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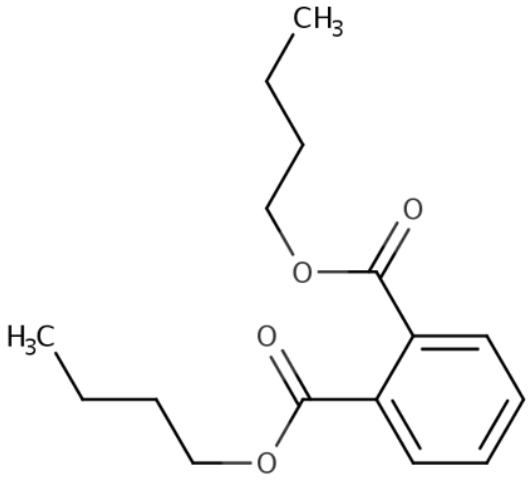
Office of Chemical Safety and
Pollution Prevention

United States
Environmental Protection Agency

Draft Scope of the Risk Evaluation for Dibutyl Phthalate (1,2-Benzenedicarboxylic acid, 1,2-dibutyl ester)

CASRN 84-74-2



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Docket

Supporting information can be found in public docket: Docket ID: EPA-HQ-OPPT-2018-0503.

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

ACGIH	American Conference of Governmental Industrial Hygienists
ADME	Absorption, Distribution, Metabolism, and Excretion
ATSDR	Agency for Toxic Substances and Disease Registry
BAF	Bioaccumulation Factor
BP	Boiling Point
BCF	Bioconcentration Factor
BMF	Biomagnification factor
BOD	Biochemical oxygen demand
BW	Body weight
CAA	Clean Air Act
CASRN	Chemical Abstracts Service Registry Number
CBI	Confidential Business Information
CDR	Chemical Data Reporting
CEHD	Chemical Exposure Health Data
CERCLA	Comprehensive Environmental Response, Compensation and Liability Act
CFR	Code of Federal Regulations
CHRIP	Chemical Risk Information Platform
COC	Concentration of Concern
CPCat	Chemical and Product Categories
CPSIA	Consumer Product Safety Improvement Act
CSCL	Chemical Substances Control Law
CWA	Clean Water Act
DMR	Discharge Monitoring Report
EC_x	Effective Concentration
ECHA	European Chemicals Agency
EC	Engineering Controls
EPA	Environmental Protection Agency
EPCRA	Emergency Planning and Community Right-to-Know Act
ERG	Eastern Research Group
ESD	Emission Scenario Document
EU	European Union
FFDCA	Federal Food, Drug and Cosmetic Act
FR	Federal Register
FYI	For Your Information
GACT	Generally Available Control Technology
GDIT	General Dynamics Information Technology
GESTIS	International Occupational Exposure Limit Database
GS	Generic Scenario
HAP	Hazardous Air Pollutant
Hg	Mercury
HHE	Health Hazard Evaluation
HMTA	Hazardous Materials Transportation Act
ICF	ICF is a global consulting services company
IDLH	Immediately Dangerous to Life and Health
IECCU	Indoor Environmental Concentrations in Buildings with Conditioned and Unconditioned Zones
IMAP	Inventory Multi-Tiered Assessment and Prioritisation (Australia)

ISHA	Industrial Safety and Health Act
K_{OC}	Organic Carbon: Water Partition Coefficient
K_{OW}	Octanol: Water Partition Coefficient
LC_x	Lethal Concentration
LOAEL	Lowest Observed Adverse Effect Level
LOEC	Lowest Observed Effect Concentration
MACT	Maximum Achievable Control Technology
MITI	Ministry of International Trade and Industry
MOA	Mode of Action
MP	Melting point
NAICS	North American Industry Classification System
NESHAP	National Emission Standards for Hazardous Air Pollutants
NICNAS	National Industrial Chemicals Notification and Assessment Scheme (Australia)
NIOSH	National Institute for Occupational Safety and Health
NITE	National Institute of Technology and Evaluation
NOAEL	No Observed Adverse Effect Level
NOEC	No Observed Effect Concentration
NPDES	National Pollutant Discharge Elimination System
NPRI	National Pollutant Release Inventory
OCSPP	Office of Chemical Safety and Pollution Prevention
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
ONU	Occupational Non-User
OPPT	Office of Pollution Prevention and Toxics
OSHA	Occupational Safety and Health Administration
P-chem	Physical-chemical
PBPK	Physiologically Based Pharmacokinetic
PBT	Persistent, Bioaccumulative, Toxic
PEC	Priority Existing Chemical
PECO	Population, Exposure, Comparator and Outcome
PEL	Permissible Exposure Limit
PESS	Potentially Exposed or Susceptible Populations
POD	Point of Departure
POTW	Publicly Owned Treatment Works
PPE	Personal Protective Equipment
PVC	Polyvinyl chloride
PVDC	Polyvinylidene chloride
PVA	Polyvinyl acetate
RCRA	Resource Conservation and Recovery Act
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals (European Union)
REL	Recommended Exposure Limit
RQ	Risk Quotient
SDS	Safety Data Sheet
SDWA	Safe Drinking Water Act
SRC	SRC Inc., formerly Syracuse Research Corporation
STEL	Short-term Exposure Limit
SVOC	Semi-volatile Organic Compound
TIAB	Title and Abstract

TBD	To be determined
TMF	Trophic Magnification Factors
TRI	Toxics Release Inventory
TSCA	Toxic Substances Control Act
TURA	Toxics Use Reduction Act (Massachusetts)
TWA	Time-weighted average
USGS	United States Geological Survey
VOC	Volatile Organic Compound
VP	Vapor Pressure
WHO	World Health Organization
WS	Water Solubility

EXECUTIVE SUMMARY

In December 2019, EPA designated dibutyl phthalate (CASRN 84-74-2) 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-2018-0503). 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 dibutyl phthalate 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. Dibutyl phthalate, is a colorless to faint yellow, oily liquid with a total production volume in the United States between 1 million and 10 million pounds.

Reasonably Available Information. EPA leveraged the data and information sources already described in the document supporting the High-Priority Substance designation to inform the development of this draft scope document. Furthermore, 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 plans to use 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 inclusion in the risk evaluation. EPA plans to apply these systematic review methods to collect reasonably available information regarding the hazards, exposures, PESS, and conditions of use that may help inform the risk evaluation for dibutyl phthalate.

Conditions of Use. EPA plans to evaluate manufacturing, including importing; processing; distribution in commerce; industrial, commercial and consumer uses; and disposal of dibutyl phthalate in the risk evaluation. Dibutyl phthalate is manufactured within, as well as imported into, the United States. Dibutyl phthalate is used in the processing and incorporation into formulations for solvents, plasticizers Dibutyl phthalate also has several commercial and consumer uses, including explosives, floor coatings, paints, adhesives, cleaning and furniture products, among others. EPA identified these conditions of use from information reported to EPA through Chemical Data Reporting (CDR) and Toxics Release Inventory (TRI), published literature, and consultation with stakeholders for both uses currently in production and uses whose production may have ceased. Section 2.2 provides details about the conditions of use within and outside 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 dibutyl phthalate 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. EPA proposes to focus the risk evaluation for dibutyl phthalate on the following exposures, hazards, and receptors with the understanding that updates may be made in the final scope document after consideration of public comments and completion of the systematic review data collection phase.

- *Exposures (Pathways and Routes), Receptors and PESS.* EPA plans to analyze both human and environmental exposures resulting from the conditions of use of dibutyl phthalate that EPA plans to consider in the risk evaluation. Exposures for dibutyl phthalate are discussed in Section 2.3. EPA identified environmental monitoring data reporting the presence of dibutyl phthalate in air, surface water and groundwater, sediment, sewage sludge, waste effluents and biomonitoring samples (U.S. EPA, 2019a). Dibutyl phthalate is subject to reporting to EPA's Toxics Release Inventory (TRI) and EPA plans to use TRI information as reasonably available information to inform dibutyl phthalate's environmental release assessment. For the 2018 reporting year, 61 facilities reported to EPA releases of dibutyl phthalate to air, water, and via land disposal. Additional information gathered through the results of 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 dibutyl phthalate 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 exposures (pathways and routes), receptors and hazards associated with the conditions of use of dibutyl phthalate 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 (ONUs) via the inhalation route and exposures to workers via the dermal route associated with the manufacturing, processing, use or disposal of dibutyl phthalate (Section 2.2.1).
  - *Consumer and bystander exposures associated with consumer conditions of use:* EPA plans to evaluate oral, inhalation and dermal exposure to dibutyl phthalate when consumers and bystanders are exposed via the use and/or handling of consumer products and articles in the following conditions of use: Adhesives and Sealants; Arts, Crafts, and Hobby Materials; Building/Construction Materials not Covered Elsewhere; Cleaning and Furnishing Care Products; Electrical and Electronic Products; Fabric, Textile, and Leather Products not Covered Elsewhere; Floor Coverings; Furniture and Furnishings not Covered Elsewhere; Paints and Coatings; Plastic and Rubber Products not Covered Elsewhere; and Toys, Playground, and Sporting Equipment.
  - *General population exposures:* EPA plans to evaluate exposure to dibutyl phthalate via ingestion of drinking water.
  - *Receptors and PESS:* EPA plans to include children, women of reproductive age (e.g., pregnant women), workers and consumers as receptors and PESS in the risk evaluation.
  - *Environmental exposures:* EPA plans to evaluate exposure to dibutyl phthalate for aquatic and terrestrial receptors.

- *Hazards.* Hazards for dibutyl phthalate 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 dibutyl phthalate as part of the prioritization

process. Environmental hazard effects were identified for aquatic and terrestrial organisms. Information collected through systematic review methods and public comments may identify additional environmental hazards that warrant inclusion in the environmental hazard assessment of the risk evaluation.

EPA plans to use systematic review methods to evaluate the epidemiological and toxicological literature for dibutyl phthalate. Relevant mechanistic evidence will also be considered, if available, to inform the interpretation of findings related to potential human health effects and the dose-repose assessment. EPA plans to evaluate all of the potential human health hazards for dibutyl phthalate identified in Section 2.4.2. The broad health effect categories identified in the prioritization document include reproductive and developmental; immunological; nervous system; genotoxicity; carcinogenicity; adsorption, distribution, metabolism, and excretion (ADME); and irritation effects.

Analysis Plan. The analysis plan for dibutyl phthalate is presented in Section 2.7. The analysis plan outlines the general science approaches that EPA plans to use for the various evidence streams (i.e., chemistry, fate, release and engineering, exposure, hazard) supporting the risk evaluation. The analysis plan is based on EPA's knowledge of dibutyl phthalate 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 dibutyl phthalate, 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 dibutyl phthalate 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 dibutyl phthalate 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) and 40 CFR Part 702, Subpart A require the Environmental Protection Agency (EPA) to 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 potentially exposed or susceptible subpopulations 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 (84 FR 71924), as required by TSCA § 6(b)(2)(B), which initiated the risk evaluation process for those chemical substances. Dibutyl phthalate 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 r dibutyl phthalate. 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 (p-chem) 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 dibutyl phthalate 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 up 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 dibutyl phthalate upon publication of the supplemental documentation of those methods.

2.1.1 Search of Gray Literature

EPA surveyed the gray literature[2] and identified 137 search results relevant to EPA's risk assessment needs for dibutyl phthalate. Appendix A lists the gray literature sources that yielded 137 discrete data or information sources relevant to dibutyl phthalate. EPA further categorized the data and information into the various topic areas (or disciplines) supporting the risk evaluation (e.g., physical chemistry, environmental fate, environmental hazard, human health hazard, exposure, engineering) and the breakdown is shown in Figure 2-1. EPA is currently identifying additional reasonably available information through systematic review methods and public comments, and the reported numbers in Figure 2-1 may change.

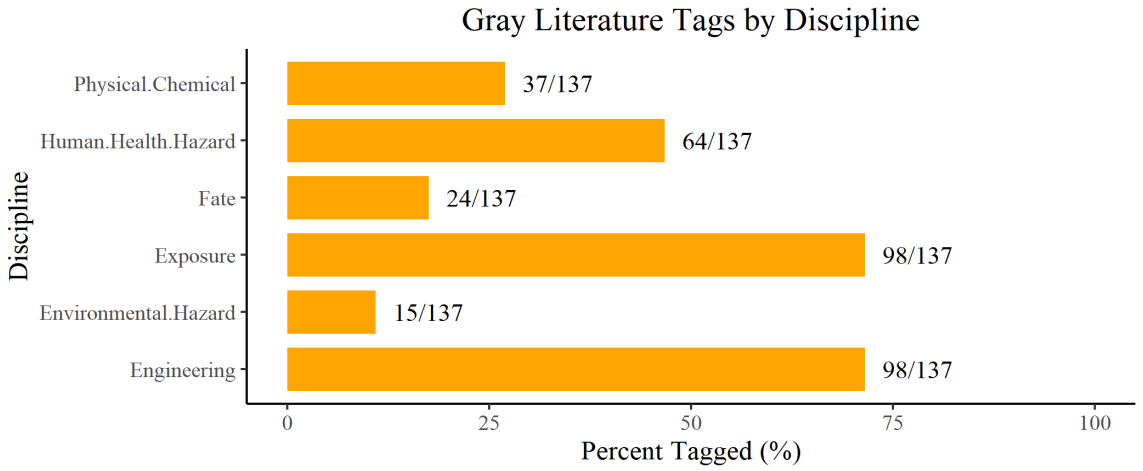

Figure 2-1 Gray Literature Search Results for Dibutyl Phthalate
The percentages across disciplines do not add up to 100%, as each source may provide data or information for various topic areas (or disciplines).

[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 p-chem properties, environmental fate and transport, engineering (environmental release and occupational exposure), exposure (environmental, general population and consumer) and environmental and human health hazards of phthalic anhydride. 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 through Figure 2-6. "TIAB" in these figures refer to "title and abstract" screening. Note that in some 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.

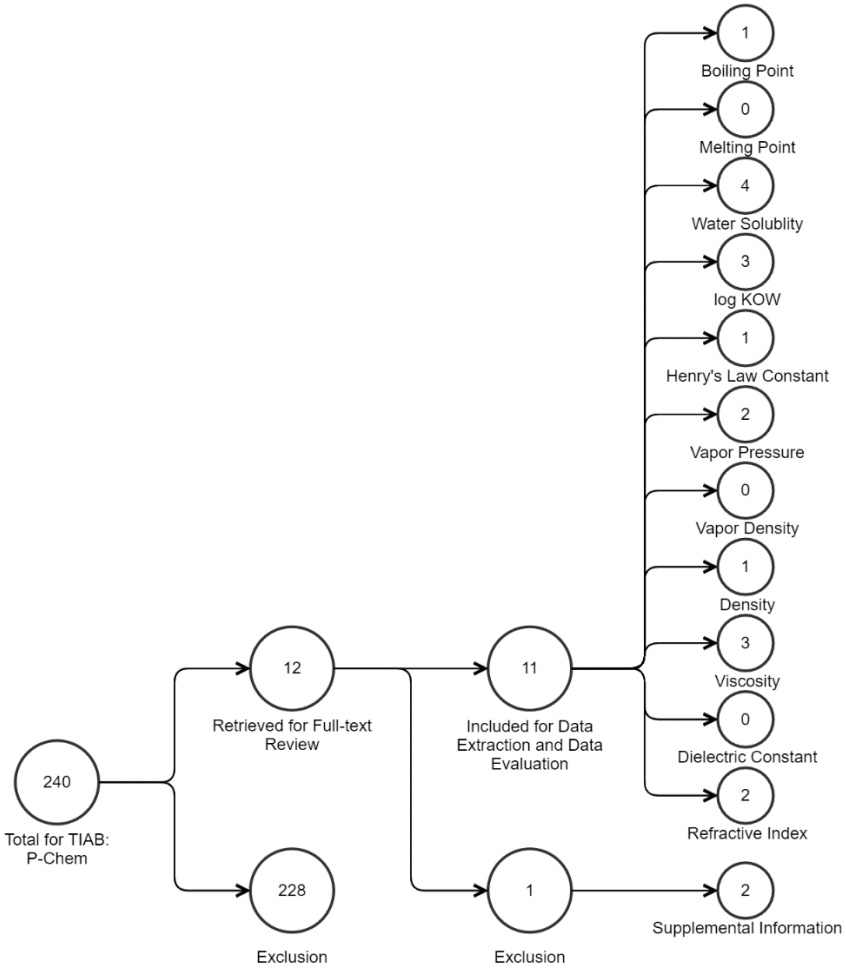

Figure 2-2 Peer-reviewed Literature - Physical and Chemical Properties for Dibutyl Phthalate

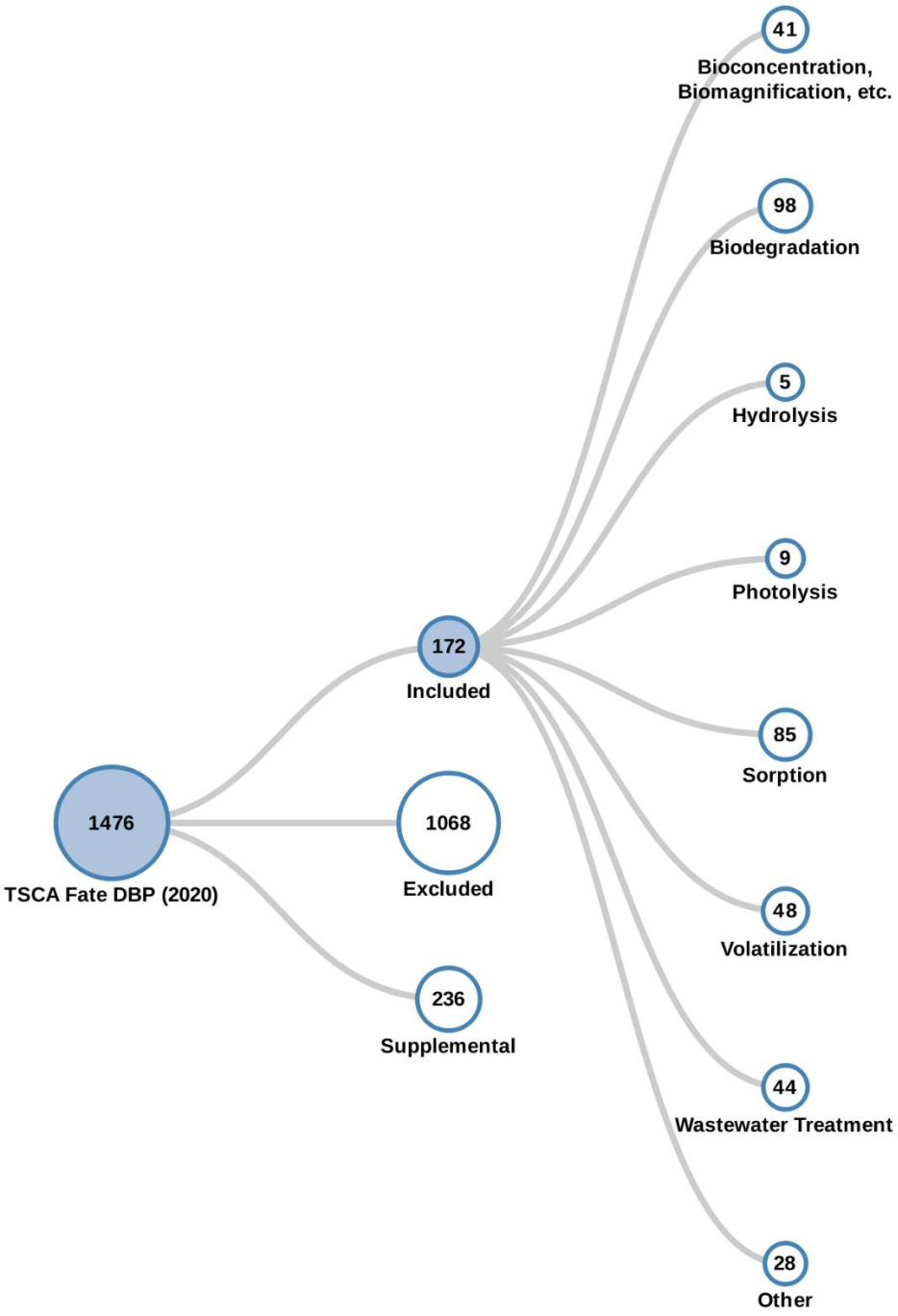

Figure 2-3 Peer-reviewed Literature - Fate and Transport Search Results for Dibutyl Phthalate
Click here for interactive Health Assessment Workplace Collaborative (HAWC) Diagram.

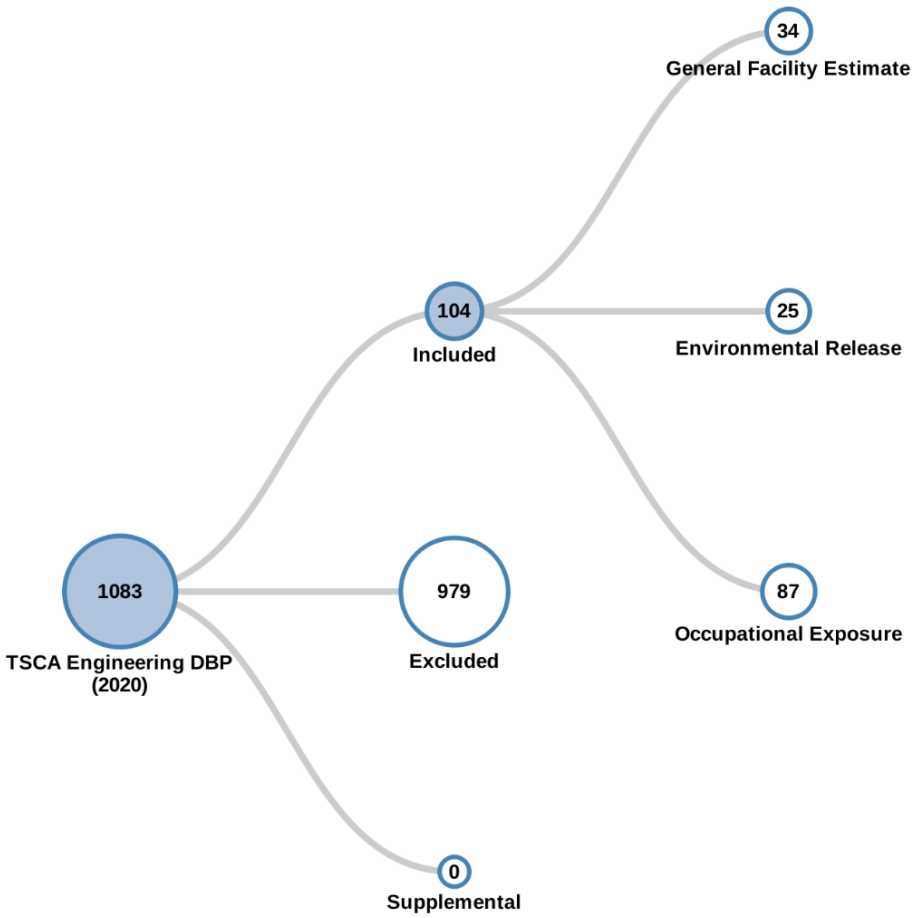

Figure 2-4 Peer-reviewed Literature - Engineering Search Results for Dibutyl Phthalate
Click here for interactive HAWC Diagram.

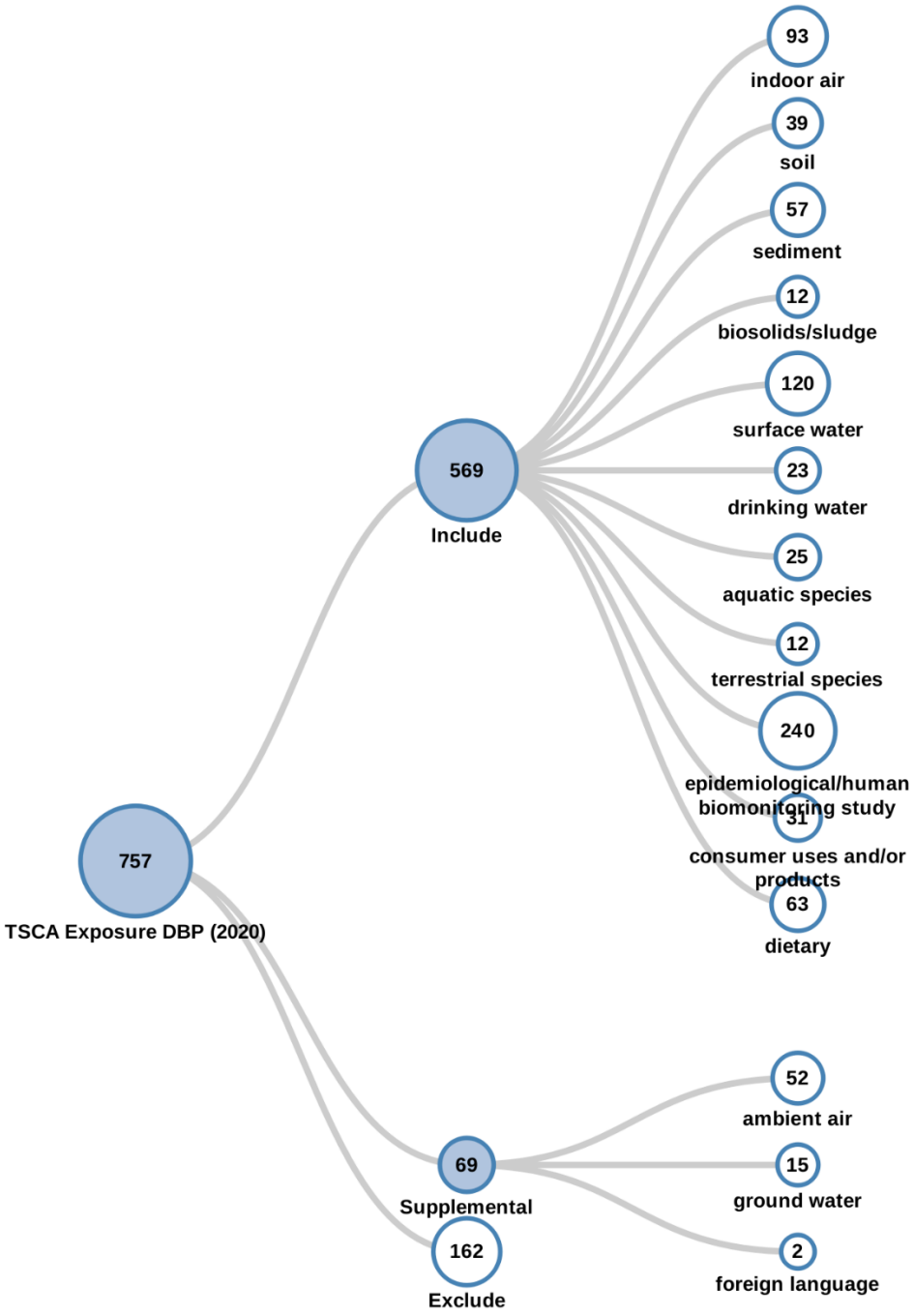

Figure 2-5 Peer-reviewed Literature - Exposure Search Results for Dibutyl Phthalate
Click here for interactive HAWC Diagram.

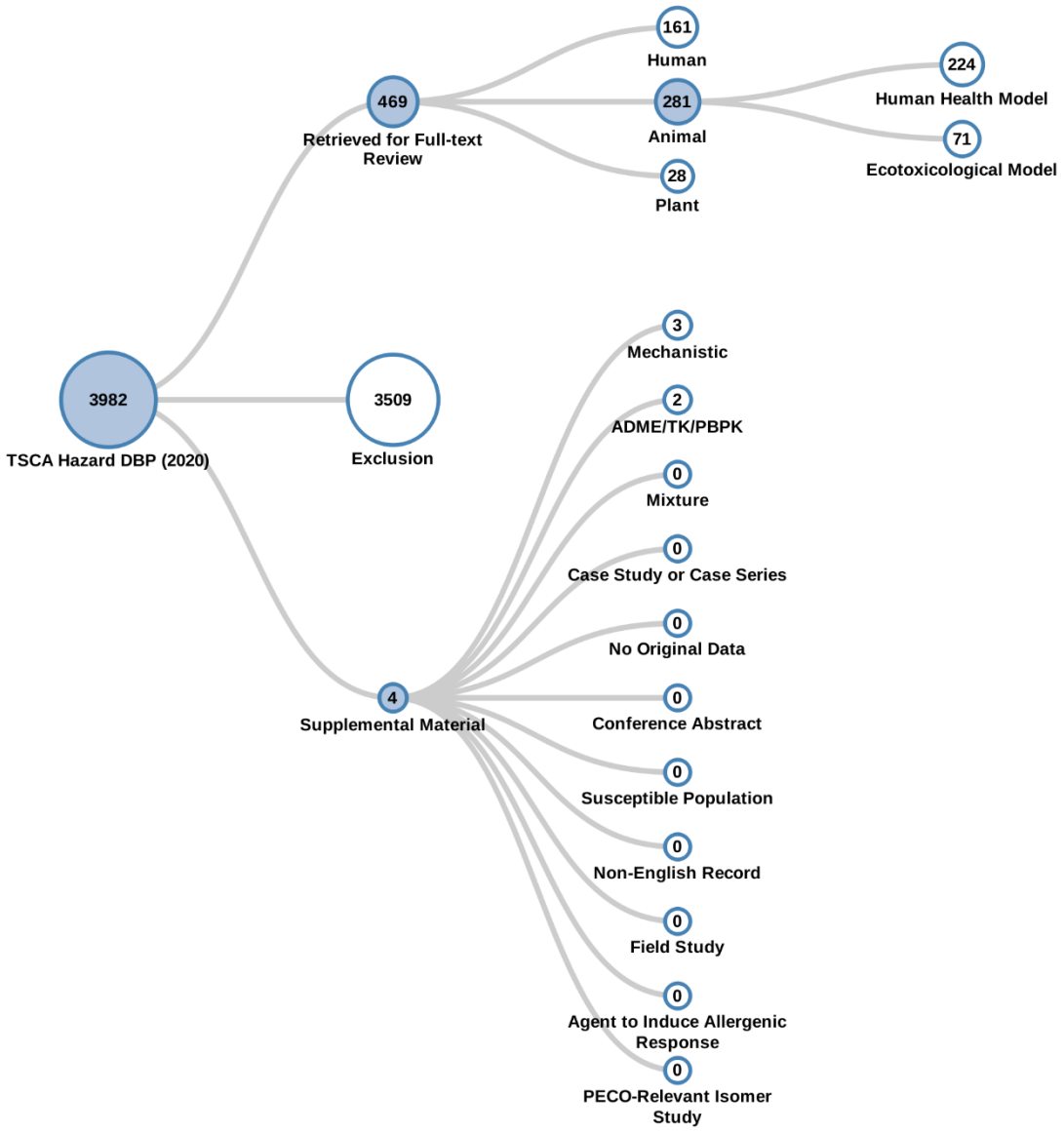

Figure 2-6 Peer-reviewed Literature - Hazard Search Results for Dibutyl Phthalate
Click here for interactive HAWC Diagram.

2.1.3 Search Results for 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, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act. EPA screened a total of 152 submissions using inclusion/ 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 118 submissions that met the inclusion criteria in these statements and identified 28 submissions with supplemental data. EPA excluded 6 submissions because the reports were identified as one of the following:

- Submission on a different chemical
- Ranking of chemicals for proposed evaluation
- Letter of notification containing no 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
P-Chem Properties	10	0
Environmental Fate and Transport	7	0
Environmental and General Population Exposure	39	0
Occupational Exposure/Release Information	9	0
Environmental Hazard	40	2
Human Health Hazard	25	28

2.2 Conditions of Use

As described in the *Proposed Designation of Dibutyl Phthalate (CASRN 84-74-2) 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 dibutyl phthalate, including: published literature, company websites, and government and commercial trade databases and publications. To identify formulated products containing dibutyl phthalate, 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. SDSs were cross-checked with company websites to make sure that each product SDS was current. In addition, and when applicable, EPA incorporated communications with companies, industry groups, environmental organizations, and public comments to supplement the use information.

After gathering reasonably available information related to the manufacture, processing, distribution in commerce, use, and disposal of dibutyl phthalate, EPA identified those categories or subcategories of use activities for dibutyl phthalate 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.

Also, 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.

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 (15 U.S.C. § 2602(4)).

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

Life-Cycle Stage[a]	Category	Subcategory	Reference
Manufacturing	Domestic manufacturing	Domestic manufacturing	U.S.EPA (2019)
	Import	Import	U.S.EPA (2019)
Processing	Processing as a reactant	Intermediates in all other basic organic chemical manufacturing	U.S.EPA (2019)
		Plasticizers in wholesale and retail trade	U.S.EPA (2019)
	Processing – incorporating into formulation, mixture, or reaction product	Solvents (which become part of product formulation or mixture) in all other chemical product and preparation manufacturing	U.S.EPA (2019); NLM (2015) 5926108; Ullmann's 2011a; Synapse Information Resources 2009
		Intermediates in asphalt paving, roofing, and coating materials manufacturing	U.S.EPA (2019)
		Adhesives and sealant chemicals in construction	U.S.EPA (2019); NLM (2015) 5926108
		Plasticizers in paint and coating manufacturing	U.S.EPA (2019); NLM (2015) 5926108; GoodGuide (2011)
		Intermediates in petrochemical manufacturing	U.S.EPA (2019)
		Plasticizers in plastic material and resin manufacturing	U.S.EPA (2019); NLM (2015) 5926108
		Plasticizers in plastic product manufacturing	U.S.EPA (2019;) NLM (2015) 5926108
		Functional fluids (closed systems) in printing and related support activities	U.S.EPA (2019)
		Intermediates in rubber product manufacturing	U.S.EPA (2019); NLM (2015) 5926108
		Plasticizers in soap, cleaning compound, and toilet preparation manufacturing	U.S.EPA (2019)
		Solvents in soap, cleaning compound, and toilet preparation manufacturing	U.S.EPA (2019)

Life-Cycle Stage[a]	Category	Subcategory	Reference
		Plasticizers in textiles, apparel, and leather manufacturing	U.S.EPA (2019); NLM (2015) 5926108
	Processing – incorporating into articles	Plasticizers in adhesive manufacturing	U.S.EPA (2019); NLM (2015) 5926108
		Plasticizers in plastics product manufacturing	U.S.EPA (2019)
		Plasticizers in rubber product manufacturing	U.S.EPA (2019)
	Repackaging	Laboratory chemicals in wholesale and retail trade	U.S.EPA (2019)
		Plasticizers in wholesale and retail trade	U.S.EPA (2019)
	Recycling	Recycling	U.S.EPA (2019)
Distribution in Commerce	Distribution in commerce		
Industrial Uses	Non-incorporative activities	Solvent in Huntsman's maleic anhydride manufacturing technology	U.S.EPA (2019)
		Solvent	NLM (2015) 5926108; Ullmann's 2011a; Synapse Information Resources 2009
Commercial Uses	Adhesives and sealants	Adhesives and sealants	U.S.EPA (2019)
	Cleaning and furnishing care products	Cleaning and furnishing care products	U.S.EPA (2019); NLM (2015) 5926108; GoodGuide (2011)
	Explosive materials	Explosive materials	U.S.EPA (2019); NLM (2015) 5926108; Kirk-Othmer (2018); Synapse Information Resources 2009
	Floor coverings	Floor coverings	U.S.EPA (2019)
	Furniture and furnishings not covered elsewhere	Furniture and furnishings not covered elsewhere	U.S.EPA (2019)
	Ink, toner, and colorant products	Ink, toner, and colorant products	U.S.EPA (2019); NLM (2015) 5926108
	Paints and coatings	Paints and coatings	U.S.EPA (2019);

Life-Cycle Stage[a]	Category	Subcategory	Reference
			NLM (2015) 5926108; GoodGuide (2011); Ullmann's (2011b)
	Personal care products	Personal care products	U.S.EPA (2019)
	Plastic and rubber products not covered elsewhere	Plastic and rubber products not covered elsewhere	U.S.EPA (2019); NLM (2015) 5926108
	Miscellaneous uses	Laboratory supply	U.S.EPA (2019)
Consumer Uses	Adhesives and sealants	Adhesives and sealants	U.S.EPA (2019)
	Arts, crafts and hobby materials	Arts, crafts and hobby materials	U.S.EPA (2019); NLM (2015) 5926108
	Cleaning and furnishing care products	Cleaning and furnishing care products	U.S.EPA (2019); NLM (2015) 5926108; GoodGuide (2011)
	Fabric, textile, and leather products not covered elsewhere	Fabric, textile, and leather products not covered elsewhere	U.S.EPA (2019)
	Floor coverings	Floor coverings	U.S.EPA (2019)
	Furniture and furnishings not covered elsewhere	Furniture and furnishings not covered elsewhere	U.S.EPA (2019)
	Paints and coatings	Paints and coatings	U.S.EPA (2019); NLM (2015) 5926108; GoodGuide (2011); Ullmann's (2011b)
	Plastic and rubber products not covered elsewhere	Plastic and rubber products not covered elsewhere	U.S.EPA (2019); NLM (2015) 5926108
	Toys, playground and sporting equipment	Toys, playground and sporting equipment	U.S.EPA (2019)
Disposal	Disposal		U.S.EPA (2019)

a) 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.

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 potentially exposed or susceptible subpopulations 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). As a result, 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.

EPA is aware of the use of dibutyl phthalate in cosmetics, primarily nail polish, which meet the definition of cosmetics under Section 201 of the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 321, and are therefore outside the scope of the definition of "chemical substance" in TSCA § 3(2)(B)(vi). Activities and releases associated with such cosmetics are therefore not "conditions of use" (defined as circumstances associated with "a chemical substance," TSCA § 3(4)) and will not be evaluated during risk evaluation. Uses of dibutyl phthalate in explosive materials in articles, or components of articles subject to Section 4181 of the Internal Revenue Code of 1954, e.g., ammunition, are similarly outside the scope of the definition of "chemical substance" TSCA § 3(2)(B)(v) and are not being considered as a "condition of use." However, manufacturing, processing, and industrial uses of these products are covered by TSCA and will be considered a condition of use.

2.2.3 Production Volume

Aggregate production volume of dibutyl phthalate in 2015, as reported to EPA during the 2016 CDR reporting period, was between 1 million and 10 million pounds (U.S. EPA,2017). EPA also uses pre-2015 CDR production volume information, as detailed in the *Proposed Designation of Dibutyl Phthalate (CASRN 84-74-2) 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 environmental release 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 as presented in Section 2.2.1. This section provides a brief overview of the industrial, commercial and consumer use categories included in the life cycle diagram. Appendix E contains more detailed descriptions (e.g., process descriptions, worker activities, process flow diagrams) for each manufacturing, processing, distribution in commerce, use and disposal category.

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 industrial, commercial and consumer uses). The production volume of dibutyl phthalate in 2015 is included in the lifecycle diagram, as reported to EPA during the 2016 CDR reporting period, as an aggregate range between 1 billion and 5 billion pounds (reference).

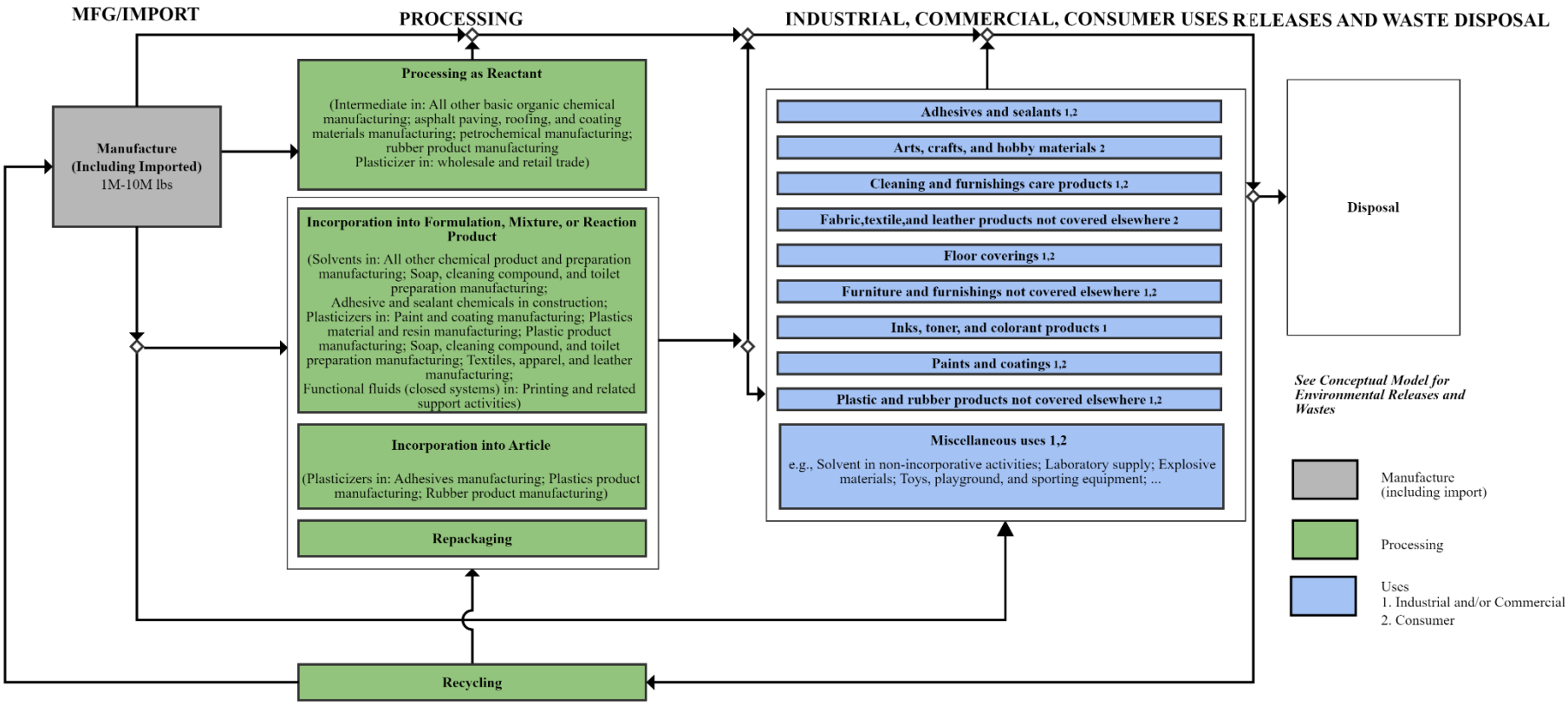

Figure 2-7 Dibutyl Phthalate Life Cycle Diagram

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 dibutyl phthalate. 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 will take into account, where relevant, the duration, intensity (concentration), frequency and number of exposures in characterizing exposures to dibutyl phthalate.

2.3.1 Physical and Chemical (P-Chem) Properties

Consideration of p-chem properties is 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 p-chem properties described in the *Proposed Designation of Dibutyl Phthalate (CASRN 84-74-2) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019a) to support the development of the risk evaluation for dibutyl phthalate (Appendix B). The values for the p-chem properties 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 dibutyl phthalate. EPA plans to use the environmental fate characteristics described in the *Proposed Designation of Dibutyl Phthalate (CASRN 84-74-2) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019a) to support the development of the risk evaluation for dibutyl phthalate (0). The values for the environmental fate properties 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 resulting in down-the-drain releases) 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 the Section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA) dibutyl phthalate is a TRI-reportable substance effective January 1, 1987 (40 CFR 372.65). For TRI reporting,[4] facilities in covered sectors in the United States are required to disclose release and other waste management activity quantities of dibutyl phthalate under the CASRN 84-74-2 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.

[4] 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 dibutyl phthalate reported by facilities to the TRI program for reporting year 2018.[5] As shown in the table, 61 facilities reported a total of nearly 1.5 million pounds of dibutyl phthalate production-related waste managed in 2018. Of this total, 808,417 pounds were treated (primarily on site) and accounted for slightly more than half of the total quantity of the chemical managed as waste during 2018. Quantities released or otherwise disposed of to the environment (351,282 pounds) and used for energy recovery (313,219 pounds) accounted for most of the remainder of the total waste quantity managed. A small portion (less than 1%) of the total quantity of dibutyl phthalate managed as waste was recycled off site.

Table 2-3 Summary of Dibutyl Phthalate 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	61	11,096	313,219	808,417	351,282	1,484,014

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 dibutyl phthalate reported as released to the environment during 2018.[2] The vast majority (approximately 92%) of dibutyl phthalate released to the environment was disposed of to land, totaling 306,655 pounds. Of this amount, "all other land disposal" accounted for nearly 64%, which was comprised of off-site disposal to landfills (146,062 pounds) other than RCRA Subtitle C landfills, or by other on-site land disposal methods such as placement in waste piles, spills, or leaks (49,441 pounds). The remaining 36% of total land disposal included disposal to on-site RCRA Subtitle C landfills and disposal to on-site Class I underground injection wells. There were zero pounds of dibutyl phthalate reported as released to water via surface water discharges, and a total of 23,850 pounds were released to air as fugitive and stack emissions.

Table 2-4 Summary of Releases of Dibutyl Phthalate to the Environment During 2018

Year		Air Releases		Water Releases (lbs)	Land Disposal			Other Releases [a] (lbs)	Total Releases [b, c] (lbs)
Year	Number of Facilities	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)		
2018	61	16,095	7,754	0	53,330	57,822	195,503	1,261	331,766
		23,850			306,655				

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 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.

[5] 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.

The total production-related waste managed quantity shown in Table 2-3 does not include any quantities reported as catastrophic or one-time releases. It does include quantities transferred off site to receiving facilities for release or disposal and these same quantities are included in the aggregate as on-site releases by the receiving facilities. This is referred to as "double counting", because the quantities are counted twice. That is, when a facility transfers a quantity of a chemical off site for disposal to another facility, the facility reports the quantity as transferred off site for disposal and, if the receiving facilities are subject to the TRI reporting requirements, they would report these same quantities as disposed of on site, and these same quantities would be included in the total release aggregate. This is referred to as "double counting" because the quantities are counted twice. This is done because total production-related waste values in the TRI database considers all instances of where and how the waste is managed (first as a quantity sent off site for disposal and next as a quantity disposed of on-site), and reflects both the off-site transfer and the on-site disposal quantities, as represented in Table 2-3. However, the TRI program recognizes that this is the same quantity of the chemical and therefore included it only once in the total release aggregation in Table 2-4. As a result, the total release quantities shown in the two tables differ slightly.

EPA plans to review these data in conducting the exposure assessment component of the risk evaluation for dibutyl phthalate.

2.3.4 Environmental Exposures

The manufacturing, processing, distribution, use and disposal of dibutyl phthalate 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 the development of the environmental exposure assessment for dibutyl phthalate.

Monitoring data were identified in EPA's data search for dibutyl phthalate and can be used in the exposure assessment. Relevant and reliable monitoring studies provide(s) information that can be used in an exposure assessment. Monitoring studies that measure environmental concentrations or concentrations of chemical substances in biota provide evidence of exposure. Monitoring data shows that dibutyl phthalate has been detected in air, surface water and groundwater, sediment, biota, sewage sludge and waste effluents (Environment Canada, 1994; ECB, 2004; MDI 2002; U.S. EPA 1990; U.S. EPA 2007; U.S. EPA, 2018b; ICES, 2018; USGS, 1991a; USGS, 1991c; USGS, 1991d); USGS, 1991e; USGS, 1991f). Environmental biomonitoring data were identified in EPA's data search for dibutyl phthalate (MDI 2002; ICES 2018; USGS 1991g). EPA plans to review available environmental monitoring data in the risk evaluation.

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, and industrial/commercial uses) described in Section 2.2.1. In addition, EPA plan to analyze exposure to ONUs, workers, who do not directly handle the chemical but perform work in an area where the chemical is present, depending on reasonably available information. 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 dibutyl phthalate will be analyzed, including, but not limited to:

- Unloading and transferring dibutyl phthalate to and from storage containers to process vessels;
- Handling, transporting and disposing of waste containing dibutyl phthalate;
- Cleaning and maintaining equipment;
- Sampling chemicals, formulations or products containing dibutyl phthalate for quality control;
- Repackaging chemicals, formulations or products containing dibutyl phthalate.

Dibutyl phthalate is a liquid at room temperature and has a vapor pressure of 2.01×10^{-5} mm Hg at 25 °C (NLM, 2015) and inhalation exposure to vapor is expected to be low when working with the material at room temperature. However, EPA plans to analyze inhalation exposure in occupational scenarios where dibutyl phthalate is applied via spray or roll application methods or is handled as a dry powder or at elevated temperatures.

Dibutyl phthalate has an Occupational Safety and Health Administration (OSHA) permissible exposure limit (PEL) (OSHA 2009). The PEL is 5 milligrams per cubic meter (mg/m^3) over an 8-hour workday, time weighted average (TWA). National Institute for Occupational Safety and Health (NIOSH) has set the Recommended Exposure Limit (REL) at 5 mg/m^3 TWA and the Immediately Dangerous to Life or Health Concentration (IDLH) at 4000 mg/m^3 (NIOSH, 2005). The American Conference of Governmental Industrial Hygienists (ACGIH) set the threshold limit value (TLV) at 5 mg/m^3 TWA.

Based on the conditions of use, EPA plans to analyze worker exposure to liquids and/or solids via the dermal route. EPA does not plan to analyze dermal exposure for ONUs because they do not directly handle dibutyl phthalate.

EPA generally does not evaluate occupational exposures through the oral route. Workers may inadvertently transfer chemicals from their hands to their mouths or ingest inhaled particles that deposit in the upper respiratory tract. 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 for certain COUs and worker activities where there is information and data on incidental ingestion of inhaled dust. EPA will consider ingestion of inhaled dust as an inhalation exposure for dibutyl phthalate.

2.3.6 Consumer Exposures

CDR reporting and conversations with industry indicate the presence of dibutyl phthalate in a number of consumer products and articles including: Adhesives and Sealants; Arts, Crafts, and Hobby Materials; Building/Construction Materials not Covered Elsewhere; Cleaning and Furnishing Care Products; Electrical and Electronic Products; Fabric, Textile, and Leather Products not Covered Elsewhere; Floor Coverings; Furniture and Furnishings not Covered Elsewhere; Paints and Coatings; Plastic and Rubber Products not Covered Elsewhere; and Toys, Playground, and Sporting Equipment (See Section 2.6.2 and Figure 2-9). These uses can result in exposures to consumers and bystanders (non-product users that are incidentally exposed to the product).

Based on reasonably available known consumer conditions of use, inhalation of dibutyl phthalate is possible through either inhalation of vapor/mist during product usage or indoor air/dust. Oral exposure of dibutyl phthalate is possible through either ingestion through product use via transfer from hand to mouth or via through mouthing of articles containing dibutyl phthalate. Dermal exposure may occur via contact with vapor or mist deposition onto the skin, via direct liquid contact during use, or direct dermal

contact of articles containing dibutyl phthalate. Based on these potential sources and pathways of exposure, EPA plans to analyze oral, dermal and inhalation exposures to consumers and inhalation exposures to bystanders that may result from the conditions of use of dibutyl phthalate.

2.3.7 General Population Exposures

Releases of dibutyl phthalate from certain conditions of use, such as manufacturing, processing, or disposal activities, may result in general population exposures. The general population may be exposed to dibutyl phthalate from contaminated air, water, and some foods (ATSDR, 2001; CPSC, 2010). Air is likely the main source of exposure for the general population, but some exposure may come from consumption of dairy products, fish, and seafood (ATSDR, 2001). The major source of dietary dibutyl phthalate intake is from consumption of fish (ECB, 2004). Monitoring data shows that dibutyl phthalate has been detected in air, surface water and groundwater, sediment, biota, sewage sludge and waste effluents (Environment Canada, 1994; ECB, 2004; MDI 2002; U.S. EPA 1990; U.S. EPA 2007; U.S. EPA, 2018b; ICES, 2018; USGS, 1991a; USGS, 1991c; USGS, 1991d; USGS, 1991e; USGS, 1991f). EPA plans to review the reasonably available information for the presence of dibutyl phthalate in the environmental media relevant to general population exposure.

Environmental and human biomonitoring data were identified in EPA's data search for dibutyl phthalate (MDI 2002; ICES 2018; USGS 1991g). The general population's daily exposure to dibutyl phthalate is estimated to be less than 10 μg/kg/d (CPSC, 2010). Biomonitoring studies measuring dibutyl phthalate from the urine of children, school teachers, and parents indicate that the primary metabolite for dibutyl phthalate was higher in the children when compared with the adults (CPSC, 2010). Dibutyl phthalate has also been detected in human breastmilk (ECB, 2004). Modeling for estimated exposures in women, infants, toddlers, and children is also available (CPSC, 2014) as are models using the NHANES 2005/2006 exposure estimates (CPSC, 2015). EPA plans to review reasonably available human biomonitoring data in the risk evaluation.

2.4 Hazards (Effects)

2.4.1 Environmental Hazards

As described in the *Proposed Designation of Dibutyl Phthalate (CASRN 84-74-2) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019a), EPA considered reasonably available information from peer-reviewed assessments and databases to identify potential environmental hazards for dibutyl phthalate. EPA considers all the potential environmental hazards for dibutyl phthalate identified during prioritization (U.S. EPA, 2019a) to be relevant for the risk evaluation and thus they remain within the scope of the evaluation. EPA is in the process of identifying additional reasonably available information through systematic review methods and public comments, which may update the list of potential environmental hazards associated with dibutyl phthalate. If necessary, EPA plans to update the list of potential hazards in the final scope document of dibutyl phthalate. Based on information identified during prioritization, environmental hazard effects were identified for aquatic and terrestrial organisms.

2.4.2 Human Health Hazards

As described in the *Proposed Designation of Dibutyl Phthalate (CASRN 84-74-2) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019a), EPA considered reasonably available information from peer-reviewed assessments and databases to identify potential human health hazards for dibutyl phthalate. EPA evaluated all of the potential human health hazards for dibutyl phthalate identified during prioritization. The health effect categories identified during prioritization included reproductive toxicity, developmental toxicity, neurotoxicity, genetic toxicity, dermal sensitization, respiratory sensitization, toxicokinetics, and irritation/corrosion, epidemiology or biomonitoring findings and ADME. 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 dibutyl phthalate 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 United States general population (U.S. EPA, 2011a).

During the Prioritization process, EPA identified the following potentially exposed or susceptible subpopulations based on CDR information and studies reporting developmental and reproductive effects: children, women of reproductive age (e.g., pregnant women), workers and consumers (U.S. EPA,2019a). EPA plans to evaluate these PESS in the risk evaluation.

In developing exposure scenarios, EPA plans to analyze reasonably available data 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, duration or location of exposure) when compared with the

general population (U.S. EPA, 2006a). Likewise, EPA plans to evaluate reasonably 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 dibutyl phthalate. Pathways and routes of exposure associated with workers and ONUs 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 dibutyl phthalate 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. 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. For each condition of use identified in

, an initial determination was made as to whether or not EPA plans to assess each combination of exposure pathway, route, and receptor will be analyzed in the risk evaluation. The supporting rationale are presented in Appendix F.

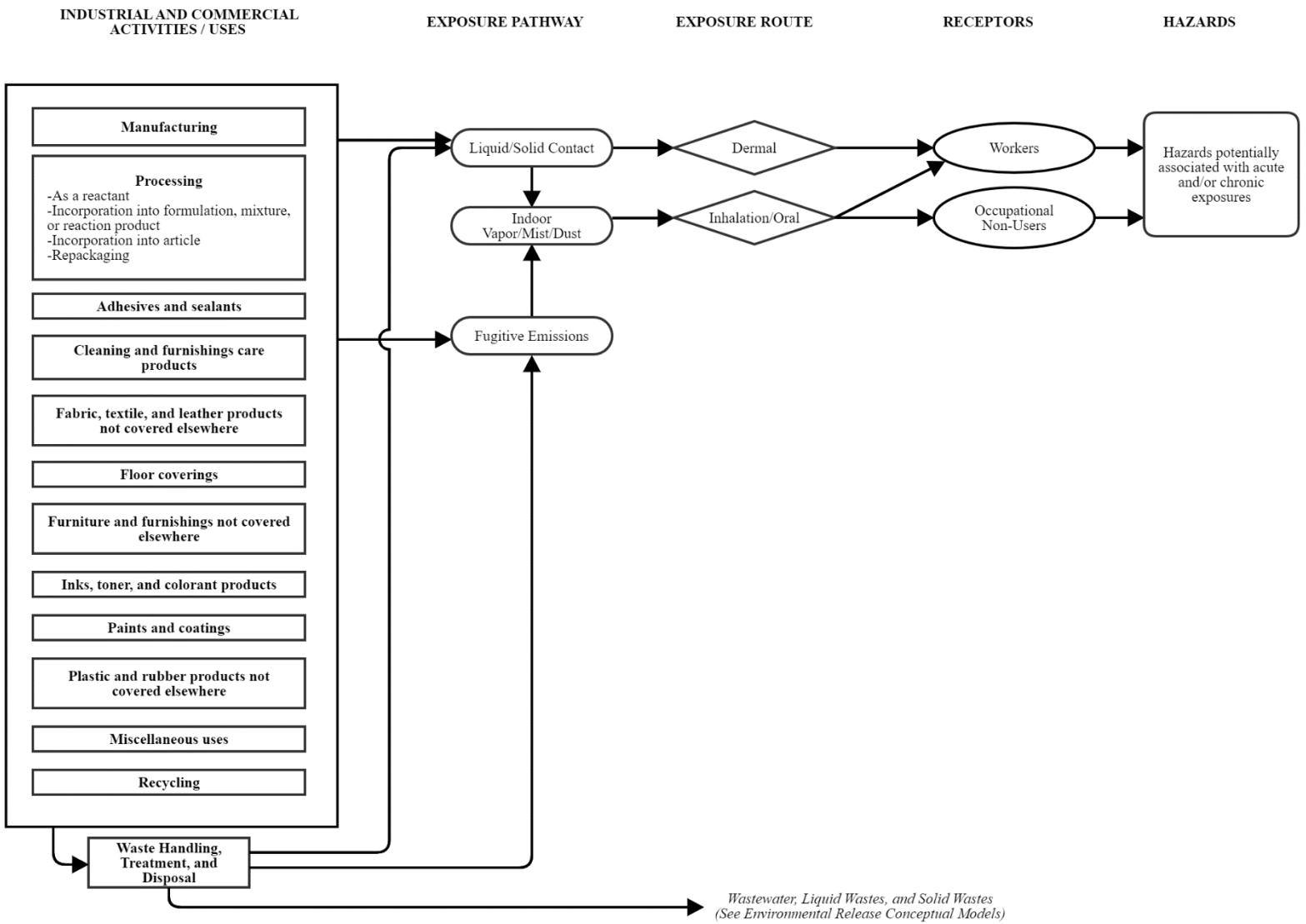

Figure 2-8 Dibutyl Phthalate Conceptual Model for Industrial and Commercial Activities and Uses: Worker and Occupational Non-User Exposures and Hazards

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

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 dibutyl phthalate. EPA expects that consumers may be exposed through use of products or articles containing dibutyl phthalate through oral, dermal, and inhalation routes. During use of articles, EPA expects that consumers may also be exposed via direct dermal contact or mouthing. Bystanders are expected to be exposed through product use via inhalation. It should be noted that some consumers may purchase and use products primarily intended for commercial use. EPA plans to evaluate pathways and routes of exposure that may occur during the varied identified consumer activities and uses. The supporting rationale for consumer pathways considered for dibutyl phthalate are included in Appendix G.

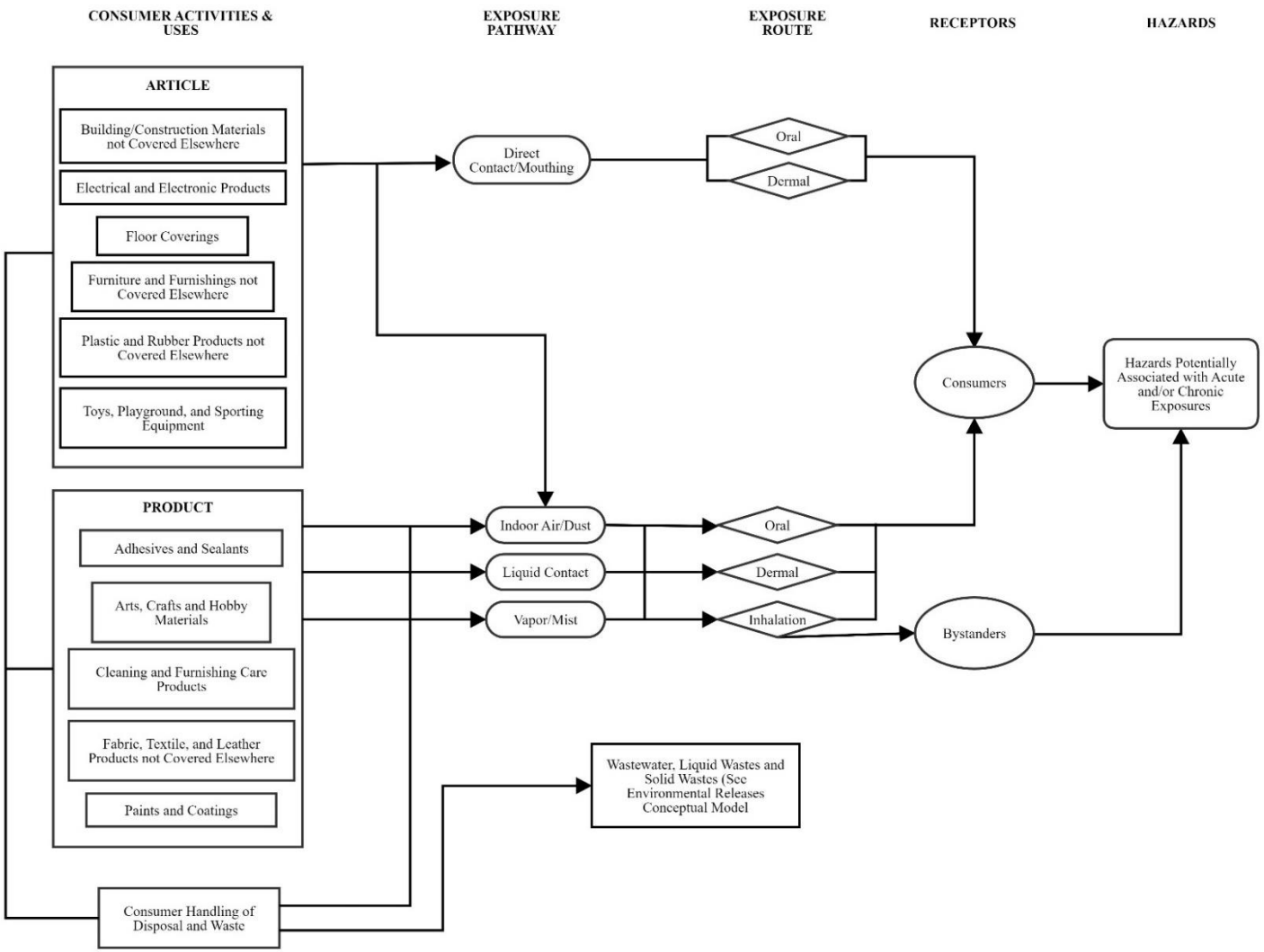

Figure 2-9 Dibutyl Phthalate Conceptual Model for Consumer Activities and Uses: Consumer Exposures and Hazards
The conceptual model presents the exposure pathways, exposure routes and hazards to human receptors from consumer activities and uses of dibutyl phthalate.

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

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 dibutyl phthalate within the scope of the risk evaluation. It also discusses those pathways that may be addressed pursuant to other Federal laws.

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 dibutyl phthalate 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, commercial, and consumer uses of dibutyl phthalate. 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 2.6.3.3.

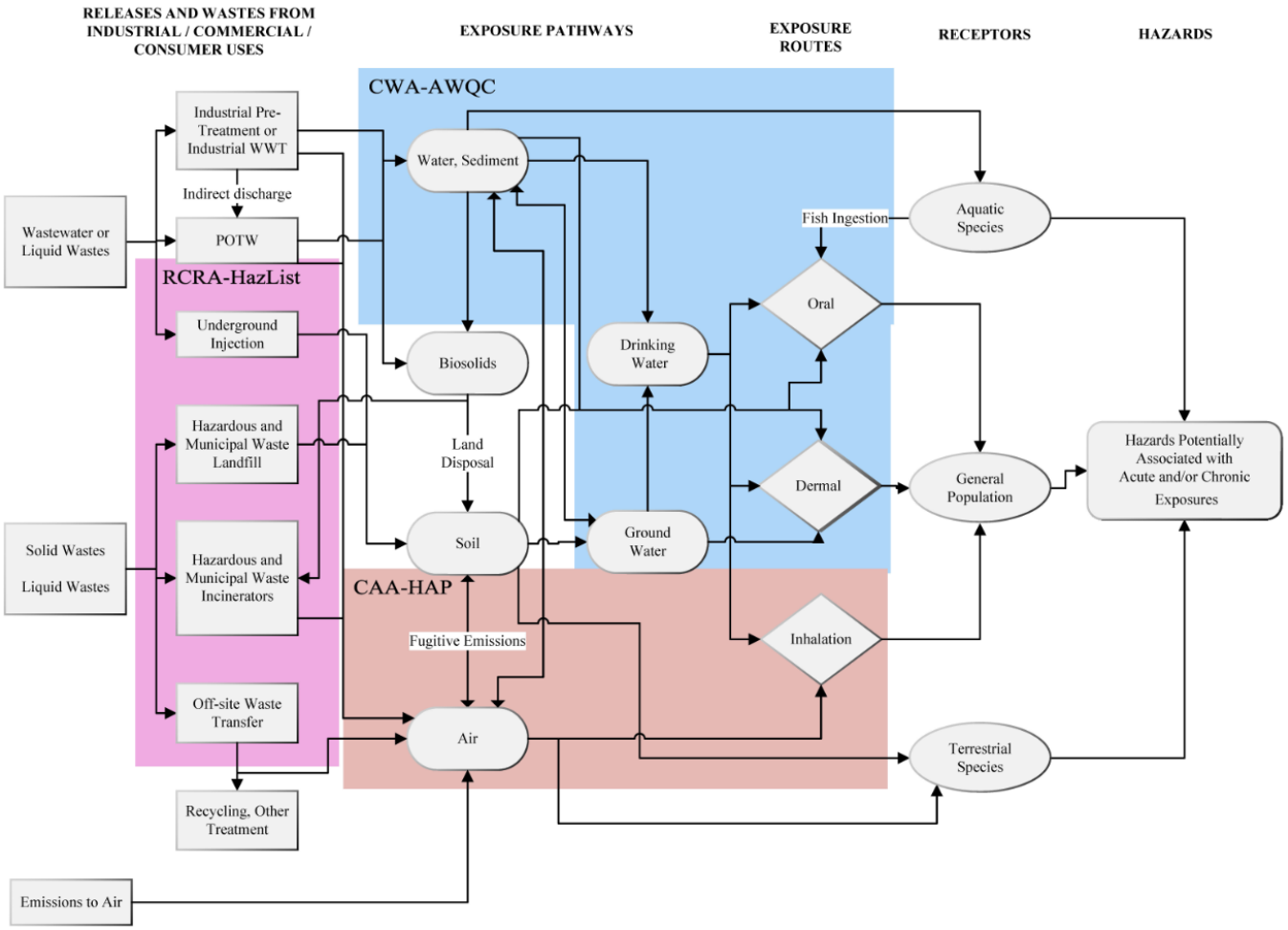

Figure 2-10 Dibutyl Phthalate Conceptual Model for Environmental Releases and Wastes: Environmental and General Population Exposures and Hazards (Regulatory Overlay)

The conceptual model presents the exposure pathways, exposure routes and hazards to human receptors from releases and wastes from industrial, commercial and consumer uses of dibutyl phthalate showing the regulatory laws that adequately assess and manage 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 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. Inhalation form drinking water may occur via showering.

b) Receptors include potentially exposed or susceptible subpopulations (see Section 2.5).

c) For regulation of hazardous and municipal waste incinerators and municipal waste landfills CAA and RCRA may have shared regulatory authority.

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 HAP, 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.

Dibutyl phthalate is a HAP. EPA has issued a number of technology-based standards for source categories that emit dibutyl phthalate 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 dibutyl phthalate 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 Ambient Water Pathway

EPA develops recommended water quality criteria under Section 304(a) of the CWA for pollutants in surface water that are protective of aquatic life or human health designated uses. EPA has developed recommended water quality criteria for protection of human health for dibutyl phthalate which are available for possible adoption into state water quality standards and are available for possible use by National Pollutant Discharge Elimination System (NPDES) permitting authorities in deriving effluent limits to meet state narrative criteria. As such, EPA does not plan to include this pathway in the risk evaluation under TSCA. EPA's OW and OPPT will continue to work together providing understanding and analysis of the CWA water quality criteria development process and to exchange information related to toxicity of chemicals undergoing risk evaluation under TSCA.

EPA has developed CWA Section 304(a) recommended human health criteria for 122 chemicals and aquatic life criteria for 47 chemicals. A subset of these chemicals is identified as "priority pollutants" (103 human health and 27 aquatic life), including dibutyl phthalate. The CWA requires that states adopt numeric criteria for priority pollutants for which EPA has published recommended criteria under Section 304(a), the discharge or presence of which in the affected waters could reasonably be expected to interfere with designated uses adopted the state.

For pollutants with recommended human health criteria, EPA regulations require that state criteria contain sufficient parameters and constituents to protect designated uses. Once states adopt criteria as water quality standards, the CWA requires that NPDES discharge permits include effluent limits as stringent as necessary to meet standards CWA Section 301(b)(1)(C). This permit issuance process accounts for risk in accordance with the applicable ambient water exposure pathway (human health or aquatic life as applicable) for the designated water use.

EPA has not developed CWA Section 304(a) recommended water quality criteria for the protection of aquatic life for dibutyl phthalate, so there are no national recommended criteria for this use available for

adoption into state water quality standards and available for use in NPDES permits. EPA may issue CWA Section 304(a) aquatic life criteria for dibutyl phthalate in the future if it is identified as a priority under the CWA.

2.6.3.3 Disposal and Soil Pathways

Dibutyl phthalate is included on the list of hazardous wastes pursuant to RCRA 3001 (40 CFR §§ 261.33) as a listed waste on the U069 list. The general standard in RCRA Section 3004(a) for the technical criteria that govern the management (treatment, storage, and disposal) of hazardous waste are those "necessary to protect human health and the environment," RCRA 3004(a). The regulatory criteria for identifying "characteristic" hazardous wastes and for "listing" a waste as hazardous also relate solely to the potential risks to human health or the environment (40 CFR §§ 261.11, 261.21-261.24). RCRA statutory criteria for identifying hazardous wastes require EPA to "tak[e] into account toxicity, persistence, and degradability in nature, potential for accumulation in tissue, and other related factors such as flammability, corrosiveness, and other hazardous characteristics." Subtitle C controls cover not only hazardous wastes that are landfilled, but also hazardous wastes that are incinerated (subject to joint control under RCRA Subtitle C and the Clean Air Act (CAA) hazardous waste combustion Maximum Achievable Control Technology (MACT) or injected into Underground Injection Control (UIC) Class I hazardous waste wells (subject to joint control under Subtitle C and the SDWA).

Emissions to ambient air from municipal and industrial waste incineration and energy recovery units that form combustion by-products from incineration treatment of dibutyl phthalate wastes may be subject to regulations, as would dibutyl phthalate burned for energy recovery.

TRI reporting in 2018 indicated 53,330 pounds released to underground injection to a Class I wells. Environmental disposal of dibutyl phthalate injected into Class I hazardous well types fall under the jurisdiction of RCRA and SDWA and disposal of dibutyl phthalate via underground injection is not likely to result in environmental and general population exposures.

EPA has identified releases to land that go to RCRA Subtitle C hazardous waste landfills in the risk evaluation. Based on 2018 reporting, TRI land disposal of dibutyl phthalate includes Subtitle C landfills (57,822 pounds identified in Table 2-3) and 195,503 pounds released to "other landfills" both on-site and off-site. Dibutyl phthalate is present in commercial and consumer products that may be disposed of in landfills, such as Municipal Solid Waste landfills. Design standards for Subtitle C landfills require double liner, double leachate collection and removal systems, leak detection system, run on, runoff, and wind dispersal controls, and a construction quality assurance program. They are also subject to closure and post-closure care requirements including installing and maintaining a final cover, continuing operation of the leachate collection and removal system until leachate is no longer detected, maintaining and monitoring the leak detection and groundwater monitoring system. Bulk liquids may not be disposed in Subtitle C landfills. Subtitle C landfill operators are required to implement an analysis and testing program to ensure adequate knowledge of waste being managed, and to train personnel on routine and emergency operations at the facility. Hazardous waste being disposed in Subtitle C landfills must also meet RCRA waste treatment standards before disposal. Given these controls, general population exposure in groundwater from Subtitle C landfill leachate is not expected to be a significant pathway.

Dibutyl phthalate is present in commercial and consumer products that may be disposed of in Municipal Solid Waste (MSW) landfills. On-site releases RCRA Subtitle D municipal solid waste landfills leading to exposures of the general population (including susceptible populations) or terrestrial species from such releases may occur based on current TRI releases for dibutyl phthalate. While permitted and

managed by the individual states, municipal solid waste (MSW) landfills are required by federal regulations to implement some of the same requirements as Subtitle C landfills. MSW landfills generally must have a liner system with leachate collection and conduct groundwater monitoring and corrective action when releases are detected. MSW landfills are also subject to closure and post-closure care requirements and must have financial assurance for funding of any needed corrective actions. MSW landfills have also been designed to allow for the small amounts of hazardous waste generated by households and very small quantity waste generators (less than 220 lb per month). Bulk liquids, such as free solvent, may not be disposed of at MSW landfills.

On-site releases to land from industrial non-hazardous and construction/demolition waste landfills may occur for dibutyl phthalate. Industrial non-hazardous and construction/demolition waste landfills are primarily regulated under authorized state regulatory programs. States must also implement limited federal regulatory requirements for siting, groundwater monitoring, and corrective action, and a prohibition on open dumping and disposal of bulk liquids. States may also establish additional requirements such as for liners, post-closure and financial assurance, but are not required to do so.

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 presents the exposure pathways, exposure routes and hazards to human and environmental receptors from releases and wastes from industrial, commercial, and consumer uses of dibutyl phthalate 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 dibutyl phthalate in exposure pathways falling under the jurisdiction of these EPA statutes.

The diagram shown in Figure 2-11 includes releases from industrial, commercial and/or consumer uses to water/sediment; biosolids and soil, via direct and indirect discharges to water, that may lead to exposure to aquatic and terrestrial receptors, and to the general population via drinking water. The supporting basis for environmental pathways considered for dibutyl phthalate are included in Appendix H.

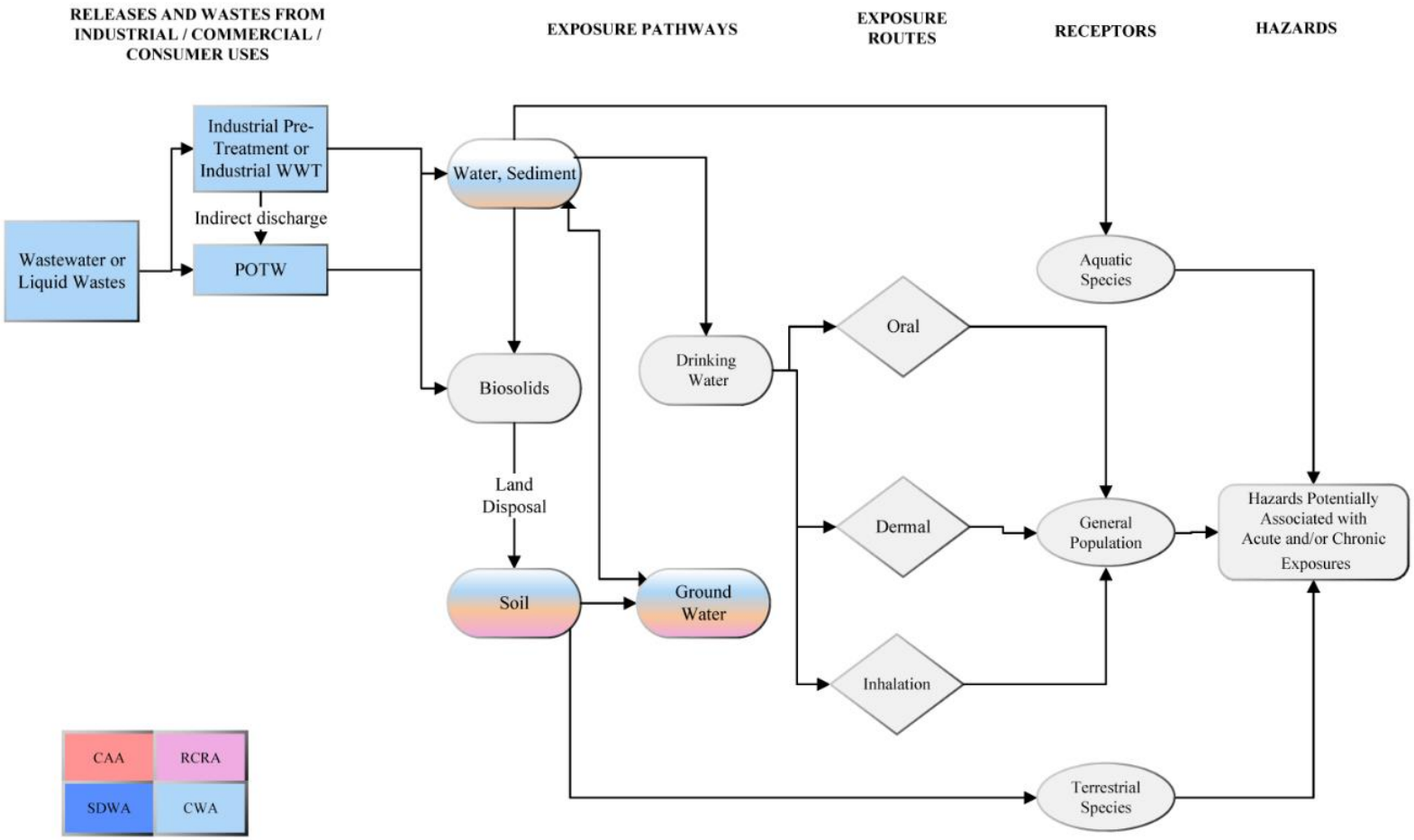

Figure 2-11 Dibutyl Phthalate Conceptual Model for Environmental Releases and Wastes: Environmental and General Population Exposures and Hazards

The conceptual model presents the exposure pathways, exposure routes and hazards to human and environmental receptors from releases and wastes from industrial, commercial, and consumer uses of dibutyl phthalate 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. Inhalation from drinking water may occur via showering.

b) Receptors include potentially exposed or susceptible subpopulations (see Section 2.5).

2.7 Analysis Plan

The analysis plan is based on EPA's knowledge of dibutyl phthalate 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 potentially exposed or susceptible subpopulations 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 P-Chem Properties and Environmental Fate

EPA plans to analyze the p-chem properties and environmental fate and transport of dibutyl phthalate as follows:

1) **Review reasonably available measured or estimated p-chem and environmental fate endpoint data collected using systematic review procedures and, where reasonably 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 (0), some of which appeared in the *Proposed Designation of Dibutyl Phthalate (CASRN 84-74-2) 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.**
   Measured data and, where necessary, model predictions of p-chem properties and environmental fate endpoints will be used to characterize the persistence and movement of dibutyl phthalate within and across environmental media. The fate endpoints of interest include volatilization, sorption to organic matter in soil and sediments, water solubility, aqueous and atmospheric photolysis rates, aerobic and anaerobic biodegradation rates, and potential bioconcentration and bioaccumulation. These endpoints will be used in exposure calculations.

3) **Conduct a weight-of-the-scientific-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 p-chem and 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 dibutyl phthalate. 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 p-chem 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 Categories and Sources of Environmental Release Data

U.S. EPA TRI Data
U.S. EPA Generic Scenarios
OECD Emission Scenario Documents
Discharge Monitoring Report (DMR) surface water discharge data 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 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 reasonably 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.**
   If surrogate data are identified, these data will be matched with applicable conditions of use for potentially filling data gaps. Measured or estimated release data for other phthalate esters may be considered as surrogates for dibutyl phthalate.

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 Adhesive Formulations, the 2011 ESD on Coating Application via Spray-Painting in the Automotive Refinishing Industry, the 2011 ESD on Chemical Industry, the 2011 ESD on Radiation Curable Coating, Inks and Adhesives, the 2015 ESD on the Use of Adhesives, and the 2019 ESD on Plastic Additives 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 assessed.

   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 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 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 dibutyl phthalate and polymer products and formulations containing dibutyl phthalate, 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 dibutyl phthalate:

1) **Review reasonably available environmental and biological monitoring data for all media relevant to environmental exposure.**
   For dibutyl phthalate, environmental media which will be analyzed sediment, soil, air, groundwater and surface water.

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, and soil 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 will include 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.**
   Any studies which relate levels of dibutyl phthalate 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 combinations of sources (use descriptors), exposure pathways including routes, and populations exposed. For dibutyl phthalate, the following are noteworthy considerations in constructing exposure scenarios for environmental receptors:
   - Estimates of surface water concentrations, sediment concentrations and soil concentrations near industrial point sources based on reasonably available monitoring data.
   - Modeling inputs for 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 additional contextualizing information for any monitored data or modeled estimates during risk evaluation. Review and characterize the spatial and temporal variability, to the extent that data are reasonably 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 OSHA and 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 PEL of 5 mg/m^3, 8-hour TWA. The NIOSH REL for dibutyl phthalate is also 5 mg/m^3. EPA plans to consider the influence of these regulatory limits and recommended exposure guidelines on occupational exposures in the occupational exposure assessment.

   Table 2-6 Potential Sources of Occupational Exposure Data

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 dibutyl phthalate.**
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. EPA believes other phthalate esters utilized in similar ways to dibutyl phthalate may serve as surrogates for dibutyl phthalate.

3) **For conditions of use where data are limited or not reasonably 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 2015 ESD on the Use of Adhesives and the 2009 ESD on Plastic Additives, the 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 assessed. EPA plans to perform additional targeted research to understand those conditions of use where ESDs or GS's were not identified, which may inform the 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 Appendix F). As presented in Table_Apx F-1, 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/grouping of occupational exposure scenarios based on factors (e.g., process equipment and handling, magnitude of production volume used, and exposure/release sources) corresponding to conditions of use as additional information is identified during risk evaluation.

7) **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 documentation 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).**
EPA plans to refine and finalize exposure scenarios for consumers by considering combinations of sources (ongoing consumer uses), exposure pathways including routes, and exposed populations.

For dibutyl phthalate, the following are noteworthy considerations in constructing consumer exposure scenarios:

- Conditions of use
- Duration 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 dibutyl phthalate use and disposal. Indoor exposure pathways expected to be relatively lower include 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 reasonably available.

3) **Review existing indoor exposure models that may be applicable in estimating indoor air.**
   Indoor exposure models that estimate emission and migration of semi-volatile organic compounds (SVOCs) into the indoor environment are reasonably available. These models generally consider mass transfer as informed by the gas-phase mass transfer coefficient, the solid-phase diffusion coefficient, and the material-air partition coefficient. These properties vary based on p-chem properties and properties of the material. The OPPT's Indoor Environmental Concentrations in Buildings with Conditioned and Unconditioned Zones (IECCU) model and other similar models can be used to estimate indoor air and dust exposures from indoor sources.

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 reasonably available.**
   To the extent other organizations have already modeled a dibutyl phthalate 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 dibutyl phthalate 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 dibutyl phthalate in specific media (e.g., indoor air).**
   The availability of dibutyl phthalate 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 potentially exposed or susceptible subpopulations 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:

1) **Refine and finalize exposure scenarios for general population by considering combinations of sources and uses, exposure pathways including routes, and exposed populations.**
For dibutyl phthalate, the following are noteworthy considerations in constructing exposure scenarios for the general population:
   - Review 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, review existing exposure models that may be applicable in estimating exposure levels.
   - Consider and incorporate applicable media-specific regulations into exposure scenarios or modeling.
   - Review reasonably available data that may be used in developing, adapting or applying exposure models to the particular risk evaluation. For example, existing models developed for a chemical assessment may be applicable to another chemical assessment if model parameter data are reasonably available.
   - Review reasonably available information on releases to determine how modeled estimates of concentrations near industrial point sources compare with reasonably available monitoring data.
   - Review reasonably available population- or subpopulation-specific exposure factors and activity patterns to determine if potentially exposed or susceptible subpopulations need be further defined.
   - Evaluate the weight of the scientific evidence of general population exposure data.
   - Map or group 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 F. 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 reasonably 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 dibutyl phthalate, media where exposure models will be considered for general population exposure include models that estimate, surface water concentrations, groundwater 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 dibutyl phthalate chemical assessment may be applicable to EPA's assessment. In addition, another chemical's assessment may also be applicable if model parameter data are reasonably available.**
To the extent other organizations have already modeled dibutyl phthalate 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 p-chem properties and similar uses are reasonably 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 potentially exposed or susceptible**

subpopulations need to be further defined (e.g., early life and/or puberty as a potential critical window of exposure).
For dibutyl phthalate, exposure scenarios that involve potentially exposed or susceptible subpopulations 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

EPA plans to conduct an environmental hazard assessment of dibutyl phthalate 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 dibutyl phthalate to aquatic and/or terrestrial organisms, including plants, invertebrates (e.g., insects, arachnids, mollusks, crustaceans, etc.), and vertebrates (e.g., mammals, birds, amphibians, fish, reptiles, etc.) across exposure durations and conditions if potential environmental hazards are identified through public comments and the results of the systematic search and screening of the literature. Additional types of environmental hazard information will also be considered (i.e., analogue and read-across data) when characterizing the potential hazards of dibutyl phthalate 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.

   Relative to appropriate exposure durations, suitable environmental hazard data will be reviewed; 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, etc.) may be derived and used to further understand the hazard characteristics of dibutyl phthalate to aquatic and/or terrestrial species. Identified environmental hazard thresholds may be used to derived concentrations of concern (COC), based on endpoints determined to be detrimental to environmental populations.

3) **Evaluate the weight of the 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 reasonably available approaches to integrate exposure and hazard assessments.**
EPA plans to consider the aquatic (e.g., water and sediment exposures) and terrestrial pathways in the dibutyl phthalate conceptual model. These organisms may be exposed to dibutyl phthalate via a number of environmental pathways (i.e., surface water, sediment, soil, air).

5) **Conduct an environmental risk characterization of dibutyl phthalate.**
EPA plans to conduct a risk characterization of dibutyl phthalate to determine whether there are risks to the aquatic and/or terrestrial environments from the measured and/or predicted concentrations of dibutyl phthalate in environmental media (i.e., water, sediment, soil). The data for environmental monitoring and toxicity will be used in this risk assessment to determine whether exposure to dibutyl phthalate poses risk for adverse effects in aquatic and/or terrestrial organisms. Environmental risk will be characterized by calculating risk quotients (RQs) (U.S. EPA, 1998; Barnthouse et al., 1982). The RQs will be derived from hazard benchmarks.

6) **Consider a Persistent, Bioaccumulative, and Toxic (PBT) Assessment of dibutyl phthalate.**
EPA plans to consider the persistence, bioaccumulation, and toxic (PBT) potential of dibutyl phthalate after reviewing relevant p-chem properties and exposure pathways. EPA plans to assess the reasonably available studies identified in the systematic review process relating to bioaccumulation and bioconcentration (BAF/BCF) of dibutyl phthalate. 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 dibutyl phthalate 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 dibutyl phthalate. 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) **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, 2011b, 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 reasonably 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 dibutyl phthalate, 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).

3) **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 dibutyl phthalate hazard(s). Susceptibility of particular human receptor groups to dibutyl phthalate 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 dibutyl phthalate exposure. EPA plans to review the current state of the literature in order to potentially quantify these differences for risk evaluation purposes.

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 reasonably 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), reasonably available route-to-route extrapolation approaches, reasonably available biomonitoring data and reasonably 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 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 dibutyl phthalate, which could be important for worker, consumer, and general population risk analysis. 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 reasonably 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 obligations under TSCA Section 26; for example, by identifying and assessing uncertainty and variability in each step of the risk evaluation, discussing considerations of data quality such as the reliability, relevance and whether the methods utilized were reasonable and consistent, explaining any assumptions used, and discussing information generated from independent peer review.

EPA will also be guided by EPA's Information Quality Guidelines (U.S, 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 potentially exposed or susceptible subpopulations affected; (3) Each appropriate upper-bound or lower-bound estimate of risk; (4) Each significant uncertainty identified in the process of the assessment of risk effects and the studies that would assist in resolving the uncertainty; and (5) Peer reviewed studies known to the Agency that support, are directly relevant to, or fail to support any estimate of risk effects and the methodology used to reconcile inconsistencies in the scientific information.

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 Risk Evaluation Rule, the purpose of peer review is for the independent review of the science underlying the risk assessment. 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 dibutyl phthalate will be peer reviewed.

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APPENDICES

Appendix A LIST OF GRAY LITERATURE SOURCES

Table_Apx A-1 List of Gray Literature Sources that Yielded Results for Dibutyl Phthalate

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: Proposition 65, Cancer	Other US Agency Resources	Assessment or Related Document
CAL EPA	Technical Support Documents for regulations: Drinking Water Public Health Goals	Other US Agency Resources	Assessment or Related Document
CDC	CDC Biomonitoring Tables	Other US Agency Resources	Database
ECHA	European Union Risk Assessment Report	International Resources	Assessment or Related Document
Env Canada	Chemicals at a Glance (fact sheets)	International Resources	Assessment or Related Document
EPA	Office of Water: STORET and WQX	US EPA Resources	Database
EPA	Office of Air: AQS, Annual	US EPA Resources	Database
EPA	TSCA Hazard Characterizations	US EPA Resources	Assessment or Related Document

Source / Agency	Source Name	Source Type	Source Category
EPA	Included in 2011 NATA	US EPA Resources	Assessment or Related Document
EPA	Office of Air: National Emissions Inventory (NEI) - National Emissions Inventory (NEI) Data (2014, 2011, 2008)	US EPA Resources	Database
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 Discharge Monitoring Report Data	US EPA Resources	Database
EPA	Office of Air: CFRs and Dockets	US EPA Resources	Regulatory Document or List
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 Guide	Other US Agency Resources	Database
NIOSH	CDC NIOSH - Health Hazard Evaluations (HHEs)	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 HazMap	Other US Agency Resources	Database
NLM	National Library of Medicine’s PubChem	Other US Agency Resources	Database

Source / Agency	Source Name	Source Type	Source Category
NTP	Technical Reports	Other US Agency Resources	Assessment or Related Document
NTP	Additional NTP 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	OSHA Chemical Exposure Health Data	Other US Agency Resources	Database
OSHA	U.S. OSHA Chemical Exposure Health Data (CEHD) program data [ERG]	Other US Agency Resources	Database
RIVM	RIVM Reports: Risk Assessments	International Resources	Assessment or Related Document
TERA	Toxicology Excellence for Risk Assessment	Other Resources	Assessment or Related Document

Appendix B PHYSICAL AND CHEMICAL PROPERTIES OF DIBUTYL PHTHALATE

This appendix provides p-chem information and data found in preliminary data gathering for dibutyl phthalate. 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 Dibutyl Phthalate (CASRN 84-74-2) 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-2018-0503).

Table_Apx B-1 Physical and Chemical Properties of Dibutyl Phthalate

Property or Endpoint	Value[a]	Reference	Data Quality Rating
Molecular formula	$C_{16}H_{22}O_4$	NA	NA
Molecular weight	278.35 g/mol	NA	NA
Physical state	Oily liquid	O'Neil, 2013	High
Physical properties	Colorless to faint yellow, oily liquid, slight aromatic odor	NLM, 2015	High
Melting point	-35°C	Rumble, 2018	High
Boiling point	340°C	O'Neil, 2013	High
Density	1.0459 - 1.0465 g/cm^3 at 20°C	NLM, 2015	High
Vapor pressure	2.01×10^{-5} mm Hg at 25°C	NLM, 2015	High
Vapor density	9.58 (air = 1)	NLM, 2015	High
Water solubility	11.2 mg/L at 25°C	Howard, 1985	High
Log Octanol/water partition coefficient (Log Kow)	4.53 at 298.15 K	Ishak, 2016	High
Henry's Law constant	1.81×10^{-6} atm-m^3/mol at 25°C	NLM, 2015	High

Property or Endpoint	Value[a]	Reference	Data Quality Rating
Flash point	157.2222°C	RSC, 2019	High
Auto flammability	Not available		
Viscosity	20.3 cP at 20°C	NLM, 2015	High
Refractive index	1.4900	NLM, 2015	High
Dielectric constant	6.36	Elsevier, 2019	High

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

Appendix C ENVIRONMENTAL FATE AND TRANSPORT PROPERTIES

Table_Apx C-1 provides the environmental fate characteristics that EPA identified and considered in developing the scope for dibutyl phthalate.

Table_Apx C-1 Environmental Fate Characteristics of Dibutyl Phthalate

Property or Endpoint	Value[a]	Reference
Direct Photodegradation	$t_{1/2}$ = 3 hours	Mackay (2006) citing Jin (1999)
Indirect Photodegradation	$t_{1/2}$ = 18.4 hours with reaction with •OH radical	Mackay (2006) citing Howard (1989)
Hydrolysis	$t_{1/2}$ = approximately 22 years	ATSDR (2001) citing U.S EPA (1989)
Biodegradation (Aerobic)	Water: 69% by BOD, 100% by UV-VIS, 100% by GC after 2 weeks at a concentration of 100 ppm unspecified method (most likely Japanese MITI)	NITE (2019)
	Soil: $t_{1/2}$ = 1.8-53 days reported by multiple sources in Mackay et al., 2006 3 days by microorganisms isolated from soil or wastewater; 11–53 days depending on pH, soil type, etc.; <5 days in garden soil; 48–552 hours based on unacclimated aerobic soil grab sample data; 1.8 days at 30 degrees in garden soil; 6.7 days in soil; 11.2 days in soil; 15.8 days in soil	Mackay (2006)
	Sediment: $t_{1/2}$ = 1.0–23 days reported by multiple sources in Mackay et al., 2006	Mackay (2006)
Biodegradation (Anaerobic)	Water: $t_{1/2}$ = 1.19–27.2 days reported by multiple sources in Mackay et al., 2006	Mackay (2006)
	Soil: $t_{1/2}$ = 1–20 days reported by multiple sources in Mackay et al., 2006	Mackay (2006)
	Sediment: $t_{1/2}$ = 7–30 days reported by multiple sources in Mackay et al., 2016	Mackay (2006)
Wastewater Treatment	56% total removal (0.52% by biodegradation, 55% by sludge adsorption, and 0.04% by volatilization to air; estimated)[b]	U.S. EPA (2012)

Property or Endpoint	Value[a]	Reference
Bioconcentration Factor	3.1–21.2 and 5.2–176 at test substance concentrations of 0.05 and 0.015 ppm, respectively (*Cyprinus carpio)*	NITE (2019)
	Accumulation of 1,2 benzenedicarboxylic acid, 1,2-dibutyl ester in the aquatic and terrestrial food chain is limited by biotransformation, which progressively increases with trophic level	ATSDR (2001) citing Staples (1997)
Soil Organic Carbon:Water Partition Coefficient (Log K_{OC})	2.17 (marine sediment/seawater); 0.3010–1.60 (clay and seawater); 4.54 (calculated, sediment-water); 3.14 (soil)	Mackay (2006)

[a]Measured unless otherwise noted; [b]EPI Suite™ physical property inputs: Log K_{ow} = 4.50, BP = 340 ºC, MP = –35 ºC, VP = 2.01×10^{-5} mm Hg, WS = 11.2 mg/L, Henry's Law Constant = 1.81×10^{-6} atm-m^3/mol, SMILES: O=C(OCCCC)c(c(ccc1)C(=O)OCCCC)c1; ·OH = hydroxyl radical; GC = gas chromatography; MITI = Ministry of International Trade and Industry, Japan; BOD = biochemical oxygen demand; K_{OC} = organic carbon-water partitioning coefficient

Appendix D REGULATORY HISTORY

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

D.1 Federal Laws and Regulations

Table_Apx D-1 Federal Laws and Regulations

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
EPA Regulations		
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.	Dibutyl phthalate 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 dibutyl phthalate as 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.	Dibutyl phthalate 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.	Dibutyl phthalate 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.	Seven substantial risk reports received for dibutyl phthalate (1996 -2010) (U.S. EPA, ChemView. Accessed April 8, 2019).
Toxic Substances Control Act (TSCA) – Section 4	Provides EPA with authority to issue rules and orders requiring manufacturers	In 1989, EPA entered an Enforceable Consent Agreement

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	(including importers) and processors to test chemical substances and mixtures.	under TSCA Section 4 with six companies to perform certain chemical fate and environmental effects on certain Alkyl Phthalates (54 FR 618). 12 chemical data submissions from test rules received for dibutyl phthalate: one acute aquatic plant toxicity, eight acute aquatic toxicity, two chronic aquatic toxicity and one vapor pressure. (U.S. EPA, ChemView. Listings undated. 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).	Dibutyl phthalate 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	Dibutyl phthalate is listed as a HAP (42 U.S. Code Section 7412).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	removed two pollutants from the original list leaving 187 at present.	
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 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.	EPA has established NESHAPs for a number of source categories that emit dibutyl phthalate to air. (See https://www.epa.gov/stationary-sources-air-pollution/national-emission-standards-hazardous-air-pollutants-neshap-9)
Clean Water Act (CWA) – Section 304(a)(1)	Requires EPA to develop and publish ambient water quality criteria (AWQC) reflecting the latest scientific knowledge on the effects on human health that may be expected from the presence of pollutants in any body of water.	In 2015, EPA published updated AWQC for dibutyl phthalate, including a recommendation of 20 µg/L for "Human Health for the consumption of Water + Organism" and 30 µg/L for "Human Health for the consumption of Organism Only" for states and authorized tribes to consider when adopting criteria into their water quality standards. (Docket ID: EPA-HQ-OW-2014-0135-0242)
Clean Water Act (CWA) – Section 301, 304, 306, 307, and 402	Clean Water Act Section 307(a) establishes a list of toxic pollutants or combination of pollutants under the CWA. The statue specifies a list of families of toxic pollutants also listed in the Code of Federal Regulations at 40 CFR Part 401.15. The "priority pollutants" specified by those families are listed in 40 CFR Part 423 Appendix A. These are pollutants for which best available technology effluent limitations must be established on either a national basis through rules (Sections 301(b), 304(b), 307(b), 306) or on a case-	Dibutyl phthalate is designated as a toxic pollutant under Section 307(a)(1) of the CWA and as such is subject to effluent limitations. Under CWA Section 304, dibutyl phthalate is included in the list of total toxic organics (TTO) (40 CFR 413.02(i)).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	by-case best professional judgement basis in NPDES permits, see Section 402(a)(1)(B). EPA identifies the best available technology that is economically achievable for that industry after considering statutorily prescribed factors and sets regulatory requirements based on the performance of that technology.	
Clean Water Act (CWA) – Section 311(b)(2)(A) and 501(a) of the Federal Water Pollution Control Act.	Requires EPA to develop, promulgate, and revise as may be appropriate, regulations designating as hazardous substances, other than oil, which, when discharged present an imminent and substantial danger to the public health or welfare, including, but not limited to, fish, shellfish, wildlife, shorelines, and beaches.	Dibutyl phthalate is a designated hazardous substance in accordance with Section 311(b)(2)(A) of the Federal Water Pollution Control Act.
Resource Conservation and Recovery Act (RCRA) – Section 3001	Directs EPA to develop and promulgate criteria for identifying the characteristics of hazardous waste, and for listing hazardous waste, taking into account toxicity, persistence, and degradability in nature, potential for accumulation in tissue and other related factors such as flammability, corrosiveness, and other hazardous characteristics.	Dibutyl phthalate is included on the list of hazardous wastes pursuant to RCRA 3001. RCRA Hazardous Waste Code: U069. (40 CFR 261.33)
Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) – Sections 102(a) and 103	Authorizes EPA to promulgate regulations designating as hazardous substances those substances which, when released 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.	Dibutyl phthalate is a hazardous substance under CERCLA. Releases of dibutyl phthalate in excess of 10 pounds must be reported (40 CFR 302.4).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
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.	Dibutyl phthalate 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.
Other Federal Regulations		
Federal Food, Drug, and Cosmetic Act (FFDCA)	Provides the FDA with authority to oversee the safety of food, drugs and cosmetics.	Dibutyl phthalate is listed as an optional substance to be used in: adhesives to be used as components of articles intended for use in packaging, transporting, or holding food (21 CFR § 175.105); the base sheet and coating of cellophane, alone or in combination with other phthalates where total phthalates do not exceed 5 percent (21 CFR § 177.1200). The FDA has reviewed phthalates in cosmetic products but does **not** restrict their use.
Consumer Product Safety Improvement Act of 2008 (CPSIA)	Under Section 108 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), CPSC prohibits the manufacture for sale, offer for sale, distribution in commerce or importation of eight phthalates in toys and child care articles at concentrations greater than 0.1 percent: di-ethylhexyl phthalate, dibutyl phthalate, butyl benzyl phthalate, di-isononyl phthalate, di-isobutyl phthalate, di-n-pentyl phthalate, di-n-hexyl phthalate and dicyclohexyl phthalate.	The use of dibutyl phthalate at concentrations greater than 0.1 percent is banned in toys and child care articles (16 CFR part 1307).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
Federal Hazardous Materials Transportation Act (HMTA)	Section 5103 of the Act directs the Secretary of Transportation to: • Designate material (including an explosive, radioactive material, infectious substance, flammable or combustible liquid, solid or gas, toxic, oxidizing or corrosive material, and compressed gas) as hazardous when the Secretary determines that transporting the material in commerce may pose an unreasonable risk to health and safety or property. • Issue regulations for the safe transportation, including security, of hazardous material in intrastate, interstate and foreign commerce.	Dibutyl phthalate is listed as a hazardous material with regard to transportation and is subject to regulations prescribing requirements applicable to the shipment and transportation of listed hazardous materials (70 FR 34381, June 14 2005). 49 CFR part 172.101Appendix A

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 Drinking Water Standards and Guidelines	Florida (Fla. Admin. Code R. Chap. 62-550), Michigan (Mich. Admin. Code r.299.44 and r.299.49, 2017), Minnesota (Minn R. Chap. 4720).
State PELs	California (PEL of 5 ppm and no STEL) (Cal Code Regs. Title 8, § 5155) Hawaii (PEL-TWA of 5 mg/m3 and PEL-STEL of 10 mg/m3) (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	Several states have adopted reporting laws for chemicals in children's products containing dibutyl phthalate, including Maine (38 MRSA Chapter 16-D), Oregon (Toxic-Free Kids Act, Senate Bill 478, 2015), Vermont (18 V.S.A § 1776) and Washington State (Wash. Admin. Code 173-334-130).
Volatile Organic Compound (VOC)	California regulations may set VOC limits for consumer products and/or ban the sale of certain consumer products as an ingredient and/or impurity. California (Title 17, California Code of Regulations, Division 3, Chapter 1,

State Actions	Description of Action
Regulations for Consumer Products	Subchapter 8.5, Articles 1, 2, 3 and 4). Under the Aerosol Coating Products Regulation, a Maximum Incremental Reactivity value has been established for dibutyl phthalate (Subchapter 8.6, Article 1, § 94700).
Other	California listed dibutyl phthalate on Proposition 65 in 2005 due to developmental toxicity, female and male reproductive toxicity. (Cal Code Regs. Title 27, § 27001). Dibutyl phthalate is listed as a Candidate Chemical under California's Safer Consumer Products Program (Health and Safety Code § 25252 and 25253). California issued a Health Hazard Alert for dibutyl phthalate (Hazard Evaluation System and Information Service, 2016). dibutyl phthalate dibutyl phthalate is on the MA Toxic Use Reduction Act (TURA) list of 2019 (300 CMR 41.00).

D.3 International Laws and Regulations

Table Apx D-3 Regulatory Actions by other Governments, Tribes, and International Agreements

Country/ Organization	Requirements and Restrictions
Canada	Dibutyl phthalate is on the Domestic Substances List (Government of Canada. Managing substances in the environment. Substances search. Database accessed April 10, 2019). Other regulations include: • Canada's National Pollutant Release Inventory (NPRI). Canada Gazette Part II, Vol. 128, No. 9, May 04 1994, SOR/94-311 • Dibutyl phthalate did not meet the criteria under subsection 73(1) of the Canadian Environmental Protection Act, 1999 (CEPA).
European Union	Dibutyl phthalate is registered for use in the EU. (European Chemicals Agency (ECHA) database. Accessed April 10, 2019.) In 2008, dibutyl phthalate was listed on the Candidate list as a Substance of Very High Concern (SVHC) under regulation (EC) No 1907/2006 - REACH (Registration, Evaluation, Authorization and Restriction of Chemicals due to its reproductive toxicity (category 1B). In 2012, dibutyl phthalate was added to Annex XIV of REACH (Authorisation List) with a sunset date of December 21, 2015. After the sunset date, only persons with approved authorization applications may continue to use the chemical (European Chemicals Agency (ECHA) database. The exempted category of use is: uses in the immediate packaging of medicinal products covered under Regulation (EC) No

Country/ Organization	Requirements and Restrictions
	726/2004, Directive 2001/82/EC, and/or Directive 2001/83/EC. Accessed April 10, 2019). Applications for authorizations to use, including in propellants, electronics manufacture and closed manufacturing processes: Under Annex XVII to REACH, dibutyl phthalate: 1. shall not be used as substances or in mixtures, individually or in any combination of the phthalates listed in column 1 of this entry, in a concentration equal to or greater than 0,1 % by weight of the plasticized material, in toys and childcare articles 2. shall not be placed on the market in toys or childcare articles, individually or in any combination of the first three phthalates listed in column 1 of this entry, in a concentration equal to or greater than 0,1 % by weight of the plasticized material. In addition, di-isobutyl phthalate shall not be placed on the market after 7 July 2020 in toys or childcare articles, individually or in any combination with the first three phthalates listed in column 1 of this entry, in a concentration equal to or greater than 0,1 % by weight of the plasticized material. 3. Shall not be placed on the market after 7 July 2020 in articles, individually or in any combination of the phthalates listed in column 1 of this entry, in a concentration equal to or greater than 0,1 % by weight of the plasticized material in the article. 4. Paragraph 3 shall not apply to: (a) articles exclusively for industrial or agricultural use, or for use exclusively in the open air, provided that no plasticized material comes into contact with human mucous membranes or into prolonged contact with human skin; (b) aircraft, placed on the market before 7 January 2024, or articles, whenever placed on the market, for use exclusively in the maintenance or repair of those aircraft, where those articles are essential for the safety and airworthiness of the aircraft; (c) motor vehicles within the scope of Directive 2007/46/EC, placed on the market before 7 January 2024, or articles, whenever placed on the market, for use exclusively in the maintenance or repair of those vehicles, where the vehicles cannot function as intended without those articles; (d) articles placed on the market before 7 July 2020; (e) measuring devices for laboratory use, or parts thereof; (f) materials and articles intended to come into contact with food within the scope of Regulation (EC) No 1935/2004 or Commission Regulation (EU) No 10/20111; (g) medical devices within the scope of Directives 90/385/EEC, 93/42/EEC or 98/79/EC, or parts thereof;

Country/ Organization	Requirements and Restrictions
	(h) electrical and electronic equipment within the scope of Directive 2011/65/EU; (i) the immediate packaging of medicinal products within the scope of Regulation (EC) No 726/2004, Directive 2001/82/EC or Directive 2001/83/EC; (j) toys and childcare articles covered by paragraphs 1 or 2. 5. For the purposes of paragraphs 1, 2, 3 and 4(a), (a) 'plasticized material' means any of the following homogeneous materials: - polyvinyl chloride (PVC), polyvinylidene chloride (PVDC), polyvinyl acetate (PVA), polyurethanes, - any other polymer (including, inter alia, polymer foams and rubber material) except silicone rubber and natural latex coatings, - surface coatings, non-slip coatings, finishes, decals, printed designs, - adhesives, sealants, paints and inks. European Commission Directive (EU) 2015/863 of 31 March 2015 amended Annex II to Directive 2011/65/EU, to restrict dibutyl phthalate at 0.1% or greater so that: - The restriction of dibutyl phthalate shall apply to medical devices, including in vitro medical devices, and monitoring and control instruments, including industrial monitoring and control instruments, from 22 July 2021. - The restriction of dibutyl phthalate shall not apply to cables or spare parts for the repair, the reuse, the updating of functionalities or upgrading of capacity of EEE placed on the market before 22 July 2019, and of medical devices, including in vitro medical devices, and monitoring and control instruments, including industrial monitoring and control instruments, placed on the market before 22 July 2021. - The restriction of dibutyl phthalate shall not apply to toys which are already subject to the restriction of di-ethylhexyl phthalate, butyl benzyl phthalate and dibutyl phthalate through entry 51 of Annex XVII to Regulation (EC) No 1907/2006. Dibutyl phthalate is subject to the Restriction of Hazardous Substances Directive (RoHS), EU/2015/863, which restricts the use of hazardous substances at more than 0.1% by weight at the 'homogeneous material' level in electrical and electronic equipment, beginning July 22, 2019. (European Commission RoHS).
Australia	Dibutyl phthalate was assessed under Human Health and Environment (Phthalate esters) Tier II of the Inventory Multi-Tiered Assessment and Prioritisation (IMAP). Dibutyl phthalate has been listed and assessed as a Priority Existing Chemical (PEC/36, November 2013). NICNAS found no reports of the phthalate being manufactured as a raw material in Australia. Dibutyl phthalate is imported into Australia mainly

Country/ Organization	Requirements and Restrictions
	as a component of finished products or mixtures and also as a raw material for local formulation and processing. There are currently no restrictions on the manufacture, import or use of dibutyl phthalate in Australia. Dibutyl phthalate is listed in the Safe Work Australia List of Designated Hazardous Substances contained in the Hazardous Substances Information System (HSIS) as a Reproductive Toxicant Category 2 (requiring it to be labelled with the risk phrase [R61]—May cause harm to the unborn child); and Reproductive Toxicant Category 3 (requiring the risk phrase [R62]—Possible risk of impaired fertility). Data accessed April 10, 2019:
Japan	Dibutyl phthalate is regulated in Japan under the following legislation: • Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Chemical Substances Control Law; CSCL) • Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof • Industrial Safety and Health Act (ISHA) • Air Pollution Control Law (National Institute of Technology and Evaluation [NITE] Chemical Risk Information Platform [CHRIP]. Accessed April 10, 2019
World Health Organization (WHO)	Established a tolerable daily intake of 66 μg dibutyl phthalate/kg body weight based on a LOAEL of 66 mg/kg body weight per day for developmental and reproductive toxicity in rats from a continuous breeding study, incorporating an uncertainty factor of 1,000. (WHO Environmental Health Criteria 189, 1997)
Australia, Austria, Belgium, Canada, Denmark, European Union, France, Germany, Ireland, Japan, Latvia, New Zealand, People's Republic of China, Poland, Singapore, South Korea, Spain, Sweden, Switzerland, United Kingdom	Occupational exposure limits for dibutyl phthalate (GESTIS International limit values for chemical agents (Occupational exposure limits, OELs) database. Accessed April 12, 2019).

Appendix E PROCESS, RELEASE AND OCCUPATIONAL EXPOSURE INFORMATION

This appendix provides information and data found in preliminary data gathering for Dibutyl Phthalate.

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)

The 2016 CDR reports 21 facilities that submitted activity data for 2015. 11 of these facilities stated that they imported dibutyl phthalate in 2015, one stated that they manufactured dibutyl phthalate in 2015, and the remaining nine facilities' 2015 manufacture or import activity is withheld or claimed as CBI (U.S. EPA,2019). According to 2016 public CDR data, dibutyl phthalate is both domestically manufactured in and imported into the United States in liquid form (U.S. EPA,2019).

E.1.1.1 Domestic Manufacturing

Dibutyl phthalate is manufactured through the esterification of the carboxyl groups of dibutyl phthalate with n-butyl alcohol in the presence of sulfuric acid as a catalyst (ECHA, 2009). After the esterification reaction, excess alcohol is recovered and dibutyl phthalate is purified through distillation or activated charcoal (ECHA, 2009).

E.1.1.2 Import

In general, chemicals may be imported into the United States in bulk via water, air, land, and intermodal shipments (Tomer and Kane, 2015). These shipments take the form of oceangoing chemical tankers, railcars, tank trucks, and intermodal tank containers. Dibutyl phthalate is shipped in liquid form according to 2016 CDR. Of the 11 facilities in 2016 CDR that imported dibutyl phthalate in 2015 (excluding the facilities for which the importation/manufacturing activity was withheld or claimed CBI), EPA has identified two sites that imported dibutyl phthalate directly to their sites for on-site processing or use and nine sites that imported dibutyl phthalate directly to other sites for processing or use (the importing site does not directly handle or store the imported dibutyl phthalate) (U.S. EPA,2019).

E.1.2 Processing and Distribution

E.1.2.1 Reactant or Intermediate

Processing as a reactant or intermediate is the use of dibutyl phthalate as a feedstock in the production of another chemical via a chemical reaction in which dibutyl phthalate is consumed to form the product. Two companies that reported to 2016 CDR indicated that dibutyl phthalate was processed as a reactant in the production of other chemicals. Dibutyl phthalate is used as an intermediate to produce plastics and rubber products, adhesives, paints and coatings, and asphalt products (U.S. EPA,2019).

Exact operations for the use of dibutyl phthalate as a reactant to produce other chemicals are not known at this time. For using a chemical as a reactant, operations would typically involve unloading the chemical from transport containers and feeding the chemical into a reaction vessel(s), where the

chemical would react either fully or to a lesser extent. Following completion of the reaction, the produced substance may be purified further, thus removing unreacted dibutyl phthalate (if any exists).

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. Exact process operations involved in the incorporation of dibutyl phthalate into a chemical formulation, mixture, or reaction product are dependent on the specific manufacturing process or processes involved. Companies reported to 2016 CDR that dibutyl phthalate is used as a plasticizer in the formulation of paint and coating, plastic material and resin, plastic products, soap, cleaning compound, and toilet preparation manufacturing (U.S. EPA,2019; NLM, 2015). Dibutyl phthalate is used as a functional fluid in printing activities and a solvent in other chemical manufacturing (U.S. EPA,2019; NLM, 2015; Ullman's, 2011a; Synapse, 2009). Dibutyl phthalate is also used in the formulation of ink, toner, and colorant products, among other formulations (NLM, 2015). The exact processes used to formulate products containing dibutyl phthalate are not known at this time; however, several ESDs published by the OECD and Generic Scenarios published by EPA have been identified that provide general process descriptions for these types of products. EPA plans to further investigate processing uses of dibutyl phthalate during risk evaluation.

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 dibutyl phthalate-containing formulations or reaction products are dependent on the article. Three companies reported to 2016 CDR that dibutyl phthalate is used as a plasticizer in the production of plastic products and one company reported the use of dibutyl phthalate as a plasticizer in rubber products (U.S. EPA, 2019). Dibutyl phthalate may also be used as a plasticizer in ceramic and in textiles and apparel (NLM, 2015). EPA plans to further investigate processing uses of dibutyl phthalate during risk evaluation.

E.1.2.1 Repackaging

Repackaging refers to preparation of a chemical substance for distribution into commerce in a different form, state, or quantity than originally received/stored, where such activities include transferring a chemical substance form a bulk storage container into smaller containers.

E.1.2.2 Recycling

In 2016 CDR, two facilities reported that dibutyl phthalate was recycled (i.e., recycled, remanufactured, reprocessed, or reused). Thirteen facilities reported that this chemical was not recycled (U.S. EPA,2019). According to 2018 TRI, a small portion (less than 1%) of the total quantity of dibutyl phthalate managed as waste was recycled off site.

E.1.3 Uses

E.1.3.1 Adhesives, Sealants, Paints, and Coatings

Dibutyl phthalate is used in a variety of adhesive, sealant, paint, and coating products. Specifically, dibutyl phthalate is used in adhesives and sealants used in food packaging and labels, wallpaper, floor sealing and coating, poly(vinyl acetate) coatings, lacquers, varnishes, paints, and coatings used in the building and construction industry (U.S. EPA,2019; NLM, 2015; GoodGuide, 2011; Ullmann's, 2011b). The application procedure depends on the type of adhesive, sealant, paint, or coating formulation and the type of substrate. The formulation is loaded into the application reservoir or apparatus and applied to the

substrate via brush, spray, roll, dip, curtain, or syringe or bead application. Application may be manual or automated. After application, the adhesive, sealant, paint, or coating is allowed to dry or cure (OECD, 2015). The drying/curing process may be promoted through the use of heat or radiation (radiation can include ultraviolet (UV) and electron beam radiation (OECD, 2010).

E.1.3.2 Building/Construction Materials Not Covered Elsewhere

Dibutyl phthalate is used in building and construction materials not covered elsewhere, including in caulking materials (GoodGuide, 2011) and in asphalt paving, roofing, and coating materials (U.S. EPA,2019). EPA did not find additional information on these products. EPA plans to further investigate these uses of dibutyl phthalate during risk evaluation.

In addition, dibutyl phthalate is an additive in polyester, vinyl ester, or epoxy resin cured-in-place pipe (CIPP) (NIOSH, 2017). CIPP is used for in-place repairs to pipes such as water mains. Workers repair pipes in place by first inserting a resin-impregnated liner in the damaged pipe, then forcing steam, hot water, or ultraviolet light across the liner to cure the resin (NIOSH, 2017).

E.1.3.3 Cleaning and Furnishings Care Products

Dibutyl phthalate may be present in cleaning and furnishing care products, such as glass window cleaning formulations, carpet and floor cleaners, spot removers, and shoe care products (U.S. EPA,2019; NLM, 2015; GoodGuide, 2011). Once formulated, cleaning solutions containing dibutyl phthalate can be applied to substrates using a variety of application methods, including roller application, brushing, dipping, pouring, spraying and wiping. Application may be automated or manual, depending on the cleaning product and the industry. Consumer cleaning solutions are likely to be applied manually, whereas professional cleaning processes are often automated. The applied cleaning solution is then removed from the substrate, along with the contaminants, and discarded as waste.

E.1.3.4 Ink, Toner, and Colorant Products

Dibutyl phthalate is used in ink, toner, and colorant products, including coloring agents, printing inks, digital inks, and inks and toners used in the electronics industry (U.S. EPA,2019; NLM, 2015). Printing inks consist of colorants (e.g., pigments, dyes and toners) dispersed in a formulation to form a paste, liquid or solid, which can be applied to a substrate surface and dried (U.S. EPA, 2010). Industrial printing processes can be categorized as lithographic, flexographic, gravure, letterpress, screen printing or digital printing. Commercial printing may involve lithographic, flexographic, gravure and letterpress printing - all of which involve the transfer of images from printing plates to a substrate. Screen printing requires a mesh screen to transfer the ink to a substrate, whereas digital printing allows for the transfer of a digital image directly onto a substrate. Inkjet printing is the most common form of digital printing. It involves the application of small drops of ink onto a substrate, with direct contact between the ink nozzle and the substrate (U.S. EPA, 2010).

E.1.3.5 Plastic and Rubber Products

As described in Section E.1.2.3, dibutyl phthalate is used in the production of plastic and rubber products, which may be used industrially, commercially, and by consumers. These products are used in a variety of products, including building and construction materials, flooring materials, and furniture and furnishings (U.S. EPA,2019; NLM, 2015). Dibutyl phthalate is likely entrained in the products; however, dibutyl phthalate may be available for exposure depending on the application of the end use products, such as if building and construction materials are cut prior to installation. EPA plans to further investigate these uses of dibutyl phthalate during risk evaluation.

E.1.3.6 Other Uses

Dibutyl phthalate is used as a solvent in Huntsman's maleic anhydride manufacturing technology (U.S. EPA,2019) and in explosives and propellants (Akhavan, 2018; NLM, 2015; Synapse, 2009). Dibutyl phthalate is also used as a laboratory chemical (non-incorporative) (U.S. EPA,2019; NLM, 2015; Ullman's, 2011a; Synapse, 2009). Laboratory procedures are generally done within a fume hood, on a bench with local exhaust ventilation or under general ventilation.

EPA plans to evaluate these uses of dibutyl phthalate during risk evaluation.

E.1.4 Disposal

Each of the conditions of use of dibutyl phthalate may generate waste streams of the chemical that are collected and transported to third-party sites for disposal, treatment, or recycling. Industrial sites that treat or dispose onsite wastes that they themselves generate are assessed in each condition of use assessment. Similarly, point source discharges of dibutyl phthalate to surface water are assessed in each condition of use assessment (point source discharges are exempt as solid wastes under RCRA). Wastes of dibutyl phthalate that are generated during a condition of use and sent to a third-party site for treatment, disposal, or recycling may include the following:

- Wastewater: Dibutyl phthalate may be contained in wastewater discharged to POTW or other, non-public treatment works for treatment. Industrial wastewater containing dibutyl phthalate discharged to a POTW may be subject to EPA or authorized NPDES state pretreatment programs. The assessment of wastewater discharges to POTWs and non-public treatment works of dibutyl phthalate is included in each of the condition of use assessments.

- Solid Wastes: Solid wastes are defined under RCRA as any material that is discarded by being: abandoned; inherently waste-like; a discarded military munition; or recycled in certain ways (certain instances of the generation and legitimate reclamation of secondary materials are exempted as solid wastes under RCRA). Solid wastes may subsequently meet RCRA's definition of hazardous waste by either being listed as a waste at 40 CFR §§ 261.30 to 261.35 or by meeting waste-like characteristics as defined at 40 CFR §§ 261.20 to 261.24. Solid wastes that are hazardous wastes are regulated under the more stringent requirements of Subtitle C of RCRA, whereas non-hazardous solid wastes are regulated under the less stringent requirements of Subtitle D of RCRA.

  Dibutyl phthalate is a U-listed hazardous waste under code U069 under RCRA; therefore, discarded, unused pure and commercial grades of dibutyl phthalate are regulated as a hazardous waste under RCRA (40 CFR § 261.33(f)).

- Wastes Exempted as Solid Wastes under RCRA: Certain conditions of use of dibutyl phthalate may generate wastes of dibutyl phthalate that are exempted as solid wastes under 40 CFR § 261.4(a). For example, the generation and legitimate reclamation of hazardous secondary materials of dibutyl phthalate may be exempt as a solid waste.

According to 2018 TRI, the vast majority (approximately 92%) of dibutyl phthalate released to the environment was disposed of to land, totaling 306,655 pounds. Of this amount, "all other land disposal" accounted for nearly 64%, which comprised off-site disposal to landfills (146,062 pounds) other than RCRA Subtitle C landfills, or by other on-site land disposal methods such as placement in waste piles, spills, or leaks (49,441 pounds). The remaining 36% of total land disposal included disposal to on-site

RCRA Subtitle C landfills and disposal to on-site Class I underground injection wells. There were zero pounds of dibutyl phthalate reported as released to water via surface water discharges, and a total of 23,850 pounds were released to air as fugitive and stack emissions.

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 Dibutyl Phthalate

Year of Publication	Report Number	Facility Description
1998	HETA 97–0214–2689	Hydraulic Door Closer Manufacture – Application of Paints and Coatings
1987	MHETA 86-191-1836	Highway Sign Fabrication and Silkscreening
1986	HETA 85-060-1670	Xerox Copying (High School Media Center)
1982	HETA 81-275-1122	Carbonless Paper Handling (Administrative) – General Telephone Company
1982	HETA 81-277-1089	Cartridge Ammunition Manufacture
1981	HE 80-094-840	Automobile Manufacture and Assembly
1977	HE 76-92-363	Acrylic Furniture Manufacture

[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 Dibutyl Phthalate Monitoring Samples Available from OSHA Inspections (2010 and 2019)

NAICS	NAICS Description	Number of Data Points
312113	Ice Manufacturing	2
313320	Fabric Coating Mills	3
325611	Soap and Other Detergent Manufacturing	2
333131	Mining Machinery and Equipment Manufacturing	2
337920	Blind and Shade Manufacturing	2
811490	Other Personal and Household Goods Repair and Maintenance	1
812112	Beauty Salons	1
928110	National Security	2

Appendix F SUPPORTING INFORMATION FOR OCCUPATIONAL EXPOSURE CONCEPTUAL MODEL

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 / Population	Plans to Evaluate	Rationale
Manufacture	Domestic Manufacture	Domestic Manufacture	Manufacture and Packaging	Liquid Contact	Dermal	Workers	Yes	2016 CDR references manufacture in liquid form. Thus, the potential for exposures to workers exists during manufacturing.
				Solid Contact	Dermal	Workers	No	2016 CDR does not include information on manufacture in solid form. Thus, the potential for exposures to workers does not exist during manufacturing.
				Vapor	Inhalation	Workers, ONU	No	Due to dibutyl phthalate's vapor pressure (VP) (VP = 2.01 × 10-5 mm Hg) at room temperature, potential for vapor generation is low.
				Mist	Inhalation/Dermal	Workers, ONU	No	Mist generation is not expected during manufacturing.
				Dust	Inhalation/Dermal	Workers, ONU	No	2016 CDR references manufacture in liquid form. Thus, the potential for dust exposures to workers does not exist during manufacturing.
				Liquid/Solid Contact	Dermal	ONU	No	Exposure is expected to be primarily restricted to workers who are directly involved in working with the chemical. ONUs are not expected to come in direct contact with the chemicals.
	Import	Import	Repackaging of import containers	Liquid Contact	Dermal	Workers	Yes	2016 CDR references import in liquid form. Thus,

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
								the potential for exposures to workers exists during manufacturing.
				Solid Contact	Dermal	Workers	No	2016 CDR does not include information on import in solid form. Thus, the potential for exposures to workers does not exist during manufacturing.
				Vapor	Inhalation	Workers, ONU	No	Due to dibutyl phthalate's vapor pressure (VP) (VP = 2.01 × 10-5 mm Hg) at room temperature, potential for vapor generation is low.
				Mist	Inhalation/Dermal	Workers, ONU	No	Mist generation is not expected during importing.
				Dust	Inhalation/Dermal	Workers, ONU	No	2016 CDR references import in liquid form. Thus, the potential for dust exposures to workers does not exist during manufacturing.
				Liquid/Solid Contact	Dermal	ONU	No	Exposure is expected to be primarily restricted to workers who are directly involved in working with the chemical. ONUs are not expected to come in direct contact with the chemicals.
Processing	Processing as a Reactant	Intermediate in: all other basic organic chemical manufacturing; Plasticizers in wholesale and retail trade	Processing as a reactant	Liquid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during processing as a reactant, as dibutyl phthalate is in liquid form.
				Solid Contact	Dermal	Workers	No	The potential for exposures to workers does not exist during processing as a reactant, as dibutyl phthalate is in liquid form.
				Vapor	Inhalation	Workers, ONU	Yes	Due to dibutyl phthalate's vapor pressure (VP) (VP =

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
								2.01 × 10-5 mm Hg) at room temperature, potential for vapor generation is low. However, some of these operations may occur at elevated temperatures, which increase the potential for vapor generation.
				Mist	Inhalation/Dermal	Workers, ONU	No	Mist generation is not expected during processing as a reactant.
				Dust	Inhalation/Dermal	Workers, ONU	No	The potential for exposures to workers does not exist during processing as a reactant, as dibutyl phthalate is in liquid form.
				Liquid/Solid Contact	Dermal	ONU	No	Exposure is expected to be primarily restricted to workers who are directly involved in working with the chemical. ONUs are not expected to come in direct contact with the chemicals.
	Incorporated into formulation, mixture or reaction product	Solvents (which become part of product formulation or mixture) in: all other chemical product and preparation manufacturing; soap, cleaning compound, and toilet preparation manufacturing Intermediates: in asphalt paving, roofing, and coating materials manufacturing;	Processing into formulations, mixtures, or reaction product	Liquid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during incorporation into formulation, mixture or reaction product, as dibutyl phthalate is in liquid form.
				Solid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during processing (incorporation into formulation, mixture, or reaction product), as dibutyl phthalate may be in solid form, such as for compounded resins.
				Vapor	Inhalation	Workers, ONU	Yes	Due to dibutyl phthalate's vapor pressure (VP) (VP = 2.01 × 10-5 mm Hg) at room temperature, potential

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
		petrochemical manufacturing; rubber product manufacturing Adhesives and sealant chemicals in: construction Plasticizers in: paint and coating manufacturing; plastic material and resin manufacturing; plastic product manufacturing; soap, cleaning compound, and toilet preparation manufacturing; textiles, apparel, and leather manufacturing Functional fluids (closed systems) in: printing and related support activities						for vapor generation is low. However, some of these operations may occur at elevated temperatures, which increase the potential for vapor generation.
				Mist	Inhalation/Dermal	Workers, ONU	No	Mist generation is not expected during incorporation into formulation, mixture or reaction product.
				Dust	Inhalation/Dermal	Workers, ONU	Yes	The potential for exposures to workers exists during processing (incorporation into formulation, mixture, or reaction product), as dibutyl phthalate may be in solid form, such as for compounded resins.
				Liquid/Solid Contact	Dermal	ONU	No	Exposure is expected to be primarily restricted to workers who are directly involved in working with the chemical. ONUs are not expected to come in direct contact with the chemicals.
	Incorporated into articles	Plasticizers in: adhesive manufacturing; plastics product manufacturing; rubber product manufacturing	Plastics and Rubber product manufacturing (Plastic Converting) Other article manufacturing	Liquid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during incorporation into articles, as dibutyl phthalate may be in liquid form.
				Solid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during processing (incorporation into articles), as dibutyl phthalate may be in solid form, such as for resins.
				Vapor	Inhalation	Workers, ONU	Yes	Due to dibutyl phthalate's vapor pressure (VP) (VP =

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
								2.01 × 10-5 mm Hg) at room temperature, potential for vapor generation is low. However, some of these operations may occur at elevated temperatures, which increase the potential for vapor generation.
				Mist	Inhalation/Dermal	Workers, ONU	No	Mist generation is not expected during incorporation into article.
				Dust	Inhalation/Dermal	Workers, ONU	Yes	The potential for exposures to workers exists during processing (incorporation into articles), as dibutyl phthalate may be in solid form, such as for resins.
				Liquid/Solid Contact	Dermal	ONU	No	Exposure is expected to be primarily restricted to workers who are directly involved in working with the chemical. ONUs are not expected to come in direct contact with the chemicals.
	Repackaging	Repackaging	Repackaging into large and small containers	Liquid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during processing (repackaging), as dibutyl phthalate is in liquid form.
				Solid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during processing (repackaging), as dibutyl phthalate may be incorporated into products in solid form.
				Vapor	Inhalation	Workers, ONU	No	Due to dibutyl phthalate's vapor pressure (VP) (VP = 2.01 × 10-5 mm Hg) at room temperature, potential for vapor generation is low.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
				Mist	Inhalation/Dermal	Workers, ONU	No	Mist generation is not expected during repackaging.
				Dust	Inhalation/Dermal	Workers, ONU	Yes	The potential for dust exposures to workers and ONUs exists during processing (repackaging), as dibutyl phthalate may be incorporated into products in solid form.
				Liquid/Solid Contact	Dermal	ONU	No	Exposure is expected to be primarily restricted to workers who are directly involved in working with the chemical. ONUs are not expected to come in direct contact with the chemicals.
	Recycling	Recycling	Recycling of dibutyl phthalate and products containing dibutyl phthalate	Liquid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during this use as liquid formulations may be recycled.
				Solid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during this use as solid formulations may be recycled.
				Vapor	Inhalation	Workers, ONU	No	Due to dibutyl phthalate's vapor pressure (VP) (VP = 2.01 × 10-5 mm Hg) at room temperature, potential for vapor generation is low.
				Mist	Inhalation/Dermal	Workers, ONU	No	Mist generation is not expected during recycling of liquid wastes.
				Dust	Inhalation/Dermal	Workers, ONU	Yes	Dust generation is possible during recycling of solid wastes.
				Liquid/Solid Contact	Dermal	ONU	No	Exposure is expected to be primarily restricted to workers who are directly

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
								involved in working with the chemical. ONUs are not expected to come in direct contact with the chemicals.
Industrial/ Commercial Use	Adhesives and sealants; cleaning and furnishings care products; paints and coatings;	Adhesives and sealants; cleaning and furnishings care products; paints and coatings;	Spray, brush, roll, dip, and other forms of application	Liquid Contact	Dermal	Workers	Yes	These products are in liquid form; therefore, exposures to workers exists for dibutyl phthalate used in these products.
				Solid Contact	Dermal	Workers	No	The potential for exposures to solid dibutyl phthalate is not expected during the use of these products because they are in liquid form.
				Vapor	Inhalation	Workers, ONU	No	Due to dibutyl phthalate's vapor pressure (VP) (VP = 2.01 × 10-5 mm Hg) at room temperature, potential for vapor generation is low.
				Mist	Inhalation/Dermal	Workers, ONU	Yes	Mist generation is possible during application of these products.
				Dust	Inhalation/Dermal	Workers, ONU	No	The potential for exposures to solid dibutyl phthalate does not exist during the use of these products because they are in liquid form.
				Liquid/Solid Contact	Dermal	ONU	No	Exposure is expected to be primarily restricted to workers who are directly involved in working with the chemical. ONUs are not expected to come in direct contact with the chemicals.
	Non-incorporative solvent use; Ink, toner, and colorant	Non-incorporative solvent use; Ink, toner, and colorant products; laboratory supplies	Use of solvents containing dibutyl phthalate in non-incorporative activities	Liquid Contact	Dermal	Workers	Yes	These products are in liquid form; therefore, exposures to workers exists for dibutyl phthalate used in these products.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
	products; laboratory supplies		Use of ink, toner, and colorant products (e.g., printing) Use in laboratories	Solid Contact	Dermal	Workers	No	The potential for exposures to solid dibutyl phthalate is not expected during the use of these products because they are in liquid form.
				Vapor	Inhalation	Workers, ONU	No	Due to dibutyl phthalate's vapor pressure (VP) (VP = 2.01 × 10-5 mm Hg) at room temperature, potential for vapor generation is low.
				Mist	Inhalation/Dermal	Workers, ONU	No	Mist generation is not expected during use of these products.
				Dust	Inhalation/Dermal	Workers, ONU	No	The potential for exposures to solid dibutyl phthalate does not exist during the use of these products because they are in liquid form.
				Liquid/Solid Contact	Dermal	ONU	No	Exposure is expected to be primarily restricted to workers who are directly involved in working with the chemical. ONUs are not expected to come in direct contact with the chemicals.
	Explosive materials; Floor coverings; furniture and furnishings not covered elsewhere; Personal care products; plastic and rubber products not covered elsewhere	Explosive materials; Floor coverings; furniture and furnishings not covered elsewhere; Personal care products; plastic and rubber products not covered elsewhere	Use of articles made using dibutyl phthalate	Liquid Contact	Dermal	Workers	No	The potential for exposures to liquid dibutyl phthalate is not expected during the use of these products because they are solid articles.
				Solid Contact	Dermal	Workers	Yes	These products may include solid articles in which dibutyl phthalate is entrained; therefore, dibutyl phthalate exposures to workers is unlikely but may occur if cutting /sawing / other machining operations occur.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
				Vapor	Inhalation	Workers, ONU	Yes	Due to dibutyl phthalate's vapor pressure (VP) (VP = 2.01 × 10-5 mm Hg) at room temperature, potential for vapor generation is low. However, these products may be used such that vapors are generated (e.g., at high temperatures, in cured-in-place pipe)
				Mist	Inhalation/Dermal	Workers, ONU	No	Mist generation is not expected during use of these products.
				Dust	Inhalation/Dermal	Workers, ONU	Yes	These products may include solid articles in which dibutyl phthalate is entrained; therefore, dibutyl phthalate exposures to workers and ONUs is unlikely but may occur if cutting /sawing / other machining operations occur.
				Liquid/Solid Contact	Dermal	ONU	No	Exposure is expected to be primarily restricted to workers who are directly involved in working with the chemical. ONUs are not expected to come in direct contact with the chemicals.
Disposal	Disposal	Disposal of dibutyl phthalate wastes	Worker handling of wastes	Liquid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during this use as liquid formulations may be disposed.
				Solid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during this use as solid formulations may be disposed

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
				Vapor	Inhalation	Workers, ONU	No	Due to dibutyl phthalate's vapor pressure (VP) (VP = 2.01 × 10-5 mm Hg) at room temperature, potential for vapor generation is low.
				Mist	Inhalation/Dermal	Workers, ONU	No	Mist generation is not expected during disposal of liquid wastes.
				Dust	Inhalation/Dermal	Workers, ONU	Yes	Dust generation is possible during disposal of solid wastes.
				Liquid/Solid Contact	Dermal	ONU	No	Exposure is expected to be primarily restricted to workers who are directly involved in working with the chemical. ONUs are not expected to come in direct contact with the chemicals.

Appendix G SUPPORTING INFORMATION FOR CONSUMER, GENERAL POPULATION AND ENVIRONMENTAL EXPOSURE CONCEPTUAL MODEL

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	Construction, Paint, Electrical, and Metal Products	Building/ Construction Materials Not Covered Elsewhere (Article)	Direct contact through handling of articles containing chemical	Direct Contact	Dermal	Consumers	Yes	Dermal exposure may occur for this condition of use.
			Direct contact through mouthing of articles containing chemical	Mouthing	Oral	Consumers	Yes	Oral exposure may occur for this condition of use.
			Long-term emission/mass-transfer, Abrasion, Transfer to Dust	Dust	Dermal, Inhalation, Oral	Consumers, Bystanders	Yes	Dermal, oral and inhalation exposure from this condition of use may occur.
Consumer Use	Construction, Paint, Electrical, and Metal Products	Electrical and Electronic Products (Article)	Direct contact through handling of articles containing chemical	Direct Contact	Dermal	Consumers	Yes	Dermal exposure may occur for this condition of use.
			Direct contact through mouthing of articles containing chemical	Mouthing	Oral	Consumers	Yes	Oral exposure may occur for this condition of use.
			Long-term emission/mass-transfer, Abrasion, Transfer to Dust	Dust	Dermal, Inhalation, Oral	Consumers, Bystanders	Yes	Dermal, oral and inhalation exposure from this condition of use may occur.

Life Cycle Stage	Category	Subcategory	Release from source	Exposure Pathway	Route	Receptor	Plans to Evaluate	Rationale
Consumer Use	Furnishing, Cleaning, Treatment/Care Products	Floor Coverings (Article)	Direct contact through handling of articles containing chemical	Direct Contact	Dermal	Consumers	Yes	Dermal exposure may occur for this condition of use.
			Direct contact through mouthing of articles containing chemical	Mouthing	Oral	Consumers	Yes	Oral exposure may occur for this condition of use.
			Long-term emission/mass-transfer, Abrasion, Transfer to Dust	Dust	Dermal, Inhalation, Oral	Consumers, Bystanders	Yes	Dermal, oral and inhalation exposure from this condition of use may occur.
Consumer Use	Furnishing, Cleaning, Treatment/Care Productss	Furniture and Furnishings not Covered Elsewhere (Article)	Direct contact through handling of articles containing chemical	Direct Contact	Dermal	Consumers	Yes	Dermal exposure may occur for this condition of use.
			Direct contact through mouthing of articles containing chemical	Mouthing	Oral	Consumers	Yes	Oral exposure may occur for this condition of use.
			Long-term emission/mass-transfer, Abrasion, Transfer to Dust	Dust	Dermal, Inhalation, Oral	Consumers, Bystanders	Yes	Dermal, oral and inhalation exposure from this condition of use may occur.
Consumer Use	Packaging, Paper, Plastic, Hobby Products	Plastic and Rubber Products not Covered Elsewhere (Article)	Direct contact through handling of articles containing chemical	Direct Contact	Dermal	Consumers	Yes	Dermal exposure may occur for this condition of use.

Life Cycle Stage	Category	Subcategory	Release from source	Exposure Pathway	Route	Receptor	Plans to Evaluate	Rationale
			Direct contact through mouthing of articles containing chemical	Mouthing	Oral	Consumers	Yes	Oral exposure may occur for this condition of use.
			Long-term emission/mass-transfer, Abrasion, Transfer to Dust	Dust	Dermal, Inhalation, Oral	Consumers, Bystanders	Yes	Dermal, oral and inhalation exposure from this condition of use may occur.
Consumer Use	Packaging, Paper, Plastic, Hobby Products	Toys, Playground, and Sporting Equipment (Article)	Direct contact through handling of articles containing chemical	Direct Contact	Dermal	Consumers	Yes	Dermal exposure may occur for this condition of use.
			Direct contact through mouthing of articles containing chemical	Mouthing	Oral	Consumers	Yes	Oral exposure may occur for this condition of use.
			Long-term emission/mass-transfer, Abrasion, Transfer to Dust	Dust	Dermal, Inhalation, Oral	Consumers, Bystanders	Yes	Dermal, oral and inhalation exposure from this condition of use may occur.
Consumer Use	Construction, Paint, Electrical, and Metal Products	Adhesives and Sealants (Product)	Long-term emission/mass-transfer, Abrasion, Transfer to Dust	Dust	Dermal, Inhalation, Oral	Consumers, Bystanders	Yes	Dermal, oral and inhalation exposure from this condition of use may occur.
			Direct contact through application or use of products	Liquid Contact	Dermal	Consumers	Yes	Exposure is expected to be primarily restricted to consumers who are directly involved in using the chemical.

Life Cycle Stage	Category	Subcategory	Release from source	Exposure Pathway	Route	Receptor	Plans to Evaluate	Rationale
			Long-term emission/mass-transfer through application or use of products	Vapor	Inhalation	Consumers and Bystanders	Yes	Inhalation is possible.
			Direct contact through application or use of products	Mist	Inhalation and Dermal	Consumers and Bystanders	Yes	If product is applied as a mist, inhalation and dermal exposures would be expected.
Consumer Use	Packaging, Paper, Plastic, Hobby Products	Arts, Crafts, and Hobby Materials (Product)	Long-term emission/mass-transfer, Abrasion, Transfer to Dust	Dust	Dermal, Inhalation, Oral	Consumers, Bystanders	Yes	Dermal, oral and inhalation exposure from this condition of use may occur.
			Direct contact through application or use of products	Liquid Contact	Dermal	Consumers	Yes	Exposure is expected to be primarily restricted to consumers who are directly involved in using the chemical.
			Long-term emission/mass-transfer through application or use of products	Vapor	Inhalation	Consumers and Bystanders	Yes	Inhalation is possible.
			Direct contact through application or use of products	Mist	Inhalation and Dermal	Consumers and Bystanders	Yes	If product is applied as a mist, inhalation and dermal exposures would be expected.
Consumer Use	Furnishing, Cleaning, Treatment/Care Products	Cleaning and Furnishing Care Products (Product)	Long-term emission/mass-transfer, Abrasion, Transfer to Dust	Dust	Dermal, Inhalation, Oral	Consumers, Bystanders	Yes	Dermal, oral and inhalation exposure from this condition of use may occur.
			Direct contact through application or use of products	Liquid Contact	Dermal	Consumers	Yes	Exposure is expected to be primarily restricted to consumers who are directly involved in using the chemical.

Life Cycle Stage	Category	Subcategory	Release from source	Exposure Pathway	Route	Receptor	Plans to Evaluate	Rationale
			Long-term emission/mass-transfer through application or use of products	Vapor	Inhalation	Consumers and Bystanders	Yes	Inhalation is possible.
			Direct contact through application or use of products	Mist	Inhalation and Dermal	Consumers and Bystanders	Yes	If product is applied as a mist, inhalation and dermal exposures would be expected.
Consumer Use	Furnishing, Cleaning, Treatment/Care Products	Fabric, Textile and Leather Products not Covered Elsewhere (Product)	Long-term emission/mass-transfer, Abrasion, Transfer to Dust	Dust	Dermal, Inhalation, Oral	Consumers, Bystanders	Yes	Dermal, oral and inhalation exposure from this condition of use may occur.
			Direct contact through application or use of products	Liquid Contact	Dermal	Consumers	Yes	Exposure is expected to be primarily restricted to consumers who are directly involved in using the chemical.
			Long-term emission/mass-transfer through application or use of products	Vapor	Inhalation	Consumers and Bystanders	Yes	Inhalation is possible.
			Direct contact through application or use of products	Mist	Inhalation and Dermal	Consumers and Bystanders	Yes	If product is applied as a mist, inhalation and dermal exposures would be expected.
Consumer Use	Construction, Paint, Electrical, and Metal Products	Paints and Coatings (Product)	Long-term emission/mass-transfer, Abrasion, Transfer to Dust	Dust	Dermal, Inhalation, Oral	Consumers, Bystanders	Yes	Dermal, oral and inhalation exposure from this condition of use may occur.
			Direct contact through application or use of products	Liquid Contact	Dermal	Consumers	Yes	Exposure is expected to be primarily restricted to consumers who are directly involved in using the chemical.

Life Cycle Stage	Category	Subcategory	Release from source	Exposure Pathway	Route	Receptor	Plans to Evaluate	Rationale
			Long-term emission/mass-transfer through application or use of products	Vapor	Inhalation	Consumers and Bystanders	Yes	Inhalation is possible.
			Direct contact through application or use of products	Mist	Inhalation and Dermal	Consumers and Bystanders	Yes	If product is applied as a mist, inhalation and dermal exposures would be expected.
Consumer Handling of Disposal and Waste	Wastewater, Liquid wastes and solid wastes	Wastewater, Liquid wastes and solid wastes	Long-term emission/mass-transfer, Abrasion, Transfer to Dust	Dust	Dermal, Inhalation, Oral	Consumers, Bystanders	Yes	Dust generation is possible during the handling of solid waste
			Direct contact through handling or disposal of products	Liquid Contact	Dermal	Consumers	Yes	Exposure is expected to be primarily restricted to consumers who are directly involved in handling and disposal of the chemical.
			Long-term emission/mass-transfer through application or use of products	Vapor	Inhalation	Consumers and Bystanders	Yes	Inhalation is possible.
			Direct contact through application or use of products	Mist	Inhalation and Dermal	Consumers and Bystanders	No	Mist generation is not expected during handling or disposal.

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

Table_Apx H-1 General Population and Environmental Exposure Conceptual Model

Life Cycle Stage	Category	Release	Exposure Pathway / Media	Exposure Routes	Receptor / Population	Plans to Evaluate[6]	Rationale
All	Emissions to Air	Emissions to Air	Near facility ambient air concentrations	Inhalation	General Population	No	Dibutyl phthalate is a HAP. Because stationary source releases of dibutyl phthalate 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	EPA has developed Ambient Water Quality Criteria for protection of human health for dibutyl phthalate.
				Oral Dermal	General Population	No	
			Drinking Water via Surface or Ground Water	Oral Dermal and Inhalation (e.g. showering)	General Population	Yes	Release of dibutyl phthalate into surface water and indirect partitioning to drinking water is an expected exposure pathway.
			Biosolids: application to soil and/or migration to groundwater	Oral (e.g. ingestion of soil) Inhalation	General Population	Yes	EPA plans to analyze the pathway from biosolids to the general population, aquatic and terrestrial species.

[6] The exposure pathways, exposure routes and hazards EPA plans to consider 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 dibutyl phthalate in exposure pathways falling under the jurisdiction of these EPA statutes.

Life Cycle Stage	Category	Release	Exposure Pathway / Media	Exposure Routes	Receptor / Population	Plans to Evaluate[6]	Rationale
			and/or surface water	TBD	Aquatic and Terrestrial receptors	Yes	
		Underground injection	Migration to groundwater, potential surface/drinking water	Oral Dermal Inhalation	General Population	No	Dibutyl phthalate is released to Class I Underground Injection Wells which are covered by RCRA. and SDWA.
					Aquatic and Terrestrial Species		
				TBD			
Disposal	Solid and Liquid Wastes	Municipal landfill and other land disposal	Leachate to soil, ground water and/or mitigation to surface water	Oral Dermal	General Population	No	Dibutyl phthalate is included on the list of hazardous wastes pursuant to RCRA 3001 (40 CFR §§ 261.33).
				TBD	Aquatic and Terrestrial Receptors		