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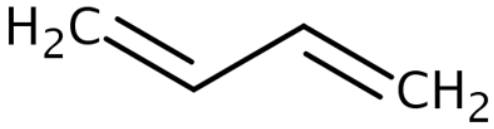
Office of Chemical Safety and
Pollution Prevention

United States
Environmental Protection Agency

Draft Scope of the Risk Evaluation for 1,3-Butadiene

CASRN 106-99-0



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ACKNOWLEDGEMENTS

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Docket

Supporting information can be found in public docket: [Docket ID: EPA-HQ-OPPT-2018-0451].

Disclaimer

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

ABBREVIATIONS AND ACRONYMS

ABS	Acrylonitrile Butadiene Styrene resin plastics
ACC	American Chemistry Council
ADME	Absorption, Distribution, Metabolism, and Excretion
ATSDR	Agency for Toxic Substances and Disease Registry
BAF	Bioaccumulation Factor
BCF	Bioconcentration Factor
BMF	Biomagnification factor
CAA	Clean Air Act
CASRN	Chemical Abstracts Service Registry Number
CBI	Confidential Business Information
CCL	Contaminant Candidate List
CDR	Chemical Data Reporting
CEHD	Chemical Exposure Health Data
CEPA	Canadian Environmental Protection Act
CERCLA	Comprehensive Environmental Response, Compensation and Liability Act
CFR	Code of Federal Regulations
COC	Concentration of Concern
CSCL	Chemical Substances Control Law
CWA	Clean Water Act
EC	Engineering Controls
ECB	European Chemicals Bureau
ECHA	European Chemicals Agency
EPA	Environmental Protection Agency
EPCRA	Emergency Planning and Community Right-to-Know Act
GACT	Generally Available Control Technology
ERG	Eastern Research Group
ESD	Emission Scenario Document
EU	European Union
FDA	Food and Drug Administration
FR	Federal Register
FYI	For Your Information
GDIT	General Dynamics Information Technology
GS	Generic Scenario
HAP	Hazardous Air Pollutant
HHE	Health Hazard Evaluation
HSDB	Hazardous Substances Data Bank
IARC	International Agency for Research on Cancer
ICES	International Council for the Exploration of the Sea
ICF	ICF is a global consulting services company
IECCU	Indoor Environmental Concentrations in Buildings with Conditioned and Unconditioned Zones
IMAP	Inventory Multi-Tiered Assessment and Prioritisation (Australia)
IRIS	Integrated Risk Information System
ISHA	Industrial Safety and Health Act
K_{OC}	Organic Carbon: Water Partition Coefficient

K_{OW}	Octanol: Water Partition Coefficient
LOEC	Lowest Observed Effect Concentration
MACT	Maximum Achievable Control Technology
MOA	Mode of Action
MSW	Municipal Solid Waste
NAICS	North American Industry Classification System
NICNAS	National Industrial Chemicals Notification and Assessment Scheme (Australia)
NIOSH	National Institute for Occupational Safety and Health
NOEC	No Observed Effect Concentration
NPDES	National Pollutant Discharge Elimination System
NPL	National Priorities List
NPRI	National Pollutant Release Inventory
NTP	National Toxicology Program
OCSPP	Office of Chemical Safety and Pollution Prevention
OECD	Organisation for Economic Co-operation and Development
OEHHA	Office of Environmental Health Hazard Assessment (California)
ONU	Occupational Non-User
OPPT	Office of Pollution Prevention and Toxics
OSHA	Occupational Safety and Health Administration
p-chem	Physical and Chemical
PBPK	Physiologically Based Pharmacokinetic
PEL	Permissible Exposure Limit
PESS	Potentially Exposed or Susceptible Subpopulations
POTW	Publicly Owned Treatment Works
PPE	Personal Protective Equipment
RAD	Risk Assessment Division
RCRA	Resource Conservation and Recovery Act
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals (European Union)
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
SDWA	Safe Drinking Water Act
SRC	SRC Inc., formerly Syracuse Research Corporation
STEL	Short-term Exposure Limit
TBD	To be determined
TIAB	Title and Abstract
TSCA	Toxic Substances Control Act
TLV	Threshold Limit Value
TMF	Trophic Magnification Factors
TRI	Toxics Release Inventory
TWA	Time-weighted average
UMCR	Unregulated Contaminants Monitoring Rule
USGS	United States Geological Survey
VOC	Volatile Organic Compound
VP	Vapor Pressure
WWT	Wastewater Treatment

EXECUTIVE SUMMARY

In December 2019, EPA designated 1,3-butadiene (CASRN 106-99-0) as a high-priority substance for risk evaluation following the prioritization process required by section 6(b) of the Toxic Substances Control Act (TSCA) and implementing regulations (40 CFR Part 702) (Docket ID: EPA-HQ-OPPT-2018-0451). The first step of the risk evaluation process is the development of the scope document and this document fulfills the TSCA regulatory requirement to issue a draft scope document as described in 40 CFR 702.41(c)(7). The draft scope for 1,3-butadiene includes the following information: the conditions of use, potentially exposed or susceptible subpopulations (PESS), hazards, and exposures that EPA plans to consider in this risk evaluation, along with a description of the reasonably available information, conceptual model, analysis plan and science approaches, and plan for peer review for this chemical substance. EPA is providing a 45-day comment period on the draft scope. Comments received on this draft scope document will help inform development of the final scope document and the risk evaluation.

General Information. 1,3-Butadiene is a colorless gas with a total production volume in the United States between 1 and 5 billion pounds.

Reasonably Available Information. EPA leveraged the data and information sources already described in the document supporting the High-Priority Substance designation for 1,3-butadiene to inform the development of this draft scope document. To further develop this draft scope document, EPA conducted a comprehensive search to identify and screen multiple evidence streams (i.e., chemistry, fate, release and engineering, exposure, hazard) and the search and screening results are provided in Section 2.1. EPA is seeking public comment on this draft scope document and will consider additional information identified following publication of this draft scope document, as appropriate, in developing the final scope document. EPA is using the systematic review process described in the *Application of Systematic Review in TSCA Risk Evaluations* document (U.S. EPA, 2018a) to guide the process of searching for and screening reasonably available information, including information already in EPA's possession, for use and inclusion in the risk evaluation. EPA applied these systematic review methods to collect reasonably available information regarding hazards, exposures, PESS, and conditions of use that will help inform the risk evaluation for 1,3-butadiene.

Conditions of Use. EPA plans to evaluate manufacturing, including importing; processing; distribution in commerce; industrial, commercial and consumer uses; and disposal of 1,3-butadiene in the risk evaluation. 1,3-Butadiene is manufactured within the U.S. as well as imported into the U.S. The chemical is processed as a reactant, incorporated into a formulation, mixture, or reaction product, and incorporated into articles. The identified processing activities also include the repackaging and recycling of 1,3-butadiene. Several industrial and commercial uses were identified that ranged from use in plastic and rubber products to use in lubricants. Only two consumer uses were reported in plastic and rubber products and automotive care products. EPA identified these conditions of use from information reported to EPA through Chemical Data Reporting (CDR) and Toxics Release Inventory (TRI) reporting, published literature, and consultation with stakeholders both for uses currently in production and used. Section 2.2 provides details regarding the conditions of use within the scope of the risk evaluation. In addition, EPA plans to analyze distribution in commerce and disposal as part of the risk evaluation.

Conceptual Model. The conceptual models for 1,3-butadiene are presented in Section 2.6. Conceptual models are graphical depictions of the actual or predicted relationships of conditions of use, exposure pathways (e.g., media), exposure routes (e.g., inhalation, dermal, oral), hazards, and receptors throughout the life cycle of the chemical substance - from manufacturing, processing, distribution in commerce, storage, or use, to release or disposal. EPA plans to focus the risk evaluation for 1,3-butadiene on the following exposures, hazards, and receptors, however, EPA also plans to consider comments received on this draft scope and other reasonably available information when finalizing this scope document, and to adjust the exposure pathways, exposure routes and hazards included in the scope document as needed.

- *Exposures (Pathways and Routes), Receptors and PESS.* EPA plans to analyze both human and environmental exposures resulting from the conditions of use of 1,3-butadiene that EPA plans to consider in risk evaluation. Exposures to 1,3-butadiene are discussed in Section 2.3. EPA identified environmental monitoring data reporting the presence of 1,3-butadiene in air, drinking water, and groundwater. 1,3-Butadiene is subject to reporting to EPA's Toxics Release Inventory (TRI), which is reasonably available information that EPA anticipates using to inform 1,3-butadiene's environmental release assessment. For the 2018 reporting year, 188 facilities reported to EPA releases of 1,3-butadiene to air, water, and via land disposal. Additional information gathered through systematic review searches will also inform expected exposures.

  EPA's plan as to evaluating environmental exposure pathways in the draft scope document considers whether and how other EPA-administered statutes and regulatory programs address the presence of 1,3-butadiene in media pathways falling under the jurisdiction of those authorities. Section 2.6.3 discusses those pathways that may be addressed pursuant to other Federal laws. In Section 2.6.4, EPA presents the conceptual model describing the identified exposure (pathways and routes), receptors and hazards associated with the conditions of use of 1,3-butadiene within the scope of the risk evaluation:

  Preliminarily, EPA plans to evaluate the following human and environmental exposure pathways, routes, receptors and PESS in the scope of the risk evaluation. However, EPA plans to consider comments received on this draft scope and other reasonably available information when finalizing this scope document, and to adjust the exposure pathways, exposure routes and hazards included in the scope document as needed.
  - *Occupational exposures associated with industrial and commercial conditions of use:* EPA plans to evaluate exposures to workers and/or occupational non-users via the inhalation route and exposures to workers via the dermal route associated with the manufacturing, processing, use or disposal of 1,3-butadiene (Section 2.2.1).
  - *Consumer and bystander exposures associated with consumer conditions of use:* EPA plans to evaluate inhalation exposures to 1,3-butadiene vapor for consumers and bystanders during use and disposal of automotive care products, and plastics and rubber products. EPA plans to evaluate dermal exposure to 1,3-butadiene for consumers but not for bystanders. EPA does not plan to evaluate oral exposures to 1,3-butadiene.
  - *General population exposures:* EPA plans to evaluate exposure to 1,3-butadiene via groundwater and fish ingestion for the general population.
  - *Environmental exposures:* EPA plans to evaluate exposure to 1,3-butadiene for aquatic and terrestrial receptors.

- *Receptors and PESS:* EPA plans to evaluate children, women of reproductive age, pregnant women, workers, and consumers as receptors and PESS in the risk evaluation.

- *Hazards.* Hazards for 1,3-butadiene are discussed in Section 2.4. EPA completed preliminary reviews of information from peer-reviewed assessments and databases to identify potential environmental and human health hazards for 1,3-butadiene as part of the prioritization process. Although EPA did not identify environmental hazard information during the prioritization process, EPA is in the process of identifying additional reasonably available information through systematic review methods and public comments that may inform potential environmental hazards associated with 1,3-butadiene exposure.

  EPA plans to use systematic review methods to evaluate the epidemiological and toxicological literature for 1,3-butadiene. Relevant mechanistic evidence will also be considered, if reasonably available, to inform the interpretation of findings related to potential human health effects and the dose-response assessment. EPA plans to evaluate all the potential human health hazards for 1,3-butadiene identified during prioritization. The broad health effect categories include reproductive and developmental, immunological, nervous system, and irritation effects. Studies were identified that reported information on genotoxicity, carcinogenicity, and ADME.

Analysis Plan. The analysis plan for 1,3-butadiene is presented in Section 2.7. The analysis plan outlines the general scientific approaches that EPA plans to use for the various information streams (i.e., chemistry, fate, release and engineering, exposure, hazard) supporting the risk evaluation. The analysis plan is based on EPA's knowledge of 1,3-butadiene to date which includes a partial, but ongoing, review of identified information as described in Section 2.1. EPA plans to continue to consider new information submitted by the public. Should additional data or approaches become reasonably available, EPA may update its analysis plan in the final scope document.

EPA plans to seek public comments on the systematic review methods supporting the risk evaluation for 1,3-butadiene, including the methods for assessing the quality of data and information and the approach for evidence synthesis and evidence integration supporting the exposure and hazard assessments. The details will be provided in a supplemental document that EPA anticipates releasing for public comment prior to the finalization of the scope document.

Peer Review. The draft risk evaluation for 1,3-butadiene will be peer reviewed. Peer review will be conducted in accordance with relevant and applicable methods for chemical risk evaluations, including using EPA's Peer Review Handbook and other methods consistent with section 26 of TSCA (See 40 CFR 702.45).

1 INTRODUCTION

This document presents for comment the draft scope of the risk evaluation to be conducted for 1,3-butadiene 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) on June 22, 2016. The new law includes statutory requirements and deadlines for actions related to conducting risk evaluations of existing chemicals.

TSCA § 6(b) the Environmental Protection Agency (EPA) must designate chemical substances as high-priority substances for risk evaluation or low-priority substances for which risk evaluations are not warranted at the time, and upon designating a chemical substance as a high-priority substance, initiate a risk evaluation on the substance. TSCA § 6(b)(4) directs EPA, in conducting risk evaluations for existing chemicals, 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.*"

TSCA § 6(b)(4)(D) and implementing regulations require that EPA publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use and PESS that the Administrator expects to consider within 6 months after the initiation of a risk evaluation. In addition, a draft scope is to be published pursuant to 40 CFR 702.41. In December 2019, EPA published a list of 20 chemical substances that have been designated high-priority substances for risk evaluations (Docket ID: EPA-HQ-OPPT-2018-0451), as required by TSCA § 6(b)(2)(B). 1,3-Butadiene is one of the chemicals designated as a high-priority substance for risk evaluation.

2 SCOPE OF THE EVALUATION

2.1 Reasonably Available Information

EPA conducted a comprehensive search for reasonably available information[1] to support the development of this draft scope document for 1,3-butadiene. EPA leveraged the data and information sources already identified in the documents supporting the chemical substance's high-priority substance designation. In addition, EPA searched for additional data and information on physical and chemical properties, environmental fate, engineering, exposure, environmental and human health hazards that could be obtained from the following general categories of sources:

1. Databases containing publicly available, peer-reviewed literature;
2. Gray literature, which is defined as the broad category of data/information sources not found in standard, peer-reviewed literature databases.
3. Data and information submitted under TSCA sections 4, 5, 8(e), and 8(d), as well as "for your information" (FYI) submissions.

Following the comprehensive search, EPA performed a title and abstract screening to identify information potentially relevant for the risk evaluation process. This step also classified the references into useful categories or tags to facilitate the sorting of information through the systematic review process. The search and screening process was conducted based on EPA's general expectations for the

[1] *Reasonably available information* means information that EPA possesses or can reasonably generate, obtain, and synthesize for use in risk evaluations, considering the deadlines specified in TSCA section 6(b)(4)(G) for completing such evaluation. Information that meets the terms of the preceding sentence is reasonably available information whether or not the information is confidential business information, that is protected from public disclosure under TSCA section 14 (40 CFR 702.33).

planning, execution and assessment activities outlined in the *Application of Systematic Review in TSCA Risk Evaluations* document (U.S. EPA, 2018a). EPA plans to publish supplemental documentation on the systematic review methods supporting the 1,3-butadiene risk evaluation to explain the literature and screening process presented in this document in the form of literature inventory trees. Please note that EPA focuses on the data collection phase (consisting of data search, data screening, and data extraction) during the preparation of the TSCA scope document, whereas the data evaluation and integration stages will occur during the development of the draft risk evaluation and thus are not part of the scoping activities described in this document.

The subsequent sections summarize the data collection activities completed to date for the general categories of sources and topic areas (or disciplines) using systematic review methods. EPA plans to seek public comments on the systematic review methods supporting the risk evaluation for 1,3-butadiene upon publication of the supplemental documentation of those methods.

2.1.1 Search of Gray Literature

EPA surveyed the gray literature[2] and identified 276 search results relevant to EPA's risk assessment needs for 1,3-butadiene. Table_Apx A-1 lists the gray literature sources that yielded 276 discrete data or information sources relevant to 1,3-butadiene. EPA further categorized the data and information into the various topic areas (or disciplines) supporting the risk evaluation (e.g., physical chemistry, environmental fate, ecological hazard, human health hazard, exposure, engineering) and the breakdown is shown in Figure 2-1. EPA is currently identifying additional reasonably available information (e.g., public comments), and the reported numbers in Figure 2-1 may change.

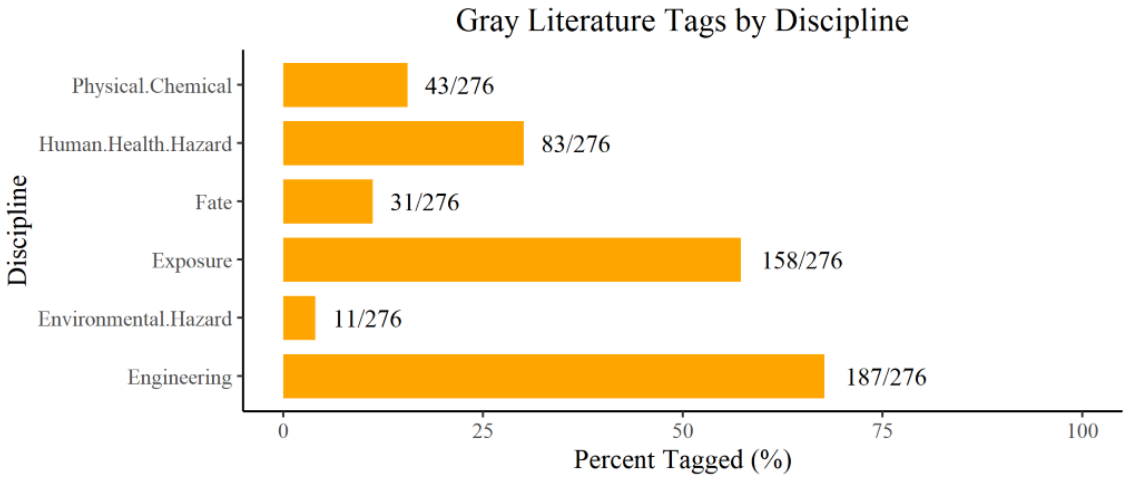

Figure 2-1 Gray Literature Search Results for 1,3-Butadiene
The percentages across disciplines do not add up to 100%, as each source may provide data or information for various topic areas (or disciplines).

[2] Gray literature is defined as the broad category of data/information sources not found in standard, peer-reviewed literature databases (e.g., PubMed and Web of Science). Gray literature includes data/information sources such as white papers, conference proceedings, technical reports, reference books, dissertations, information on various stakeholder websites, and other databases.

2.1.2 Search of Literature from Publicly Available Databases (Peer-Reviewed Literature)

EPA is currently conducting a systematic review of the reasonably available literature. This includes performing a comprehensive search of the reasonably available peer review literature on physical-chemical properties, environmental fate and transport, engineering (environmental release and occupational exposure), exposure (environmental, general population and consumer) and environmental and human health hazards of 1,3-butadiene. Eligibility criteria were applied in the form of PECO (population, exposure, comparator, outcome) statements. Included references met the PECO criteria, whereas excluded references did not meet the criteria (i.e., not relevant), and supplemental material was considered as potentially relevant. EPA plans to analyze the reasonably available information identified for each discipline during the development of the risk evaluation. The literature inventory trees depicting the number of references that were captured and those that were included, excluded, or tagged as supplemental material during the screening process for each discipline area are shown in Figure 2-2. Peer-reviewed Literature - Physical-Chemical Properties Search Results for 1,3-Butadiene. through Figure 2-6. “TIAB” in these figures refer to “title and abstract” screening. Note that in some of the figures the sum of the numbers for the various sub-categories may be larger than the broader category because some studies may be included under multiple sub-categories. In other cases, the sum of the various sub-categories may be smaller than the main category because some studies may not be depicted in the sub-categories if their relevance to the risk evaluation was unclear.

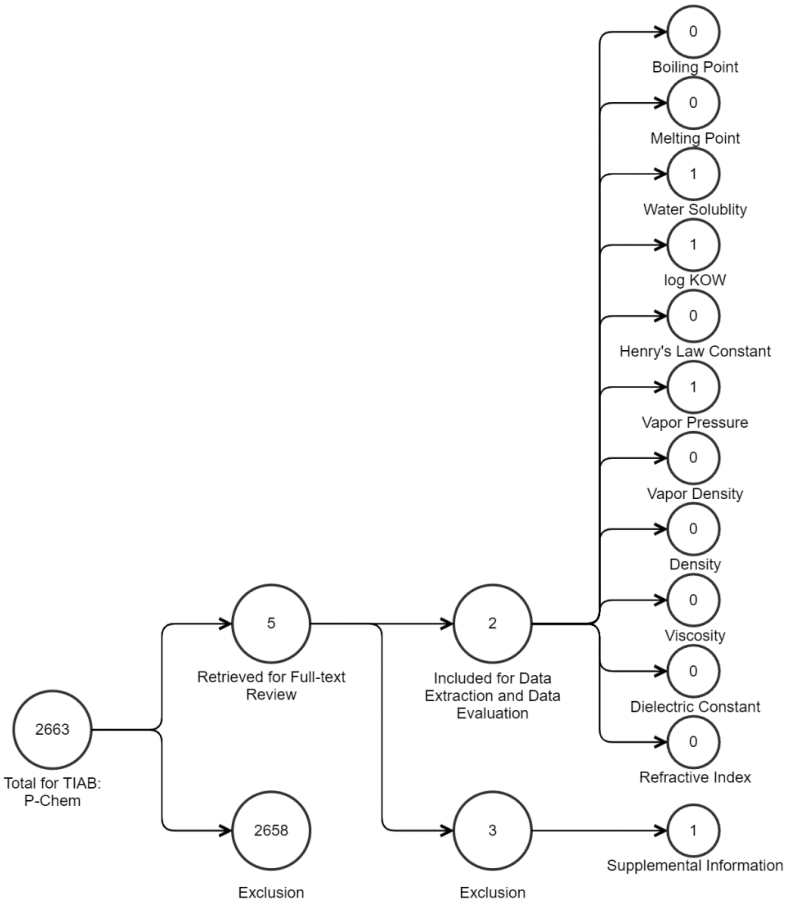

Figure 2-2. Peer-reviewed Literature - Physical-Chemical Properties Search Results for 1,3-Butadiene.

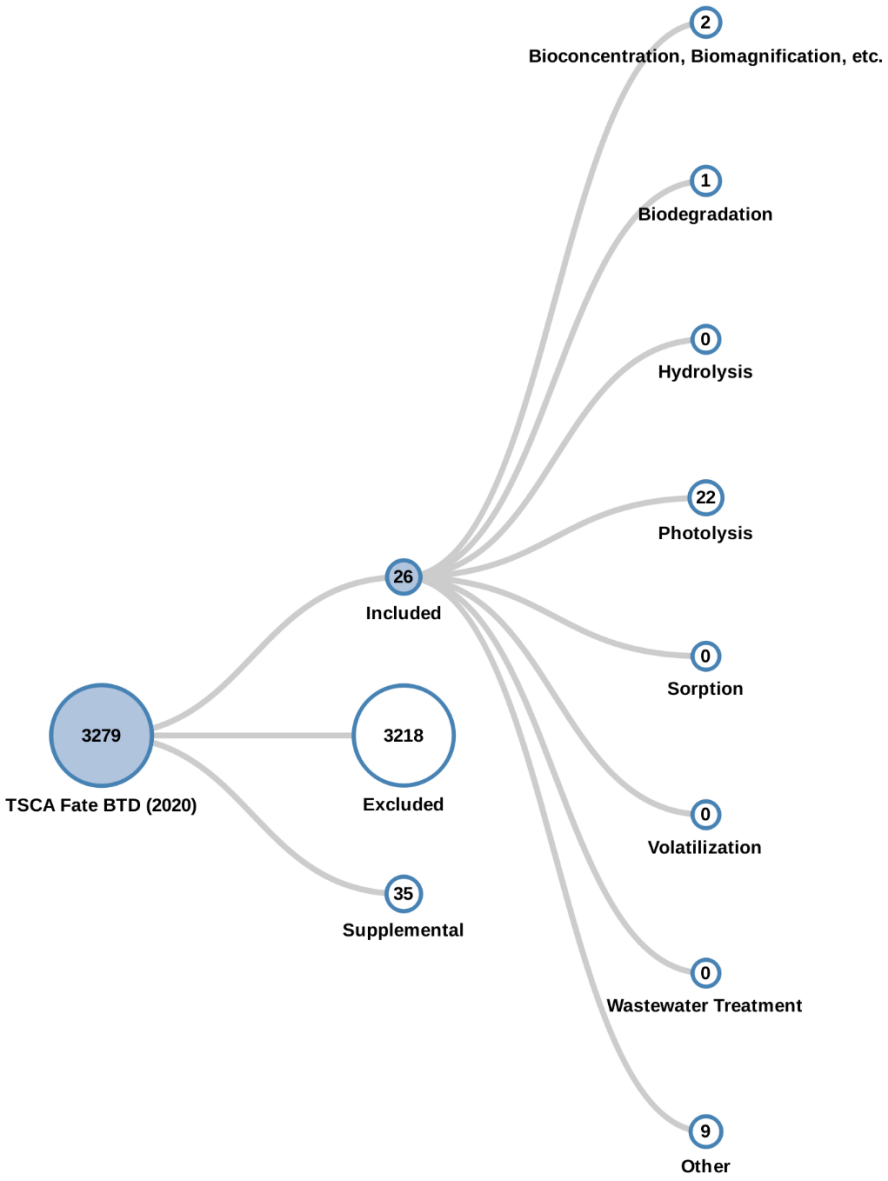

Figure 2-3. Peer-reviewed Literature – Fate and Transport Search Results for 1,3-Butadiene.
Click here for interactive Health Assessment Workplace Collaborative (HAWC) Diagram.

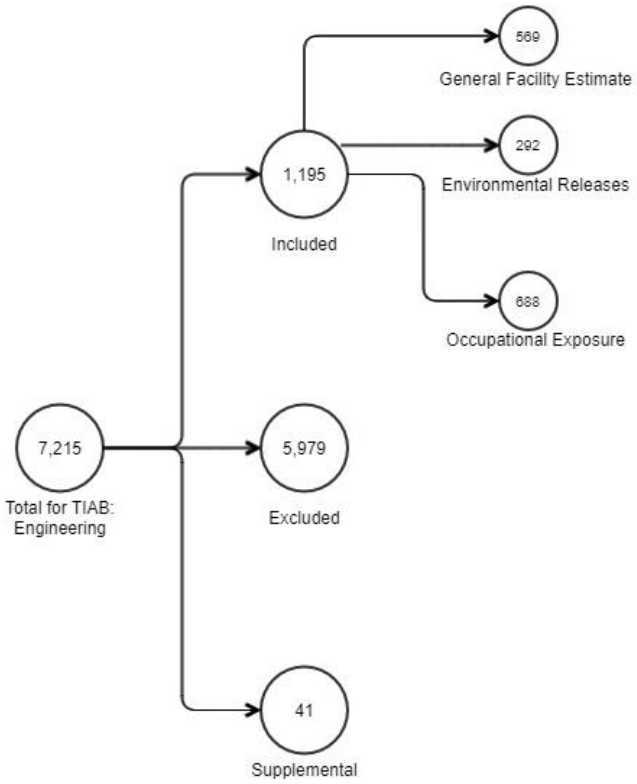

Figure 2-4. Peer-reviewed Literature - Engineering Search Results for 1,3-Butadiene

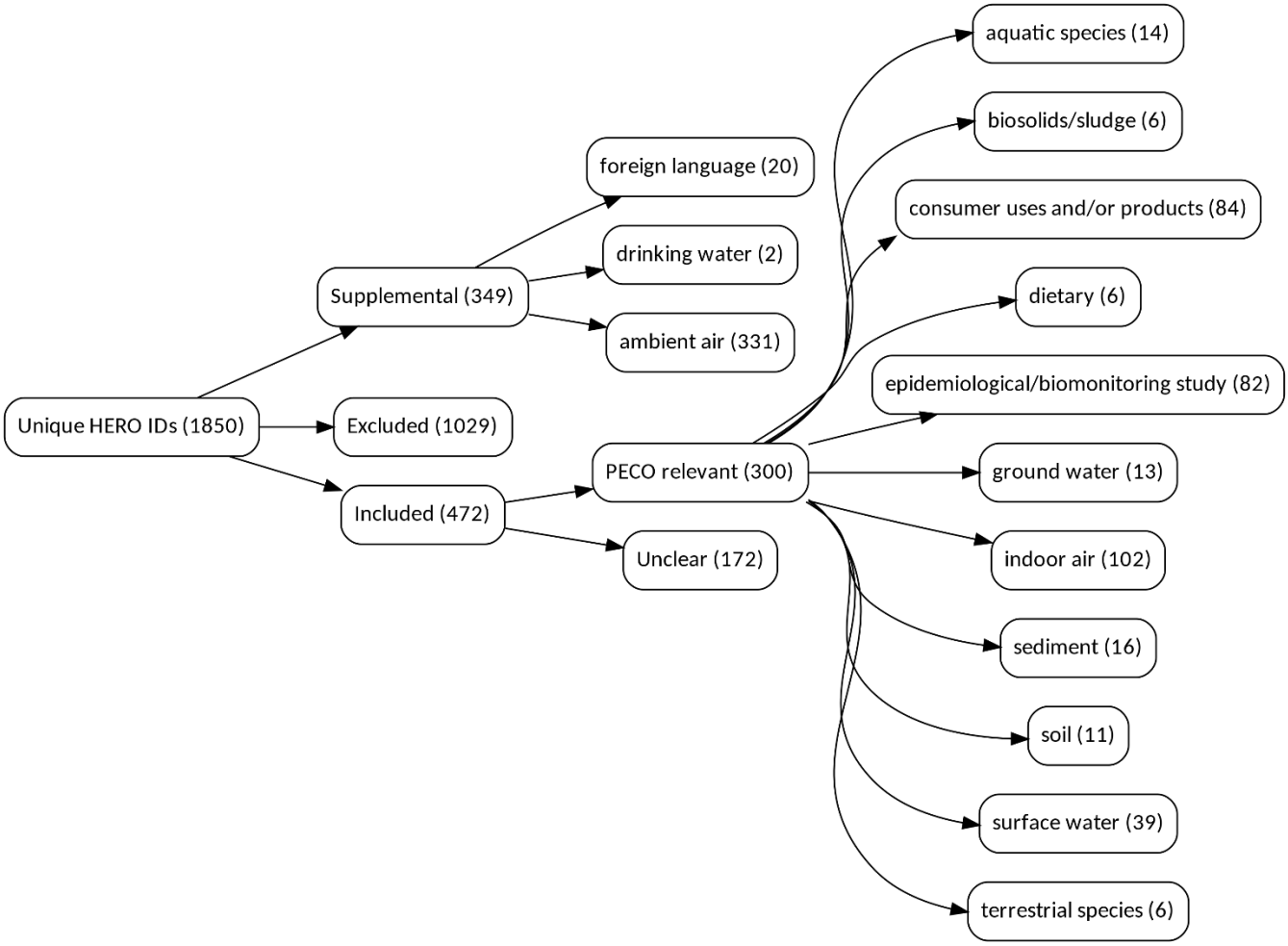

Figure 2-5. Peer-reviewed Exposure Search Results for 1,3-Butadiene

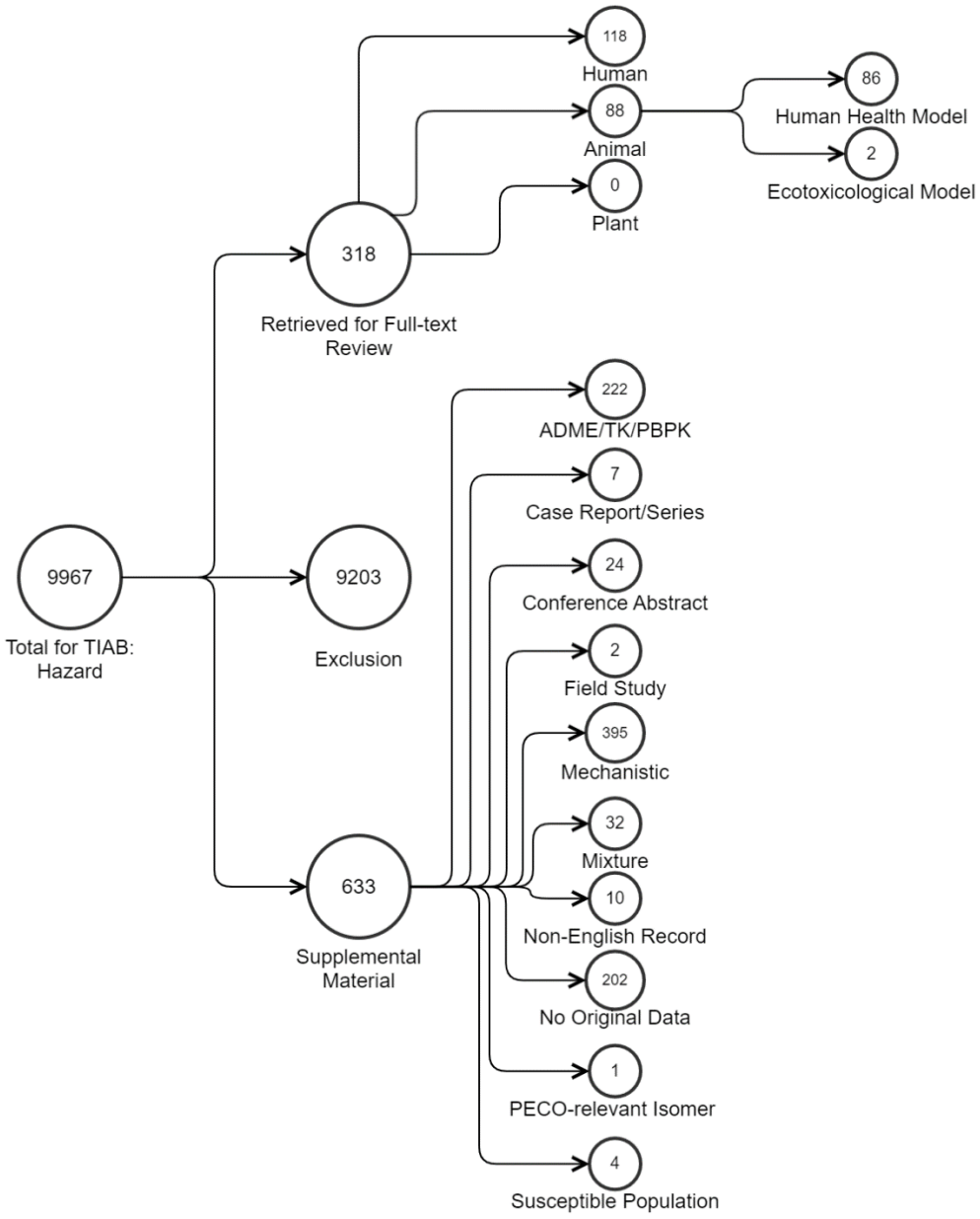

Figure 2-6. Peer-reviewed Hazard Search Results for 1,3-Butadiene

2.1.3 Search of TSCA Submissions

Table 2-1 presents the results of screening the titles of data sources and reports submitted to EPA under various sections of TSCA. EPA screened a total of 109 submissions using inclusion and exclusion criteria specific to individual disciplines (see Table 2-1 for the list of disciplines). The details about the criteria are not part of this document but will be provided in a supplemental document that EPA anticipates releasing prior to the finalization of the scope document.

EPA identified 92 submissions that met the inclusion criteria and identified 18 submissions with supplemental human health data. EPA excluded 17 submissions because the reports were identified as one of the following:

- Published report that would be identified via other peer or gray literature searches

- Summary of other reports
- Preliminary report of a final available submitted report
- Duplicate of another report
- Submission on a different chemical
- List of references with no original data

EPA plans to conduct additional deduplication at later stages of the systematic review process (e.g., full-text screening), when more information regarding the reports is available.

Table 2-1. Results of Title Screening of Submissions to EPA Under Various Sections of TSCA

Discipline	Included	Supplemental
Physicochemical Properties	1	0
Environmental Fate and Transport	0	0
Environmental and General Population Exposure	14	0
Occupational Exposure/Release Information	34	0
Environmental Hazard	0	0
Human Health Hazard	43	18

2.2 Conditions of Use

As described in the *Proposed Designation of 1,3-Butadiene (CASRN 106-99-0) as a High-Priority Substance for Risk Evaluation* (U.S. EPA 2019a), EPA assembled information from the CDR and TRI programs to determine conditions of use[3] or significant changes in conditions of use of the chemical substance. EPA also consulted a variety of other sources to identify uses of 1,3-butadiene, including: published literature, company websites, and government and commercial trade databases and publications. To identify formulated products containing 1,3-butadiene, EPA searched for safety data sheets (SDS) using internet searches, EPA Chemical and Product Categories (CPCat) data, and other resources in which SDSs could be found. In addition, EPA incorporated communications with companies, industry groups, environmental organizations, and public comments to supplement the conditions of use information.

EPA identified and described the categories and subcategories of conditions of use that EPA plans to include in the scope of the risk evaluation (Section 2.2.1; Table 2-2). The conditions of use that EPA plans to include in the scope are those reflected in the life cycle diagrams and conceptual models. After gathering reasonably available information related to the manufacture, processing, distribution in commerce, use, and disposal of 1,3-butadiene, EPA identified those categories or subcategories of use activities for 1,3-butadiene the Agency determined not to be conditions of use or will otherwise be excluded during scoping. These categories and subcategories are described in Section 2.2.2.

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

Table 2-2 lists the conditions of use that are included in the scope of the risk evaluation.

[3] *Conditions of use* means 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.

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

Life Cycle Stage	Category	Subcategory	References
Manufacture	Domestic manufacturing	Domestic manufacturing	U.S. EPA (2019b)
	Importing	Importing	U.S. EPA (2019b)
Processing	Processing as a reactant	Other: Fuel binder for solid rocket fuels in: Aerospace	U.S. EPA (2019b)
		Intermediate in: Adhesive manufacturing; All other basic organic chemical manufacturing; Organic fiber manufacturing; Petrochemical manufacturing; Petroleum refineries; Plastic material and resin manufacturing; Synthetic rubber manufacturing; Wholesale and retail trade	U.S. EPA (2019b)
		Other: Monomer used in polymerization process in: Plastic material and resin manufacturing; Manufacturing synthetic rubber and plastics	U.S. EPA (2019b); EPA-HQ-OPPT-2018-0451-0004
		Plasticizers in: Plastic material and resin manufacturing	U.S. EPA (2019b)
		Solvents (which become part of product formulation or mixture) in: Synthetic rubber manufacturing	U.S. EPA (2019b)
	Processing – incorporation into formulation, mixture, or reaction product	Processing aids, not otherwise listed in: Petrochemical manufacturing	U.S. EPA (2019b)
		Other: Adhesive manufacturing, paints and coatings manufacturing, petroleum lubricating oil and grease manufacturing, and all other chemical product and preparation manufacturing	EPA-HQ-OPPT-2018-0451-0003; EPA-HQ-OPPT-2018-0451-0005; EPA-HQ-OPPT-2018-0451-0009; EPA-HQ-OPPT-2019-0131-0022
	Processing – incorporation into article	Other: Polymer in: Rubber product manufacturing	U.S. EPA (2019b)
	Repackaging	Intermediate in: Wholesale and retail trade	U.S. EPA (2019b)
	Recycling	Recycling	U.S. EPA (2019b); TRI (2017)
Distribution in commerce	Distribution in commerce	Distribution in commerce (e.g., Sold to a trader; Sold to re-	U.S. EPA (2019b)

Life Cycle Stage	Category	Subcategory	References
		sellers for petroleum fuel and petrochemical industry in: Petrochemical manufacturing)	
Industrial Use	Adhesives and sealants	Adhesives and sealants	EPA-HQ-OPPT-2018-0451-0003; EPA-HQ-OPPT-2018-0451-0005; EPA-HQ-OPPT-2018-0451-0009; EPA-HQ-OPPT-2019-0131-0022
	Processing aids, specific to petroleum production	Hydraulic fracturing	U.S. EPA (2016)
Commercial Use	Fuels and related products	Fuels and related products	U.S. EPA (2019b)
	Plastic and rubber products not covered elsewhere	Plastic and rubber products not covered elsewhere, including rubber tires	U.S. EPA (2019b); EPA-HQ-OPPT-2018-0451-0003
	Automotive care products	Automotive care products	U.S. EPA (2019b)
	Other use	Monomer used in polymerization process	U.S. EPA (2019b); EPA-HQ-OPPT-2018-0451-0005
		Laboratory chemicals	Sigma-Aldrich (2020)
	Lubricants and lubricant additives	Lubricant additives, including viscosity modifier	EPA-HQ-OPPT-2018-0451-0003; EPA-HQ-OPPT-2019-0131-0022
	Paints and coatings	Paints and coatings, including aerosol spray paint	EPA-HQ-OPPT-2018-0451-0005; EPA-HQ-OPPT-2019-0131-0022
	Adhesives and sealants	Adhesives and sealants	EPA-HQ-OPPT-2018-0451-0003; EPA-HQ-OPPT-2018-0451-0009; EPA-HQ-OPPT-2019-0131-0022
Consumer Use	Plastic and rubber products not covered elsewhere	Plastic and rubber products not covered elsewhere, including rubber tires	U.S. EPA (2019b); EPA-HQ-OPPT-2019-0131-0012
	Automotive care products	Automotive care products	U.S. EPA (2019b)
Disposal	Disposal	Disposal	

Life Cycle Stage Use Definitions (40 CFR § 711.3)

- "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.

Life Cycle Stage	Category	Subcategory	References
• Although EPA has identified both industrial and commercial uses here for purposes of distinguishing scenarios in this document, the Agency interprets the authority over "any manner or method of commercial use" under TSCA section 6(a)(5) to reach both. • "Monomer used in polymerization process," as reported to the 2016 CDR under commercial use, indicates processing of 1,3-butadiene for a polymerization reaction. This reported use will be evaluated under processing as a reactant.			

2.2.2 Activities Excluded from the Scope of the Risk Evaluation

As explained in the final rule, *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 PESS the Administrator expects to consider in a risk evaluation, suggesting that EPA may exclude certain activities that it determines to be conditions of use on a case-by-case basis (82 FR 33726, 33729; July 20, 2017). TSCA section 3(4) also grants EPA the authority to determine what constitutes a condition of use for a particular chemical substance. EPA does not plan to include in this scope or in the risk evaluation the activities described below that the Agency has concluded do not constitute conditions of use.

Organizations submitted docket comments to EPA regarding the presence of 1,3-butadiene in smoke from tobacco (EPA-HQ-OPPT-2018-0451-0016) and smoke from wildfires (EPA-HQ-OPPT-2018-0451-0014), but these activities and releases are not TSCA conditions of use and will not be evaluated during the risk evaluation. TSCA's definition of "chemical substance"[4] separately excludes tobacco (TSCA section 3(2)(B)(iii)) and tobacco use is therefore outside the scope of TSCA. Wildfires are also outside the scope of the risk evaluation because there is no condition of use for 1,3-butadiene (i.e., manufacture, processing, distribution in commerce, use, or disposal) associated with wildfire activity.

2.2.3 Production Volume

As reported to EPA during the 2016 CDR reporting period and described here as a range to protect production volumes that were claimed as confidential business information (CBI), total production volume of 1,3-butadiene in 2015 was between 1 billion and 5 billion pounds (U.S. EPA 2017a). EPA also uses pre-2015 CDR production volume information, as detailed in the *Proposed Designation of 1,3-Butadiene (CASRN 106-99-0) as a High-Priority Substance for Risk Evaluation* (U.S. EPA 2019a) and will include future production volume information as it becomes available to support the exposure assessment.

2.2.4 Overview of Conditions of Use and Lifecycle Diagram

The life cycle diagram provided in Figure 2-7 depicts the conditions of use that EPA plans to consider in the risk evaluation for the various life cycle stages. This section provides a brief overview of the

[4] *Chemical substance* means any organic or inorganic substance of a particular molecular identity, including any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and any element or uncombined radical. Chemical substance does not include (1) any mixture; (2) any pesticide (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act) when manufactured, processed, or distributed in commerce for use as a pesticide; (3) tobacco or any tobacco product; (4) any source material, special nuclear material, or byproduct material (as such terms are defined in the Atomic Energy Act of 1954 and regulations issued under such Act); (5) any article the sale of which is subject to the tax imposed by section 4181 of the Internal Revenue Code of 1954 (determined without regard to any exemptions from such tax provided by section 4182 or 4221 or any other provision of such Code), and; (6) any food, food additive, drug, cosmetic, or device (as such terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device.

industrial, commercial, and consumer use categories included in the life cycle diagram. Appendix E contains more detailed descriptions (e.g., process descriptions, worker activities) for each manufacturing, processing, distribution in commerce, use, and disposal category based on preliminary information.

The information in the life cycle diagram is grouped according to the CDR processing codes and use categories (including functional use codes for industrial uses and product categories for commercial and consumer uses).[5]

[5] The descriptions are primarily based on the corresponding industrial function category and/or commercial and consumer product category descriptions and can be found in EPA's Instructions for Reporting 2016 TSCA Chemical Data Reporting.

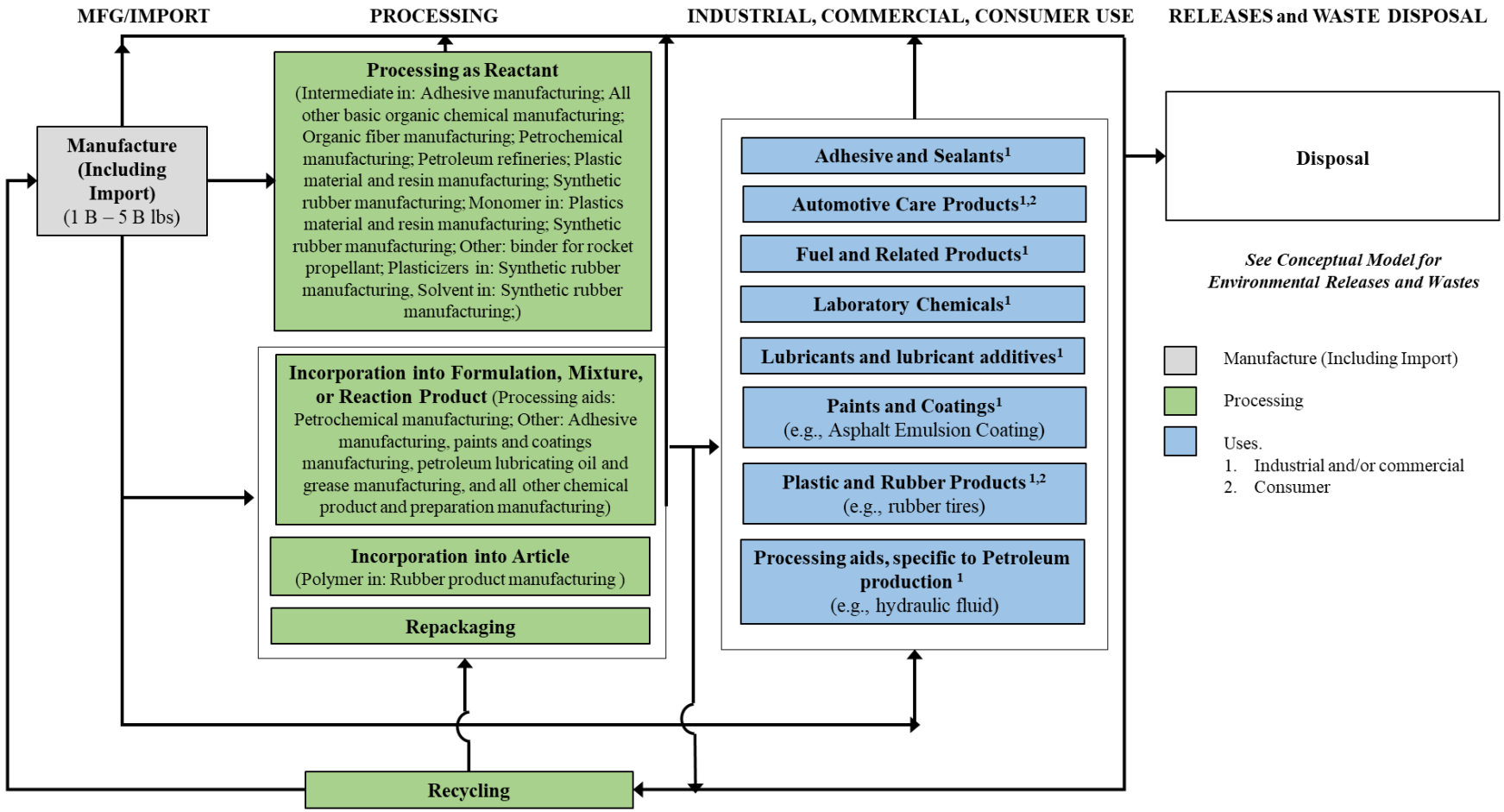

Figure 2-7. 1,3-Butadiene Life Cycle Diagram

Volume is not depicted in the life cycle diagram for processing and industrial, commercial, and consumer uses as specific production volume is claimed confidential business information (CBI) or withheld pursuant to TSCA section § 14.

2.3 Exposures

For TSCA exposure assessments, EPA plans to analyze exposures and releases to the environment resulting from the conditions of use within the scope of the risk evaluation for of 1,3-butadiene. Release pathways and routes will be described to characterize the relationship or connection between the conditions of use of the chemical and the exposure to human receptors, including potentially exposed or susceptible subpopulations, and environmental receptors. EPA plans to consider, where relevant, the duration, intensity (concentration), frequency, and number of exposures in characterizing exposures to 1,3-butadiene.

2.3.1 Physical and Chemical Properties

Physical and chemical properties are essential for a thorough understanding or prediction of environmental fate (i.e., transport and transformation) and the eventual environmental concentrations. They can also inform the hazard assessment. EPA plans to use the physical and chemical properties described in the *Proposed Designation of 1,3-Butadiene (CASRN 106-99-0) as a High-Priority Substance for Risk Evaluation* (reference) to support the development of the risk evaluation for 1,3-butadiene. The values for the physical and chemical properties (Appendix B) may be updated as EPA collects additional information through systematic review methods.

2.3.2 Environmental Fate and Transport

Understanding of environmental fate and transport processes assists in the determination of the specific exposure pathways and potential human and environmental receptors that need to be assessed in the risk evaluation for 1,3-butadiene. EPA plans to use the environmental fate characteristics described in Appendix C of the *Proposed Designation of 1,3-Butadiene (CASRN 106-99-0) as a High-Priority Substance for Risk Evaluation* (U.S. EPA 2019) to support the development of the risk evaluation for 1,3-butadiene. The values for the environmental fate properties (Appendix C) may be updated as EPA collects additional information through systematic review methods.

2.3.3 Releases to the Environment

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

A source of information that EPA plans to consider in evaluating exposure are data reported to the Toxics Release Inventory (TRI) program. EPA's TRI database contains information on chemical waste management activities that are reported to EPA by industrial and federal facilities, including quantities released into the environment (i.e., to air, water, and disposed of to land), treated, burned for energy, recycled, or transferred off-site to other facilities for these purposes.

Under Section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA) 1,3-butadiene is a TRI-reportable substance effective January 1, 1987 (40 CFR 372.65). For TRI reporting,[6] facilities in covered sectors in the United States are required to disclose release and other waste management activity quantities of 1,3-butadiene under the CASRN 106-99-0 if they manufacture (including import) or process more than 25,000 pounds or otherwise use more than 10,000 pounds of the chemical in a given year by July 1 of the following year.

[6] For TRI reporting criteria see https://www.epa.gov/toxics-release-inventory-tri-program/basics-tri-reporting

Table 2-3 provides production-related waste management data for 1,3-butadiene reported by facilities to the TRI program for reporting year 2018. As shown in the table, 188 facilities reported a total of nearly 114 million pounds of 1,3-butadiEene production-related waste managed in 2018. Of this total, roughly equal amounts were recycled or treated (49 million pounds or 43% each). Quantities of 1,3-butadiene burned for energy recovery or released to the environment accounted for 15 million pounds (13%) and 1.2 million pounds (1%) of the total, respectfully. Overall, nearly all production-related waste of 1,3-butadiene was managed on site, with only 2.4% managed off site.

Table 2-3. Summary of 1,3-Butadiene TRI Production-related Waste Managed in 2018

Year	Number of Facilities	Recycled (lbs)	Recovered for Energy (lbs)	Treated (lbs)	Released[a,b,c] (lbs)	Total Production Related Waste (lbs)
2018	188	48,924,121	14,931,906	48,818,860	1,236,393	113,911,280

Data source: 2018 TRI Data (Updated November 2019)
[a] Terminology used in these columns may not match the more detailed data element names used in the TRI public data and analysis access points.
[b] Does not include releases due to one-time event not associated with production such as remedial actions or earthquakes.
[c] Counts all releases including release quantities transferred and release quantities disposed of by a receiving facility reporting to TRI.

Table 2-4 provides a summary of the quantities of 1,3-butadiene released to the environment during 2018 as reported to TRI.[7] Of the total quantity released to the environment during 2018, 98% was released to air. Roughly three-quarters of these air emissions originated from point sources, with the remainder from fugitive sources. Land disposal accounted for nearly all remaining releases, with 93% disposed of on-site to Class I underground injection wells. Overall, more than 99% of disposal and other releases of 1,3-butadiene to the environment occurred on site.

Table 2-4. Summary of Releases of 1,3-Butadiene to the Environment During 2018

	Number of Facilities	Air Releases		Water Releases (lbs)	Land Disposal			Other Releases [a] (lbs)	Total Releases [b, c] (lbs)
		Stack Air Releases (lbs)	Fugitive Air Releases (lbs)		Class I Under-ground Injection (lbs)	RCRA Subtitle C Landfills (lbs)	All other Land Disposal [a] (lbs)		
Totals 2018	188	918,009	303,486	248.98	22,340	34	1,698	10.715	1,245,827
		1,221,495			24,073				

Data source: 2018 TRI Data (Updated November 2019)
[a] Terminology used in these columns may not match the more detailed data element names used in the TRI public data and analysis access points.
[b] These release quantities do include releases due to one-time events not associated with production such as remedial actions or earthquakes.
[c] Counts release quantities once at final disposition, accounting for transfers to other TRI reporting facilities that ultimately dispose of the chemical waste.

While the production-related waste managed shown in Table 2-3 excludes any quantities reported as catastrophic or one-time releases (TRI section 8 data), release quantities shown in Table 2-4 include both production-related and non-production-related quantities. Approximately 9,660 pounds of 1,3-

[7] Reporting year 2018 is the most recent TRI data available. Data presented in Table 2-3 were queried using TRI Explorer and uses the 2018 National Analysis data set (released to the public in November 2019). This dataset includes revisions for the years 1988 to 2018 processed by EPA.

butadiene waste not related to production were reported for 2018. These waste quantities are included in the total releases stated in Table 2-4.

EPA plans to review these data in conducting the exposure assessment component of the risk evaluation for 1,3-butadiene.

2.3.4 Environmental Exposures

The manufacturing, processing, distribution, use, and disposal of 1,3-butadiene can result in releases to the environment and exposure to aquatic and terrestrial receptors (biota). Environmental exposures to biota are informed by releases into the environment, overall persistence, degradation, and bioaccumulation, and partitioning across different media. Concentrations of chemical substances in biota provide evidence of exposure. EPA plans to review reasonably available information on environmental exposures in biota to inform development of the environmental exposure assessment for 1,3-butadiene.

2.3.5 Occupational Exposures

EPA plans to analyze worker activities where there is a potential for exposure under the various conditions of use (manufacturing, processing, industrial/commercial uses and disposal) described in Section 2.2. In addition, EPA plans to analyze exposure to occupational non-users (ONU's), workers who do not directly handle the chemical but perform work in an area where the chemical is present. EPA also expects to consider the effect(s) that engineering controls (EC) and/or personal protective equipment (PPE) have on occupational exposure levels as part of the draft risk evaluation.

Worker activities associated with the conditions of use within the scope of the risk evaluation for 1,3-butadiene that will be analyzed include, but are not limited to

- Unloading and transferring 1,3-butadiene to and from storage containers to process vessels;
- Handling, transporting and disposing of waste containing 1,3-butadiene;
- Cleaning and maintaining equipment;
- Sampling chemicals, formulations, or products containing 1,3-butadiene for quality control;
- Repackaging chemicals, formulations, or products containing 1,3-butadiene;
- Performing other work activities in or near areas where 1,3-butadiene is used.

Several commercial uses (adhesives, automotive care products, lubricant additive, and plastic and rubber products) in Section 2.2 are reported to be downstream uses of the polymers produced using 1,3-butadiene as a monomer (ACC, 2019a). Residual 1,3 butadiene in plastic and rubber products is expected to be low, so occupational exposures for the commercial use of these products have been reported to be low (ECB, 2002). Additional key data that EPA expects will inform occupational exposure assessment include: OSHA Chemical Exposure Health Data (CEHD) and NIOSH Health Hazard Evaluation (HHE) program data, presented in Appendix E.

1,3-Butadiene is a gas with a vapor pressure of 2,110 mm Hg (at 25 °C); hence, inhalation exposure is expected to be a significant route of exposure for workers and ONU's from potential fugitive emissions. Where mist generation is expected (e.g. spray application), EPA will also analyze inhalation exposure to mist for workers and ONU. 1,3-Butadiene has an Occupational Safety and Health Administration (OSHA) standard (29 CFR 1910.1051). The Permissible Exposure Limit (PEL) is 1 part per million (ppm) over an 8-hour work day, time-weighted average (TWA), and there is a Short-Term Exposure Limit (STEL) of 5 ppm (OSHA 2019).

EPA generally does not evaluate occupational exposures through the oral route. Workers may inadvertently transfer chemicals from their hands to their mouths, ingest inhaled particles that deposit in the upper respiratory tract or consume contaminated food. The frequency and significance of this exposure route are dependent on several factors including the p-chem properties of the substance during expected worker activities, workers' awareness of the chemical hazards, the visibility of the chemicals on the hands while working, workplace practices, and personal hygiene that is difficult to predict (Cherrie et al., 2006). However, EPA will consider oral exposure on a case-by-case basis.

EPA plans to evaluate dermal exposure to workers for the conditions of use described in Section 2.2. The manufacturing processes as described Appendix E are noted to include handling of 1,3-butadiene in a pressurized liquid form within closed systems. Review of preliminary data sources suggest exposure by dermal contact may be limited for these processes, information collected through systematic review methods and public comments will help inform this assessment. ONU's do not directly handle 1,3-butadiene; therefore, direct liquid contact with 1,3-butadiene is not expected for any condition of use.

2.3.6 Consumer Exposures

According to reports in the 2016 CDR, automotive care products, and plastic and rubber products including synthetic rubbers, were identified as consumer products for 1,3-butadiene. Consumers using or disposing of automotive care products may be exposed to 1,3-butadiene through direct liquid contact which may lead to a dermal exposure, or through vapor emissions which may lead to inhalation exposure, given its volatility at room temperature. In addition, consumers using or disposing of plastic and rubber products may be exposed to 1,3-butadiene through vapor emissions which may lead to inhalation exposure, given its volatility at room temperature. Bystanders present during the consumer use of automotive care products, plastic, rubber products, or disposal of 1,3-butadiene may also be exposed to vapor emissions leading to an inhalation exposure. Of note, 1,3-butadiene, a monomer used in polymer-derived products such as synthetic rubbers, is stable and is not expected to degrade to the 1,3-butadiene monomer. Therefore, the potential for dermal exposure to 1,3-butadiene during consumer use of articles produced from synthetic rubber may be negligible (ECHA 2019). EPA plans to evaluate 1,3-butadiene monomer, not the polymer which is expected to be stable in products. Based on these potential sources and pathways of exposure, EPA plans to analyze inhalation and dermal routes of exposures to consumers and the inhalation route of exposure to bystanders that may result from the conditions of use of the 1,3-butadiene monomer. EPA does not plan to evaluate consumer exposures to 1,3-butadiene via the oral route since it is not expected given the expected consumer conditions of use.

2.3.7 General Population Exposures

Monitoring data were identified in EPA's data search for 1,3-butadiene and can be used in the exposure assessment. Relevant and reliable monitoring studies provide 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. EPA plans to review reasonably available environmental monitoring data for 1,3-butadiene. EPA's Ambient Monitoring Technology Information Center Air Toxics database has identified 1,3-butadiene in air. In addition, EPA's Unregulated Contaminant Monitoring Rule has identified 1,3-butadiene in drinking water. USGS's Monitoring Data – National Water Quality Monitoring Council has identified 1,3-butadiene in ground water.

Releases of 1,3-butadiene from certain conditions of use, such as manufacturing, processing, distribution, use, and disposal activities, may result in general population exposures (OEHHA 2013). 1,3-Butadiene is likely present at low ambient air concentrations in U.S. cities and large suburban areas (OEHHA 2013). Elevated ambient air concentrations of 1,3-butadiene have been measured in the vicinity of heavily trafficked areas, refineries, chemical manufacturing plants, and plastic and rubber

factories (OEHHA 2013). Reasonably available assessments note the general population is exposed to low levels of 1,3-butadiene in the air due to its presence in gasoline, motor-vehicle exhausts as a product of incomplete combustion of gasoline and diesel oil, and thermal breakdown of plastics (NTP 2016). In addition, the general population is also exposed to low levels of 1,3-butadiene in U.S. drinking water supplies (NTP 2016, ATSDR 2012).

2.4 Hazards (Effects)

2.4.1 Environmental Hazards

As described in the *Proposed Designation of 1,3-Butadiene (CASRN 106-99-0) as a High-Priority Substance for Risk Evaluation* (U.S. EPA 2019), EPA considered reasonably available information from peer-reviewed assessments and databases to identify potential environmental hazards for 1,3-butadiene. EPA did not identify environmental hazard information for 1,3-butadiene during the prioritization process. However, EPA is in the process of identifying additional reasonably available information through systematic review methods and public comments that may inform potential environmental hazards associated with 1,3-butadiene exposure.

2.4.2 Human Health Hazards

As described in the *Proposed Designation of 1,3-Butadiene (CASRN 106-99-0) as a High-Priority Substance for Risk Evaluation* (U.S. EPA 2019), EPA considered reasonably available information from peer-reviewed assessments and databases to identify potential human health hazards for 1,3-butadiene. EPA plans to evaluate all of the potential human health hazards for 1,3-butadiene identified during prioritization. The health effect categories screened for during prioritization included acute toxicity, irritation/corrosion, dermal sensitization, respiratory sensitization, genetic toxicity, repeated dose toxicity, reproductive toxicity, developmental toxicity, immunotoxicity, neurotoxicity, carcinogenicity, epidemiological or biomonitoring studies and ADME[1]. EPA is in the process of identifying additional reasonably available information through systematic review methods and public input, which may update the list of potential human health hazards under the scope of the risk evaluation. If necessary, EPA plans to update the list of potential hazards in the final scope document of the 1,3-butadiene risk evaluation.

2.5 Potentially Exposed or Susceptible Subpopulations

TSCA § 6(b)(4) requires EPA to determine whether a chemical substance presents an unreasonable risk to "a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation." 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 for 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).

During the Prioritization process, EPA identified the following PESS based on CDR information and studies reporting developmental and reproductive effects: children, women of reproductive age (including, but not limited to, pregnant women), workers and consumers (U.S. EPA 2019). EPA plans to evaluate these potentially exposed or susceptible subpopulations in the risk evaluation.

[1] ADME= absorption, distribution, metabolism, and excretion

In developing exposure scenarios, EPA plans to analyze reasonably available information to ascertain whether some human receptor groups may be exposed via exposure pathways that may be distinct to a particular subpopulation or life stage (e.g., children's crawling, mouthing or hand-to-mouth behaviors) and whether some human receptor groups may have higher exposure via identified pathways of exposure due to unique characteristics (e.g., activities that would lead to elevated fish ingestion or otherwise lead to increased duration or level of exposure) when compared with the general population (U.S. EPA, 2006a). For example, elevated ambient air concentrations of 1,3-butadiene have been measured in the vicinity of heavily trafficked areas, refineries, chemical manufacturing plants, and plastic and rubber factories (OEHHA 2013). Populations living in areas near oil refineries, chemical manufacturing plants, and plastic and rubber factories where 1,3-butadiene is manufactured or used would be expected to have higher exposures (ATSDR 2012). Likewise, EPA plans to evaluate available human health hazard information to ascertain whether some human receptor groups may have greater susceptibility than the general population to the chemical's hazard(s).

2.6 Conceptual Models

In this section, EPA presents the conceptual models describing the identified exposures (pathways and routes), receptors and hazards associated with the conditions of use of 1,3-butadiene. Pathways and routes of exposure associated with workers and ONU's are described in Section 2.6.1, and pathways and routes of exposure associated with consumers are described in Section 2.6.2. Pathways and routes of exposure associated with environmental releases and wastes, including those pathways that may be addressed pursuant to other Federal laws are discussed and depicted the conceptual model shown in Section 2.6.3. Pathways and routes of exposure associated with environmental releases and wastes, excluding those pathways that may be addressed pursuant to other Federal laws are presented in the conceptual model shown in Section 2.6.4.

2.6.1 Conceptual Model for Industrial and Commercial Activities and Uses

Figure 2-8 illustrates the conceptual model for the pathways of exposure from industrial and commercial activities and uses of 1,3-butadiene that EPA plans to include in the risk evaluation. There is potential for exposures to workers and/or ONU's via inhalation routes and exposures to workers via dermal routes. Due to 1,3-butadiene high vapor pressure, it is expected that inhalation exposure to vapors is the most likely exposure pathway. In addition, workers at waste management facilities may be exposed via inhalation or dermal routes during waste handling, treatment, and disposal. EPA plans to 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, and disposal) rather than a single distribution scenario.

One of the commercial uses of 1,3-butadiene is in fuel and fuel products, EPA plans to assess occupational exposures related to the processing and handling of fuel. Preliminary literature suggests 1,3-butadiene presence in fuel is low (ECB, 2002). However, 1,3-butadiene is also generated as a byproduct from the incomplete combustion of fuel, EPA does not plan to assess occupational exposures resulting 1,3-butadiene formed as a byproduct (e.g., exhaust emissions). EPA believes it is more appropriate to evaluate the potential risks arising from the byproduct within the scope of the risk evaluation for the chemical substances from which the byproduct is produced, rather than the 1,3-butadiene risk evaluation. For each condition of use identified in Table 2-2, a determination was made as to whether or not EPA plans to assess each unique combination of exposure pathway, route, and receptor in the risk evaluation. The supporting rationale is presented in Appendix F.

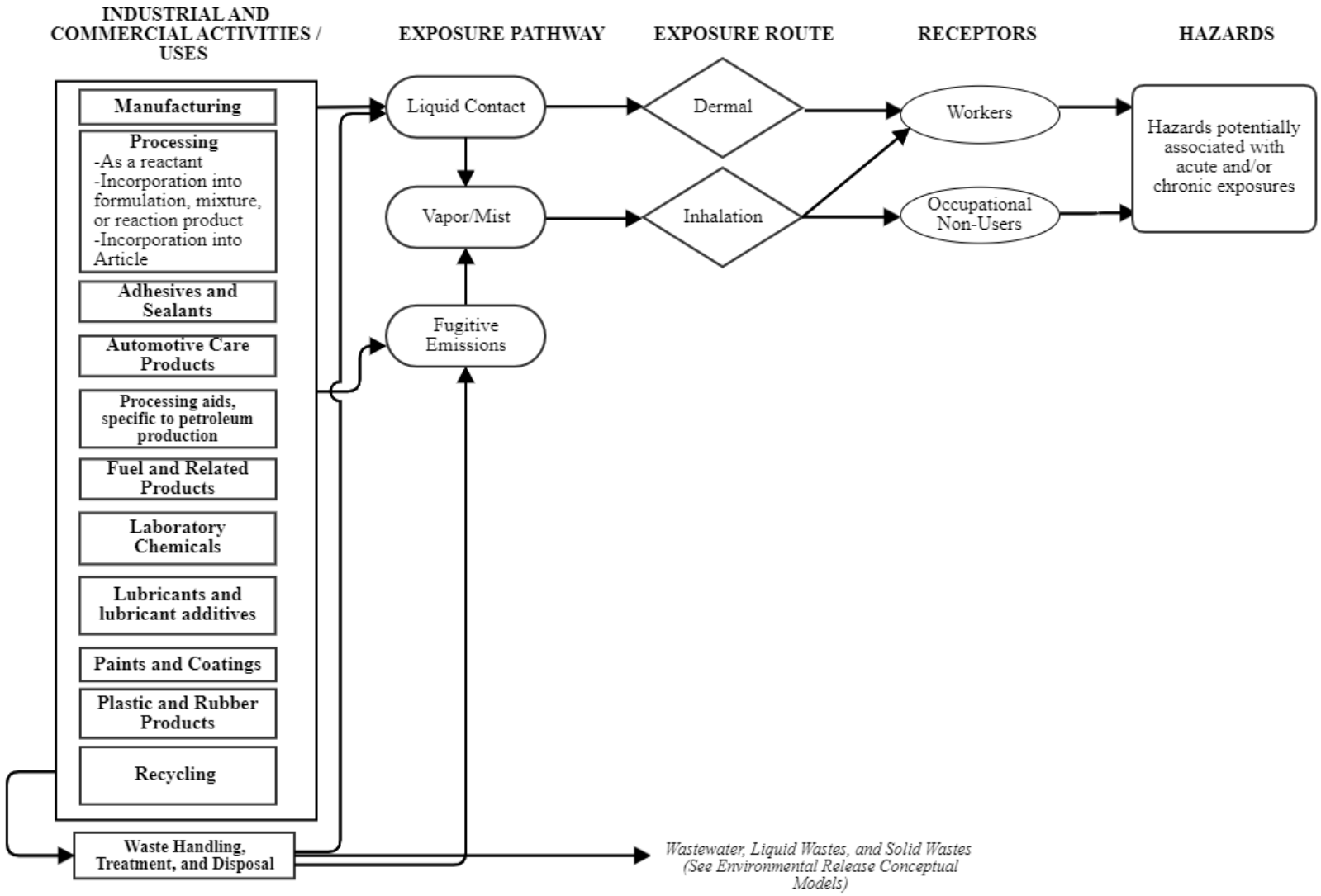

Figure 2-8. 1,3-Butadiene Conceptual Model for Industrial and Commercial Activities and Uses: Worker and ONU Exposures and Hazards

The conceptual model presents the exposure pathways, exposure routes, and hazards to human receptors from industrial and commercial activities and uses of 1,3-butadiene.

2.6.2 Conceptual Model for Consumer Activities and Uses

The conceptual model in Figure 2-9 presents the exposure pathways, exposure routes and hazards to human receptors from consumer activities and uses of 1,3-butadiene that EPA plans to include in the risk evaluation. EPA expects inhalation to be the primary route of exposure and plans to evaluate inhalation exposures to 1,3-butadiene vapor for consumers and bystanders during use and disposal of automotive care products, and plastics and rubber products. There is potential for consumer dermal exposures to 1,3-butadiene via direct contact during use of automotive care products, such as lubricants. Bystanders are not expected to have direct dermal contact to 1,3-butadiene. Therefore, EPA plans to evaluate dermal exposure to1,3-butadiene for consumers but not for bystanders. In addition, oral exposures to 1,3-butadiene are expected to be negligible and, as a result, EPA does not expect to evaluate this route of exposure for consumers nor bystanders. The supporting rationale for consumer pathways considered for 1,3 butadiene are included in 94.

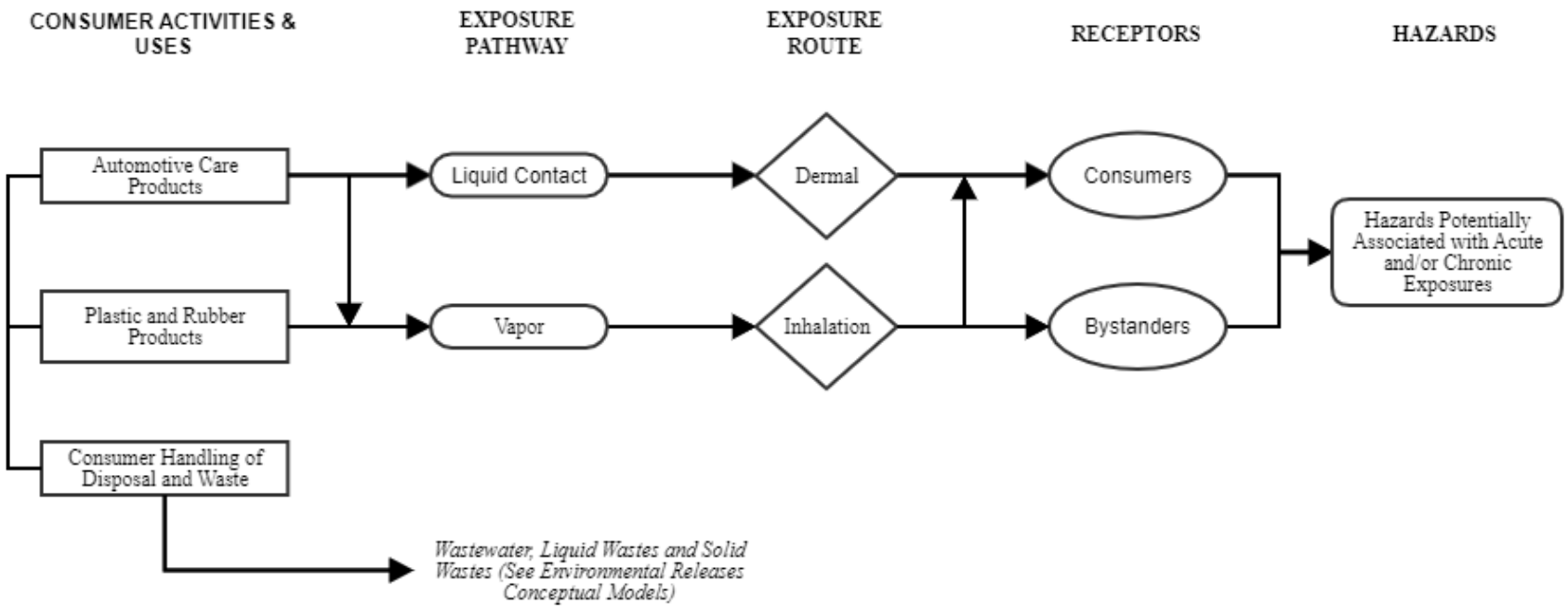

Figure 2-9. 1,3-Butadiene Conceptual Model for Consumer Activities and Uses: Consumer Exposures and Hazards
The conceptual model presents the exposure pathways, exposure routes, and hazards to human receptors from consumer activities and uses of 1,3-butadiene.

2.6.3 Conceptual Models for Environmental Releases and Wastes: Potential Exposures and Hazards (Regulatory Overlay)

In complying with TSCA, EPA plans to efficiently use Agency resources, avoid duplicating efforts taken pursuant to other Agency programs, maximize scientific and analytical efforts, and meet the statutory deadline for completing risk evaluations. OPPT is working closely with the offices within EPA that administer and implement the Clean Air Act (CAA), the Safe Drinking Water Act (SDWA), the Clean Water Act (CWA) and the Resource Conservation and Recovery Act (RCRA), to identify how those statutes and any associated regulatory programs address the presence of 1,3-butadiene in exposure pathways falling under the jurisdiction of these EPA statutes.

The conceptual model in Figure 2-10 presents the potential exposure pathways, exposure routes and hazards to human and environmental receptors from releases and waste streams associated with industrial and commercial uses of 1,3-butadiene. This figure includes overlays, labeled and shaded to depict the regulatory programs (e.g., CAA, SDWA, CWA, RCRA) and associated pathways that EPA considered in developing this conceptual model for the draft scope document. The pathways are further described in Section 2.6.3.1 through Section 2.6.3.2.

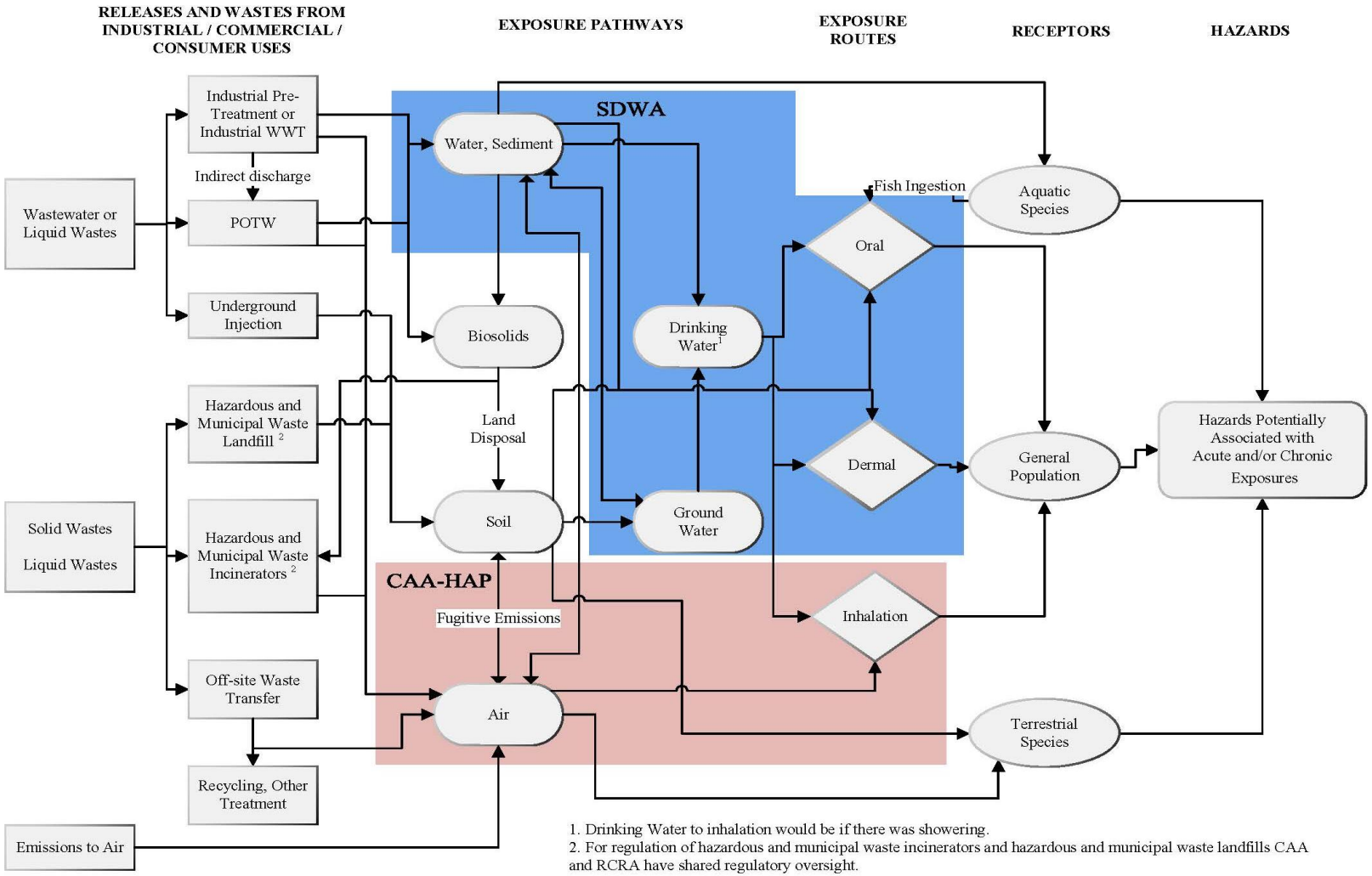

Figure 2-10. 1,3-Butadiene Conceptual Model for Environmental Releases and Wastes: Environmental and General Population Exposures and Hazards (Regulatory Overlay)

The conceptual model presents the exposure pathways, exposure routes and hazards to human receptors from releases and wastes from industrial and commercial uses of 1,3-butadiene showing the environmental statutes covering those pathways. Notes:

a) Industrial wastewater or liquid wastes may be treated on-site and then released to surface water (direct discharge), or pre-treated and released to a Publicly Owned Treatment Works (POTW) (indirect discharge). For consumer uses, such wastes may be released directly to POTW. Drinking water will undergo further treatment in drinking water treatment plant. Ground water may also be a source of drinking water.

b) Receptors include PESS (see Section 2.5).

2.6.3.1 Ambient Air Pathway

The Clean Air Act (CAA) contains a list of hazardous air pollutants (HAP) and provides EPA with the authority to add to that list pollutants that present, or may present, a threat of adverse human health effects or adverse environmental effects. For stationary source categories emitting HAPs, the CAA requires issuance of technology-based standards and, if necessary, additions or revisions to address developments in practices, processes, and control technologies, and to ensure the standards adequately protect public health and the environment. The CAA thereby provides EPA with comprehensive authority to regulate emissions to ambient air of any hazardous air pollutant. 1,3-Butadiene is a HAP. EPA has issued a number of technology-based standards for source categories that emit 1,3-butadiene to ambient air and, as appropriate, has reviewed or is in the process of reviewing remaining risks.

Emission pathways to ambient air from commercial and industrial stationary sources and associated inhalation exposure of the general population or terrestrial species in this TSCA evaluation from stationary source releases of 1,3-butadiene to ambient air are covered under the jurisdiction of the CAA. EPA's Office of Air and Radiation and Office of Pollution Prevention and Toxics will continue to work together to provide an understanding and analysis of the CAA regulatory analytical processes and to exchange information related to toxicity and occurrence data on chemicals undergoing risk evaluation under TSCA.

2.6.3.2 Drinking Water Pathway

EPA has regular analytical processes to identify and evaluate drinking water contaminants of potential regulatory concern for public water systems under the Safe Drinking Water Act (SDWA). Under SDWA EPA must also review and revise "as appropriate" existing drinking water regulations every 6 years.

The Contaminant Candidate List (CCL) is a list of unregulated contaminants that are known or anticipated to occur in public water systems and that may require regulation. EPA must publish a CCL every 5 years and make Regulatory Determinations to regulate (or not) at least five CCL contaminants every 5 years. To regulate a contaminant, EPA must conclude the contaminant may have adverse health effects, occurs or is substantially likely to occur in public water systems at a level of concern and that regulation, in the sole judgement of the Administrator, presents a meaningful opportunity for health risk reduction.

Once contaminants have been placed on the CCL, EPA identifies if there are any additional data needs, including gaps in occurrence data for evaluation under the Regulatory Determination; if sufficient occurrence data is lacking, the contaminant may be considered for monitoring under the Unregulated Contaminant Monitoring Rule.

1,3-Butadiene is currently listed on EPA's Fourth Contaminant Candidate List (CCL 4) and was subject to occurrence monitoring in public water systems under the third Unregulated Contaminants Monitoring Rule (UMCR 3). Under UMCR 3, water systems were monitored for 1,3-butadiene during 2013-2015. Of the 4,916 water systems monitored, 2 systems had detections of 1,3-butadiene in at least one sample. In accordance with EPA Office of Water's process, 1,3-butadiene is currently being evaluated under the fourth Regulatory Determination process under SDWA.

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

As described in Section 2.6.3, some pathways in the conceptual models are covered under the jurisdiction of other environmental statutes administered by EPA. The conceptual model depicted in Figure 2-11. 1,3-Butadiene Conceptual Model for Environmental Releases and Wastes: Environmental and General Population Exposures and Hazards presents the exposure pathways, exposure routes and hazards to human and environmental receptors from releases and wastes from industrial and commercial uses of 1,3-butadiene that EPA plans to consider in the risk evaluation. The exposure pathways, exposure routes and hazards presented in this conceptual model are subject to change in the final scope, in light of comments received on this draft scope and other reasonably available information. EPA continues to consider whether and how other EPA-administered statutes and any associated regulatory programs address the presence of 1,3-butadiene in exposure pathways falling under the jurisdiction of these EPA statutes.

Figure 2-11 depicts the environmental pathways that remain in scope after applying EPA's regulatory overlay. EPA plans to evaluate exposures to general population, aquatic, terrestrial species that may occur from industrial and/or commercial and consumer releases to water/sediment; biosolids and soil. Some aquatic species may be exposed to 1,3 butadiene in water bodies in which 1,3-butadiene is found. In addition, some terrestrial species may be exposed to 1,3-butadiene via surface water, soil and biosolids found in their natural habitats. The general population may be exposed to 1,3-butadiene via fish consumption and may be dermally exposed to 1,3 butadiene through ambient water. The supporting basis for general population and environmental pathways considered for 1,3 butadiene are included in 96.

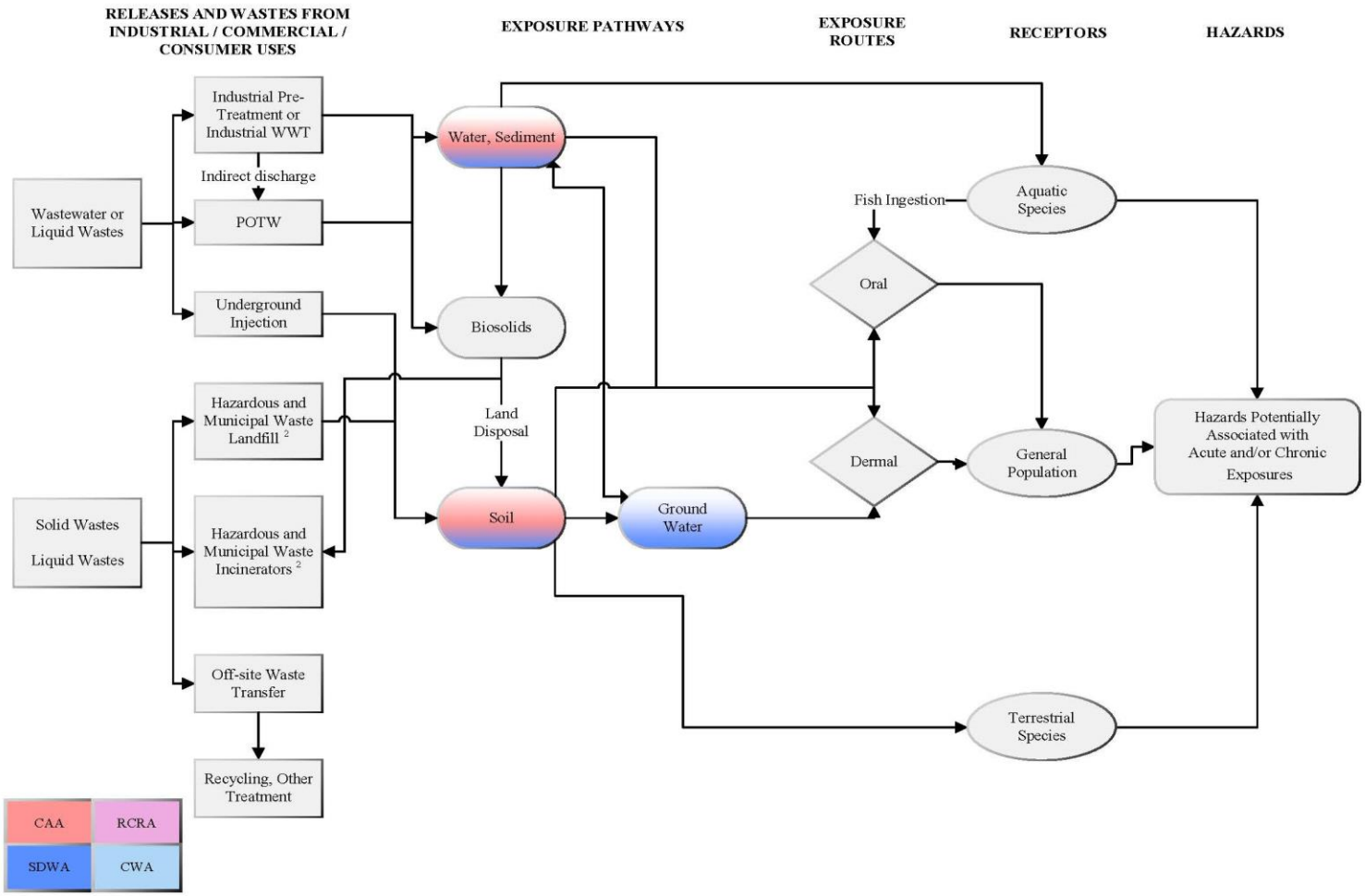

Figure 2-11. 1,3-Butadiene Conceptual Model for Environmental Releases and Wastes: Environmental and General Population Exposures and Hazards

The conceptual model presents the exposure pathways, exposure routes and hazards to human receptors from releases and wastes from industrial and commercial uses of 1,3-butadiene that EPA plans to consider in the risk evaluation. Notes:

a) Industrial wastewater or liquid wastes may be treated on-site and then released to surface water (direct discharge), or pre-treated and released to POTW (indirect discharge). For consumer uses, such wastes may be released directly to POTW. Drinking water will undergo further treatment in drinking water treatment plant. Ground water may also be a source of drinking water.

b) Receptors include PESS (see Section 2.5).

2.7 Analysis Plan

The analysis plan is based on EPA's knowledge of 1,3-butadiene to date which includes a partial, but not complete, review of reasonably available information as described in Section 2.1 EPA encourages submission of additional data, such as full study reports or workplace monitoring from industry sources, that may be relevant for EPA's evaluation of conditions of use, exposures, hazards, and PESS during risk evaluation. Further, EPA may consider any relevant CBI in a manner that protects the confidentiality of the information from public disclosure. EPA plans to continue to consider new information submitted by the public. Should additional data or approaches become reasonably available, EPA may update its analysis plan in the final scope document.

2.7.1 Physical and Chemical Properties and Environmental Fate

EPA plans to analyze the physical and chemical (p-chem) properties and environmental fate and transport of 1,3-butadiene as follows:

1) **Review reasonably available measured or estimated p-chem and environmental fate endpoint data collected using systematic review procedures and, where available, environmental assessments conducted by other regulatory agencies.**
   EPA plans to review data and information collected through the systematic review methods and public comments about the p-chem properties (Appendix B) and fate endpoints (Appendix C) previously summarized in the *Proposed Designation of 1,3-Butadiene (CASRN 106-99-0) as a High-Priority Substance for Risk Evaluation* (U.S. EPA 2019a). All sources cited in EPA's analysis will be evaluated according to the procedures described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document. Where the systematic review process fails to identify experimentally measured chemical property values of sufficiently high quality, these values will be estimated using chemical parameter estimation models as appropriate. Model-estimated fate properties will be reviewed for applicability and quality.

2) **Using measured data and/or modeling, determine the influence of p-chem properties and environmental fate endpoints (e.g., persistence, bioaccumulation, partitioning, transport) on exposure pathways and routes of exposure to human and environmental receptors.**
   EPA plans to use measured data and, where necessary, model predictions of p-chem properties and environmental fate endpoints to characterize the persistence and movement of 1,3-butadiene within and across environmental media. The p-chem and fate properties to be assessed are listed in Appendix B and Appendix C, respectively. Given preliminary findings for physical chemical property and fate data, EPA believes it is unlikely that 1,3-butadiene will sorb to biosolids due to its volatility (vapor pressure and Henry's Law Constant), water solubility and unlikely sorption to sludge (Log Koc). However, no assessment pathway will be removed until the full systematic review of available literature is complete. EPA plans to use p-chem and fate endpoints in exposure calculations.

3) **Conduct a weight-of-evidence evaluation of p-chem and environmental fate data, including qualitative and quantitative sources of information.**
   During risk evaluation, EPA plans to evaluate and integrate the environmental fate evidence identified in the literature inventory using the methods described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document.

2.7.2 Exposure

EPA plans to analyze exposure levels for indoor air, surface water, sediment, soil, aquatic biota, and terrestrial biota associated with exposure to 1,3-butadiene. EPA has not yet determined the exposure levels in these media or how they may be used in the risk evaluation. Exposure scenarios are sources (uses), exposure pathways, and exposed receptors. EPA plans to analyze scenario-specific exposures. 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. Exposure level(s) can be characterized through a combination of reasonably available monitoring data and modeling approaches.

2.7.2.1 Environmental Releases

EPA plans to analyze releases to environmental media as follows:

1) **Review reasonably available published literature and other reasonably available information on processes and activities associated with the conditions of use to analyze 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 described in Appendix E. EPA plans to continue to review data sources during risk evaluation using the evaluation strategy in the systematic review documentation that EPA plans to publish prior to finalizing the scope document. Potential sources of environmental release data are summarized in Table 2-5 below:

Table 2-5. Potential Categories and Sources of Environmental Release Data

U.S. EPA TRI Data
U.S. EPA Generic Scenarios
OECD Emission Scenario Documents
EU Risk Assessment Reports
Discharge Monitoring Report (DMR) surface water discharge data for 1,3-butadiene from NPDES-permitted facilities

2) **Review reasonably available chemical-specific release data, including measured or estimated release data (e.g., data from risk assessments by other environmental agencies).**
   EPA has reviewed key release data sources including the Toxics Release Inventory (TRI), and the data from this source is summarized in Section 2.3.3. EPA plans to continue to review relevant data sources during risk evaluation. EPA plans to match identified data to applicable conditions of use and identify data gaps where no data are found for particular conditions of use. EPA plans to attempt to address data gaps identified as described in steps 3 and 4 below by considering potential surrogate data and models.

   Additionally, for conditions of use where no measured data on releases are available, EPA may use a variety of methods including release estimation approaches and assumptions in the Chemical Screening Tool for Occupational Exposures and Releases ChemSTEER (U.S. EPA, 2013).

3) **Review reasonably available measured or estimated release data for surrogate chemicals that have similar uses and physical properties.**
   Data for monomers used in the same types of applications may be considered as surrogate data for 1,3-butadiene. As with 1,3-butadiene, styrene is used as a monomer in rubber and plastic

polymer manufacturing. EPA plans to consider the use of data for monomers such as styrene as surrogates to fill data gaps where uses of 1,3-butadiene and other monomers align. If surrogate data are used, EPA normally converts air concentrations using the ratio of the vapor pressures of the two chemicals. EPA plans to review literature sources identified and if surrogate data are found, EPA plans to match these data to applicable conditions of use for potentially filling data gaps.

4) **Review reasonably available data that may be used in developing, adapting or applying exposure models to the particular risk evaluation.**
This item will be performed after completion of #2 and #3 above. EPA plans to evaluate relevant data to determine whether the data can be used to develop, adapt, or apply models for specific conditions of use (and corresponding release scenarios). EPA has identified information from various EPA statutes (including, for example, regulatory limits, reporting thresholds or disposal requirements) that may be relevant to release estimation. EPA plans to further consider relevant regulatory requirements in estimating releases during risk evaluation.

5) **Review and determine applicability of OECD Emission Scenario Documents (ESDs) and EPA Generic Scenarios to estimation of environmental releases.**
EPA has identified potentially relevant OECD Emission Scenario Documents (ESDs) and EPA Generic Scenarios (GS) that correspond to some conditions of use; for example, the 2009 ESD on Plastics Additives, the 2004 ESD on Additives in the Rubber Industry, the 2011 ESD on the Chemical Industry, the 1991 Petroleum Refining Processing, Crude Separation Process, and Catalytic Cracking GS, and the 1994 Synthetic Fiber Manufacture GS may be useful to assess potential releases. EPA plans to critically review these generic scenarios and ESDs to determine their applicability to the conditions of use.

   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 was not able to identify ESDs or GSs corresponding to several conditions of use, including use of 1,3-butadiene in automotive care products and recycling of 1,3-butadiene. EPA plans to perform additional targeted research to understand those conditions of use which may inform identification of release scenarios. EPA may also need to perform targeted research for applicable models and associated parameters that EPA may use to estimate releases for certain conditions of use. If ESDs and GSs are not available, other methods may be considered. 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%).

6) **Map or group each condition of use to a release assessment scenario(s).**
EPA has identified release scenarios and mapped (i.e., grouped) them to relevant conditions of use as shown in Appendix F. EPA was not able to identify release scenarios corresponding to some conditions of use (e.g., automotive care products, and recycling). EPA plans to perform targeted research to understand those uses, which may inform identification of release scenarios. EPA may further refine the mapping of release scenarios based on factors (e.g., process equipment and handling, magnitude of production volume used, and release sources and usage

rates of 1,3-butadiene and polymer products and formulations containing 1,3-butadiene, or professional judgment) corresponding to conditions of use as additional information is identified during risk evaluation.

7) **Evaluate the weight of the scientific evidence of environmental release data.**
   During risk evaluation, EPA plans to evaluate and integrate the exposure evidence identified in the literature inventory using the methods described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document. The data integration strategy will be designed to be fit-for-purpose in which EPA plans to 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.

2.7.2.2 Environmental Exposures

EPA plans to analyze the following in developing its environmental exposure assessment of 1,3-butadiene:

1) **Review reasonably available environmental and biological monitoring data for all media relevant to environmental exposure.**
   For 1,3-butadiene, environmental media which EPA plans to evaluate are biosolids, sediment, soil, and water. EPA believes it is unlikely that 1,3-Butadiene will sorb to biosolids due to its volatility (vapor pressure and Henry's Law Constant), water solubility and unlikely sorption to sludge (Log Koc). This pathway will not be ruled out until further evaluation.

2) **Review reasonably available information on releases to determine how modeled estimates of concentrations near industrial point sources compare with reasonably available monitoring data.**
   Reasonably available environmental exposure models that meet the TSCA section 26(h) and (i) Science Standards and that estimate water, sediment, soil and biosolids concentrations will be analyzed and considered alongside reasonably available water, sediment, and soil monitoring data to characterize environmental exposures. Modeling approaches to estimate surface water concentrations, sediment concentrations, and soil concentrations generally, consider the following inputs: direct release into water, sediment, or soil, indirect release into water, sediment, or soil *(*i.e., air deposition), fate and transport (partitioning within media) and characteristics of the environment (e.g., river flow, volume of lake, meteorological data).

3) **Determine applicability of existing additional contextualizing information for any monitored data or modeled estimates during risk evaluation.**
   There have been changes to use patterns of 1,3-butadiene over the last few years. Monitoring data or modeled estimates will be reviewed to determine how representative they are of applicable use patterns.

   Any studies which relate levels of 1,3-butadiene in the environment or biota with specific sources or groups of sources will be evaluated.

4) **Group each condition(s) of use to environmental assessment scenario(s).**
   EPA plans to refine and finalize exposure scenarios for environmental receptors by considering sources (use descriptors), exposure pathways including routes, and populations exposed. For 1,3-

butadiene, the following are noteworthy considerations in constructing exposure scenarios for environmental receptors:

- Estimates of surface water concentrations, sediment concentrations, soil concentrations and biosolids concentrations near industrial point sources based on available monitoring data.
- Generally, consider the following modeling inputs: release into the media of interest, fate and transport and characteristics of the environment.
- Reasonably available biomonitoring data. Monitoring data could be used to compare with species or taxa-specific toxicological benchmarks.
- Applicability of existing contextualizing information for any monitored data or modeled estimates during risk evaluation. Review and characterize the spatial and temporal variability, to the extent that data are available, and characterize exposed aquatic and terrestrial populations.
- Weight of the scientific evidence of environmental occurrence data and modeled estimates.

5) **Evaluate the weight of the scientific evidence of environmental occurrence data and modeled estimates.**
   During risk evaluation, EPA plans to evaluate and integrate the exposure evidence identified in the literature inventory using the methods described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document.

2.7.2.3 Occupational Exposures

EPA plans to analyze both worker and ONU exposures as follows:

1) **Review reasonably available exposure monitoring data for specific condition(s) of use.**
   EPA plans to review exposure data including workplace monitoring data collected by government agencies such as the Occupational Safety and Health Administration (OSHA) and the National Institute for Occupational Safety and Health (NIOSH), and monitoring data found in published literature. These workplace monitoring data include personal exposure monitoring data (direct exposures) and area monitoring data (indirect exposures).

   EPA has preliminarily reviewed reasonably available monitoring data collected by OSHA and NIOSH and will match these data to applicable conditions of use. EPA has also identified additional data sources that may contain relevant monitoring data for the various conditions of use. EPA plans to review these sources (identified in Table 2-6) and extract relevant data for consideration and analysis during risk evaluation.

   OSHA has established a permissible exposure limit (PEL) of 1 ppm 8-hour time-weighted average (TWA). The OSHA Short-Term Exposure Limit (STEL) for 1,3-Butadiene is 5 ppm (OSHA 2019). EPA plans to consider the influence of these regulatory limits on occupational exposures in the occupational exposure assessment. The following are some data sources identified thus far:

Table 2-6. Potential Sources of Occupational Exposure Data

2012 ATSDR Toxicological Profile for 1,3-Butadiene
U.S. OSHA Chemical Exposure Health Data (CEHD) program data
U.S. NIOSH Health Hazard Evaluation (HHE) Program reports

2) **Review reasonably available exposure data for surrogate chemicals that have uses, volatility and chemical and physical properties similar to 1,3-butadiene.**
EPA plans to review literature sources identified and if surrogate data are found, these data will be matched to applicable conditions of use for potentially filling data gaps. For several conditions of use (e.g., monomer in polymer manufacturing), EPA believes monomers utilized in similar ways to 1,3-butadiene may serve as surrogates for 1,3-butadiene.

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 ESDs and EPA GS corresponding to some conditions of use. For example, the ESD on Additives in Rubber Industry, the ESD on Plastics Additives, the ESD on Chemical Industry, the Petroleum Refining Processing, Crude Separation Process, and Catalytic Cracking GS, and the Synthetic Fiber Manufacture GS are some of the ESDs and GS's that EPA may use to estimate occupational exposures. EPA plans to critically review these generic scenarios and ESDs to determine their applicability to the conditions of use. EPA was not able to identify ESDs or GS's corresponding to some conditions of use, including use of 1,3-butadiene in automotive care products and recycling of 1,3-butadiene. EPA plans to perform additional targeted research to 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.

4) **Review reasonably available data that may be used in developing, adapting or applying exposure models to a particular risk evaluation scenario.**
This step will be performed after Steps #2 and #3 are completed. Based on information developed from Steps #2 and #3, EPA plans to evaluate 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). EPA may utilize existing, peer-reviewed exposure models developed by EPA or other government agencies, or reasonably available in the scientific literature, or EPA may elect to develop additional models to assess specific condition(s) of use. Inhalation exposure models may be simple box models or two-zone (near-field/far-field) models. In two-zone models, the near-field exposure represents potential inhalation exposures to workers, and the far-field exposure represents potential inhalation exposures to ONU's.

5) **Consider and incorporate applicable EC and/or PPE into exposure scenarios.**
EPA plans to review potentially relevant data sources on EC and PPE to determine their applicability and incorporation into exposure scenarios during risk evaluation. EPA plans to assess worker exposure pre- and post-implementation of EC, using reasonably available information on available control technologies and control effectiveness. For example, EPA may assess worker exposure in industrial use scenarios before and after implementation of local exhaust ventilation.

6) **Map or group each condition of use to occupational exposure assessment scenario(s).**
EPA has identified occupational exposure scenarios and mapped them to relevant conditions of use (see 2.8Appendix F). As presented in the fourth column in Table_Apx F-1. Worker and Occupational Non-User Exposure Conceptual Model Supporting Table, EPA has grouped the scenarios into representative release/exposure scenarios. EPA was not able to identify occupational scenarios corresponding to some conditions of use. EPA plans to perform targeted

research to understand those uses which may inform identification of occupational exposure scenarios. EPA may further refine the mapping 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) **Evaluate the weight of the scientific evidence of occupational exposure data, which may include qualitative and quantitative sources of information.**
During risk evaluation, EPA plans to evaluate and integrate the exposure evidence identified in the literature inventory using the methods described in the systematic review document that EPA plans to publish prior to finalizing the scope document. EPA plans to rely on the weight of the scientific evidence when evaluating and integrating occupational data. The data integration strategy will be designed to be fit-for-purpose in which EPA plans to 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.

2.7.2.4 Consumer Exposures

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

1) **Group each condition of use to consumer exposure assessment scenario(s).**
Refine and finalize exposure scenarios for consumers by considering combinations of sources (ongoing consumer uses), exposure pathways including routes, and exposed populations.

   For 1,3-butadiene, the following are noteworthy considerations in constructing consumer exposure scenarios:
   - Conditions of use and type of consumer product
   - Duration, frequency and magnitude of exposure
   - Weight fraction of chemical in products
   - Amount of chemical used

2) **Evaluate the relative potential of indoor exposure pathways based on reasonably available data.**
Indoor exposure pathways expected to be relatively higher include inhalation of vapors from indoor air during 1,3-butadiene use and disposal. Indoor exposure pathways expected to be relatively lower include dermal contact to liquid dermal contact to liquid. The data sources associated with these respective pathways have not yet been comprehensively evaluated, so quantitative comparisons across exposure pathways or in relation to toxicity thresholds are not yet available.

3) **Review existing indoor exposure models that may be applicable in estimating indoor air concentrations.**
Indoor exposure models that estimate emissions from consumer products are available. These models generally consider p-chem properties (e.g., vapor pressure, molecular weight), product specific properties (e.g., weight fraction of the chemical in the product), use patterns (e.g., duration and frequency of use), user environment (e.g., room of use, ventilation rates), and receptor characteristics (e.g., exposure factors, activity patterns). The OPPT's Consumer Exposure Model (CEM) and other similar models can be used to estimate indoor air exposures from consumer products.

4) **Review reasonably available empirical data that may be used in developing, adapting or applying exposure models to a particular risk evaluation scenario. 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 1,3-butadiene consumer exposure scenario that is relevant to the OPPT's assessment, EPA plans to evaluate those modeled estimates. In addition, if other chemicals similar to 1,3-butadiene have been modeled for similar uses, those modeled estimates will also be evaluated. The underlying parameters and assumptions of the models will also be evaluated.

5) **Review reasonably available consumer product-specific sources to determine how those exposure estimates compare with each other and with indoor monitoring data reporting 1,3-butadiene in specific media (e.g., indoor air).**
   The availability of 1,3-butadiene concentration for various ongoing uses will be evaluated. This data provides the source term for any subsequent indoor modeling. Source attribution between overall indoor air levels and various indoor sources will be analyzed.

6) **Review reasonably available population- or subpopulation-specific exposure factors and activity patterns to determine if PESS need to be further refined.**
   During risk evaluation, EPA plans to evaluate and integrate the exposure evidence identified in the literature inventory using the methods described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document.

7) **Evaluate the weight of the scientific evidence of consumer exposure estimates based on different approaches.**
   EPA plans to rely on the weight of the scientific evidence when evaluating and integrating data related to consumer exposure. The weight of the scientific evidence may include qualitative and quantitative sources of information. The data integration strategy will be designed to be fit-for-purpose in which EPA plans to 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.

2.7.2.5 General Population

EPA plans to analyze general population exposures as follows:

While the primary route of exposure to 1,3-butadiene is inhalation, the general population may be exposed via the oral route (i.e., fish ingestion). Dermal exposures to the general population are expected to be negligible. However, depending on information identified and evaluated through EPA's systematic review process, exposure through dermal routes may be considered in the risk evaluation of 1,3-butadiene (NTP 2016, ATSDR 2012).

1) **Refine and finalize exposure scenarios for general population by considering combinations of sources and uses, exposure pathways including routes, and exposed populations.**
   For 1,3-butadiene, the following are noteworthy considerations in constructing exposure scenarios for the general population: routes of exposure, releases to air, water or land resulting from industrial, commercial, and other conditions of use, in addition to:
   - Reviewing reasonably available environmental and biological monitoring data for media to which general population exposures are expected.

- For exposure pathways where data are not reasonably available, reviewing existing exposure models that may be applicable in estimating exposure levels.
- Considering and incorporating applicable media-specific regulations into exposure scenarios or modeling.
- Reviewing 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 reasonably available.
- Reviewing reasonably available information on releases to determine how modeled estimates of concentrations near industrial point sources compare with reasonably available monitoring data.
- Reviewing reasonably available population- or subpopulation-specific exposure factors and activity patterns to determine if PESS need to be further defined.
- Evaluating the weight of the scientific evidence of general population exposure data. Mapping or grouping each condition of use to general population exposure assessment scenario(s).

EPA plans to evaluate 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 plans to 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 G. 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 reasonably available data and approaches. For example, EPA may consider the co-location of TSCA industrial facilities with reasonably available monitoring data or modeled estimates. EPA may compare modeled estimates for discrete outdoor and indoor sources/uses that apply to unique receptor groups.

After refining and finalizing exposure scenarios, EPA plans to quantify concentrations and/or doses for these scenarios. The number of scenarios will depend on how combinations of uses, exposure pathways, and receptors are characterized. The number of scenarios is also dependent upon the reasonably 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 reasonably available without a significant number of additional inputs or assumptions, and may be qualitative, semi-quantitative, or quantitative. 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) **For exposure pathways where empirical data is not reasonably available, review existing exposure models that may be applicable in estimating exposure levels.**
For 1,3-butadiene, media where exposure models will be considered for general population exposure include models that estimate surface water concentrations, sediment concentrations,

soil concentrations, and uptake from aquatic and terrestrial environments into edible aquatic and terrestrial organisms.

3) **Review reasonably available exposure modeled estimates. For example, existing models developed for a previous 1,3-butadiene chemical assessment may be applicable to EPA's assessment. In addition, another chemical's assessment may also be applicable if model parameter data are available.**
   To the extent other organizations have already modeled 1,3-butadiene general population exposure scenario that is relevant to this assessment, EPA plans to evaluate those modeled estimates. In addition, if modeled estimates for other chemicals with similar physical chemical properties and similar uses are available, those modeled estimates will also be evaluated. The underlying parameters and assumptions of the models will also be evaluated.

4) **Review reasonably available information on releases to determine how modeled estimates of concentrations near industrial point sources compare with reasonably available monitoring data.**
   The expected releases from industrial facilities are changing over time. Any modeled concentrations based on recent release estimates will be carefully compared with reasonably available monitoring data to determine representativeness.

5) **Review reasonably available information about population- or subpopulation-specific exposure factors and activity patterns to determine if PESS need to be further defined (e.g., early life and/or puberty as a potential critical window of exposure).**
   For 1,3-butadiene, exposure scenarios that involve PESS will consider age-specific behaviors, activity patterns, and exposure factors unique to those subpopulations. For example, children will have different intake rates for soil than adults.

6) **Evaluate the weight of the scientific evidence of general population exposure estimates based on different approaches.**
   During risk evaluation, EPA plans to evaluate and integrate the exposure evidence identified in the literature inventory using the methods described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document.

2.7.3 Hazards (Effects)

2.7.3.1 Environmental Hazards

If EPA identifies hazards through the current systematic review methods and public input, EPA plans to conduct an environmental hazard assessment of 1,3-butadiene as follows:

1) **Review reasonably available environmental hazard data, including data from alternative test methods (e.g., computational toxicology and bioinformatics; high-throughput screening methods; data on categories and read-across; in vitro studies).**
   EPA plans to analyze the hazards of 1,3-butadiene to aquatic and/or terrestrial organisms, including plants, invertebrates (e.g., insects, arachnids, mollusks, crustaceans), and vertebrates (e.g., mammals, birds, amphibians, fish, reptiles) across exposure durations and conditions if potential environmental hazards are identified through systematic review results and public comments. Additional types of environmental hazard information will also be considered (e.g.,

analogue and read-across data) when characterizing the potential hazards of 1,3-butadiene to aquatic and/or terrestrial organisms.

Environmental hazard data will be evaluated using the environmental toxicity data quality criteria outlined in the systematic review documentation that EPA plans to publish prior to finalizing the scope document. The study evaluation results will be documented in the risk evaluation phase and data from suitable studies will be extracted and integrated in the risk evaluation process.

Hazard endpoints (e.g., mortality, growth, immobility, reproduction) will be evaluated, while considering data availability, relevance, and quality.

2) **Derive hazard thresholds for aquatic and/or terrestrial organisms.**
Depending on the robustness of the evaluated data for a particular organism or taxa (e.g., aquatic invertebrates), environmental hazard values (e.g., EC_x, LC_x, NOEC, LOEC) may be derived and used to further understand the hazard characteristics of 1,3-butadiene to aquatic and/or terrestrial species. Identified environmental hazard thresholds may be used to derive concentrations of concern (COC), based on endpoints that may affect populations of organisms or taxa analyzed.

3) **Evaluate the weight of scientific evidence of environmental hazard data.**
During risk evaluation, EPA plans to evaluate and integrate the environmental hazard evidence identified in the literature inventory using the methods described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document.

4) **Consider the route(s) of exposure, based on reasonably available monitoring and modeling data and other available approaches to integrate exposure and hazard assessments.**
EPA plans to consider aquatic (e.g., water and sediment exposures) and terrestrial pathways in the 1,3-butadiene conceptual model. These organisms may be exposed to 1,3-butadiene via a number of environmental pathways (e.g., surface water, sediment, soil, diet).

5) **Conduct an environmental risk characterization of 1,3-butadiene.**
EPA plans to conduct a risk characterization of 1,3-butadiene to identify if there are risks to the aquatic and/or terrestrial environments from the measured and/or predicted concentrations of 1,3-butadiene in environmental media (i.e., water, sediment, soil). Risk quotients (RQs) may be derived by the application of hazard and exposure benchmarks to characterize environmental risk (U.S. EPA, 1998; Barnthouse et al., 1982).

6) **Consider a Persistent, Bioaccumulative, and Toxic (PBT) Assessment of 1,3-butadiene.**
EPA plans to consider the persistence, bioaccumulation, and toxic (PBT) potential of 1,3-butadiene after reviewing relevant physical-chemical properties and exposure pathways. EPA plans to assess the reasonably available studies collected from the systematic review process relating to bioaccumulation and bioconcentration (e.g., BAF, BCF) of 1,3-butadiene. In addition, EPA plans to integrate traditional environmental hazard endpoint values (e.g., LC_{50}, LOEC) and exposure concentrations (e.g., surface water concentrations, tissue concentrations) for 1,3-butadiene with the fate parameters (e.g., BAF, BCF, BMF, TMF).

2.7.3.2 Human Health Hazards

EPA plans 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).**
EPA plans to use systematic review methods to evaluate the epidemiological and toxicological literature for 1,3-butadiene. EPA plans to publish the systematic review documentation prior to finalizing the scope document.

Relevant mechanistic evidence will also be considered, if reasonably available, to inform the interpretation of findings related to potential human health effects and the dose-repose assessment. Mechanistic data may include analyses of alternative test data such as novel *in vitro* test methods and high throughput screening. The association between acute and chronic exposure scenarios to the agent and each health outcome will also be integrated. Study results will be extracted and presented in evidence tables or another appropriate format by organ/system.

2) **In evaluating reasonably available data, determine whether particular human receptor groups may have greater susceptibility to the chemical's hazard(s) than the general population.**
Reasonably available human health hazard data will be evaluated to ascertain whether some human receptor groups may have greater susceptibility than the general population to 1,3-butadiene hazard(s). Susceptibility of particular human receptor groups to 1,3-butadiene will be determined by evaluating information on factors that influence susceptibility.

EPA has reviewed some sources containing hazard information associated with PESS and lifestages such as pregnant women and infants. Pregnancy (i.e., gestation) and childhood are potential susceptible lifestages for 1,3-butadiene exposure. EPA plans to review the current state of the literature in order to potentially quantify these differences for risk evaluation purposes.

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 identified human health hazard endpoints.**
Human health hazards from acute and chronic exposures will be identified by evaluating the human and animal data that meet the systematic review data quality criteria described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document. Hazards identified by studies meeting data quality criteria will be grouped by routes of exposure relevant to humans (e.g., 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 may be used if the data meet data quality criteria and if additional information on the identified hazard endpoints are not available or would not alter the analysis.
The cancer mode of action (MOA) determines how cancer risks can be quantitatively evaluated. If cancer hazard is determined to be applicable to 1,3-butadiene, EPA plans to evaluate information on genotoxicity and the mode of action for all cancer endpoints to determine the appropriate approach for quantitative cancer assessment in accordance with the U.S. EPA Guidelines for Carcinogen Risk Assessment (U.S. EPA, 2005).

4) **Derive points of departure (PODs) where appropriate; conduct benchmark dose modeling depending on the reasonably 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 EPA's *Benchmark Dose Technical Guidance Document*. Where dose-response modeling is not feasible, NOAELs or LOAELs will be identified. Non-quantitative data will also be evaluated for contribution to weight of the scientific evidence or for evaluation of qualitative endpoints that are not appropriate for dose-response assessment.

   EPA plans to 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 standard exposure durations (e.g., lifetime continuous exposure). If application of the PBPK model is not possible, oral PODs may be adjusted by $BW^{3/4}$ scaling in accordance with U.S. EPA (2011), and inhalation PODs may be adjusted by exposure duration and chemical properties in accordance with U.S. EPA (1994).

5) **Evaluate the weight of the scientific evidence of human health hazard data.**
During risk evaluation, EPA plans to evaluate and integrate the human health hazard evidence identified in the literature inventory under acute and chronic exposure conditions using the methods described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document.

6) **Consider the route(s) of exposure (oral, inhalation, dermal), available route-to-route extrapolation approaches, reasonably available biomonitoring data and available approaches to correlate internal and external exposures to integrate exposure and hazard assessment.**
At this stage of review, EPA believes there will be sufficient data to conduct a dose-response analysis and/or benchmark dose modeling for the oral route of exposure. EPA plans to also evaluate any potential human health hazards following dermal and inhalation exposure to 1,3-butadiene, which could be important for the worker, consumer, and general population risk analyses. Reasonably available data will be assessed to determine whether or not a POD can be identified for the dermal and inhalation routes. This may include using route-to-route extrapolation methods, where appropriate and depending on the nature of available data.

   If sufficient toxicity studies are not identified in the literature search to assess risks from dermal and inhalation exposures, then a route-to-route extrapolation from oral toxicity studies would be needed to assess systemic risks from dermal or inhalation exposures. Without an adequate PBPK model, the approaches described in 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, 2004) could be applied to extrapolate from oral to dermal exposure. These approaches may be able to further inform the relative importance of dermal exposures compared with other routes of exposure. Similar methodology may also be used for assessing inhalation exposures

2.7.4 Summary of Risk Approaches for Characterization

Risk characterization is an integral component of the risk assessment process for both environmental and human health risks. EPA plans to 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.

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 (U.S. EPA, 2000) and consistent with the requirements of the *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act* (82 FR 33726). For instance, in the risk characterization summary, EPA plans to further carry out the requirements 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 plans to be guided by EPA's Information Quality Guidelines (U.S. EPA 2002) as it provides guidance for presenting risk information. Consistent with those guidelines, EPA plans to identify in the risk characterization the following: (1) Each population addressed by an estimate of applicable risk effects; (2) The expected risk or central estimate of risk for the PESS 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.

2.8 Peer Review

Peer review will be conducted in accordance with EPA's regulatory procedures for chemical risk evaluations, including using EPA's Peer Review Handbook and other methods consistent with section 26 of TSCA (See 40 CFR 702.45). As explained in the preamble to the Risk Evaluation Rule, the purpose of peer review is for the independent review of the science underlying the risk assessment (See 82 Fed. Reg. 33726, 33744 (July 12, 2017). Peer review will therefore address aspects of the underlying science as outlined in the charge to the peer review panel such as hazard assessment, assessment of dose-response, exposure assessment, and risk characterization. The draft risk evaluation for 1,3-butadiene will be peer reviewed.

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APPENDICES

Appendix A LIST OF GRAY LITERATURE SOURCES

Table Apx A-1 provides a list of gray literature sources that yielded results for 1,3-Butadiene.

Table_Apx A-1 Gray Literature Sources for 1,3-Butadiene

Source / Agency	Source Name	Source Type	Source Category
ATSDR	ATSDR Tox Profile Updates and Addendums	Other US Agency Resources	Assessment or Related Document
ATSDR	ATSDR Toxicological Profiles (original publication)	Other US Agency Resources	Assessment or Related Document
Australian Government Department of Health	NICNAS Assessments (human health, Tier I, II or III)	International Resources	Assessment or Related Document
CAL EPA	Technical Support Documents for regulations: Cancer Potency Information	Other US Agency Resources	Assessment or Related Document
CAL EPA	Technical Support Documents for regulations: Reference Exposure Levels (RELs)	Other US Agency Resources	Assessment or Related Document
ECHA	European Union Risk Assessment Report	International Resources	Assessment or Related Document
ECHA	ECHA Documents	International Resources	Assessment or Related Document
Env Canada	Priority Substances List Assessment Report; State of Science Report, Environment Canada Assessment	International Resources	Assessment or Related Document
EPA	Office of Water: STORET and WQX	US EPA Resources	Database
EPA	Office of Air: TRI	US EPA Resources	Database
EPA	Office of Air: AQS, Annual	US EPA Resources	Database

Source / Agency	Source Name	Source Type	Source Category
EPA	TSCA Hazard Characterizations	US EPA Resources	Assessment or Related Document
EPA	IRIS Summary	US EPA Resources	Assessment or Related Document
EPA	Office of Air: National Emissions Inventory (NEI) Data (2014, 2011, 2008)	US EPA Resources	Database
EPA	Other EPA: Misc sources	US EPA Resources	General Search
EPA	EPA: AP-42	US EPA Resources	Regulatory Document or List
EPA	TRI: Envirofacts Toxics Release Inventory 2017 Updated Dataset	US EPA Resources	Database
EPA	Chemical Data Reporting (2012 and 2016 non-CBI CDR database)	US EPA Resources	Database
EPA	Chemical Data Reporting (2012 and 2016 CBI CDR database)	US EPA Resources	Database
EPA	EPA: Generic Scenario	US EPA Resources	Assessment or Related Document
EPA	EPA Discharge Monitoring Report Data	US EPA Resources	Database
EPA	EPA Ambient Monitoring Technology Information Center – Air Toxics Data	US EPA Resources	Database
EPA	IRIS Tox Review	US EPA Resources	Assessment or Related Document
EPA	Office of Water: CFRs	US EPA Resources	Regulatory Document or List
EPA	Office of Air: CFRs and Dockets	US EPA Resources	Regulatory Document or List
IARC	IARC Monograph	International Resources	Assessment or Related Document
Japan	Japanese Ministry of the Environment Assessments - Environmental Risk	International Resources	Regulatory Document or List

Source / Agency	Source Name	Source Type	Source Category
	Assessments (Class I Designated Chemical Substances Summary Table)		
KOECT	Kirk-Othmer Encyclopedia of Chemical Technology Journal Article	Other Resource	Encyclopedia
NIOSH	CDC NIOSH - Occupational Health Guideline Documents	Other US Agency Resources	Assessment or Related Document
NIOSH	CDC NIOSH - Pocket Guides	Other US Agency Resources	Database
NIOSH	CDC NIOSH - Health Hazard Evaluations (HHEs)	Other US Agency Resources	Assessment or Related Document
NIOSH	CDC NIOSH - Workplace Survey Reports	Other US Agency Resources	Assessment or Related Document
NIOSH	CDC NIOSH - Publications and Products	Other US Agency Resources	Assessment or Related Document
NLM	National Library of Medicine's Hazardous Substance Databank	Other US Agency Resources	Database
NLM	National Library of Medicine's HazMap	Other US Agency Resources	Database
NTP	OHAT Monographs	Other US Agency Resources	Assessment or Related Document
NTP	RoC Monographs	Other US Agency Resources	Assessment or Related Document
NTP	Technical Reports	Other US Agency Resources	Assessment or Related Document
OECD	OECD Emission Scenario Documents	International Resources	Assessment or Related Document
OECD	OECD: General Site	International Resources	General Search
OSHA	U.S. OSHA Chemical Exposure Health Data (CEHD) program data [ERG]	Other US Agency Resources	Database
TERA	Toxicology Excellence for Risk Assessment	Other Resources	Assessment or Related Document

Appendix B PHYSICAL AND CHEMICAL PROPERTIES OF 1,3-BUTADIENE

This appendix provides p-chem information and data found in preliminary data gathering for 1,3-butadiene. Table_Apx B-1 summarizes the p-chem property values preliminarily selected for use in the risk evaluation from among the range of reported values collected as of March 2020. This table differs from that presented in the *Proposed Designation of 1,3-Butadiene (CASRN 106-99-0) as a High-Priority Substance for Risk Evaluation* (U.S. EPA 2019a) and may be updated as EPA collects additional information through systematic review methods. All p-chem property values that were extracted and evaluated as of March 2020 are presented in the supplemental file *Data Extraction and Data Evaluation Tables for Physical Chemical Property Studies* (EPA-HQ-OPPT-2018-0451).

Table_Apx B-1 Physical and Chemical Properties of 1,3-Butadiene

Property or Endpoint	Value[a]	Reference	Data Quality Rating
Molecular formula	C_4H_6	NA	NA
Molecular weight	54.09 g/mol	NA	NA
Physical state	Colorless gas	Rumble, 2018	High
Physical properties	Colorless, mildly aromatic or gasoline-like odor	NLM, 2003	High
Melting point	-108.966°C	O'Neil, 2013	High
Boiling point	-4.5°C at 760 mm Hg	O'Neil, 2013	High
Density	0.6149 g/cm^3 at 25°C and >1 atm	Rumble, 2018	High
Vapor pressure	2110 mm Hg	U.S. EPA, 2019	High
Vapor density	1.87 (air = 1)	NLM, 2003	High
Water solubility	735 mg/L at 20°C	NLM, 2003	High
Log Octanol/water partition coefficient (Log Kow)	1.99 at 25°C	Rumble, 2018	High
Henry's Law constant	0.204 atm·m^3/mol at 25°C	Rumble, 2018	High

Property or Endpoint	Value[a]	Reference	Data Quality Rating
Flash point	-76.111°C	RSC, 2019	High
Auto flammability	420°C	Rumble, 2018	High
Viscosity	0.00754 cP at 20°C	NLM, 2003	High
Refractive index	1.4292	Rumble, 2018	High
Dielectric constant	2.050	Rumble, 2018	High

[a] Measured unless otherwise noted.
NA = Not applicable

Appendix C ENVIRONMENTAL FATE AND TRANSPORT PROPERTRIES

Table Apx C-1 provides the environmental fate characteristics that EPA identified and considered in developing the scope for 1,3-butadiene.

Table_Apx C-1. Environmental Fate Characteristics of 1,3-Butadiene

Property or Endpoint	Value	Reference
Direct Photodegradation	Absorbs at wavelengths >290 nm, and therefore, may be susceptible to direct photolysis by sunlight	PubChem (2020)
	The primary pathway of destruction of 1,3-butadiene is likely to occur by photo-initiated bimolecular processes rather than direct photochemical degradation	ATSDR (2012); Kopczynski et al. (1972)
Indirect Photodegradation	$t_{1/2}$ = 3.7 hours (based on a 12-hour day with 1.5 × 10^6 OH/cm^3 and hydroxyl radical reaction rate constant of 6.93 × 10^{-11} cm^3/molecule-sec at 25 °C)	PubChem (2020)
	$t_{1/2}$ = 5.6 hours (based on a 12-hour day with 5 × 10^5 molecules OH /cm^3 and hydroxyl radical reaction rate constant of 6.93 × 10^{-11} cm^3/molecule-sec at 25 °C) Major products formed from the reaction include acrolein and formaldehyde	ATSDR (2012) citing Atkinson (1989) and Baker et al. (2005)
	$t_{1/2}$ = 1.4–1.7 days (based on a 12-hour day with 7 × 10^{11} molecules ozone/cm^3 and an ozone reaction rate constant of 6.7 × 10^{-18} cm^3/molecule-sec at 25 °C) Major products formed from the reaction of 1,3-butadiene with ozone are acrolein, formaldehyde, acetylene, ethylene, and formic anhydride	PubChem (2020); ATSDR (2012) citing Atkinson and Carter (1984)
	$t_{1/2}$ = 14.9 hours (based on a 12-hour day with 2.4 × 10^8 nitrate molecules/cm^3 and a nitrate radical reaction rate constant of 5.4 × 10^{-14} cm^3/molecule-sec at 22 °C) Acrolein was identified as the major product of this reaction	PubChem (2020); ATSDR (2012) citing Atkinson et al. (1984)

Hydrolysis	Not expected to hydrolyze due to lack of hydrolysable functional groups	ECB (2002)
	Metabolic byproducts of 1,3-butadiene can be hydrolyzed rapidly	ATSDR (2012) citing Kirman (2010)
Biodegradation	0–4%/28 days (based on OECD 301C study with 1-drop of sludge/L)[b]	NITE (2019)
	Biodegradation of 1,3-butadiene in water and soil proceeds through oxidation to form 3,4-epoxy-1-butene, a potent electrophile (with pure cultures)	ATSDR (2012) citing Hou et al. (1979); Patel et al. (1982), and Watkinson and Somerville (1976)
Wastewater Treatment	97% total removal (0.02% by biodegradation, 0.53% by sludge, 96% by volatilization to air; estimated)[b]	U.S. EPA (2012)
Bioconcentration Factor	10 (estimated)[c]	U.S. EPA (2012)
Bioaccumulation Factor	10 (estimated)[c]	U.S. EPA (2012)
Soil Organic Carbon:Water Partition Coefficient (Log K_{OC})	2.46	ATSDR (2012) citing Hansch et al. (1995) and Lyman et al. (1990)

[a]Measured unless otherwise noted
[b]OECD 301C may be an inappropriate test method for volatile substances if precautions are not taken to prevent sample loss
[c]EPI Suite™ physical property inputs: Log K_{OW} = 1.99, BP = -4.40 °C, MP = -108.90 °C, VP = 2110 mm Hg, WS = 735 mg/L SMILES C(C=C)=C

Appendix D REGULATORY HISTORY

The chemical substance, 1,3-butadiene, is subject to federal and state laws and regulations in the United States (Table_Apx D-1and Table_Apx D-2). Regulatory actions by other governments, tribes and international agreements applicable to 1,3-butadiene are listed in Table Apx_A-3.

D.1 Federal Laws and Regulations

Table_Apx D-1. Federal Laws and Regulations

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
Toxic Substances Control Act (TSCA) – Section 6(b)	EPA is directed to identify high-priority chemical substances for risk evaluation; and conduct risk evaluations on at least 20 high priority substances no later than three and one-half years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.	1,3-Butadiene is one of the 20 chemicals EPA designated as a High-Priority Substance for risk evaluation under TSCA (84 FR 71924, December 30, 2019). Designation of 1,3-butadiene as a high-priority substance constitutes the initiation of the risk evaluation on the chemical.
Toxic Substances Control Act (TSCA) – Section 8(a)	The TSCA section 8(a) 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 United States.	1,3-Butadiene manufacturing (including importing), processing, and use information is reported under the 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 (including imported) or processed in the United States.	1,3-Butadiene was on the initial TSCA Inventory and therefore was not subject to EPA's new chemicals review process under TSCA section 5 (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.	20 risk reports received for 1,3-butadiene (2017, 2011, 2008-2007, 2005, 2002-1997, 1995-1994, 1992, 1990) (U.S. EPA, ChemView. Accessed April 8, 2019).

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 TRI-listed chemical in quantities above threshold levels. A facility that meets reporting requirements must submit a reporting form for each chemical for which it triggered reporting, providing data across a variety of categories, including activities and uses of the chemical, releases and other waste management (e.g., quantities recycled, treated, combusted) and pollution prevention activities (under section 6607 of the Pollution Prevention Act). These data include on- and off-site data as well as multimedia data (i.e., air, land and water).	1,3-Butadiene is a listed substance subject to reporting requirements under 40 CFR 372.65, effective as of January 01, 1987.
Clean Air Act (CAA) – Section 112(b)	Defines the original list of 189 hazardous air pollutants (HAPs). Under 112(c) of the CAA, EPA must identify and list source categories that emit HAP and then set emission standards for those listed source categories under CAA section 112(d). CAA section 112(b)(3)(A) specifies that any person may petition the Administrator to modify the list of HAP by adding or deleting a substance. Since 1990, EPA has removed two pollutants from the original list leaving 187 at present.	1,3-Butadiene is listed as a HAP (42 U.S. Code section 7412).
Clean Air Act (CAA) – Section 112(d)	Directs EPA to establish, by rule, NESHAPs for each category or subcategory of listed major sources and area sources of HAPs (listed pursuant to Section 112(c)). For major sources, the standards must require the maximum degree of emission reduction that EPA	EPA has established NESHAPs for a number of source categories that emit 1,3-butadiene to air. (See https://www.epa.gov/stationary-sources-air-pollution/national-emission-standards-hazardous-air-pollutants-neshap-9)

	determines is achievable by each particular source category. This is generally referred to as maximum achievable control technology (MACT). For area sources, the standards must require generally achievable control technology (GACT) though may require MACT.	
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.	1,3-Butadiene is listed under the National Volatile Organic Compound Emission Standards for Aerosol Coatings (40 CFR part 59, subpart E). 1,3-Butadiene has a reactivity factor of 13.58 g O3/g VOC.
Safe Drinking Water Act (SDWA) – Section 1412(b)	Every 5 years, EPA must publish a list of contaminants that: (1) are currently unregulated, (2) are known or anticipated to occur in public water systems (PWSs) and (3) may require regulations under SDWA. EPA must also determine whether to regulate at least five contaminants from the list every 5 years.	1,3-Butadiene was identified on both the Third (2009) and Fourth (2016) Contaminant Candidate Lists (CCL) (74 FR 51850, October 8, 2009) (81 FR 81099, November 17, 2016).
Safe Drinking Water Act (SDWA) – Section 1445(a)	Every 5 years, EPA must issue a new list of no more than 30 unregulated contaminants to be monitored by PWSs. The data obtained must be entered into the National Drinking Water Contaminant Occurrence Database.	1,3-Butadiene was identified in the Third Unregulated Contaminant Monitoring Rule (UCMR3), issued in 2012 (77 FR 26071, May 2, 2012).
Comprehensive Environmental	Authorizes EPA to promulgate regulations designating as hazardous substances those substances which, when released	1,3-Butadiene is a hazardous substance under CERCLA. Releases of 1,3-butadiene in

Response, Compensation and Liability Act (CERCLA) – Sections 102(a) and 103	into the environment, may present substantial danger to the public health or welfare or the environment. EPA must also promulgate regulations establishing the quantity of any hazardous substance the release of which must be reported under Section 103. Section 103 requires persons in charge of vessels or facilities to report to the National Response Center if they have knowledge of a release of a hazardous substance above the reportable quantity threshold.	excess of 10 pounds must be reported (40 CFR 302.4).
Superfund Amendments and Reauthorization Act (SARA) –	Requires the Agency to revise the hazardous ranking system and update the National Priorities List of hazardous waste sites, increases state and citizen involvement in the superfund program and provides new enforcement authorities and settlement tools.	1,3-Butadiene is listed on SARA, an amendment to CERCLA and the CERCLA Priority List of Hazardous Substances. This list includes substances most commonly found at facilities on the CERCLA National Priorities List (NPL) that have been deemed to pose the greatest threat to public health.
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 (29 U.S.C section 651 et seq.). Under the Act, OSHA can issue occupational safety and health standards including such provisions as Permissible Exposure Limits (PELs), exposure monitoring, engineering and	OSHA established a PEL for 1,3-butadiene of 1 ppm / 5 ppm short-term exposure limit (STEL) as an 8-hour, TWA (29 CFR 1910.1051).

	administrative control measures, and respiratory protection.	

D.2 State Laws and Regulations

Table_Apx D-2. State Laws and Regulations

State Actions	Description of Action
State Air Regulations	Allowable Ambient Levels: New Hampshire (Env-A 1400: Regulated Toxic Air Pollutants). Rhode Island (Air Pollution Regulation No. 22).
State PELs	California (PEL of 1 ppm and a STEL of 5) (Cal Code Regs. Title 8, § 5155) Hawaii PEL: 1 ppm (Hawaii Administrative Rules section 12-60-50).
State Right-to-Know Acts	Massachusetts (105 Code Mass. Regs. § 670.000 Appendix A), New Jersey (N.J.A.C. 7:1G) and Pennsylvania (P.L. 734, No. 159 and 34 Pa. Code § 323).
Chemicals of High Concern to Children	Two states have adopted reporting laws for chemicals in children's products containing 1,3-butadiene, including Maine (38 MRSA Chapter 16-D) and Minnesota (Toxic Free Kids Act Minn. Stat. 116.9401 to 116.9407).
Other	California listed 1,3-butadiene on Proposition 65 in 1998 due to cancer, and in 2004 due to developmental toxicity and female/male reproductive toxicity. (Cal Code Regs. Title 27, § 27001). 1,3-Butadiene is listed as a Candidate Chemical under California's Safer Consumer Products Program established under Health and Safety Code § 25252 and 25253 (California, Candidate Chemicals List. Accessed April 15, 2019). California lists 1,3-butadiene as a designated priority chemical for biomonitoring under criteria established by California SB 1379 (Biomonitoring California, Priority Chemicals, February 2019). 1,3-Butadiene is on the MA Toxic Use Reduction Act (TURA) list of 2019 (301 CMR 41.00).

D.3 International Laws and Regulations

Table_Apx D-3. Regulatory Actions by other Governments, Tribes, and International Agreements

Country/Tribe/ Organization	Requirements and Restrictions
Canada	1,3-Butadiene is on the Canadian List of Toxic Substances (CEPA 1999 Schedule 1). Other regulations include: Canada's National Pollutant Release Inventory (NPRI) Part 1A as a VOC.
European Union	1,3-Butadiene is registered for use in the EU with no restrictions. CoRAP (Final) 1,3-Butadiene was evaluated under the 2014 Community rolling action plan (CoRAP) under regulation European Commission (EC) No1907/2006 - REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) ECHA database. Accessed April 10, 2019.
Australia	1,3-Butadiene was assessed under Human Health Tier II of the Inventory Multi-Tiered Assessment and Prioritisation (IMAP). Uses reported include: • Producing synthetic rubber (used to manufacture automotive tyres and tyre products); • Producing plastics such as acrylics, high impact polystyrene and acrylonitrile butadiene styrene (ABS) resin plastics, nylon and neoprene; • Producing resins; • Processing petroleum; • As a chemical intermediate in producing some fungicides; and • In manufacturing latex adhesives and paints. (NICNAS, 2013, Human Health Tier II assessment for 1,3-butadiene. Accessed April 16, 2019).
Japan	1,3-Butadiene 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 (Accessed April 10, 2019.)
Basel Convention	Solid Plastic Waste is listed as a category of waste under the Basel Convention. Although the United States is not currently a party to the Basel Convention, this treaty still affects U.S. importers and exporters.

Australia, Austria, Belgium, Canada, Denmark, European Union, Finland, France, Germany, Hungary, Ireland, Latvia, New Zealand, People's Republic of China, Poland, Romania, Singapore, South Korea, Spain, Sweden, Switzerland, The Netherlands, United Kingdom	Occupational exposure limits for 1,3-butadiene (GESTIS International limit values for chemical agents (Occupational exposure limits, OELs) database. (Accessed April 16, 2019.)

Appendix E PROCESS, RELEASE AND OCCUPATIONAL EXPOSURE INFORMATION

This appendix provides information and data found in preliminary data gathering for 1,3-butadiene.

E.1 Process Information

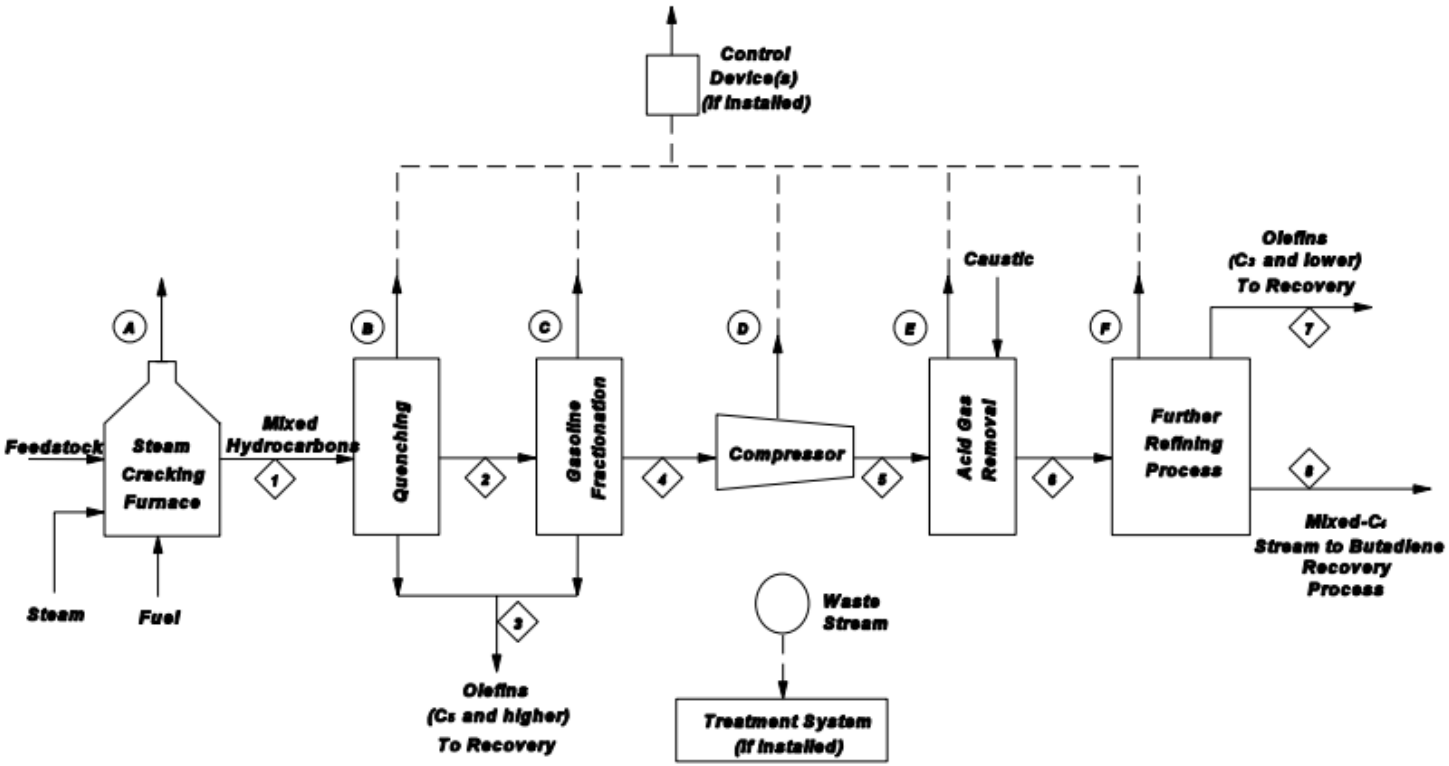
Process-related information potentially relevant to the risk evaluation may include process diagrams, descriptions and equipment. Such information may inform potential release sources and worker exposure activities. EPA plans to consider this information in combination with available monitoring data and estimation methods and models, as appropriate, to quantify occupational exposure and releases for the various conditions of use in the risk evaluation.

E.1.1 Manufacture (Including Import)

E.1.1.1 Domestic Manufacture

1,3 Butadiene can be produced by three processes: dehydrogenation of n-butane, oxydehydrogenation of n-butenes, and in the process of the steam cracking of hydrocarbon streams for ethylene production. The most common method is as a co-product during ethylene production (Sun, 2002). The process can use a variety of hydrocarbon feedstocks, the heavier fractions generally giving a higher 1,3-butadiene yield/amount of ethylene produced (Miller, 1978)

In the production process, the hydrocarbon feedstock is pre-heated and cracked in the presence of steam. The product then passes to a pyrolysis/quench system and additional refinery steps and a mixed C_4-hydrocarbon stream is obtained. Figure_Apx E-1 is provided as an example process flow diagram of the 1,3-butadiene manufacturing process. The 1,3-butadiene content in the 'crude butadiene' can be as high as 75% (ACC, 2019b). 1,3-Butadiene cannot normally be obtained from the mixed C_4-stream by simple distillation and so an extractive distillation process is often used. In this process, a polar solvent (e.g., furfural, acetonitrile, cuprous ammonium acetate, dimethylformamide, a furfural-methoxypropionitrile system, dimethylacetamide or *n*-methylpyrrolidone) is added in order to change the relative volatilities of the components of the mixture (Miller, 1978; Peterson et al., 1980; IARC, 1986).



Figure_Apx E-1. Process Flow Diagram of Manufacture of 1,3-butadiene via Steam Cracking of Hydrocarbons (EPA, 1996)

E.1.1.2 Import

According to (Sun, 2002), 1,3-butadiene is primarily shipped in pressurized containers via railroads or tankers. Other forms of transport include pipeline and barge (NTP, 1999). Uses of 1,3-butadiene are covered by other conditions of use including, but not limited to: processing as a reactant, and to form polymers for rubber and plastics manufacturing, formulated into processing aids and coatings, incorporated into plastic and rubber articles, and used as a laboratory chemical.

E.1.2 Processing and Distribution

Based on the reported industrial processing operations in the 2016 CDR, 1,3-butadiene may be incorporated into a variety of formulations, products and articles, or used industrially as a chemical intermediate (U.S. EPA, 2019). The main use being as a monomer to produce plastic and rubber products. Some industrial or commercial products may also be repackaged into appropriately-sized containers to meet specific customer demands (U.S. EPA, 2019).

E.1.2.1 Reactant or Intermediate

Polymerization of Butadiene

Processing as a reactant includes the polymerization of butadiene with itself or with other monomers (Sun, 2002). Some of the common polymers derived from the use of 1,3-butadiene as a monomer feedstock are:

- Polybutadiene
- Styrene-butadiene rubber
- Styrene-butadiene latex
- Acrylonitrile-butadiene-styrene polymer

The general process at polymerization sites is unloading of 1,3-butadiene, a washing or purification step to remove polymerization inhibitors, then the different monomers are added to the reactor. After completion of reaction, the content of unreacted monomer may vary depending on the reactions and additives used. Typically, this may be followed with a butadiene monomer recovery system to recycle 1,3 butadiene back to feed into the reactor. Polymer production can be done either via emulsion polymerization or solution polymerization depending on the end product use. The final polymer products may be packaged to sale to downstream users (EPA, 1996). This polymerization product is incorporated into various rubber and plastic articles as discussed below.

Chemical Intermediate

1,3-Butadiene has also been noted as a chemical intermediate for

- Ethylidene norbornene (EPA, 1996)
- Trans-1,4-hexadiene (EPA, 1996)
- Chloroprene (EPA, 1996)
- Sulfolane (EPA, 1996)
- Adiponitrile (EPA, 1996)
- in petrochemical manufacturing operations, including fuels (U.S. EPA, 2019).

E.1.2.2 Incorporated into a 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 single product or preparation. 1,3-Butatiene is used as processing aids and butadiene polymers are used in several petrochemical manufacturing operations, adhesives, lubricants and in formulated paints and coatings (U.S. EPA, 2019).

E.1.2.3 Incorporated into an Article

Incorporation into an article typically refers to a process in which a chemical becomes an integral component of an article (as defined at 40 CFR 704.3) for distribution in commerce. Exact process operations involved in the incorporation of 1.3-butadiene-containing formulations or reaction products are dependent on the article. EPA identified the following processing activities that incorporate 1,3-butadiene and 1,3-butadiene formulations or reaction products into articles.

Plastics and Rubber Product Manufacturing

1,3-Butadiene is used as a monomer or co-monomer in the manufacture of synthetic rubbers as described earlier. These synthetic rubbers and latex are used to manufacture tires, other rubber components and plastic materials (U.S. EPA, 2019).

In plastic manufacturing, the final plastic article is produced in a conversion process that forms the compounded plastic into the finished products (U.S. EPA, 2014; OECD, 2009). The converting process is different depending on whether the plastic is a thermoplastic or a thermosetting material (OECD, 2009). Thermoplastics converting involves the melting of the plastic material, forming it into a new shape and then cooling it (U.S. EPA, 2014; OECD, 2009). The converting of thermoplastics may involve extrusion, injection molding, blow molding, rotational molding or thermoforming (U.S. EPA, 2014; OECD, 2009).

Conversion of thermosetting materials involves using heat and pressure to promote curing, typically through cross-linking (OECD, 2009). The primary conversion process for thermosetting materials is compression molding; however, fiber reinforced thermosetting plastics are converted using hand layup, spray molding and filament winding (OECD, 2009). After the forming process, finishing operations such as filing, grinding, sanding, polishing, painting, bonding, coating and engraving are performed to complete the process (U.S. EPA, 2014).

E.1.2.4 Repackaging

Typical 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

E.1.2.5 Recycling

Recovery and recycling of unreacted 1,3-butadiene from the various synthetic rubber manufacturing operations is common. 1,3-Butadiene and other monomers (such as styrene) are recovered and reused in rubber manufacturing to the extent possible (ECB, 2002).

E.1.3 Other Uses

Other Industrial Uses

Based on information identified in *Use Report: 1,3-Butadiene*, a variety of other industrial uses may exist for may exist for chemicals, synthetic rubbers, and thermoplastics derived from 1,3-butadiene, including: adhesives and sealants and laboratory chemicals. There are unconfirmed uses of 1,3-butadiene in fabric, textile, and leather products. More information on these uses will be gathered through expanded literature searches in subsequent phases of the risk evaluation process.

Other Commercial/Consumer Uses

Based on information identified in *High Priority Chemical: Use Report: 1,3-Butadiene*, a variety of other commercial and consumer uses may exist for chemicals, synthetic rubbers, and thermoplastics derived from 1,3-butadiene, including: paints and coatings, lubricants, and automotive care products.

There are unconfirmed uses of 1,3-butadiene in propellants/blowing agents. Similar to the "Other" industrial uses, more information on these uses will be gathered through expanded literature searches in subsequent phases of the risk evaluation process.

E.1.4 Disposal

1,3-Butadiene is not listed as a hazardous waste under RCRA. Incineration is the recommended waste management method for 1,3-butadiene (HSDB, 2009). TRI data indicate 1,3-butadiene may be land disposed, deep well injected, or discharged to water following pretreatment (TRI, 2017).

E.2 Preliminary Occupational Exposure Data

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

Table Apx E-1 summarizes NIOSH Health Hazard Evaluations identified during EPA's preliminary data gathering.

Table_Apx E-1. Summary of NIOSH HHEs with Monitoring for 1,3-Butadiene[a]

Year of Publication	Report Number	Facility Description
1990	HETA-90-198-L2060	Polymer manufacturing
1980	HE-80-188-797	Plastic products manufacturing
1980	HE-79-36-656	Plastic helmet manufacturing
1979	HE-78-110-585	Plastic aircraft parts manufacturing
1977	HE-77-1-426	Rubber manufacturing
1976	HE-74-120-260	Rubber tire manufacturing
1973	HE-72-86-38	Rubber hose manufacturing

[a] Table includes HHEs identified to date

Table Apx E-2 summarizes OSHA CEHD identified during EPA's preliminary data gathering.

Table_Apx E-2. Summary of Industry Sectors with 1,3-Butadiene Monitoring Samples Available from OSHA Inspections Conducted Between 2010 and 2019

NAICS	NAICS Description	Number of Data Points
No NAICS code reported		16
236220	Commercial and Institutional Building Construction	2
324110	Petroleum Refineries	4
325212	Synthetic Rubber Manufacturing	1

NAICS	NAICS Description	Number of Data Points
326121	Unlaminated Plastics Profile Shape Manufacturing	3
326122	Plastics Pipe and Pipe Fitting Manufacturing	1
326199	All Other Plastics Product Manufacturing	13
326212	Tire Retreading	14
326220	Rubber and Plastics Hoses and Belting Manufacturing	15
326291	Rubber Product Manufacturing for Mechanical Use	8
332323	Ornamental and Architectural Metal Work Manufacturing	8
333220	Plastics and Rubber Industry Machinery Manufacturing	4
337215	Showcase, Partition, Shelving, and Locker Manufacturing	9
453998	All Other Miscellaneous Store Retailers (except Tobacco Stores)	2
611310	Colleges, Universities, and Professional Schools	17
926150	Regulation, Licensing, and Inspection of Miscellaneous Commercial Sectors	3

Appendix F SUPPORTING INFORMATION – CONCEPTUAL MODEL FOR INDUSTRIAL AND COMMERCIAL ACTIVITIES AND USES

Table_Apx F-1. Worker and Occupational Non-User Exposure Conceptual Model Supporting Table

Life-Cycle Stage	Category	Subcategory	Release/Exposure Scenario	Exposure Pathway	Exposure Route	Receptor	Plans to Evaluate	Rationale
Manufacturing	Domestic manufacturing	Domestic manufacturing	Manufacturing of 1,3-butadiene	Liquid Contact	Dermal	Worker	Yes	1,3-Butadiene is expected to be handle as liquid under pressure[8]. EPA plans to evaluate dermal exposure.
				Vapor	Inhalation	Worker	Yes	1,3-Butadiene is volatile at room temperature, EPA plans to evaluate the inhalation exposure.
				Liquid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
				Vapor	Inhalation	ONU	Yes	1,3-Butadiene is volatile at room temperature, EPA plans to evaluate the inhalation exposure.
				Mist	Dermal/ Inhalation	Workers, ONU	No	Mist generation not expected during manufacturing.

[8] EPA expects the process to be enclosed to avoid exposure to air that can cause formation of polymeric peroxides as well as based on its volatility (Sun, 2002; EPA, 1996), potential exposure to workers from loading and sampling activities could occur. However, review of preliminary data sources suggest exposure by dermal contact may be limited for these processes, information collected through systematic review methods and public comments will help inform this exposure pathway.

Life-Cycle Stage	Category	Subcategory	Release/Exposure Scenario	Exposure Pathway	Exposure Route	Receptor	Plans to Evaluate	Rationale
Manufacturing	Importing	Importing	Repackaging of import containers	Liquid Contact	Dermal	Worker	Yes	Dermal exposure may occur if there is repackaging. EPA plans to evaluate dermal exposure.
				Vapor	Inhalation	Worker	Yes	1,3-Butadiene is volatile at room temperature, EPA plans to evaluate the inhalation exposure.
				Liquid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
				Vapor	Inhalation	ONU	Yes	1,3-Butadiene is volatile at room temperature, EPA plans to evaluate the inhalation route.
				Mist	Dermal/ Inhalation	Workers, ONU	No	Mist generation not expected during import.

Life-Cycle Stage	Category	Subcategory	Release/Exposure Scenario	Exposure Pathway	Exposure Route	Receptor	Plans to Evaluate	Rationale
Processing	Processing as a reactant	Intermediate in: Adhesive manufacturing; All other basic organic chemical manufacturing; Organic fiber manufacturing; Petrochemical manufacturing; Petroleum refineries; Plastic material and resin manufacturing; Synthetic rubber manufacturing; Wholesale and retail trade; Other: Monomer used in polymerization process in: Plastic material and resin manufacturing; Manufacturing synthetic rubber and plastics; Plasticizers in: Plastic material and resin manufacturing; Solvents (which become part of product formulation or mixture) in: Synthetic rubber manufacturing; Other: Fuel binder for	Processing of 1,3-butadiene as a reactant or monomer (polymerization)	Liquid Contact	Dermal	Worker	Yes	Workers may have dermal exposure during unloading and sampling, EPA plans to evaluate dermal pathway.
				Vapor	Inhalation	Worker	Yes	1,3-Butadiene is volatile at room temperature, EPA plans to evaluate the inhalation pathway.
				Liquid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.

Life-Cycle Stage	Category	Subcategory	Release/Exposure Scenario	Exposure Pathway	Exposure Route	Receptor	Plans to Evaluate	Rationale
		solid rocket fuels in: Aerospace		Vapor	Inhalation	ONU	Yes	1,3-Butadiene is volatile at room temperature, EPA plans to evaluate the inhalation pathway.
				Mist	Dermal/ Inhalation	Workers, ONU	No	Mist generation not expected during processing as a reactant.
Processing	Processing – incorporation into formulation, mixture, or reaction product	Processing aids, not otherwise listed in: Petrochemical manufacturing; Processing aids, not otherwise listed in: Adhesive manufacturing, paints and coatings manufacturing, petroleum lubricating oil and grease manufacturing, and all other chemical product and preparation manufacturing	Processing into formulations, mixtures, or reaction product	Liquid Contact	Dermal	Worker	Yes	Dermal exposure to liquids containing 1,3-butadiene may occur for this exposure scenario. EPA plans to evaluate dermal pathway
				Vapor	Inhalation	Worker	Yes	1,3-Butadiene is volatile at room temperature, EPA plans to evaluate the inhalation route.
				Liquid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
				Vapor	Inhalation	ONU	Yes	1,3-Butadiene is volatile at room temperature, EPA plans to evaluate the inhalation route.

Life-Cycle Stage	Category	Subcategory	Release/Exposure Scenario	Exposure Pathway	Exposure Route	Receptor	Plans to Evaluate	Rationale
				Mist	Dermal/ Inhalation	Workers, ONU	No	Mist generation not expected during processing/formulation operations.
Processing	Processing – incorporation into article	Other: Polymer in: Rubber product manufacturing	Plastics and Rubber product manufacturing	Liquid Contact	Dermal	Worker	Yes	Dermal exposure to liquids containing 1,3-butadiene may occur for this exposure scenario. EPA plans to evaluate dermal pathway
				Vapor	Inhalation	Worker	Yes	1,3-Butadiene is volatile at room temperature, EPA plans to evaluate the inhalation route.
				Liquid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
				Vapor	Inhalation	ONU	Yes	1,3-Butadiene is volatile at room temperature, EPA plans to evaluate the inhalation route.
				Mist	Dermal/ Inhalation	Workers, ONU	No	Mist generation not expected during processing operations.
Processing	Repackaging	Intermediate in: Wholesale and retail trade	Repackaging (same exposure scenario as Import)	Liquid Contact	Dermal	Worker	Yes	Dermal exposure may occur if there is repackaging. EPA plans to evaluate dermal exposure.

Life-Cycle Stage	Category	Subcategory	Release/Exposure Scenario	Exposure Pathway	Exposure Route	Receptor	Plans to Evaluate	Rationale
				Vapor	Inhalation	Worker	Yes	1,3-Butadiene is volatile at room temperature, EPA plans to evaluate the inhalation route.
				Liquid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
				Vapor	Inhalation	ONU	Yes	1,3-Butadiene is volatile at room temperature, EPA plans to evaluate the inhalation pathway.
				Mist	Dermal/ Inhalation	Workers, ONU	No	Mist generation not expected during repackaging.
Distribution in commerce	Distribution in commerce	Distribution in commerce	Distribution	Liquid Contact, Vapor	Dermal/ Inhalation	Worker, ONU	Yes	EPA plans to 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) rather than as a single distribution scenario.
Processing	Recycling	Recycling	Recycling of 1,3-butadiene	Liquid Contact	Dermal	Worker	Yes	Dermal exposure may occur for this condition of use, EPA plans to evaluate dermal exposure
				Vapor	Inhalation	Worker	Yes	1,3-Butadiene is volatile at room temperature, EPA plans to evaluate the inhalation pathway.
				Liquid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they

Life-Cycle Stage	Category	Subcategory	Release/Exposure Scenario	Exposure Pathway	Exposure Route	Receptor	Plans to Evaluate	Rationale
								are not expected to directly handle the chemical.
				Vapor	Inhalation	ONU	Yes	1,3-Butadiene is volatile at room temperature, EPA plans to evaluate the inhalation pathway.
				Mist	Dermal/ Inhalation	Workers, ONU	No	Mist generation not expected during processing recycling.
Industrial Uses	Processing aids, specific to petroleum production	Hydraulic fracturing	Use of 1,3-butadiene in hydraulic fracturing	Liquid Contact	Dermal	Worker	Yes	Dermal exposure to liquids containing 1,3-butadiene may occur for this exposure scenario. EPA plans to evaluate dermal exposure
				Vapor	Inhalation	Worker	Yes	1,3-Butadiene is volatile at room temperature, EPA plans to evaluate the inhalation exposure.
				Liquid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
				Vapor	Inhalation	ONU	Yes	1,3-Butadiene is volatile at room temperature, EPA plans to evaluate the inhalation pathway.
				Mist	Dermal/ Inhalation	Workers, ONU	No	Mist generation not expected during processing recycling.
Industrial /Commercial Uses	Adhesives and sealants	Adhesives and sealants	Use of rubber adhesives and sealants	Liquid Contact	Dermal	Worker	Yes	Dermal exposure may occur for this condition of use. EPA plans to evaluate dermal exposure.
				Vapor	Inhalation	Worker	Yes	1,3-Butadiene is volatile at room temperature, EPA plans to evaluate the inhalation pathway.

Life-Cycle Stage	Category	Subcategory	Release/Exposure Scenario	Exposure Pathway	Exposure Route	Receptor	Plans to Evaluate	Rationale
				Liquid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
				Vapor	Inhalation	ONU	Yes	1,3-Butadiene is volatile at room temperature, EPA plans to evaluate the inhalation pathway.
				Mist	Dermal/ Inhalation	Workers	Yes	EPA plans to evaluate mist generation for this scenario.
				Mist	Inhalation	ONU	Yes	EPA plans to evaluate mist generation for this scenario.
				Mist	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical
Commercial Uses	Fuel and Related Products	Fuel and Related Products	Use of fuel and fuel related products	Liquid Contact	Dermal	Workers	Yes	Dermal exposure may occur for this condition of use, EPA plans to evaluate dermal exposure
				Vapor	Inhalation	Worker	Yes	1,3-Butadiene is volatile at room temperature, EPA plans to evaluate the inhalation pathway.
				Liquid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical

Life-Cycle Stage	Category	Subcategory	Release/Exposure Scenario	Exposure Pathway	Exposure Route	Receptor	Plans to Evaluate	Rationale
				Vapor	Inhalation	ONU	Yes	1,3-Butadiene is volatile at room temperature, EPA plans to evaluate the inhalation pathway.
Commercial Uses	Plastic and rubber products not covered elsewhere;	Plastic and rubber products not covered elsewhere, including rubber tires;	Use of finished plastic and rubber products not covered elsewhere (e.g. tires)	Liquid Contact	Dermal	Worker, ONUs	No	Products covered under this exposure scenario are expected to be solid articles where dermal exposure to 1,3-butadiene is not expected.
				Vapor	Inhalation	Worker	Yes	1,3-Butadiene is volatile at room temperature, EPA plans to evaluate the inhalation pathway.
				Mist	Dermal/ Inhalation	Workers, ONU	No	Mist generation not expected during plastic and rubber products manufacturing.
Commercial Uses	Automotive care products; Lubricant and lubricant additives	Automotive care products; Lubricants additive	Use of other products developed from butadiene-based polymers	Liquid	Dermal	Worker	Yes	Dermal exposure may occur for this condition of use, EPA plans to evaluate dermal exposure
				Vapor	Inhalation	Worker	Yes	1,3-Butadiene is volatile at room temperature, EPA plans to evaluate the inhalation pathway.
				Liquid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
				Vapor	Inhalation	ONU	Yes	1,3-Butadiene is volatile at room temperature, EPA plans to evaluate the inhalation pathway.
				Mist	Dermal/ Inhalation	Workers, ONU	No	Mist generation not expected during plastic

Life-Cycle Stage	Category	Subcategory	Release/Exposure Scenario	Exposure Pathway	Exposure Route	Receptor	Plans to Evaluate	Rationale
								and rubber products manufacturing.
Commercial Uses	Paints and Coatings	Paints and Coatings	Spray coating application; and Other paint and coating applications (e.g., roll, dip)	Liquid Contact	Dermal	Worker	Yes	Dermal exposure may occur for this condition of use, EPA plans to evaluate dermal exposure
				Vapor	Inhalation	Worker	Yes	1,3-Butadiene is volatile at room temperature, EPA plans to evaluate the inhalation pathway.
				Liquid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
				Vapor	Inhalation	ONU	Yes	1,3-Butadiene is volatile at room temperature, EPA plans to evaluate the inhalation pathway.
				Mist	Dermal/ Inhalation	Workers	Yes	EPA plans to evaluate mist generation for this scenario.
				Mist	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical
				Mist	Inhalation	ONU	Yes	EPA plans to evaluate mist generation for this scenario.
Commercial Uses	Other Use	Laboratory chemicals;	Laboratory Use	Liquid Contact	Dermal	Workers	Yes	Dermal exposure may occur for this condition of use, EPA plans to evaluate dermal exposure

Life-Cycle Stage	Category	Subcategory	Release/Exposure Scenario	Exposure Pathway	Exposure Route	Receptor	Plans to Evaluate	Rationale
				Vapor	Inhalation	Workers	Yes	1,3-Butadiene is volatile at room temperature, EPA plans to evaluate the inhalation pathway
				Liquid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
				Vapor	Inhalation	ONU	Yes	1,3-Butadiene is volatile at room temperature, EPA plans to evaluate the inhalation pathway
				Mist	Dermal/ Inhalation	Workers, ONU	No	Mist generation not expected from waste handling.
Disposal	Waste Handling, Treatment and Disposal	Disposal of 1,3-butadiene wastes	Worker handling of wastes	Liquid Contact	Dermal	Worker	Yes	Dermal exposure is expected for this condition of use
				Vapor	Inhalation	Worker	Yes	1,3-Butadiene is volatile at room temperature, EPA plans to evaluate the inhalation pathway.
				Liquid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
				Vapor	Inhalation	ONU	Yes	1,3-Butadiene is volatile at room temperature, EPA plans to evaluate the inhalation pathway.

Life-Cycle Stage	Category	Subcategory	Release/Exposure Scenario	Exposure Pathway	Exposure Route	Receptor	Plans to Evaluate	Rationale
				Mist	Dermal/ Inhalation	Workers, ONU	No	Mist generation not expected from waste handling.

Appendix G SUPPORTING INFORMATION – CONCEPTUAL MODEL FOR CONSUMER ACTIVITIES AND USES

Table_Apx G-1. Consumer Exposure Conceptual Model Supporting Table

Life Cycle Stage	Category	Subcategory	Release from source	Exposure Pathway	Route	Receptor	Plans to Evaluate	Rationale
Consumer Use	Automotive Care Products	Automotive Care Products	Direct contact through application or use of products using butadiene-based polymers	Liquid Contact	Dermal	Consumers	Yes	Dermal exposure may occur for this condition of use. EPA plans to evaluate dermal exposure.
			Long-term emission/mass-transfer through application or use of products using butadiene-based polymers	Vapor	Inhalation	Consumers and Bystanders	Yes	1,3-Butadiene is volatile at room temperature, EPA plans to evaluate the inhalation pathway.
Consumer Use	Plastic and Rubber Products	Plastic and rubber products not covered elsewhere, including rubber tires	Direct contact through application or use of products using butadiene-based polymers	Liquid Contact	Dermal	Consumers	Yes	Dermal exposure may occur for this condition of use. EPA plans to evaluate dermal exposure.
			Long-term emission/mass-transfer through application or use of products using butadiene-based polymers	Vapor	Inhalation	Consumers and Bystanders	Yes	1,3-Butadiene is volatile at room temperature, EPA plans to evaluate the inhalation pathway.

Life Cycle Stage	Category	Subcategory	Release from source	Exposure Pathway	Route	Receptor	Plans to Evaluate	Rationale
Consumer Handling of Disposal and Waste	Wastewater, Liquid wastes and solid wastes	Wastewater, Liquid wastes and solid wastes	Direct contact through application or use of products using butadiene-based polymers	Liquid Contact	Dermal	Consumers	Yes	Dermal exposure may occur for this condition of use, dermal exposure will be further analyzed.
			Long-term emission/mass-transfer through application or use of products using butadiene-based polymers	Vapor	Inhalation	Consumers and Bystanders	Yes	1,3-Butadiene is volatile at room temperature, EPA plans to evaluate the inhalation pathway.

Appendix H SUPPORTING INFORMATION – CONCEPTUAL MODEL FOR ENVIRONMENTAL RELEASES AND WASTES

Table_Apx H-1. General Population and Environmental Exposure Conceptual Model Supporting Table

Life Cycle Stage	Categories	Release	Exposure Pathway / Media	Exposure Routes	Receptor / Population	Plans to Evaluate[9]	Rationale
All	Emissions to Air	Emissions to Air	Near facility ambient air concentrations	Inhalation	General Population	No	1,3-Butadiene is a HAP. Because stationary source releases of 1,3-butadiene to ambient air are under the jurisdiction of the CAA.
			Indirect deposition to nearby bodies of water and soil catchments	Oral; Dermal	General Population	No	
				TBD	Aquatic and Terrestrial Receptors	No	
	Wastewater or Liquid Wastes	Industrial pre-treatment and wastewater treatment, or POTW	Direct release into surface water and indirect partitioning to sediment	TBD	Aquatic and Terrestrial Receptors	Yes	This chemical may be released to surface water

[9] The exposure pathways, exposure routes and hazards plans to evaluate are subject to change in the final scope, in light of comments received on this draft scope and other reasonably available information. EPA continues to consider whether and how other EPA-administered statutes and any associated regulatory programs address the presence of 1,3-butadiene in exposure pathways falling under the jurisdiction of these EPA statutes.

Life Cycle Stage	Categories	Release	Exposure Pathway / Media	Exposure Routes	Receptor / Population	Plans to Evaluate[9]	Rationale
			Direct release into surface water and partitioning to sediment and bioaccumulation into edible aquatic species	Oral Inhalation	General Population	Yes	
			Drinking Water via Surface or Ground Water	Oral Dermal and Inhalation (e.g. showering)	General Population	No	The drinking water exposure pathway for 1,3-butadiene is currently addressed in the SDWA regulatory analytical process for public water systems.
			Biosolids: application to soil and/or migration to groundwater and/or surface water	Oral (e.g. ingestion of soil) Inhalation	General Population	Yes	Although 1,3-butadiene is a volatile chemical and not expected to sorb onto biosolids, EPA plans to analyze this pathway. However, it is expected to be a minor pathway of exposure to the general population and terrestrial species.
				TBD	Terrestrial receptors	Yes	
		Underground injection	Migration to groundwater, potential surface/drinking water	Oral Dermal Inhalation	General Population	No	1,3-Butadiene is released to Class I Underground Injection Wells
				TBD	Aquatic and Terrestrial Receptors	No	
	Solid and Liquid Wastes	Municipal landfill and other land disposal	Leachate to soil, ground water and/or	Oral (e.g., ingestion) Dermal Inhalation	General Population	Yes	Based, on TRI data, this chemical is expected to be

Life Cycle Stage	Categories	Release	Exposure Pathway / Media	Exposure Routes	Receptor / Population	Plans to Evaluate[9]	Rationale
			mitigation to surface water	TBD	Aquatic and Terrestrial Receptors	Yes	released to municipal landfills.