	Consumers Bystanders	Yes	Based on the VP (146 mm Hg) of 1-BP and the conditions of use, inhalation exposures to 1-BP in the vapor phase is expected.
			Spray	Dermal contact; incl occluded dermal contact	Dermal	Consumers	Yes	Based on conditions of use, consumers may have direct dermal contact to 1-BP. Occluded exposures may be higher.
			Spray	Direct Dermal Contact;	Dermal	Bystanders	No	Bystanders are not expected to have direct dermal contact to 1-BP
			Spray	Vapor/mist	Oral	Consumers Bystanders	No	Ingestion of 1-BP is anticipated to be low since 1-BP is expected to be absorbed in the lung quickly and not have appreciable ability to travel up the mucosal elevator and be swallowed.
Consumer Use	Other Uses	Arts, crafts and hobby materials – adhesive accelerant	Spray	Vapor/mist	Inhalation	Consumers Bystanders	Yes	Based on the VP (146 mm Hg) of 1-BP and the conditions of use, inhalation exposures to 1-BP in the vapor phase is expected.
			Spray	Dermal contact; incl occluded dermal contact	Dermal	Consumers	Yes	Based on conditions of use, consumers may have direct dermal contact to 1-BP. Occluded exposures may be higher.
			Spray	Direct Dermal Contact	Dermal	Bystanders	No	Bystanders are not expected to have direct dermal contact to 1-BP
			Spray	Vapor/mist	Oral	Consumers Bystanders	No	Ingestion of 1-BP is anticipated to be low since 1-BP is expected to be absorbed in the lung quickly and not have appreciable ability to travel up the mucosal elevator and be swallowed.

Table_Apx E-1. Consumer Scenario Table

Life Cycle Stage	Category	Subcategory	Release from source	Exposure Pathway	Route	Receptor	Further Analysis	Rationale for Further Analysis / No Further Analysis
Consumer Use	Other Uses	Anti-adhesive agents – mold cleaning and release product	Spray	Vapor/mist	Inhalation	Consumers Bystanders	Yes	Based on the VP (146 mm Hg) of 1-BP and the conditions of use, inhalation exposures to 1-BP in the vapor phase is expected.
			Spray	Dermal contact; incl occluded dermal contact	Dermal	Consumers	Yes	Based on conditions of use, consumers may have direct dermal contact to 1-BP. Occluded exposures may be higher.
			Spray	Direct Dermal Contact	Dermal	Bystanders	No	Bystanders are not expected to have direct dermal contact to 1-BP
			Spray	Vapor/mist	Oral	Consumers Bystanders	No	Ingestion of 1-BP is anticipated to be low since 1-BP is expected to be absorbed in the lung quickly and not have appreciable ability to travel up the mucosal elevator and be swallowed.
Consumer Use	Other Uses	Automotive Care Products, refrigerant flush	Spray	Vapor/mist	Inhalation	Consumers Bystanders	Yes	Emissions to air from spray applied consumer uses is expected.
			Spray	Dermal contact; incl occluded dermal contact	Dermal	Consumers	Yes	Dermal contact from emissions to air from spray applied consumer uses is expected.
			Spray	Direct Dermal Contact	Dermal	Bystanders	No	Direct dermal contact by bystanders from is not expected.
			Spray	Vapor/mist	Oral	Consumers Bystanders	No	Ingestion of 1-BP is anticipated to be low since 1-BP is expected to be absorbed in the lung quickly and not have appreciable ability to travel up the mucosal elevator and be swallowed.
Consumer Use	Other Uses	Building/Construction materials not covered elsewhere - insulation	Offgassing	Vapor	Inhalation	Consumers Bystanders	Yes	Based on the VP (146 mm Hg) of 1-BP and the conditions of use, inhalation exposures to 1-BP in the vapor phase is expected.

Table_Apx E-1. Consumer Scenario Table

Life Cycle Stage	Category	Subcategory	Release from source	Exposure Pathway	Route	Receptor	Further Analysis	Rationale for Further Analysis / No Further Analysis
			Offgassing	Vapor	Dermal Oral	Consumers Bystanders	No	Bystanders are not expected to have direct dermal contact to 1-BP. Ingestion of 1-BP is anticipated to be low.
All	All	All	n/a	Solid/Liquid Contact from Handling and Disposal of Waste	Inhalation, Dermal, Ingestion	Consumers	No	1-BP is expected to be disposed of in closed containers.

Table_Apx E-2. General Population, Ecological Receptors, and Environmental Releases and Wastes Scenario Table

Life Cycle Stage	Release	Exposure Pathway / Media	Exposure Routes	Receptor / Population	Further Analysis	Rationale for Further Analysis / No Further Analysis
All	Stack Emissions to Air	Near Facility Ambient Air Concentrations	Inhalation	General Population: Adults and Children living near facilities	Yes	Releases of 1-BP to air are expected based on TRI data. Based on the relatively long hydroxy radical oxidation half-life ($t_{½}$ = 14 days) emissions to ambient air could travel far enough from the release point to reach both near facility human receptors and the general population.
All	Fugitive Emissions to Air	Near Facility Ambient Air Concentrations	Inhalation	General Population: Adults and Children living near facilities	Yes	
All	Stack Emissions to Air	Indirect deposition to nearby bodies of water and soil catchments	Surface water and sediment (lakes)-Ingestion Soil (catchments)-Ingestion	General Population: Adults and Children living near facilities	No	Based on the Koc of 40, 1-BP is not expected to adsorb strongly to sediment or soil. 1-BP is volatile and has a relatively high Henry's law constant. It is somewhat biodegradable and is not expected to sorb to solids in water.
All	Stack Emissions to Air	Indirect deposition to nearby bodies of water and soil catchments	Surface water and sediment (lakes) Soil (catchments)	Aquatic and Terrestrial Receptors	No	

Table_Apx E-2. General Population, Ecological Receptors, and Environmental Releases and Wastes Scenario Table

Life Cycle Stage	Release	Exposure Pathway / Media	Exposure Routes	Receptor / Population	Further Analysis	Rationale for Further Analysis / No Further Analysis
All	Fugitive Emissions to Air	Indirect deposition to nearby bodies of water and soil catchments	Surface water and sediment (lakes)- Ingestion Soil (catchments)- Ingestion Uptake from environment into food sources- Ingestion	General Population: Adults and Children living near facilities	No	
All	Fugitive Emissions to Air	Indirect deposition to nearby bodies of water and soil catchments	Surface water and sediment (lakes) Soil (catchments)	Aquatic and Terrestrial Receptors	No	
All	Industrial pre-treatment and wastewater treatment-	Direct release into surface water and partitioning to sediment	Surface water and Sediment (rivers)	Aquatic and Terrestrial Receptors	No	Recent TRI reporting indicated 0 pounds released to POTWs and 5 pounds released directly to water in 2016. Based on 1-BP surface water concentrations estimated using TRI 2016 releases to water, EFAST modeling and the acute fish toxicity EC_{50} value 24.3 mg/L, the concentration of concern is not expected to be exceeded. Based on the Koc of 40, 1-BP is not expected to adsorb strongly to sediment. Ingestion of surface water is not expected to be a significant route of exposure.
All	Industrial pre-treatment and wastewater treatment-	Direct release into surface water and partitioning to sediment	Surface water and Sediment (rivers)- Ingestion	General Population: Adults and Children living near facilities	No	
All	Industrial pre-treatment and wastewater treatment-	Biosolids application to soil	Soil ingestion	General Population: Adults and Children living near facilities	No	Based on the Koc of 40, 1-BP is not expected to adsorb strongly to sediment or soil. If present in biosolids, 1-BP would be expected to associate with the aqueous component and volatilize to air as the biosolids are applied to soil and allowed to dry.
All	Industrial pre-treatment and	Biosolids application to soil	Soil	Terrestrial receptors	No	Based on the Koc of 40, 1-BP is not expected to adsorb strongly to sediment or soil.

Table_Apx E-2. General Population, Ecological Receptors, and Environmental Releases and Wastes Scenario Table

Life Cycle Stage	Release	Exposure Pathway / Media	Exposure Routes	Receptor / Population	Further Analysis	Rationale for Further Analysis / No Further Analysis
	wastewater treatment-					
All	Wastewater injected underground	Any	Any	Any	No	TRI reporting only indicated 10 pounds released to underground injection to a Class I well in 2016. The underground injection of certain classes of chemicals/wastes (i.e., hazardous) may be limited to practices that mitigate groundwater impacts.
All	Industrial pre-treatment and wastewater treatment-	Direct release into surface water and indirect partitioning to sediment	Surface water and Sediment (rivers)	Aquatic and Terrestrial Receptors	No	Recent TRI reporting indicated 0 pounds released to POTWs and 5 pounds released directly to water in 2016. Based on 1-BP surface water concentrations estimated using TRI 2016 releases to water, EFAST modeling and the acute fish toxicity EC_{50} value 24.3 mg/L, the concentration of concern is not expected to be exceeded. Based on the Koc of 40, 1-BP is not expected to adsorb strongly to sediment. Ingestion of surface water is not expected to be a significant route of exposure.
All	Industrial pre-treatment and wastewater treatment-	Direct release into surface water and partitioning to sediment	Surface water and Sediment (rivers)- Ingestion	General Population: Adults and Children living near facilities	No	
All	Industrial pre-treatment and wastewater treatment-	Biosolids application to soil	Soil	Terrestrial receptors	No	Based on the Koc of 40, 1-BP is not expected to adsorb strongly to sediment or soil. HBCD has not been detected in soil samples.
Disposal	Hazardous Waste Landfill	All	All	All	No	Due to design and operating practices for Subtitle C landfills, general population exposure to 1-BP in groundwater from Subtitle C hazardous waste landfill leachate is not expected to be a significant pathway and will not be further analyzed.
Disposal	Solid and Liquid Wastes sent to On or Off-site Incineration/ Energy Recovery	Near Facility Ambient Air Concentrations	Inhalation	General Population: Adults and Children living near facilities	Yes	Air emissions resulting from these operations are included in the TRI reports. Municipal incinerators may release 1-BP due to incomplete removal during burning.

Table_Apx E-2. General Population, Ecological Receptors, and Environmental Releases and Wastes Scenario Table

Life Cycle Stage	Release	Exposure Pathway / Media	Exposure Routes	Receptor / Population	Further Analysis	Rationale for Further Analysis / No Further Analysis
Disposal	Solid and Liquid Wastes sent to On-Site or Off-site Incineration/ Energy Recovery	Near Facility Ambient Air Concentrations	Inhalation	Terrestrial Receptors	No	Low Hazard: No available sediment, soil, nor avian toxicity studies found in the scientific literature for 1-BP. The toxicity of 1-BP is expected to be low based on the lack of on-topic environmental hazard data for 1-BP to sediment and terrestrial organisms in the published literature and the physical/chemical/fate properties (relatively high volatility (Henry's Law constant of $7.3X10^{-3}$ atm-m^3/mole), high water solubility (2.4 g/L), and low log K_{oc} (1.6) suggesting that 1-BP will only be present at low concentrations in these environmental compartments.
Disposal	Municipal landfill and other land disposal	Soil	Soil	Terrestrial Receptors	No	Low Hazard: No available sediment, soil, nor avian toxicity studies found in the scientific literature for 1-BP. The toxicity of 1-BP is expected to be low based on the lack of on-topic environmental hazard data for 1-BP to sediment and terrestrial organisms in the published literature and the physical/chemical/fate properties (relatively high volatility (Henry's Law constant of $7.3X10^{-3}$ atm-m^3/mole), high water solubility (2.4 g/L), and low log K_{oc} (1.6) suggesting that 1-BP will only be present at low concentrations in these environmental compartments.
Disposal	Municipal landfill and other land disposal	Soil to air	Inhalation	General Population: Adults and Children living near facilities	No	Releases from municipal landfill to soil are not expected. States ensure the federal criteria for operating RCRA Subtitle D municipal solid waste and industrial waste landfills regulations are met.
Recycling	Recycling of 1-BP	All	All	All	No	Recycling of 1-BP is not expected.

Table_Apx E-2. General Population, Ecological Receptors, and Environmental Releases and Wastes Scenario Table

Life Cycle Stage	Release	Exposure Pathway / Media	Exposure Routes	Receptor / Population	Further Analysis	Rationale for Further Analysis / No Further Analysis
All	Background	Surface water	Ingestion	General Population: Adults and Children Aquatic and Terrestrial Receptors	No	TRI reporting indicates little to no releases to water.
All	Background	Sediment	Ingestion	Aquatic Receptors	No	TRI reporting indicates little to no releases to water. Based on the Koc of 40, 1-BP is not expected to adsorb strongly to sediment.
All	Background	Soil	Ingestion	General Population: Adults and Children Terrestrial Receptors	No	Based on the Koc of 40, 1-BP is not expected to adsorb strongly to sediment or soil. HBCD has not been detected in soil samples.
All	Background	Aquatic Biota	n/a	Aquatic Receptors	No	
All	Background	Terrestrial Biota	n/a	Terrestrial receptors	No	
All	Background	Ambient Air	Inhalation	General Population	Yes	Based on the VP (146 mm Hg) of 1-BP and the conditions of use, inhalation exposures to 1-BP in the vapor phase is expected.
All	Background	Indoor Air	Inhalation	General Population	Yes	Based on the VP (146 mm Hg) of 1-BP and the conditions of use, inhalation exposures to 1-BP in the vapor phase is expected.
All	Background	Indoor Dust	Ingestion, Dermal	General Population	No	There are no data indicating 1-BP is present in dust.
All	Background	Dietary Food Sources	Ingestion	General Population	No	There are no data indicating 1-BP is present in food.
All	Background	Human Biomonitoring - breast milk	n/a	General Population	No	

APPENDIX F INCLUSION AND EXCLUSION CRITERIA FOR FULL TEXT SCREENING

Appendix F contains the eligibility criteria for various data streams informing the TSCA risk evaluation: environmental fate; engineering and occupational exposure; exposure to consumers; and human health hazard. The criteria are applied to the *on-topic* references that were identified following title and abstract screening of the comprehensive search results published on June 22, 2017.

Systematic reviews typically describe the study eligibility criteria in the form of PECO statements or a modified framework. PECO stands for Population, Exposure, Comparator and Outcome and the approach is used to formulate explicit and detailed criteria about those characteristics in the publication that should be present in order to be eligible for inclusion in the review. EPA/OPPT adopted the PECO approach to guide the inclusion/exclusion decisions during full text screening.

Inclusion and exclusion criteria were also used during the title and abstract screening, and documentation about the criteria can be found in the *Strategy for Conducting Literature Searches* document published in June 2017 along with each of the TSCA Scope documents. The list of *on-topic* references resulting from the title and abstract screening is undergoing full text screening using the criteria in the PECO statements. The overall objective of the screening process is to select the most relevant evidence for the TSCA risk evaluation. As a general rule, EPA is excluding non-English data/information sources and will translate on a case by case basis.

The inclusion and exclusion criteria for ecotoxicological data have been documented in the ECOTOX SOPs. The criteria can be found at https://cfpub.epa.gov/ecotox/help.cfm?helptabs=tab4) and in the *Strategy for Conducting Literature Searches* document published along with each of the TSCA Scope documents.

F.1 Inclusion Criteria for Data Sources Reporting Environmental Fate Data

EPA/OPPT developed a generic PESO statement to guide the full text screening of environmental fate data sources. PESO stands for Pathways and Processes, Exposure, Setting or Scenario, and Outcomes. Subsequent versions of the PESO statement may be produced throughout the process of screening and evaluating data for the chemicals undergoing TSCA risk evaluation. Studies that comply with the inclusion criteria in the PESO statement are eligible for inclusion, considered for evaluation, and possibly included in the environmental fate assessment. On the other hand, data sources are excluded if they do not meet the criteria in the PESO statement.

Assessors seek information on various chemical-specific fate endpoints and associated fate processes, environmental media and exposure pathways as part of the process of developing the environmental fate assessment (Table_Apx F-2). The PESO statement and information in Table_Apx F-1 will be used when screening the fate data sources to ensure complete coverage of the processes, pathways and data relevant to the fate of the chemical substance of interest.

Table_Apx F-1. Inclusion Criteria for Data Sources Reporting Environmental Fate Data	
PESO Element	**Evidence**
Pathways and **P**rocesses	• Environmental fate, transport, partitioning and degradation behavior across environmental media to inform exposure pathways of the chemical substance of interest • Media of interest may include: – Air Please refer to the conceptual models for more information about the exposure pathways included in the TSCA risk evaluation.
Exposure	• Environmental exposure of ecological receptors (i.e., aquatic and terrestrial organisms) to the chemical substance of interest and/or its degradation products and metabolites • Environmental exposure of human receptors, including any potentially exposed or susceptible subpopulations, to the substance of interest and/or its degradation products and metabolites Please refer to the conceptual models for more information about the ecological and human receptors included in the TSCA risk evaluation.
Setting or **S**cenario	Any setting or scenario resulting in releases of the chemical substance of interest into the natural or built environment (e.g., buildings including homes or workplaces, or wastewater treatment facilities) that would expose ecological (i.e., aquatic and terrestrial organisms) or human receptors (i.e., general population, and potentially exposed or susceptible subpopulation)
Outcomes	• Fate properties which allow assessments of exposure pathways: o Abiotic and biotic degradation rates, mechanisms, pathways, and products o Bioaccumulation magnitude and metabolism rates o Partitioning within and between environmental media (see Pathways and Processes)

Table_Apx F-2. Fate Endpoints and Associated Processes, Media and Exposure Pathways Considered in the Development of the Environmental Fate Assessment

Fate Data Endpoint	Associated Process(es)	Associated Media/Exposure Pathways				
		Surface water, Sediment	Soil, Biosolids	Ground-water	Air	[Indoor environment, anthropogenic materials, other media]
Required Environmental Fate Data						
Abiotic reduction rates or half-lives	Abiotic reduction, Abiotic dehalogenation	X				
Aerobic biodegradation rates or half-lives	Aerobic biodegradation	X	X			
Anaerobic biodegradation rates or half-lives	Anaerobic biodegradation	X	X	X		
Aqueous photolysis (direct and indirect) rates or half-lives	Aqueous photolysis (direct and indirect)	X				
Atmospheric photolysis (direct and indirect) rates or half-lives	Atmospheric photolysis (direct and indirect)				X	
Bioconcentration factor (BCF), Bioaccumulation factor (BAF)	Bioconcentration, Bioaccumulation	X				
Hydrolysis rates or half-lives	Hydrolysis	X				
K_{AW}, Henry's Law constant, and other volatilization information	Volatilization	X	X		X	
K_{OC} and other sorption information	Sorption, Mobility	X	X	X		
[Other required data)						
Optional Environmental Fate Data						
Abiotic transformation products	Hydrolysis, Photolysis	X			X	
Aerobic biotransformation products	Aerobic biodegradation	X	X			

Table_Apx F-2. Fate Endpoints and Associated Processes, Media and Exposure Pathways Considered in the Development of the Environmental Fate Assessment						
Anaerobic biotransformation products	Anaerobic biodegradation	X	X	X		
Atmospheric deposition information	Atmospheric deposition				X	
Biomagnification and related information	Trophic magnification	X				
Coagulation information	Coagulation, Mobility	X				
Desorption information	Sorption, Mobility	X	X	X		
Incineration removal information	Incineration				X	
Suspension/resuspension information	Suspension/resuspension, Mobility	X				
Wastewater treatment removal information	Wastewater treatment	X				
[Other optional data]						

F.2 Inclusion Criteria for Data Sources Reporting Exposure Data on Consumers, General Population, and Ecological Receptors

EPA/OPPT developed PECO statements to guide the full text screening of exposure data/information for human (i.e., consumers, potentially exposed or susceptible subpopulations). Subsequent versions of the PECO statements may be produced throughout the process of screening and evaluating data for the chemicals undergoing TSCA risk evaluation. Studies that comply with the inclusion criteria in the PECO statement are eligible for inclusion, considered for evaluation, and possibly included in the exposure assessment. On the other hand, data sources are excluded if they do not meet the criteria in the PECO statement. The 1-BP-specific PECO is provided in **Table_Apx F-3**.

Table_Apx F-3. Inclusion Criteria for the Data Sources Reporting 1-BP Exposure Data on Consumers and General Population	
PECO Element	**Evidence**
Population	**Human:** General population, consumers (i.e., receptors who use a product directly) and bystanders (i.e., receptors who are non-product users that are incidentally exposed to the product or article) in residential settings, near-facility populations (includes industrial and commercial facilities manufacturing, processing or using 1-BP); populations in co-located residences or businesses; including potentially exposed or susceptible subpopulations such as infants, children, pregnant women, lactating women, women of child bearing age, and high-end consumers.
	Ecological: None.
Exposure	**Expected Primary Exposure Sources, Pathways, Routes:** *See Figure 2-3 and Figure 2-4*

Table_Apx F-3. Inclusion Criteria for the Data Sources Reporting 1-BP Exposure Data on Consumers and General Population	
PECO Element	**Evidence**
	Source: Manufacturing, processing, commercial and consumer use of products containing 1-BP as an ingredient, and associated emissions to air or dermal contact. Pathway: indoor air (including transfer from outdoor air), outdoor air, dermal contact with 1-BP in consumer products Routes of Exposure: Inhalation of outdoor air or indoor air (consumer and bystander populations) and dermal exposure via contact with consumer products containing 1-BP.
Comparator (Scenario)	**Human:** Consider media-specific background exposure scenarios and use/source specific exposure scenarios as well as which receptors are and are not reasonably exposed across the projected exposure scenarios.
	Ecological: None.
Outcomes for Exposure Concentration or Dose	**Human:** Acute, subchronic, and/or chronic external dose estimates (mg/kg/day); acute, subchronic, and/or chronic air concentration estimates (µg/m^3, mg/m^3). Both external potential dose and internal dose based on biomonitoring and reverse dosimetry mg/kg/day will be considered.
	Ecological: None.

F.3 Inclusion Criteria for Data Sources Reporting Engineering and Occupational Exposure Data

EPA/OPPT developed a generic RESO statement to guide the full text screening of engineering and occupational exposure literature (Table_Apx F-4). RESO stands for Receptors, Exposure, Setting or Scenario, and Outcomes. Subsequent versions of the RESO statement may be produced throughout the process of screening and evaluating data for the chemicals undergoing TSCA risk evaluation. Studies that comply with the inclusion criteria specified in the RESO statement will be eligible for inclusion, considered for evaluation, and possibly included in the environmental release and occupational exposure assessments, while those that do not meet these criteria will be excluded.

The RESO statement should be used along with the engineering and occupational exposure data needs table (Table_Apx F-5) when screening the literature.

Table_Apx F-4. Inclusion Criteria for Data Sources Reporting Engineering and Occupational Exposure Data	
RESO Element	**Evidence**
Receptors	• **Humans:** Workers, including occupational non-users Please refer to the conceptual models for more information about the human receptors included in the TSCA risk evaluation.

Table_Apx F-4. Inclusion Criteria for Data Sources Reporting Engineering and Occupational Exposure Data	
Exposure	• Worker exposure to and relevant environmental releases of the chemical substance of interest o Any exposure route (list included: dermal, inhalation, oral) as indicated in the conceptual model o Any relevant media/pathway [list included: water, land, air, incineration, and other(s)] as indicated in the conceptual model Please refer to the conceptual models for more information about the routes and media/pathways included in the TSCA risk evaluation.
Setting or **S**cenario	• Any occupational setting or scenario resulting in worker exposure and relevant environmental releases (includes all manufacturing, processing, use, disposal indicated in Table_Apx F-5 below except (state none excluded or list excluded uses)
Outcomes	• Quantitative estimates* of worker exposures and of relevant environmental releases from occupational settings • General information and data related and relevant to the occupational estimates*

* Metrics (e.g., mg/kg/day or mg/m^3 for worker exposures, kg/site/day for releases) are determined by toxicologists for worker exposures and by exposure assessors for releases; also, the Engineering Data Needs (Table_Apx F-5) provides a list of related and relevant general information.

Table_Apx F-5. Engineering, Environmental Release and Occupational Data Necessary to Develop the Environmental Release and Occupational Exposure Assessments	
Objective Determined during Scoping	**Type of Data**
General Engineering Assessment (may apply for either or both Occupational Exposures and / or Environmental Releases)	1. Description of the life cycle of the chemical(s) of interest, from manufacture to end-of-life (e.g., each manufacturing, processing, or use step), and material flow between the industrial and commercial life cycle stages. {Tags: Life cycle description, Life cycle diagram}[a] 2. The total annual U.S. volume (lb/yr or kg/yr) of the chemical(s) of interest manufactured, imported, processed, and used; and the share of total annual manufacturing and import volume that is processed or used in each life cycle step. {Tags: Production volume, Import volume, Use volume, Percent PV} [a] 3. Description of processes, equipment, unit operations, and material flows and frequencies (lb/site-day or kg/site-day and days/yr; lb/site-batch and batches/yr) of the chemical(s) of interest during each industrial/ commercial life cycle step. Note: if available, include weight fractions of the chemicals (s) of interest and material flows of all associated primary chemicals (especially water). {Tags: Process description, Process material flow rate, Annual operating days, Annual batches, Weight fractions (for each of above, manufacture, import, processing, use)} [a] 4. Basic chemical properties relevant for assessing exposures and releases, e.g., molecular weight, normal boiling point, melting point, physical forms, and room temperature vapor pressure. {Tags: Molecular weight, Boiling point, Melting point, Physical form, Vapor pressure, Water solubility} [a] 5. Number of sites that manufacture, process, or use the chemical(s) of interest for each industrial/ commercial life cycle step and site locations. {Tags: Numbers of sites (manufacture, import, processing, use), Site locations} [a]
Occupational Exposures	6. Description of worker activities with exposure potential during the manufacture, processing, or use of the chemical(s) of interest in each industrial/commercial life cycle stage. {Tags: Worker activities (manufacture, import, processing, use)} [a]

Table_Apx F-5. Engineering, Environmental Release and Occupational Data Necessary to Develop the Environmental Release and Occupational Exposure Assessments

Objective Determined during Scoping	Type of Data
	7. Potential routes of exposure (e.g., inhalation, dermal). {Tags: Routes of exposure (manufacture, import, processing, use)} [a] 8. Physical form of the chemical(s) of interest for each exposure route (e.g., liquid, vapor, mist) and activity. {Tags: Physical form during worker activities (manufacture, import, processing, use)} [a] 9. Breathing zone (personal sample) measurements of occupational exposures to the chemical(s) of interest, measured as time-weighted averages (TWAs), short-term exposures, or peak exposures in each occupational life cycle stage (or in a workplace scenario similar to an occupational life cycle stage). {Tags: PBZ measurements (manufacture, import, processing, use)} [a] 10. Area or stationary measurements of airborne concentrations of the chemical(s) of interest in each occupational setting and life cycle stage (or in a workplace scenario similar to the life cycle stage of interest). {Tags: Area measurements (manufacture, import, processing, use)} [a] 11. For solids, bulk and dust particle size characterization data. {Tags: PSD measurements (manufacture, import, processing, use)} [a] 12. Dermal exposure data. {Tags: Dermal measurements (manufacture, import, processing, use)} 13. Data needs associated with mathematical modeling (will be determined on a case-by-case basis). {Tags: Worker exposure modeling data needs (manufacture, import, processing, use)} [a] 14. Exposure duration (hr/day). {Tags: Worker exposure durations (manufacture, import, processing, use)} [a] 15. Exposure frequency (days/yr). {Tags: Worker exposure frequencies (manufacture, import, processing, use)} [a] 16. Number of workers who potentially handle or have exposure to the chemical(s) of interest in each occupational life cycle stage. {Tags: Numbers of workers exposed (manufacture, import, processing, use)} [a] 17. Personal protective equipment (PPE) types employed by the industries within scope. {Tags: Worker PPE (manufacture, import, processing, use)} [a] 18. Engineering controls employed to reduce occupational exposures in each occupational life cycle stage (or in a workplace scenario similar to the life cycle stage of interest), and associated data or estimates of exposure reductions. {Tags: Engineering controls (manufacture, import, processing, use), Engineering control effectiveness data} [a]
Environmental Releases (to relevant environmental media)	19. Description of relevant sources of potential environmental releases, including cleaning of residues from process equipment and transport containers, involved during the manufacture, processing, or use of the chemical(s) of interest in each life cycle stage. {Tags: Release sources (manufacture, import, processing, use)} [a] 20. Estimated mass (lb or kg) of the chemical(s) of interest released from industrial and commercial sites to each environmental medium (water) and treatment and disposal methods (POTW), including releases per site and aggregated over all sites (annual release rates, daily release rates) {Tags: Release rates (manufacture, import, processing, use)} [a] 21. Release or emission factors. {Tags: Emission factors (manufacture, import, processing, use)} [a] 22. Number of release days per year. {Tags: Release frequencies (manufacture, import, processing, use)} [a] 23. Data needs associated with mathematical modeling (will be determined on a case-by-case basis). {Tags: Release modeling data needs (manufacture, import, processing, use)} [a] 24. Waste treatment methods and pollution control devices employed by the industries within scope and associated data on release/emission reductions. {Tags: Treatment/ emission controls (manufacture, import, processing, use), Treatment/ emission controls removal/ effectiveness data} [a]

Notes:

[a]These are the tags included in the full text screening form. The screener makes a selection from these specific tags, which describe more specific types of data or information.

F.4 Inclusion Criteria for Data Sources Reporting Human Health Hazards

EPA/OPPT developed a 1-BP-specific PECO statement (Table_Apx F-6) to guide the full text screening of the human health hazard literature. Subsequent versions of the PECOs may be produced throughout the process of screening and evaluating data for the chemicals undergoing TSCA risk evaluation. Studies that comply with the criteria specified in the PECO statement will be eligible for inclusion, considered for evaluation, and possibly included in the human health hazard assessment, while those that do not meet these criteria will be excluded according to the exclusion criteria.

In general, the PECO statements were based on (1) information accompanying the TSCA Scope document, and (2) preliminary review of the health effects literature from sources cited in the TSCA Scope documents. When applicable, these sources (e.g., IRIS assessments, EPA/OPPT's Work Plan Problem Formulations or risk assessments) will serve as starting points to identify PECO-relevant studies.

Table_Apx F-6. Inclusion and Exclusion Criteria for the Data Sources Reporting Human Health Hazards Related to 1-BP Exposure[a]

PECO Element	Evidence Stream	Papers/Features Included	Papers/Features Excluded
Population [b]	*Human*	• Any population • All lifestages • Study designs: o Controlled exposure, cohort, case-control, cross-sectional, case-crossover o Case studies and case series that are related to deaths from acute exposure	• Case studies and case series for all endpoints ***other than*** death from acute exposure
	Animal	• All non-human whole-organism mammalian species • All lifestages	• Non-mammalian species
Exposure	*Human*	• Exposure based on administered dose or concentration of 1-BP, biomonitoring data (e.g., urine, blood or other specimens), environmental or occupational-setting monitoring data (e.g., air, water levels), job title or residence • Primary metabolites of interest as identified in biomonitoring studies • Exposure identified as ***or presumed to be*** from oral, dermal, inhalation routes • Any number of exposure groups • Quantitative, semi-quantitative or qualitative estimates of exposure • Exposures to multiple chemicals/mixtures only if 1-BP or related metabolites were independently measured and analyzed	• Route of exposure ***not*** by inhalation, oral or dermal type (e.g., intraperitoneal, injection) • Multiple chemical/mixture exposures with no independent measurement of or exposure to 1-BP (or related metabolite)
	Animal	• A minimum of 2 quantitative dose or concentration levels of 1-BP plus a negative control group[a] • Acute, subchronic, chronic exposure from oral, dermal, inhalation routes • Exposure to 1-BP only (no chemical mixtures) • Quantitative and/or qualitative relative/rank-order estimates of exposure	• Only 1 quantitative dose or concentration level in addition to the control • Route of exposure ***not*** by inhalation, oral or dermal type (e.g., intraperitoneal, injection) • No duration of exposure stated • Exposure to 1-BP in a chemical mixture
Comparator	*Human*	• A comparison population [not exposed, exposed to lower levels, exposed below detection] for endpoints ***other than***	• No comparison population for endpoints other than death from acute

Table_Apx F-6. Inclusion and Exclusion Criteria for the Data Sources Reporting Human Health Hazards Related to 1-BP Exposure[a]			
		death from acute exposure	exposure
	Animal	• Negative controls that are vehicle-only treatment and/or no treatment	• Negative controls ***other than*** vehicle-only treatment or no treatment
Outcome	*Human*	• Endpoints described in the 1-BP scope document [c]: o Kidney toxicity o Liver toxicity o Neurotoxicity o Reproductive toxicity o Developmental toxicity o Cancer • Other endpoints [d]	
	Animal		
General Considerations		**Papers/Features Included**	**Papers/Features Excluded**
		• Written in English [e] • Reports primary source or meta-analysis. [a] • Full-text available • Reports both 1-BP exposure ***and*** a health outcome	• Not written in English • Reports a secondary source (e.g., review papers) [a] • No full-text available (e.g., only a study description/abstract, out-of-print text) • Reports a 1-BP-related exposure ***or*** a health outcome, but not both (e.g. incidence, prevalence report)

[a]Some of the studies that are excluded based on the PECO statement may be considered later during the systematic review process. For 1-BP, EPA will evaluate studies related to susceptibility and may evaluate, toxicokinetics and physiologically based pharmacokinetic models after other data (e.g., human and animal data identifying adverse health outcomes) are reviewed. EPA may need to evaluate mechanistic data depending on the review of health effects data. Finally, EPA may also review other data as needed (e.g., animal studies using one concentration, review papers).

[b] Mechanistic data are excluded during the full text screening phase of the systematic review process but may be considered later (see footnote *a*).

[c] EPA will review key and supporting studies that were considered in the 2016 Draft Risk Assessment (U.S. EPA, 2016b) for 1-BP for non-cancer and cancer endpoints as well as studies published after the draft. assessment.

[d] EPA may screen for hazards other than those listed in the scope document if they were identified in the updated literature search that accompanied the scope document.

[e] EPA may translate studies as needed.