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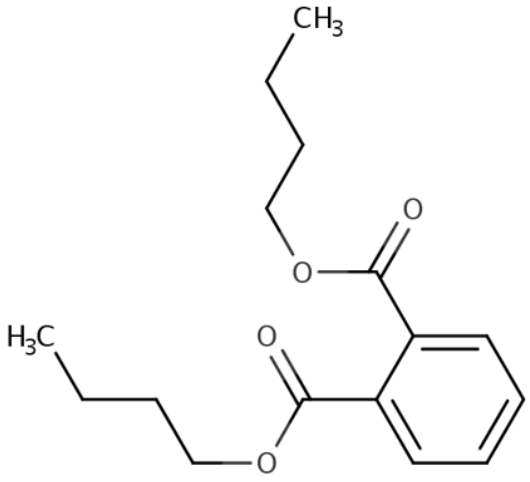
Office of Chemical Safety and
Pollution Prevention

United States
Environmental Protection Agency

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

CASRN 84-74-2



August 2020

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Docket

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

Disclaimer

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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
NEI	National Emissions Inventory
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 for 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
PBPK	Physiologically Based Pharmacokinetic
PBT	Persistent, Bioaccumulative, Toxic
PEC	Priority Existing Chemical
PECO	Population, Exposure, Comparator and Outcome
PEL	Permissible Exposure Limit
PESO	Pathways and Process, Exposure, Setting or Scenario, and Outcomes
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
RESO	Receptors, Exposure, Setting or Scenario, and Outcomes
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 as required by Section 6(b) of the Toxic Substances Control Act (TSCA) and implementing regulations (40 CFR Part 702) (Docket ID: EPA-HQ-OPPT-2019-0131). The first step of the risk evaluation process is the development of the draft scope document. EPA published the *Draft Scope of the Risk Evaluation for Dibutyl Phthalate (1,2-Benzenedicarboxylic acid, 1,2-dibutyl ester) CASRN 84-74-2* (EPA Document No. 740-D-20-016) (U.S. EPA, 2020c) and provided a 45-day comment period on the draft scope per 40 CFR 702.41(c)(7). EPA has considered comments received (Docket ID: EPA-HQ-OPPT-2018-0503) during the public comment period to inform the development of this final scope document, and public comments received will continue to inform the development of the risk evaluation for dibutyl phthalate. This document fulfills the TSCA requirement to issue a final scope document per TSCA Section 6(b)(4)(D) and as described in 40 CFR 702.41(c)(8). The 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.

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 *Proposed Designation of dibutyl phthalate (CASRN 84-74-2) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019c) to inform the development of this final 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 used the systematic review process described in Appendix A to search for and screen reasonably available information, including information already in EPA's possession, for inclusion in the risk evaluation. This information includes the hazards, exposures, PESS, and conditions of use that may help inform the risk evaluation for dibutyl phthalate. EPA has focused on the data collection phase (consisting of data search, data screening, and data extraction) during the preparation of the scope document, whereas the data evaluation and integration stages will occur during the development of the risk evaluation and thus are not part of the scoping activities described in this document. EPA will consider additional information identified following publication of this scope document, as appropriate, in developing the risk evaluation, including the Chemical Data Reporting (CDR) information that the Agency will receive by the end of November 2020.

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. It is used in the processing and incorporation into formulations for solvents and 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. EPA revised the conditions of use in the final scope of the

risk evaluation based on additional information and public comments (Docket ID: EPA-HQ-OPPT-2018-0503) on the draft scope document for dibutyl phthalate.

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 considered reasonably available information as well as public comments received on the draft scope document for dibutyl phthalate in finalizing the exposure pathways, exposure routes, and hazards EPA plans to evaluate in the risk evaluation. As a result, EPA plans to focus the risk evaluation for dibutyl phthalate on the following exposures, hazards and receptors:

- *Exposures (Pathways and Routes), Receptors and PESS.* EPA plans to evaluate releases to the environment as well as 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. Additional information gathered through the results of systematic review searches will also inform expected exposures.

  EPA's plan for evaluating environmental exposure pathways in the scope of the risk evaluation considers whether and how other EPA administered statutes and regulatory programs cover the presence of dibutyl phthalate in media pathways falling under the jurisdiction of those authorities. Section 2.6.3.1 discusses pathways under the jurisdiction of other EPA-administered laws. In Section 2.6.3.2, 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.

  EPA considered reasonably available information and comments received on the draft scope for dibutyl phthalate in determining the human and environmental exposure pathways, routes, receptors and PESS for inclusion in the final scope. EPA plans to evaluate the following human and environmental exposure pathways, routes, receptors and PESS in the scope of the risk evaluation:

  - *Occupational exposures:* EPA plans to evaluate exposures to workers and occupational non-users via the inhalation route and exposure to workers via the dermal route associated with the manufacturing, processing, distribution, industrial/commercial use, and disposal of dibutyl phthalate. EPA plans to analyze dermal exposure for workers and ONUs to mists and dusts that deposit on surfaces.
  - *Consumer and bystander exposure:* EPA plans to evaluate oral, inhalation and dermal exposure to dibutyl phthalate for consumers and bystanders from 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; Toys, Playground, and Sporting Equipment; and Miscellaneous; and mouthing of products/articles containing dibutyl phthalate for consumers.
  - *General population exposure:* EPA plans to evaluate general population exposure to dibutyl phthalate from drinking water via the oral, dermal and inhalation routes.

  - *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 exposure:* EPA plans to evaluate exposure to dibutyl phthalate for aquatic receptors.

- *Hazards.* Hazards for dibutyl phthalate are discussed in Section 2.4. EPA completed preliminary reviews of information (*e.g.*, federal and international government chemical assessments) to identify potential environmental and human health hazards for dibutyl phthalate as part of the prioritization (U.S. EPA, 2019c) and scoping process (U.S. EPA, 2020c). EPA also considered reasonably available information collected through systematic review methods as outlined in Appendix A and public comments received on the draft scope for dibutyl phthalate in determining the broad categories of environmental and human health hazard effects to be evaluated in the risk evaluation. EPA will use systematic review methods to evaluate the epidemiological and toxicological literature for dibutyl phthalate.

  EPA plans to evaluate all potential environmental and human health hazard effects identified for dibutyl phthalate in Sections 2.4.1 and 2.4.2, respectively. Identified through the data screening phase of systematic review, the potential environmental hazard effects and related information that EPA plans to consider for the risk evaluation include: ADME, cancer, cardiovascular, developmental, endocrine, hematological and immune, hepatic, mortality, musculoskeletal, neurological, nutritional and metabolic, ocular and sensory, renal, reproductive, respiratory, skin and connective tissue for dibutyl phthalate. Similarly, the potential human health hazard effects and related information identified through prioritization and the data screening phase of systematic review for dibutyl phthalate that EPA plans to consider for the risk evaluation include: ADME, PBPK, cancer, cardiovascular, developmental, endocrine, gastrointestinal, hematological and immune, hepatic, mortality, musculoskeletal, neurological, nutritional and metabolic, ocular and sensory, renal, reproductive, respiratory and skin and connective tissue.

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 review of identified information as described in Section 2.1. Should additional data or approaches become reasonably available, EPA may consider them for the risk evaluation.

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 (U.S. EPA, 2015b) and other methods consistent with Section 26 of TSCA (see 40 CFR 702.45).

1 INTRODUCTION

This document presents the 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 TSCA on June 22, 2016. The new law includes statutory requirements and deadlines for actions related to conducting risk evaluations of existing chemicals.

Under TSCA § 6(b), the Environmental Protection Agency (EPA) must designate chemical substances as high-priority substances for risk evaluation or low-priority substances for which risk evaluations are not warranted at the time, and upon designating a chemical substance as a high-priority substance, initiate a risk evaluation on the substance. TSCA § 6(b)(4) directs EPA to conduct 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 nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator under the conditions of use*."

TSCA § 6(b)(4)(D) and implementing regulations require that EPA publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use and PESS that the Administrator expects to consider, within 6 months after the initiation of a risk evaluation. In addition, a draft scope is to be published pursuant to 40 CFR 702.41. In December 2019, EPA published a list of 20 chemical substances that have been designated high priority substances for risk evaluations (Docket ID: EPA-HQ-OPPT-2019-0131) (84 FR 71924, December 30, 2019), 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. On April 23, 2020, EPA published the *Draft Scope of the Risk Evaluation for Dibutyl Phthalate (1,2-Benzenedicarboxylic acid, 1,2-dibutyl ester) CASRN 84-74-2* (EPA Document No. 740-D-20-016) (85 FR 22733, April 23, 2020) (U.S. EPA, 2020c) for a 45-day public comment period. After reviewing and considering the public comments (Docket ID: EPA-HQ-OPPT-2018-0503) received on the draft scope document, EPA is now publishing this final scope document pursuant to 40 CFR 702.41(c)(8).

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 scope document for dibutyl phthalate. EPA leveraged the data and information sources already collected in the documents supporting the chemical substance's high-priority substance designation. In addition, EPA searched for additional data and information on physical and chemical properties, environmental fate, engineering, exposure, environmental and human health hazards that could be obtained from the following general categories of sources:

1. Databases containing publicly available, peer-reviewed literature;
2. Gray literature, which is defined as the broad category of data/information sources not found in standard, peer-reviewed literature databases;

[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).

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.

Search terms were used to search each of the literature streams and gather dibutyl phthalate studies. These terms and the methods used to develop them are listed in Appendix A. The studies resulting from the search process were loaded into the EPA Health and Environmental Research Online (HERO) database and then prioritized to screen first the literature likely relevant for each of the disciplines: fate, physical and chemical properties, engineering, exposure and hazard. The tools and methods used to manage the screening process are also outlined in Appendix A. The studies resulting from the search underwent a title/abstract screening process, which tagged them by topic or category. Following this, a determination was made to move studies forward into full-text screening. The criteria used in the screening process for each discipline are found in the population, exposure, comparator, outcome (PECO) statements listed in Appendix A. The screening process results are presented in the form of literature inventory trees and heat maps in Section 2.1.2. The screening process was conducted based on EPA's planning, execution and assessment activities outlined in Appendix A.

EPA has focused on the data collection phase (consisting of data search, data screening, and data extraction) during the preparation of the scope document, whereas the data evaluation and integration stages will occur during the development of the risk evaluation and thus are not part of the scoping activities described in this document.

The subsequent sections summarize the data collection activities completed to date for the general categories of sources and topic areas (or disciplines) using systematic review methods.

2.1.1 Search of Gray Literature

EPA surveyed the gray literature[2] and identified 131 search results relevant to EPA's risk evaluation needs for dibutyl phthalate. Appendix A.3.4 lists the gray literature sources that yielded 131 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 and chemical properties, environmental fate, environmental hazard, human health hazard, exposure, engineering), and the breakdown is shown in Figure 2-1. EPA will consider additional reasonably available information from gray literature if it becomes available during the risk evaluation phase.

[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.

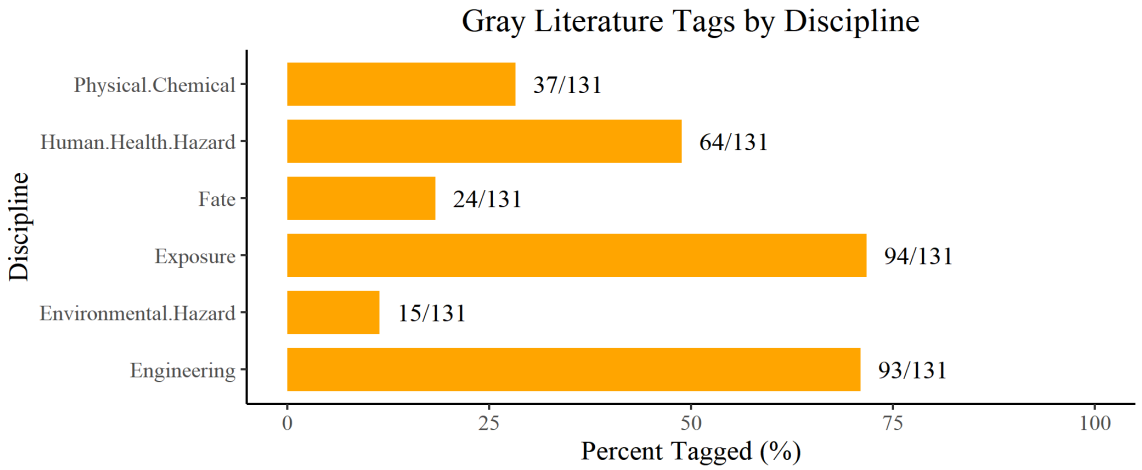

Figure 2-1. Gray Literature Search Results for Dibutyl Phthalate
The percentages across disciplines do not add up to 100%, as each source may provide data or information for various topic areas (or disciplines).

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

EPA has begun the systematic review process and has conducted searching and screening of the reasonably available literature using the process outlined in Appendix A. This includes performing a comprehensive search of the reasonably available peer review literature on physical and chemical properties, environmental fate and transport, engineering (environmental release and occupational exposure), exposure (environmental, general population and consumer) and environmental and human health hazards of dibutyl phthalate. Eligibility criteria were applied in the form of PECO statements (see Appendix A). 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 (see Appendix A.2). EPA plans to evaluate the reasonably available information identified for each discipline during the development of the risk evaluation.

EPA created literature inventory trees to graphically illustrate the flow of data and information sources following full-text screening (see Figure 2-2, Figure 2-3, Figure 2-5, Figure 2-7, and Figure 2-9). EPA used the Health Assessment Workplace Collaborative (HAWC) tool to develop web-based literature inventory trees illustrating, through interactive links, studies that were included or excluded. These literature inventory trees enhance the transparency of the decisions resulting from the screening process described in Appendix A. For each of the corresponding disciplines, the literature was tagged to be included for evaluation during the risk evaluation. Literature inventory trees for physical and chemical properties are provided as static diagrams (Figure 2-2). For all other disciplines, static screen captures are provided in addition to links within each figure's caption to the interactive trees. The links show individual studies that were tagged as included, excluded, or supplemental. Supplemental studies did not meet all inclusion criteria but may be considered during the risk evaluation as supporting information (see Appendix A)These studies can be accessed through the hyperlink provided in the associated caption below each figure. 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.

In addition, EPA tabulated the number and characteristics of the data and information sources included in the full-text screening process in the form of literature inventory heat maps for the fate, engineering, exposure and hazard disciplines (see Figure 2-4, Figure 2-6, Figure 2-8, and Figure 2-10). For each of these four disciplines, a static image of the literature inventory heat map is provided, and a link to the interactive version presented in HAWC is included in the caption below each diagram.

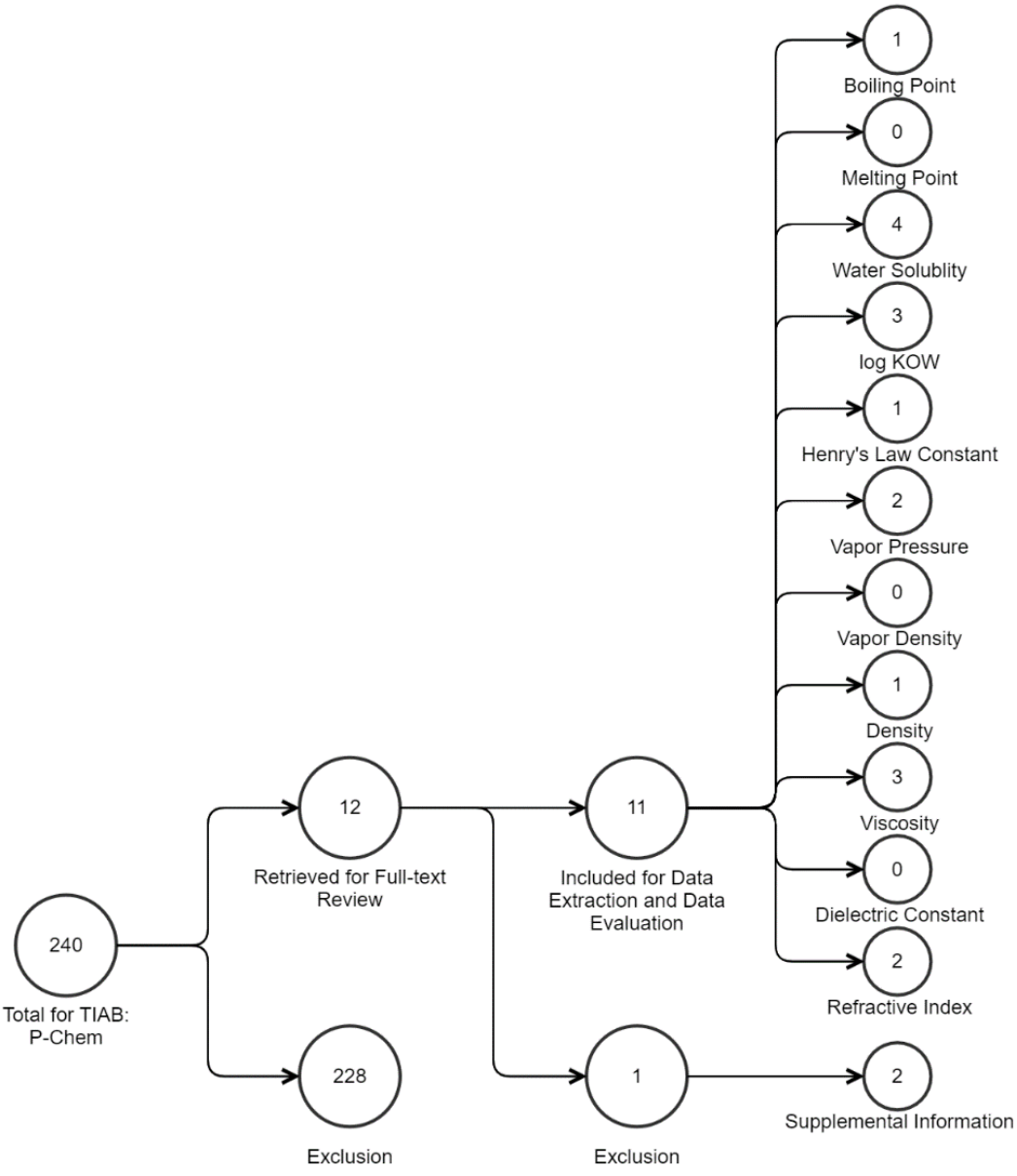

Figure 2-2. Peer-reviewed Literature Inventory Tree - Physical and Chemical Properties Search Results for Dibutyl Phthalate

Data in this static figure represent references obtained from the publicly available database searches (see Appendix A.1.2) that were included during full-text screening as of June 2, 2020. TIAB refers to "title and abstract" screening.

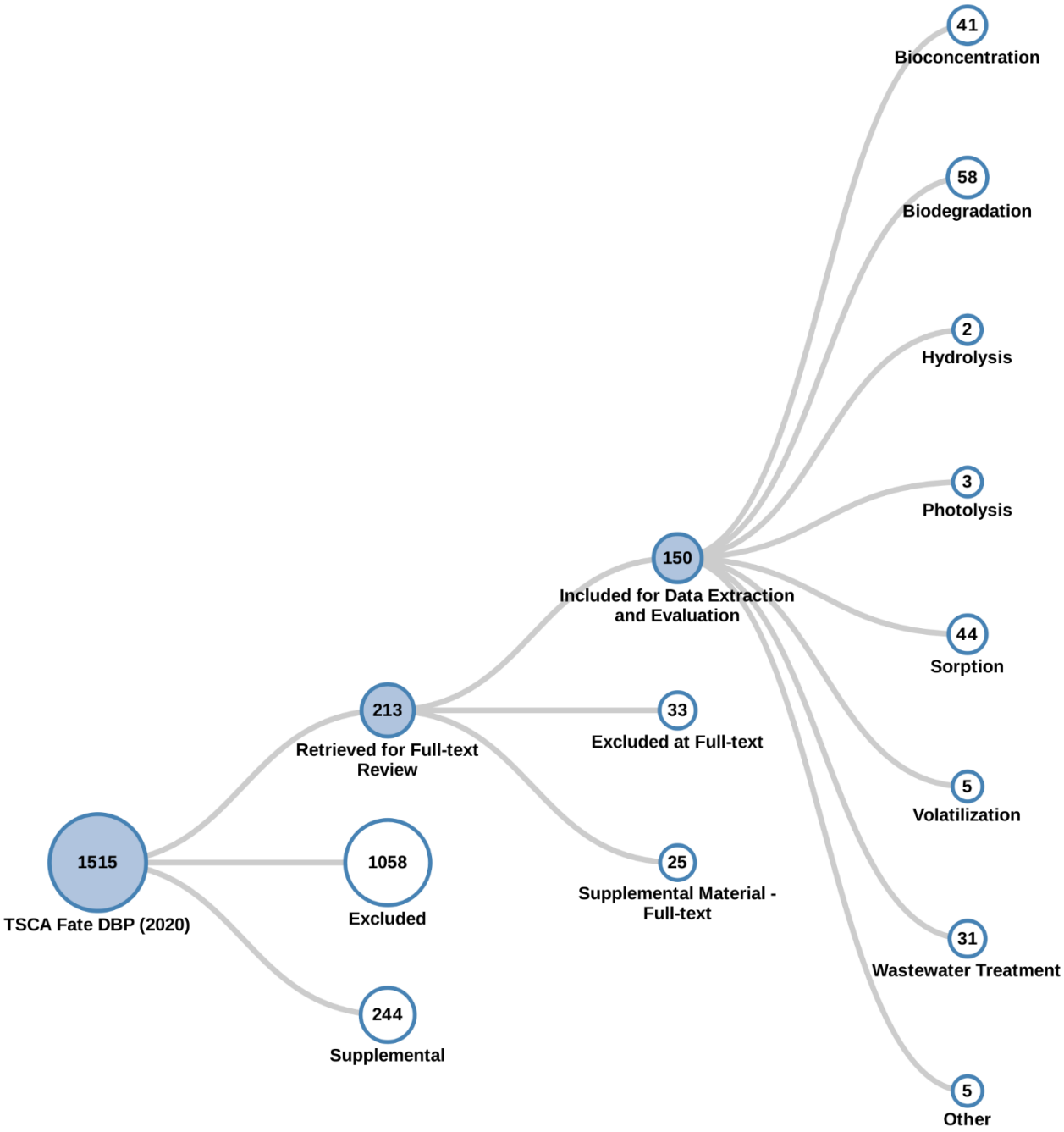

Figure 2-3. Peer-reviewed Literature Inventory Tree - Fate and Transport Search Results for Dibutyl Phthalate

Click here to view the interactive literature inventory tree. Data in this figure represent references obtained from the publicly available databases search (see Appendix A.1.2) that were included during full-text screening as of June 2, 2020. Additional data may be added to the interactive version as they become available.

	Media					
Endpoint	Air	Soil, Sediment	Wastewater, Biosolids	Water	Other	Grand Total
Bioconcentration	3	32	8	25		41
Biodegradation		34	27	22		58
Hydrolysis				2		2
Photolysis	1			2		3
Sorption	3	35	10	33		44
Volatilization	3	3	1	3		5
Wastewater Treatment		6	30	17		31
Other	1	2	2	2	1	5
Grand Total	7	89	59	86	1	150

Figure 2-4. Peer-reviewed Literature Inventory Heat Map - Fate and Transport Search Results for Dibutyl Phthalate

Click here to view the interactive version for additional study details. The column totals, row totals, and grand totals indicate total numbers of unique references, as some references may be included in multiple cells. The various shades of color visually represent the number of relevant references identified by media or endpoint. The darker the color, the more references are available for a given media or endpoint. Data in this figure represents references obtained from the publicly available databases search (see Appendix A.1.2) that were included during full-text screening as of June 2, 2020. Additional data may be added to the interactive version as they become available.

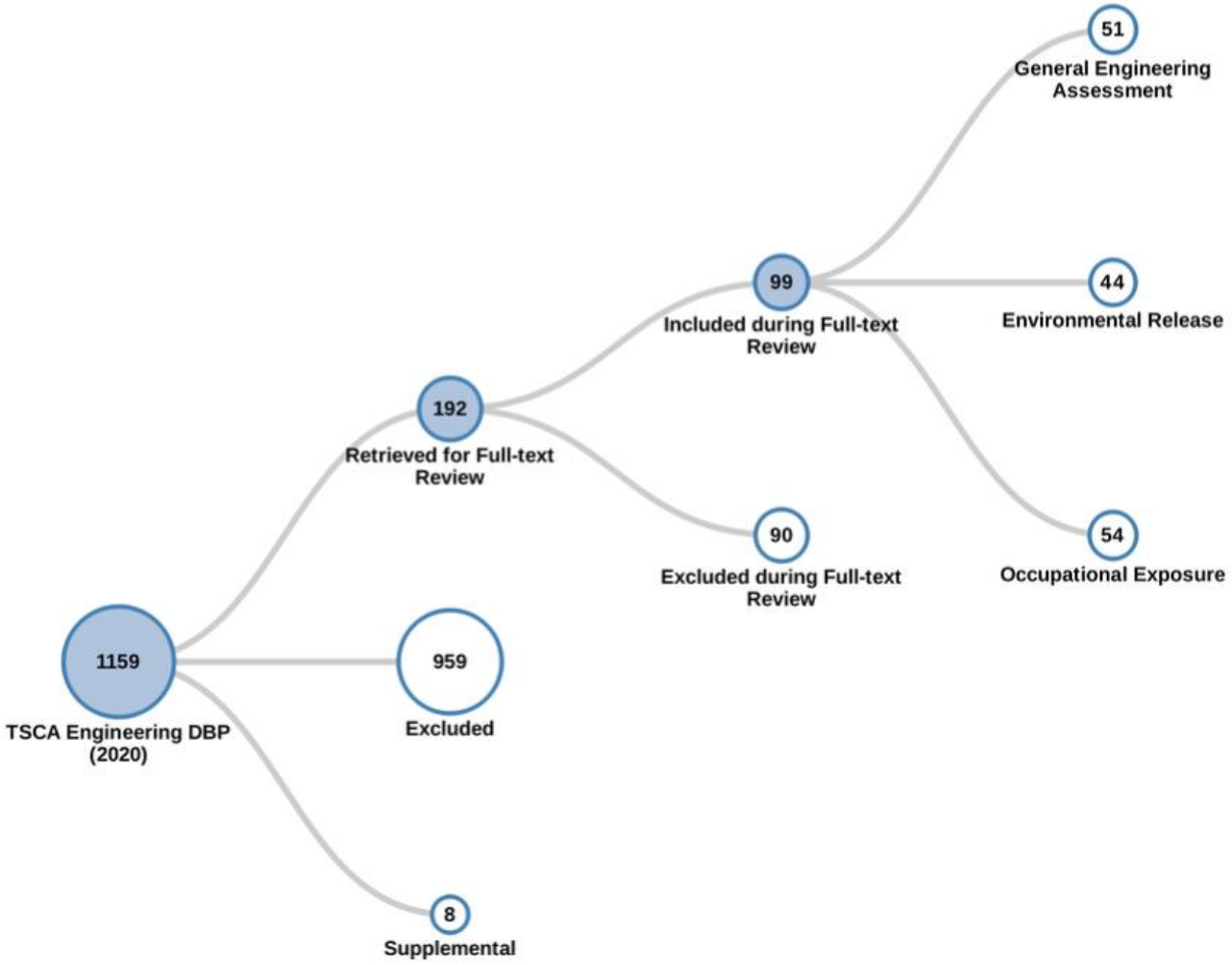

Figure 2-5. Peer-reviewed Literature Inventory Tree - Engineering Search Results for Dibutyl Phthalate

Click here to view the interactive literature inventory tree. Data in this figure represent references obtained from the publicly available databases search (see Appendix A.1.2) that were included during full-text screening as of August 5, 2020. Additional data may be added to the interactive version as they become available.

Data Type	Evidence Tags	
Environmental Releases	Description of release source	26
	Release frequency	4
	Release or emission factors	24
	Release quantity	17
	Waste treatment methods and pollution control	20
	Total	44
General Engineering Assessment	Chemical concentration	31
	Life cycle description	9
	Number of sites	8
	Process description	27
	Production, import, or use volume	15
	Throughput	6
	Total	51
Occupational Exposures	Area sampling data	28
	Dermal exposure data	14
	Engineering control	9
	Exposure duration	13
	Exposure frequency	5
	Exposure route	35
	No evidence tag	1
	Number of workers	15
	Particle size characterization	
	Personal protective equipment	8
	Personal sampling data	21
	Physical form	18
	Worker activity description	25
	Total	54
Grand Total		99

Figure 2-6. Peer-reviewed Literature Inventory Heat Map - Engineering Search Results for Dibutyl Phthalate.
Click here to view the interactive version for additional study details. Data in this figure represents references obtained from the publicly available databases search (see Appendix A.1.2) that were included during full-text screening as of August 5, 2020. Additional data may be added to the interactive version as they become available.

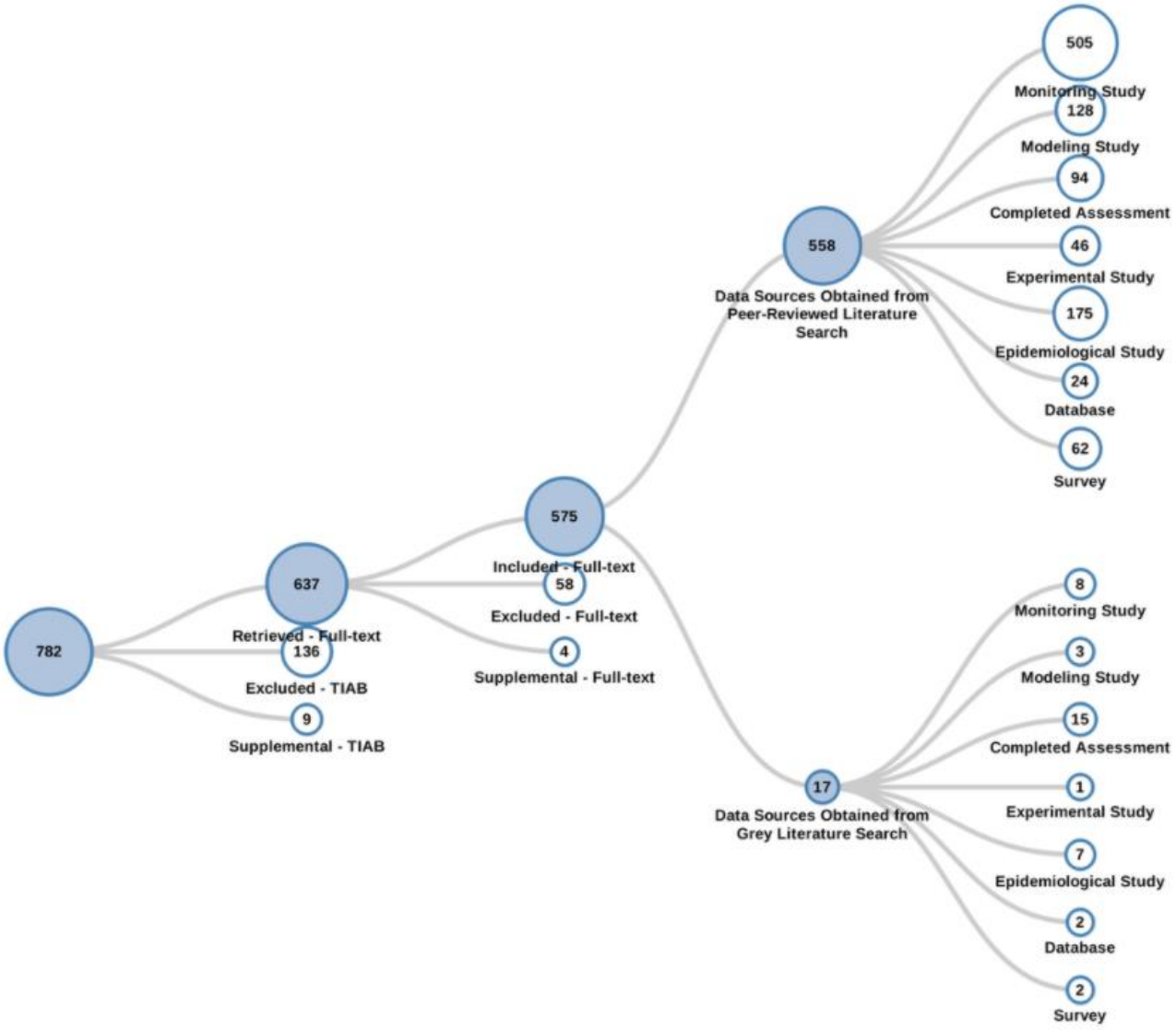

Figure 2-7. Peer-reviewed Literature Inventory Tree - Exposure Search Results for Dibutyl Phthalate

Click here to view the interactive literature inventory tree. Data in this figure represent all references obtained from the publicly available databases search (see Appendix A.1.2), and gray literature references search (see Appendix A.3) that were included during full-text screening as of July 31, 2020. Additional data may be added to the interactive version as they become available.

Media (group)	Data Type: Monitoring Study	Modeling Study	Completed Assessment	Experimental Study	Epidemiological Study	Database	Survey	Grand Total
Ambient Air								
Biosolids/Sludge	7	1	2	2	1			7
Drinking Water	12	5	5	4	2		2	14
Groundwater								
Land Disposal/ Landfill								
Sediment	7	2	3	2	1			9
Soil	19	8	14	1	3		1	27
Surface Water	7	3	4	1	1	1		9
Wastewater	3	1	1		1			3
Aquatic Species	4	3	3	1	2		1	4
Terrestrial Species	3	2	3	1	2		1	4
Consumer	59	23	29	34	10	1	13	84
Dietary	51	29	25	13	5	1	7	68
Dust	89	42	38	5	20		15	108
Exposure Factors	28	24	12	4	11	4	7	39
Exposure Pathway	18	10	11	3	6	2	2	28
Human Biomonitoring	341	67	47	6	161	23	49	356
Indoor Air	82	35	33	16	8	1	6	102
Isomers	5	2	4	1	1		2	7
Use Information	11	6	12	2	6	1	3	19
No Evidence Type	2		1		1		1	2
Grand Total	513	131	109	47	182	26	64	576

Figure 2-8. Peer-reviewed and Gray Literature Inventory Heat Map –Exposure Search Results for Dibutyl Phthalate

Click here to view the interactive version for additional study details. The column totals, row totals, and grand totals indicate total numbers of unique references, as some references may be included in multiple cells. The various shades of color visually represent the number of relevant references identified by exposure media or data type. The darker the color, the more references are available for a given exposure media or data type. Data in this figure represent all references obtained from the publicly available databases search (see Appendix A.1.2), and gray literature references search (see Appendix A.3) that were included during full-text screening as of July 31, 2020. Additional data may be added to the interactive version as they become available.

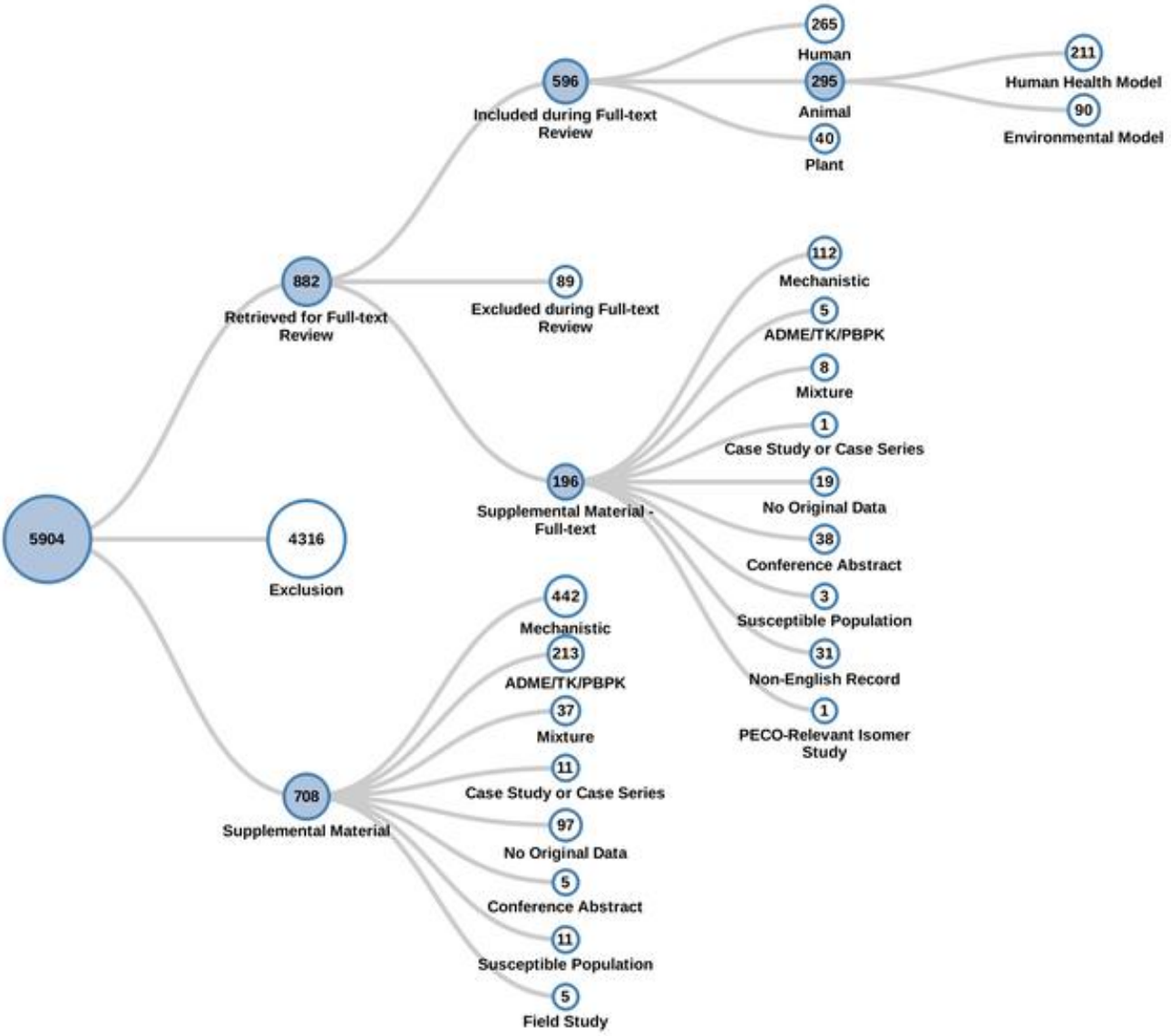

Figure 2-9. Peer-reviewed Literature - Hazard Search Results for Dibutyl Phthalate
Click here to view the interactive literature inventory tree. Data in this figure represent references obtained from the publicly available databases search (see Appendix A.1.2) that were included during full-text screening as of June 16, 2020. Additional data may be added to the interactive version as they become available.

	Evidence Type				
Health Outcomes	Human	Animal - Human Health Model	Animal - Environmental Model	Plant	Grand Total
ADME	239	56	15	14	321
Cancer	19	31	3		53
Cardiovascular	16	12	3		31
Developmental	176	144	38	11	365
Endocrine	101	130	27	3	259
Gastrointestinal	2	19			21
Hematological and Immune	108	86	11		203
Hepatic	2	51	13		66
Mortality	9	15	25	2	49
Musculoskeletal	14	32	12		55
Neurological	43	33	10		85
Nutritional and Metabolic	83	31	12	11	137
Ocular and Sensory	24	13	2		39
PBPK	7	1			8
Renal	148	28	5		180
Reproductive	161	166	30	1	354
Respiratory	26	13	8		47
Skin and Connective Tissue	20	14	5		39
No Tag	1	7	24	12	42
Grand Total	265	211	90	40	596

Figure 2-10. Peer-reviewed Literature Inventory Heat Map – Human Health and Environmental Hazards Search Results for Dibutyl Phthalate

Click here to view the interactive version for additional study details. The numbers indicate the number of studies with TIAB keywords related to a health outcome, not the number of studies that observed an association with dibutyl phthalate. Evidence types were manually extracted, and Health Systems were determined via machine learning. Therefore, the studies examining multiple Health Outcomes and Evidence types, connections between health outcome, and evidence type may not be accurately represented. If a study evaluated multiple health outcomes or included multiple populations or study designs, it is shown here multiple times. Data in this figure represents references obtained from the publicly available databases search (see Appendix A.1.2) that were included during full-text screening as of June 16, 2020. Additional data may be added to the interactive version as they become available.

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. EPA screened a total of 152 submissions using PECO or similar statements that identify inclusion/exclusion criteria specific to individual disciplines (see Table 2-1 for the list of disciplines). The details about the criteria are presented in Appendix A.2.1. EPA identified 118 submissions that met the inclusion criteria in these statements and identified 28 submissions with

supplemental data.[3] EPA excluded 6 submissions because the reports were identified as one of the following:

- Published report that would be identified via other peer or gray literature searches
- Summary of other reports
- Preliminary report of a final available submitted report
- Duplicate of another report
- Submission on a different chemical
- List of references with no original data

Table 2-1. Results of Title Screening of Submissions to EPA under Various Sections of TSCA[a]

Discipline	Included	Supplemental [b]
Physical and Chemical 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

[a] Individual submissions may be relevant to multiple disciplines.
[b] Included submissions may contain supplemental data for other disciplines, which will be identified at full-text review.

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, 2019c), EPA assembled information from the CDR and TRI programs to determine conditions of use[4] or significant changes in conditions of use of the chemical substance. Once the 2020 CDR reporting period ends in November 2020, EPA utilize the most recent CDR information. 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) (U.S. EPA, 2019b) 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, EPA incorporated communications with companies, industry groups, environmental organizations, and public comments to supplement the use information.

EPA identified and described the categories and subcategories of conditions of use that will be included 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.

[3] EPA may further consider some supplemental or excluded references depending on the reasons for tagging as supplemental or excluded.
[4] *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)).

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

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.

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

Life-Cycle Stage[a]	Category[b]	Subcategory[c]	Reference
Manufacturing	Domestic manufacturing	Domestic manufacturing	U.S. EPA (2019a)
	Import	Import	U.S. EPA (2019a)
Processing	Processing as a reactant	Intermediates in all other basic organic chemical manufacturing	U.S. EPA (2019a)
		Plasticizers in wholesale and retail trade	U.S. EPA (2019a)
	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 (2019a); NLM (2015); Kosaric et al. (2011); Ash and Ash (2009)
		Intermediates in asphalt paving, roofing, and coating materials manufacturing	U.S. EPA (2019a)
		Adhesives and sealant chemicals in construction	U.S. EPA (2019a); NLM (2015)
		Plasticizers in paint and coating manufacturing	U.S. EPA (2019a); NLM (2015); GoodGuide (2011)

Life-Cycle Stage[a]	Category[b]	Subcategory[c]	Reference
		Intermediates in petrochemical manufacturing	U.S. EPA (2019a)
		Plasticizers in plastic material and resin manufacturing	U.S. EPA (2019a); NLM (2015)
		Plasticizers in plastic product manufacturing	U.S. EPA (2019a); NLM (2015)
		Functional fluids (closed systems) in printing and related support activities	U.S. EPA (2019a)
		Intermediates in rubber product manufacturing	U.S. EPA (2019a); NLM (2015)
		Plasticizers in soap, cleaning compound, and toilet preparation manufacturing	U.S. EPA (2019a)
		Solvents in soap, cleaning compound, and toilet preparation manufacturing	U.S. EPA (2019a)
		Plasticizers in textiles, apparel, and leather manufacturing	U.S. EPA (2019a); NLM (2015)
	Processing – incorporating into articles	Plasticizers in adhesive manufacturing	U.S. EPA (2019a); NLM (2015)
		Plasticizers in plastics product manufacturing	U.S. EPA (2019a)
		Plasticizers in rubber product manufacturing	U.S. EPA (2019a)

Life-Cycle Stage[a]	Category[b]	Subcategory[c]	Reference
	Repackaging	Laboratory chemicals in wholesale and retail trade	U.S. EPA (2019a)
		Plasticizers in wholesale and retail trade	U.S. EPA (2019a)
	Recycling	Recycling	U.S. EPA (2019a)
Distribution in Commerce	Distribution in commerce		
Industrial Uses	Non-incorporative activities	Solvent in Huntsman's maleic anhydride manufacturing technology	U.S. EPA (2019a)
		Solvent	NLM (2015); Kosaric et al. (2011); Ash and Ash (2009)
Commercial Uses	Adhesives and sealants	Adhesives and sealants	U.S. EPA (2019a)
	Cleaning and furnishing care products	Cleaning and furnishing care products	U.S. EPA (2019a); NLM (2015); GoodGuide (2011)
	Explosive materials	Explosive materials	U.S. EPA (2019a); NLM (2015); Akhavan (2018); Ash and Ash (2009)
	Floor coverings	Floor coverings	U.S. EPA (2019a)
	Furniture and furnishings not covered elsewhere	Furniture and furnishings not covered elsewhere	U.S. EPA (2019a)
	Ink, toner, and colorant products	Ink, toner, and colorant products	U.S. EPA (2019a); NLM (2015)
	Paints and coatings	Paints and coatings	U.S. EPA (2019a); NLM (2015); GoodGuide (2011); Streitberger et al. (2011)
	Personal care products	Personal care products	U.S. EPA (2019a)

Life-Cycle Stage[a]	Category[b]	Subcategory[c]	Reference
	Plastic and rubber products not covered elsewhere	Plastic and rubber products not covered elsewhere	U.S. EPA (2019a); NLM (2015)
	Miscellaneous uses	Laboratory chemical Chemiluminescent light sticks Inspection penetrant kit Lubricants[d]	U.S. EPA (2019a) EPA-HQ-OPPT-2018-0503-0036
Consumer Uses	Adhesives and sealants	Adhesives and sealants	U.S. EPA (2019a)
	Arts, crafts and hobby materials	Arts, crafts and hobby materials	U.S. EPA (2019a); NLM (2015)
	Cleaning and furnishing care products	Cleaning and furnishing care products	U.S. EPA (2019a); NLM (2015); GoodGuide (2011)
	Fabric, textile, and leather products not covered elsewhere	Fabric, textile, and leather products not covered elsewhere	U.S. EPA (2019a)
	Floor coverings	Floor coverings	U.S. EPA (2019a)
	Furniture and furnishings not covered elsewhere	Furniture and furnishings not covered elsewhere	U.S. EPA (2019a)
	Paints and coatings	Paints and coatings	U.S. EPA (2019a); NLM (2015); GoodGuide (2011); Streitberger et al. (2011)
	Plastic and rubber products not covered elsewhere	Plastic and rubber products not covered elsewhere	U.S. EPA (2019a); NLM (2015)
	Toys, playground and sporting equipment	Toys, playground and sporting equipment	U.S. EPA (2019a)
	Miscellaneous Uses[e]	Chemiluminescent light sticks	EPA-HQ-OPPT-2018-0503-0036

Life-Cycle Stage[a]	Category[b]	Subcategory[c]	Reference
Disposal	Disposal		U.S. EPA (2019a)

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.
   - Although EPA has identified both industrial and commercial uses here for purposes of distinguishing scenarios in this document, the Agency interprets the authority over "any manner or method of commercial use" under TSCA Section 6(a)(5) to reach both.

b. These categories of conditions of use appear in the Life Cycle Diagram, reflect CDR codes, and broadly represent conditions of use of *dibutyl phthalate* in industrial and/or commercial settings.

c. These subcategories reflect more specific conditions of use of dibutyl phthalate.

d. In the final scope, EPA added "chemiluminescent light stick," "inspection penetrant kit" and "lubricants" to the subcategory of this condition of use based on consultation with the Department of Defense. (EPA-HQ-OPPT-2018-0503-0036)

e. In the final scope, EPA added the condition of use for *dibutyl phthalate* for consumer uses – miscellaneous uses – chemiluminescent light stick based on consultation with the Department of Defense. (waiting for docket number).

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* (82 FR 33726, July 20, 2017) TSCA Section 6(b)(4)(D) requires EPA to identify the hazards, exposures, conditions of use, and the PESS the Administrator expects to consider in a risk evaluation, suggesting that EPA may exclude certain activities that it determines to be conditions of use on a case-by-case basis (82 FR 33726, 33729; July 20, 2017). TSCA Section 3(4) also grants EPA discretion to determine the circumstances that are appropriately considered to be conditions of use for a particular chemical substance. As a result, EPA does not plan to include in this scope or in the risk evaluation the activities described below that the Agency does not consider to be conditions of use or for which EPA is exercising discretionary authority provided by TSCA Section 6(b)(4)(D).

TSCA Section 3(2) also excludes from the definition of "chemical substance" "any food, food additive, drug, cosmetic, or device (as such terms are defined in Section 201 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 321]) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device" as well as "any pesticide (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 et seq.]) when manufactured, processed, or distributed in commerce for use as a pesticide." EPA has determined that the following uses of dibutyl phthalate are non-TSCA uses:

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[5]" in TSCA §

[5] *Chemical substance* means any organic or inorganic substance of a particular molecular identity, including any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and any element or uncombined radical. Chemical substance does not include (1) any mixture; (2) any pesticide (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act) when manufactured, processed, or distributed in commerce for use as a

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. EPA recognizes that the Food and Drug Administration lists dibutyl phthalate as an optional substance to be used in food packaging materials. Food packaging materials meet the definition for a "food additive" described in Section 201 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. § 321. Therefore, the uses are excluded from the definition of "chemical substance" in TSCA § 3(2)(B)(vi) and are not included in Table 2-2. Activities and releases associated with the use of such food packaging materials 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." Activities and releases associated with the use of such explosive materials 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.

2.2.3 Production Volume

As reported to EPA during the 2016 CDR reporting period and described here as a range to protect production volumes that were claimed as confidential business information (CBI), total production volume of dibutyl phthalate was between 1 million and 10 million pounds (U.S. EPA, 2020a). 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, 2019c) and will include more recent production volume information from the 2020 CDR reporting period in the risk evaluation to support the environmental release assessment.

2.2.4 Overview of Conditions of Use and Lifecycle Diagram

Figure 2-11 provides the life cycle diagram for dibutyl phthalate. The life cycle diagram is a graphical representation of the various life stages of the industrial, commercial and consumer use categories included within the scope of the risk evaluation. 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). Appendix E contains additional descriptions (*e.g.*, process descriptions, worker activities, process flow diagrams) for each manufacture, processing, distribution in commerce, use and disposal category.

pesticide; (3) tobacco or any tobacco product; (4) any source material, special nuclear material, or byproduct material (as such terms are defined in the Atomic Energy Act of 1954 and regulations issued under such Act); (5) any article the sale of which is subject to the tax imposed by Section 4181 of the Internal Revenue Code of 1954 (determined without regard to any exemptions from such tax provided by Section 4182 or 4221 or any other provision of such Code), and; (6) any food, food additive, drug, cosmetic, or device (as such terms are defined in Section 201 of the Federal Food, Drug, and Cosmetic Act) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device (TSCA § 3(2)).

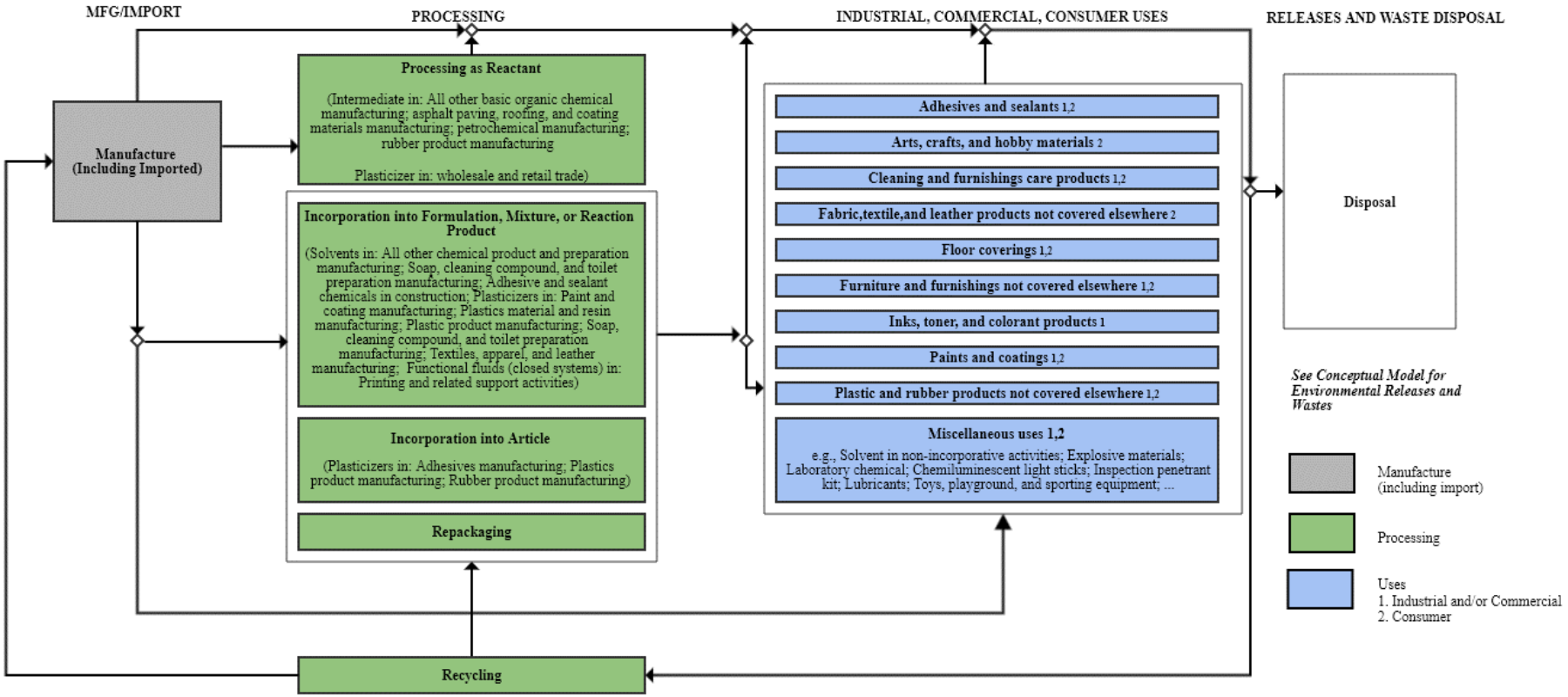

Figure 2-11. Dibutyl Phthalate Life Cycle Diagram

2.3 Exposures

For TSCA exposure assessments, EPA plans to analyze human and environmental exposures and releases to the environment resulting from the conditions of use within the scope of the risk evaluation of dibutyl phthalate. In this section, the physical and chemical properties, environmental fate and transport properties and releases to the environment are described in addition to potential human and environmental exposures from TSCA conditions of use and from other possible or known sources. Release pathways and routes will be described in Section 2.6 to characterize the relationship or connection between the conditions of use of the chemical and the exposure to human receptors, including PESS, and environmental receptors. EPA plans to consider, where relevant, the duration, intensity (concentration), frequency and number of exposures in characterizing exposures to dibutyl phthalate.

2.3.1 Physical and Chemical Properties

Consideration of physical and chemical properties is essential for a thorough understanding or prediction of environmental fate (*i.e.*, transport and transformation) and the eventual environmental concentrations. It can also inform the hazard assessment. Table 2-3 summarizes the physical and chemical property values preliminarily selected for use in the risk evaluation from among the range of reported values collected as of June 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, 2019c) and may be updated as EPA continues to evaluate and integrate additional information through systematic review methods. Figure 2-12 summarizes the distribution of reported values for eight physical and chemical properties routinely used in existing chemical risk evaluations. Appendix B presents summary statistics for reported physical and chemical property values. All physical and chemical property values that were extracted and evaluated as of June 2020 are presented in the supplemental file *Data Extraction and Data Evaluation Tables for Physical and Chemical Property Studies* (EPA-HQ-OPPT-2018-0503).

Table 2-3. Physical and Chemical Properties of Dibutyl Phthalate

Property or Endpoint	Value*	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

Property or Endpoint	Value*	Reference	Data Quality Rating
Vapor density	9.58 (air = 1)	NLM (2015)	High
Water solubility	11.2 mg/L at 25°C	Howard et al. (1985)	High
Octanol/water partition coefficient (log Kow)	4.53 at 298.15 K	Ishak et al. (2016)	High
Henry's Law constant	1.81×10^{-6} atm-m^3/mol at 25°C	NLM (2015)	High
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

* Measured unless otherwise noted.
N/A = Not applicable

Figure 2-12 displays a summary of the data collected as of June 2020 for eight physical and chemical values routinely used in TSCA existing chemical risk evaluations. The box and whisker plots for each endpoint illustrate the mean (average, indicated by the blue diamond) and the 10^{th}, 25^{th}, 50^{th} (median), 75^{th}, and 90^{th} percentiles. All individual data points are indicated by black squares, and value preliminarily selected for use in the risk evaluation is overlaid (indicated by the orange circle) to provide context for where it lies within the distribution of the dataset. The number of unique primary data sources is indicated below each box and whisker plot. If multiple sources presented equivalent values and cited the same primary source, only one of those was included in the statistical calculations. As a result, the number of sources listed in Figure 2-12 may differ from the total number of data sources presented in Figure 2-2.

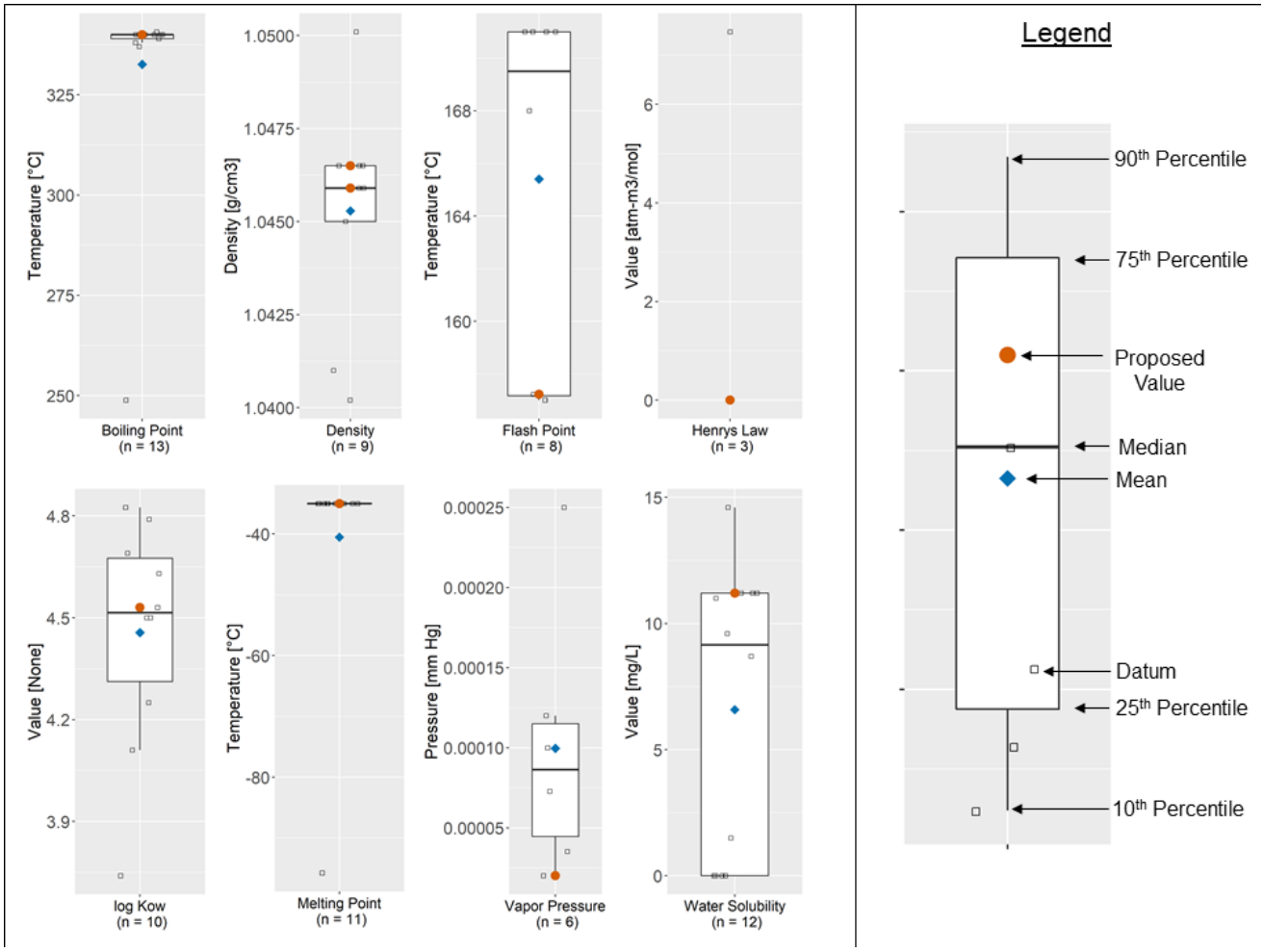

Figure 2-12. Box and Whisker Plots of Reported Physical and Chemical Property Values

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 Appendix C to support the development of the risk evaluation for dibutyl phthalate. The values for the environmental fate properties may be updated as EPA evaluates and integrates additional information into the risk evaluation through systematic review methods.

2.3.3 Releases to the Environment

Releases to the environment from conditions of use are a component of potential exposure and may be derived from reported data that are obtained through direct measurement, calculations based on empirical data and/or assumptions and models.

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 disclosed 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,[6] 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.

Table 2-4 provides production-related waste management data for dibutyl phthalate reported by facilities to the TRI program for reporting year 2018.[7] 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 2-4. 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: U.S. EPA (2019d) (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 events 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 2-5 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.

[6] For TRI reporting criteria see https://www.epa.gov/toxics-release-inventory-tri-program/basics-tri-reporting
[7] Reporting year 2018 is the most recent TRI data available. Data presented in Table 2-3 were queried using TRI Explorer and uses the 2018 National Analysis data set (released to the public in November 2019). This dataset includes revisions for the years 1988 to 2018 processed by EPA.

Table 2-5. Summary of Releases of Dibutyl Phthalate to the Environment During 2018

Year	Number of Facilities	Air Releases		Water Releases (lbs)	Land Disposal			Other Releases [a] (lbs)	Total Releases [b, c] (lbs)
		Stack Air Releases (lbs)	Fugitive Air Releases (lbs)		Class I Under-ground Injection (lbs)	RCRA Subtitle C Landfills (lbs)	All other Land Disposal [a] (lbs)		
2018	61	16,095	7,754	0	53,330	57,822	195,503	1,261	331,766
		23,850			306,655				

Data source: U.S. EPA (2019d) (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.

The total production-related waste managed quantity shown in Table 2-4 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 2-4. 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 2-5. 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 within the environment, and partitioning across different media. Concentrations of chemical substances in biota provide evidence of exposure. EPA plans to review reasonably available environmental monitoring data 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 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 (ICES, 2018; U.S. EPA, 2018c, 2007; ECB, 2004; MDI, 2002; Environment Canada, 1994; USGS, 1991a, b, c, d, f; U.S. EPA, 1990). Environmental biomonitoring data were

identified in EPA's data search for dibutyl phthalate (ICES, 2018; MDI, 2002; USGS, 1991e). EPA plans to review reasonably available environmental monitoring data for dibutyl phthalate.

2.3.5 Occupational Exposures

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

Examples of worker activities associated with the conditions of use within the scope of the risk evaluation for dibutyl phthalate that EPA may analyze include, but are not limited to:

- Unloading and transferring dibutyl phthalate to and from storage containers and process vessels;
- Handling 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;
- Performing other work activities in or near areas where dibutyl phthalate is used.

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 for workers and ONUs 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. In addition, for certain COUs, dibutyl phthalate may be present as a component of solid products. For these COUs, EPA plans to consider inhalation exposure to dust/particulates (*e.g.*, particulate generated during handling of plastic resins, finishing operations associated with the manufacture and finishing of plastics and plastic articles and incorporation of plastics and other article components into finished products) for workers and ONUs.

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). The American Conference of Governmental Industrial Hygienists (ACGIH) set the threshold limit value (TLV) at 5 mg/m^3 TWA. National Institute for Occupational Safety and Health (NIOSH) has set the Recommended Exposure Limit (REL) at 5 mg/m^3 TWA (NIOSH, 2019) and the Immediately Dangerous to Life or Health Concentration (IDLH) at 4000 mg/m^3 (NIOSH, 2020, 2016).

Based on the conditions of use, EPA plans to analyze worker exposure to liquids and/or solids via the dermal route. EPA plans to analyze dermal exposure for workers and ONUs to mists and dusts that deposit on surfaces.

EPA generally does not evaluate occupational exposures through the oral route. Workers and ONUs may inadvertently ingest inhaled particles that deposit in the upper respiratory tract. In addition, workers may transfer chemicals from their hands to their mouths. The frequency and significance of this exposure route are dependent on several factors including the physical and chemical properties of the substance during worker activities, the visibility of the chemicals on the hands while working, workplace training and practices, and personal hygiene that is difficult to predict (Cherrie et al., 2006).

EPA will consider the relevance of this exposure route on a case-by-case basis, taking into consideration the aforementioned factors and any reasonably available information, and may assess oral exposure for workers for certain COUs and worker activities where warranted. For certain conditions of use of dibutyl phthalate, EPA plans to consider inhalation exposure to dust/particulates for workers and ONUs. As inhalation exposure to dust/particulates may occur, EPA plans to consider potential exposure for particulates that deposit in the upper respiratory tract from inhalation exposure and may be ingested via the oral route.

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; Miscellaneous; Paints and Coatings; Plastic and Rubber Products not Covered Elsewhere; and Toys, Playground, and Sporting Equipment (see Section 2.6.2 and Figure 2-14). 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, through mouthing of articles containing dibutyl phthalate, or via dust. Dermal exposure may occur via contact with vapor, mist, or dust deposition onto the skin; via direct liquid contact during use; or direct dermal contact of articles containing dibutyl phthalate. The consumer exposure pathways in the scope of this evaluation are described in Sections 2.6.2 and 2.7.2.4.

2.3.7 General Population Exposures

Releases of dibutyl phthalate from certain conditions of use, such as manufacturing, processing, distribution, use, distribution, use, 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 (CPSC, 2010; ATSDR, 2001). 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 (ICES, 2018; U.S. EPA, 2018c, 2007; ECB, 2004; MDI, 2002; Environment Canada, 1994; USGS, 1991a, b, c, d, f; U.S. EPA, 1990).

Environmental and human biomonitoring data were identified in EPA's data search for dibutyl phthalate (ICES, 2018; MDI, 2002; USGS, 1991e). 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). The general population pathways in the scope of this evaluation are described in Sections 2.6.3.2 and 2.7.2.5.

2.4 Hazards (Effects)

2.4.1 Environmental Hazards

EPA considered reasonably available information (*e.g.,* federal and international government chemical assessments) on dibutyl phthalate as well as public comments received on the *Proposed Designation of Dibutyl Phthalate (CASRN 84-74-2) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019c) and draft scope for dibutyl phthalate (U.S. EPA, 2020c) to identify potential environmental hazards. During prioritization, EPA identified environmental hazard effects for aquatic and terrestrial organisms.

Since prioritization, EPA applied automated techniques during the data screening phase of systematic review to identify the following potential environmental hazards and related information that may be considered for the risk evaluation (as explained in Appendix A): ADME, cancer, cardiovascular, developmental, endocrine, hematological and immune, hepatic, mortality, musculoskeletal, neurological, nutritional and metabolic, ocular and sensory, renal, reproductive, respiratory, skin and connective tissue (Figure 2-10). A summary of references identified during the screening step of systematic review is included in the interactive literature inventory trees (Figure 2-9). As EPA continues to evaluate reasonably available and relevant hazard information identified through systematic review, EPA may update the list of potential hazard effects to be analyzed in the risk evaluation.

2.4.2 Human Health Hazards

EPA considered reasonably available information (*e.g.,* federal and international government chemical assessments) on dibutyl phthalate as well as public comments received on the *Proposed Designation of Dibutyl Phthalate (CASRN 84-74-2) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019c) and draft scope for dibutyl phthalate (U.S. EPA, 2020c) to identify potential human health hazards. During prioritization, EPA identified the following potential human health hazards and related information: reproductive, developmental, and systemic effects.

Since prioritization, EPA applied automated techniques during the data screening phase of systematic review to identify the following additional potential human health hazards and related information that may be considered for the risk evaluation (as explained in Appendix A): ADME, PBPK, cancer, cardiovascular, endocrine, gastrointestinal, hematological and immune, hepatic, mortality, musculo-skeletal, neurological, nutritional and metabolic, ocular and sensory, renal, respiratory and skin and connective tissue (Figure 2-10). A summary of references identified during the screening step of systematic review is included in the interactive literature inventory trees (Figure 2-9). As EPA continues to evaluate reasonably available and relevant hazard information identified through systematic review, EPA may update the list of potential hazard effects to be analyzed in the 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).

EPA identified the following PESS based on CDR information and studies reporting developmental and reproductive effects: children, women of reproductive age (*e.g.*, pregnant women), workers, including ONUs and users, and consumers, including users and bystanders (U.S. EPA, 2019c). EPA plans to evaluate these PESS in the risk evaluation. Following further evaluation of the reasonably available information, EPA may evaluate PESS in the general population as they relate to fence line communities.

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, ingestion of breast milk) 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, 2006b). 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). Based on these analyses, EPA may update the list of PESS in the risk evaluation

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 are under the jurisdiction of other EPA-administered laws are discussed and depicted the conceptual model shown in Section 2.6.2. Pathways and routes of exposure associated with environmental releases and wastes, excluding those pathways that may be addressed pursuant to other EPA-administered laws, are presented in the conceptual model shown in Section 2.6.3.2.

2.6.1 Conceptual Model for Industrial and Commercial Activities and Uses

Figure 2-13 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 ONUs via inhalation and/or oral routes and exposures to workers via dermal routes. The conceptual model includes potential worker and ONU dermal exposures to dibutyl phthalate in mists and dusts. 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 Table 2-2, a determination was made as to whether or not EPA plans to evaluate each combination of exposure pathway, route, and receptor in the risk evaluation. The results of that analysis along with the supporting rationale are presented in Appendix F.

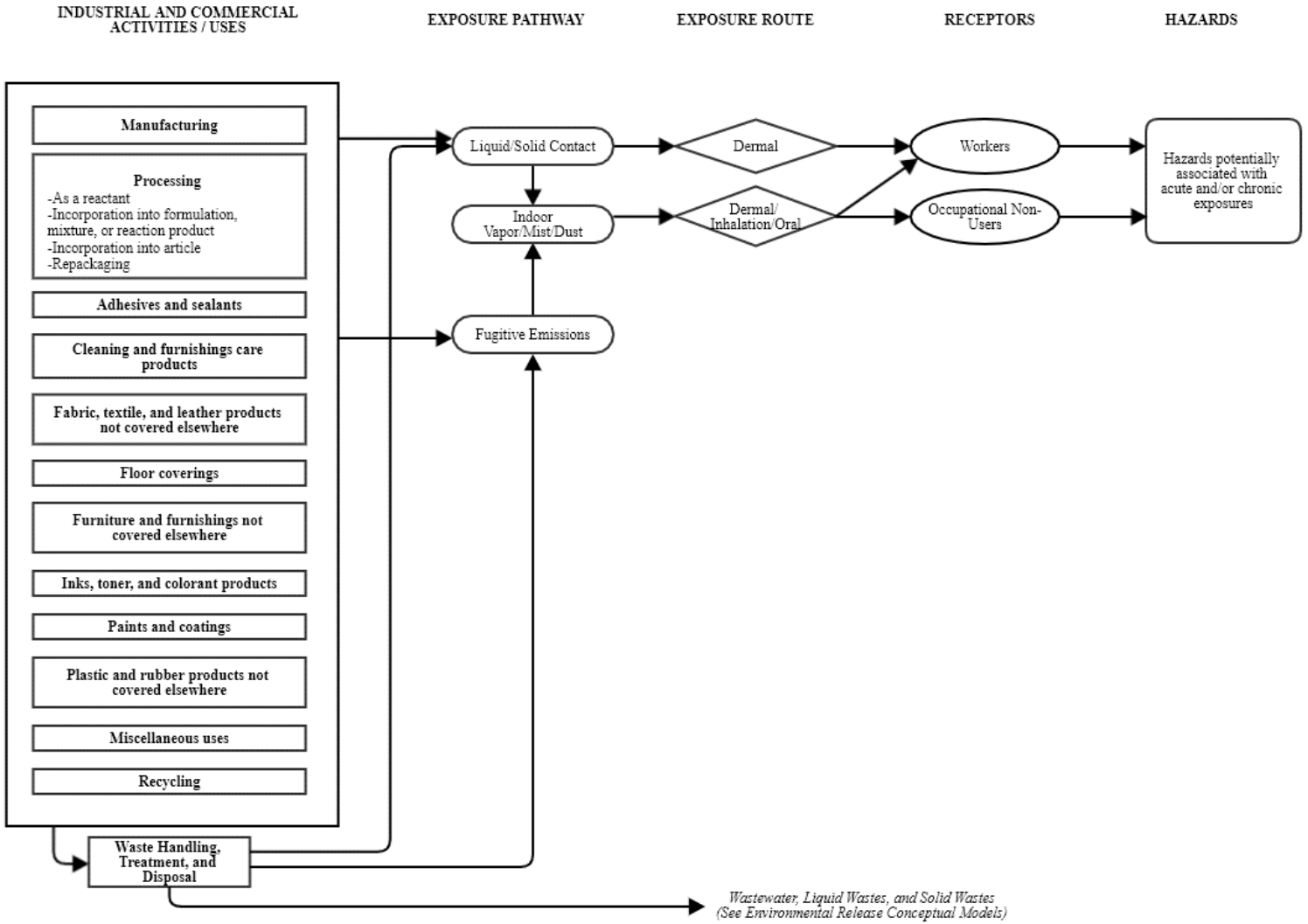

Figure 2-13. Dibutyl Phthalate Conceptual Model for Industrial and Commercial Activities and Uses: Worker and Occupational Non-User Exposures and Hazards

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 2-14 presents the exposure pathways, exposure routes and hazards to human receptors from consumer activities and uses of dibutyl phthalate. EPA expects that consumers and bystanders may be exposed through use of products or articles or via dust 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. 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.

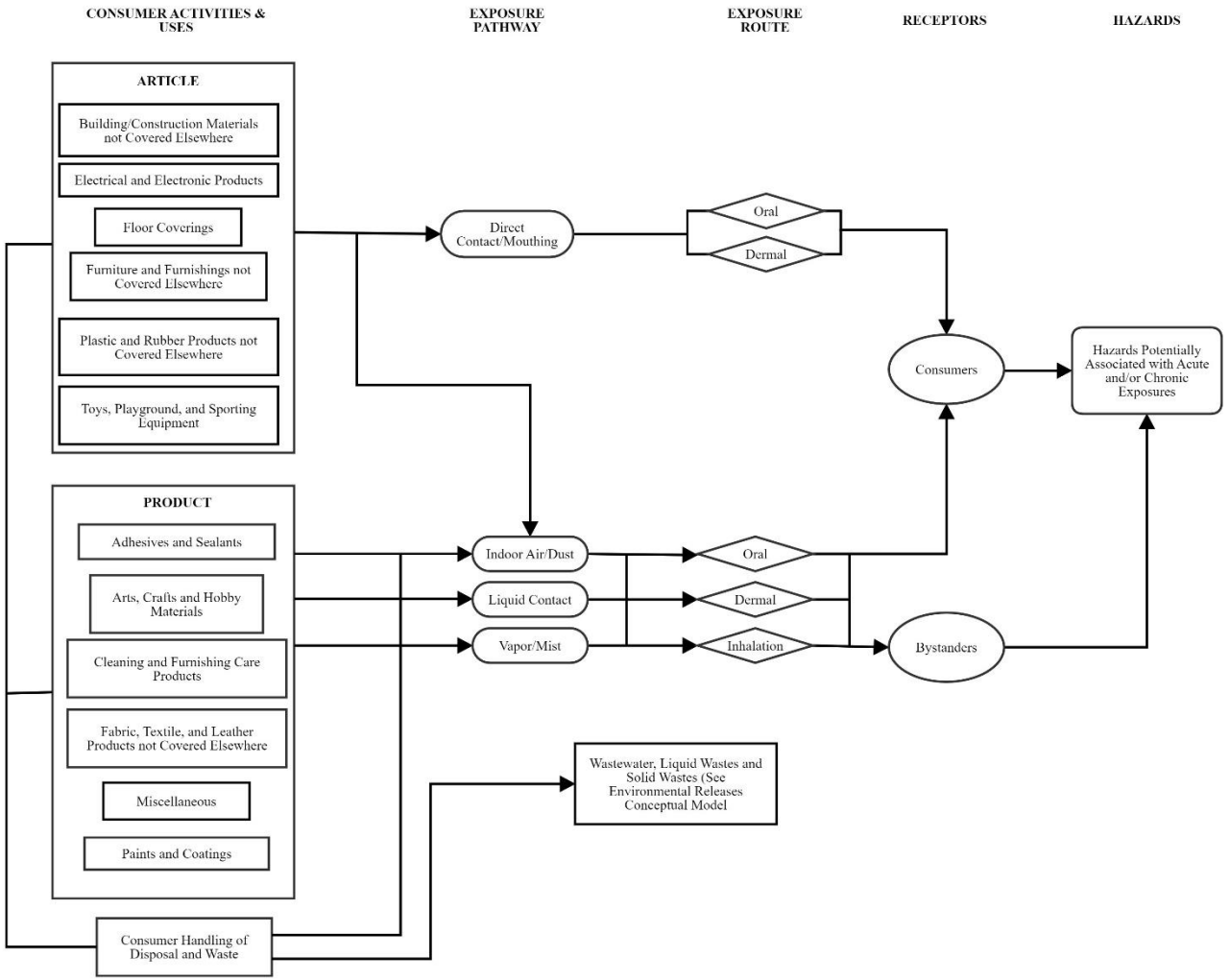

Figure 2-14. Dibutyl Phthalate Conceptual Model for Consumer Activities and Uses: Consumer Exposures and Hazards
The conceptual model presents the exposure pathways, exposure routes and hazards to human receptors from consumer activities and uses of dibutyl phthalate.

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 from environmental releases and wastes) and hazards to general population and environmental receptors associated with the conditions of use of dibutyl phthalate within the scope of the risk evaluation. This section also discusses those pathways that may be addressed pursuant to other EPA-administered laws.

The conceptual model in Figure 2-15 presents the potential exposure pathways, exposure routes and hazards to general population and environmental receptors from releases and waste streams associated with industrial, commercial and consumer uses of dibutyl phthalate. The conceptual model shows the overlays, labeled and shaded to depict the regulatory programs under EPA-administered statutes and associated pathways that EPA considered for the scope of the risk evaluation. The regulatory programs that cover these environmental release and waste pathways are further described in Section 2.6.3.1.

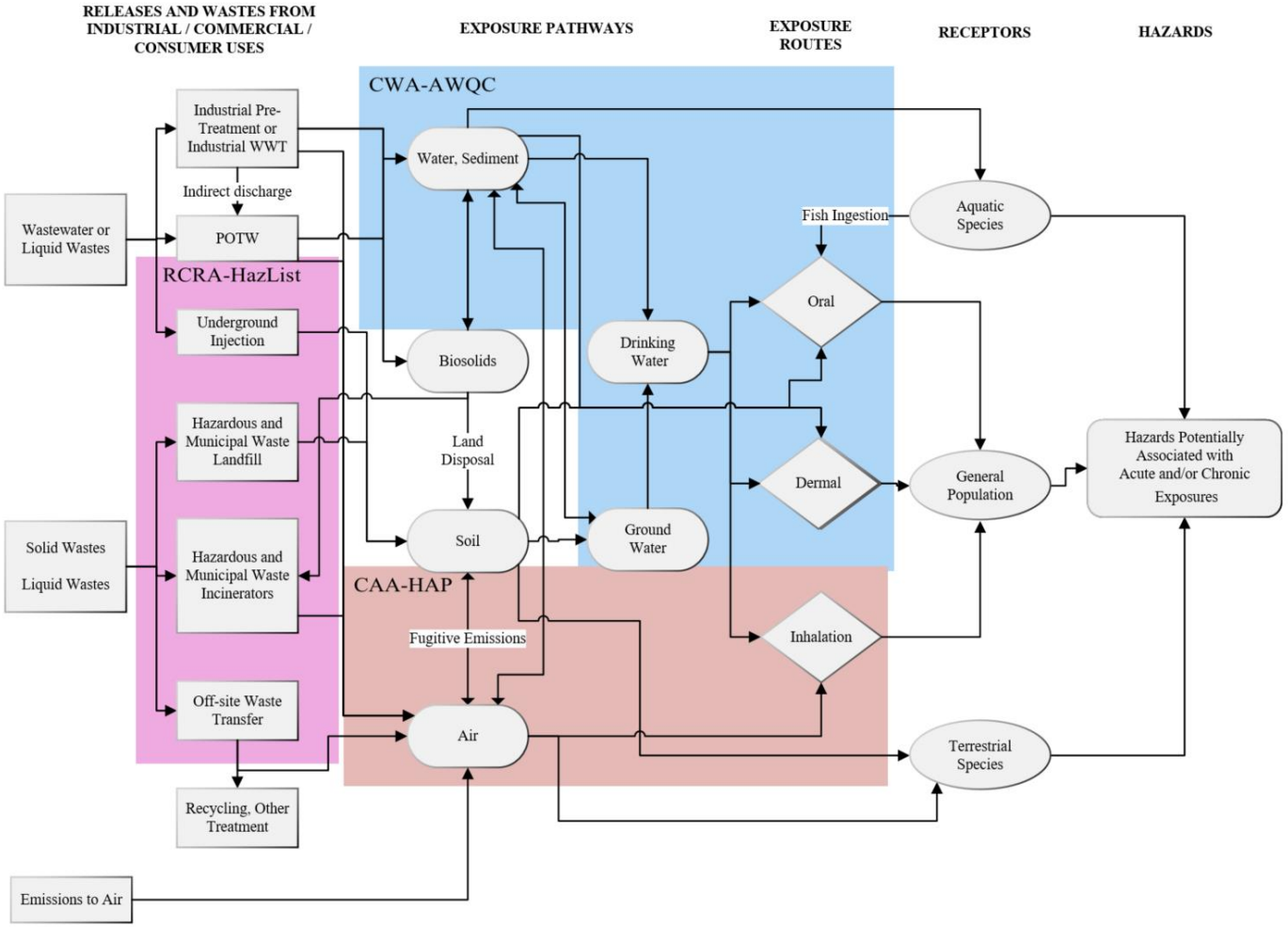

Figure 2-15. Dibutyl Phthalate Conceptual Model for Environmental Releases and Wastes: Environmental and General Population Exposures and Hazards (Regulatory Overlay)

The conceptual model presents the exposure pathways, exposure routes and hazards to human and environmental 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.

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 from drinking water may occur via showering.

b) Receptors include PESS (see Section 2.5).

2.6.3.1 Exposure Pathways and Risks Addressed by Other EPA Administered Statutes

In its TSCA Section 6(b) risk evaluations, EPA is coordinating action on certain exposure pathways and risks falling under the jurisdiction of other EPA-administered statutes or regulatory programs. More specifically, EPA is exercising its TSCA authorities to tailor the scope of its risk evaluations, rather than focusing on environmental exposure pathways addressed under other EPA-administered statutes or regulatory programs or risks that could be eliminated or reduced to a sufficient extent by actions taken under other EPA-administered laws. EPA considers this approach to be a reasonable exercise of the Agency's TSCA authorities, which include:

- TSCA Section 6(b)(4)(D): "The Administrator shall, not later than 6 months after the initiation of a risk evaluation, publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider…"
- TSCA Section 9(b)(1): "The Administrator shall coordinate actions taken under this chapter with actions taken under other Federal laws administered in whole or in part by the Administrator. If the Administrator determines that a risk to health or the environment associated with a chemical substance or mixture could be eliminated or reduced to a sufficient extent by actions taken under the authorities contained in such other Federal laws, the Administrator shall use such authorities to protect against such risk unless the Administrator determines, in the Administrator's discretion, that it is in the public interest to protect against such risk by actions taken under this chapter."
- TSCA Section 9(e): "…[I]f the Administrator obtains information related to exposures or releases of a chemical substance or mixture that may be prevented or reduced under another Federal law, including a law not administered by the Administrator, the Administrator shall make such information available to the relevant Federal agency or office of the Environmental Protection Agency."
- TSCA Section 2(c): "It is the intent of Congress that the Administrator shall carry out this chapter in a reasonable and prudent manner, and that the Administrator shall consider the environmental, economic, and social impact of any action the Administrator takes or proposes as provided under this chapter."
- TSCA section 18(d)(1): "Nothing in this chapter, nor any amendment made by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, nor any rule, standard of performance, risk evaluation, or scientific assessment implemented pursuant to this chapter, shall affect the right of a State or a political subdivision of a State to adopt or enforce any rule, standard of performance, risk evaluation, scientific assessment, or any other protection for public health or the environment that— (i) is adopted or authorized under the authority of any other Federal law or adopted to satisfy or obtain authorization or approval under any other Federal law…"

These TSCA authorities supporting tailored risk evaluations and intra-agency referrals are described in more detail below:

TSCA Section 6(b)(4)(D)

TSCA Section 6(b)(4)(D) requires EPA, in developing the scope of a risk evaluation, to identify the hazards, exposures, conditions of use, and PESS the Agency "expects to consider" in a risk evaluation. This language suggests that EPA is not required to consider all conditions of use, hazards, or exposure pathways in risk evaluations. As EPA explained in the "*Procedures for Chemical Risk Evaluation Under*

the Amended Toxic Substances Control Act (82 FR 33726, July 20, 2017)" ("Risk Evaluation Rule"), "EPA may, on a case-by-case basis, tailor the scope of the risk evaluation e in order to focus its analytical efforts on those exposures that are likely to present the greatest concern, and consequently merit an unreasonable risk determination." 82 FR 33726, 33729 (July 20, 2017).

In the problem formulation documents for many of the first 10 chemicals undergoing risk evaluation, EPA applied the same authority and rationale to certain exposure pathways, explaining that "EPA is planning to exercise its discretion under TSCA 6(b)(4)(D) to focus its analytical efforts on exposures that are likely to present the greatest concern and consequently merit a risk evaluation under TSCA, by excluding, on a case-by-case basis, certain exposure pathways that fall under the jurisdiction of other EPA-administered statutes." This is informed by the legislative history of the amended TSCA, which supports the Agency's exercise of discretion to focus the risk evaluation on areas that raise the greatest potential for risk. See June 7, 2016 Cong. Rec., S3519-S3520. Consistent with the approach articulated in the problem formulation documents, and as described in more detail below, EPA is exercising its authority under TSCA to tailor the scope of exposures evaluated in TSCA risk evaluations, rather than focusing on environmental exposure pathways addressed under other EPA-administered, media-specific statutes and regulatory programs.

TSCA Section 9(b)(1)

In addition to TSCA Section 6(b)(4)(D), the Agency also has discretionary authority under the first sentence of TSCA Section 9(b)(1) to "coordinate actions taken under [TSCA] with actions taken under other Federal laws administered in whole or in part by the Administrator." This broad, freestanding authority provides for intra-agency coordination and cooperation on a range of "actions." In EPA's view, the phrase "actions taken under [TSCA]" in the first sentence of Section 9(b)(1) is reasonably read to encompass more than just risk management actions, and to include actions taken during risk evaluation as well. More specifically, the authority to coordinate intra-agency actions exists regardless of whether the Administrator has first made a definitive finding of risk, formally determined that such risk could be eliminated or reduced to a sufficient extent by actions taken under authorities in other EPA-administered Federal laws, and/or made any associated finding as to whether it is in the public interest to protect against such risk by actions taken under TSCA. TSCA Section 9(b)(1) therefore provides EPA authority to coordinate actions with other EPA offices without ever making a risk finding or following an identification of risk. This includes coordination on tailoring the scope of TSCA risk evaluations to focus on areas of greatest concern rather than exposure pathways addressed by other EPA-administered statutes and regulatory programs, which does not involve a risk determination or public interest finding under TSCA Section 9(b)(2).

In a narrower application of the broad authority provided by the first sentence of TSCA Section 9(b)(1), the remaining provisions of Section 9(b)(1) provide EPA authority to identify risks and refer certain of those risks for action by other EPA offices. Under the second sentence of Section 9(b)(1), "[i]f the Administrator determines that a risk to health or the environment associated with a chemical substance or mixture could be eliminated or reduced to a sufficient extent by actions taken under the authorities contained in such other Federal laws, the Administrator shall use such authorities to protect against such risk unless the Administrator determines, in the Administrator's discretion, that it is in the public interest to protect against such risk by actions taken under [TSCA]." Coordination of intra-agency action on risks under TSCA Section 9(b)(1) therefore entails both an identification of risk, and a referral of any risk that could be eliminated or reduced to a sufficient extent under other EPA-administered laws to the

EPA office(s) responsible for implementing those laws (absent a finding that it is in the public interest to protect against the risk by actions taken under TSCA).

Risk may be identified by OPPT or another EPA office, and the form of the identification may vary. For instance, OPPT may find that one or more conditions of use for a chemical substance present(s) a risk to human or ecological receptors through specific exposure routes and/or pathways. This could involve a quantitative or qualitative assessment of risk based on reasonably available information (which might include, *e.g.*, findings or statements by other EPA offices or other federal agencies). Alternatively, risk could be identified by another EPA office. For example, another EPA office administering non-TSCA authorities may have sufficient monitoring or modeling data to indicate that a particular condition of use presents risk to certain human or ecological receptors, based on expected hazards and exposures. This risk finding could be informed by information made available to the relevant office under TSCA Section 9(e), which supports cooperative actions through coordinated information-sharing.

Following an identification of risk, EPA would determine if that risk could be eliminated or reduced to a sufficient extent by actions taken under authorities in other EPA-administered laws. If so, TSCA requires EPA to "use such authorities to protect against such risk," unless EPA determines that it is in the public interest to protect against that risk by actions taken under TSCA. In some instances, EPA may find that a risk could be sufficiently reduced or eliminated by future action taken under non-TSCA authority. This might include, *e.g.*, action taken under the authority of the Safe Drinking Water Act (SDWA) to address risk to the general population from a chemical substance in drinking water, particularly if the Office of Water has taken preliminary steps such as listing the subject chemical substance on the Contaminant Candidate List (CCL). This sort of risk finding, and referral could occur during the risk evaluation process, thereby enabling EPA to use more a relevant and appropriate authority administered by another EPA office to protect against hazards or exposures to affected receptors.

Legislative history on TSCA Section 9(b)(1) supports both broad coordination on current intra-agency actions, and narrower coordination when risk is identified and referred to another EPA office for action. A Conference Report from the time of TSCA's passage explained that Section 9 is intended "to assure that overlapping or duplicative regulation is avoided while attempting to provide for the greatest possible measure of protection to health and the environment." S. Rep. No. 94-1302 at 84. See also H. Rep. No. 114-176 at 28 (stating that the 2016 TSCA amendments "reinforce TSCA's original purpose of filling gaps in Federal law," and citing new language in Section 9(b)(2) intended "to focus the Administrator's exercise of discretion regarding which statute to apply and to encourage decisions that avoid confusion, complication, and duplication"). Exercising TSCA Section 9(b)(1) authority to coordinate on tailoring TSCA risk evaluations is consistent with this expression of Congressional intent.

Legislative history also supports a reading of Section 9(b)(1) under which EPA coordinates intra-agency action, including information-sharing under TSCA Section 9(e), and the appropriately positioned EPA office is responsible for the identification of risk and actions to protect against such risks. See, *e.g.*, Senate Report 114-67, 2016 Cong. Rec. S3522 (under TSCA Section 9, "if the Administrator finds that disposal of a chemical substance may pose risks that could be prevented or reduced under the Solid Waste Disposal Act, the Administrator should ensure that the relevant office of the EPA receives that information"); H. Rep. No. 114-176 at 28, 2016 Cong. Rec. S3522 (under Section 9, "if the Administrator determines that a risk to health or the environment associated with disposal of a chemical substance could be eliminated or reduced to a sufficient extent under the Solid Waste Disposal Act, the Administrator should use those authorities to protect against the risk"). Legislative history on Section

9(b)(1) therefore supports coordination with and referral of action to other EPA offices, especially when statutes and associated regulatory programs administered by those offices could address exposure pathways or risks associated with conditions of use, hazards, and/or exposure pathways that may otherwise be within the scope of TSCA risk evaluations.

TSCA Sections 2(c) and 18(d)

Finally, TSCA Section 2(c) supports coordinated action on exposure pathways and risks addressed by other EPA-administered statutes and regulatory programs. Section 2(c) directs EPA to carry out TSCA in a "reasonable and prudent manner" and to consider "the environmental, economic, and social impact" of its actions under TSCA. Legislative history from around the time of TSCA's passage indicates that Congress intended EPA to consider the context and take into account the impacts of each action under TSCA. S. Rep. No. 94-698 at 14 ("the intent of Congress as stated in this subsection should guide each action the Administrator takes under other sections of the bill").

Section 18(d)(1) specifies that state actions adopted or authorized under any Federal law are not preempted by an order of no unreasonable risk issued pursuant to TSCA Section 6(i)(1) or a rule to address unreasonable risk issued under TSCA Section 6(a). Thus, even if a risk evaluation were to address exposures or risks that are otherwise addressed by other federal laws and, for example, implemented by states, the state laws implementing those federal requirements would not be preempted. In such a case, both the other federal and state laws, as well as any TSCA Section 6(i)(1) order or TSCA Section 6(a) rule, would apply to the same issue area. See also TSCA Section 18(d)(1)(A)(iii). In legislative history on amended TSCA pertaining to Section 18(d), Congress opined that "[t]his approach is appropriate for the considerable body of law regulating chemical releases to the environment, such as air and water quality, where the states have traditionally had a significant regulatory role and often have a uniquely local concern." Sen. Rep. 114-67 at 26.

EPA's careful consideration of whether other EPA-administered authorities are available, and more appropriate, for addressing certain exposures and risks is consistent with Congress' intent to maintain existing federal requirements and the state actions adopted to locally and more specifically implement those federal requirements, and to carry out TSCA in a reasonable and prudent manner . EPA believes it is both reasonable and prudent to tailor TSCA risk evaluations when other EPA offices have expertise and experience to address specific environmental media, rather than attempt to evaluate and regulate potential exposures and risks from those media under TSCA. This approach furthers Congressional direction and EPA aims to efficiently use Agency resources, avoid duplicating efforts taken pursuant to other Agency programs, and meet the statutory deadline for completing risk evaluations.

EPA-administered statutes and regulatory programs that address specific exposure pathways and/or risks are listed as follows:

<u>Ambient Air Pathway</u>
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.

See 42 U.S.C. 7412. 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. See 40 CFR part 63.

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 exchange information related to toxicity and occurrence data on chemicals undergoing risk evaluation under TSCA. As such, EPA does not plan to evaluate exposures to the general population from ambient air in the risk evaluation under TSCA. This regulatory coverage is represented by the red shading in Figure 2-15.

Ambient Water Pathway

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 National Pollutant Discharge Elimination System (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 develops recommended water quality criteria under Section 304(a) of the Clean Water Act (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 and/or numeric criteria. See, *e.g.*, 40 CFR part 423, Appendix A; 40 CFR 131.11(b)(1); 40 CFR 122.44(d)(1)(vii). As such, EPA does not plan to evaluate exposures to general population from surface water in the risk evaluation under TSCA. This regulatory coverage is represented by the light blue shading in Figure 2-15 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. As such, EPA is not evaluating exposures to the general population from surface water in the risk evaluation under TSCA. This regulatory coverage is represented by the light blue shading in Figure 2-15.

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.

Onsite Releases to Land Pathway

The Comprehensive Environmental Response, Compensation, and Liability Act, otherwise known as CERCLA, provides broad authority under the statute (generally referred to as Superfund) to clean up uncontrolled or abandoned hazardous-waste sites as well as accidents, spills, and other releases of hazardous substances, pollutants and contaminants into the environment. Through CERCLA, EPA was given authority to seek out those parties potentially responsible for the release of hazardous substances and either have them clean up the release or compensate the Federal government for undertaking the response action.

CERCLA Section 101(14) defines “hazardous substance” by referencing other environmental statutes, including toxic pollutants listed under CWA Section 307(a); hazardous substances designated pursuant to CWA Section 311(b)(2)(A); hazardous air pollutants listed under CAA Section 112; imminently hazardous substances with respect to which EPA has taken action pursuant to TSCA Section 7; and hazardous wastes having characteristics identified under or listed pursuant to RCRA Section 3001. See 40 CFR 302.4. CERCLA Section 102(a) also 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 within a 24-hour period must be reported (40 CFR 302.4, 302.6). The scope of this EPA TSCA risk evaluation does not include on-site releases of dibutyl phthalate to the environment at Superfund sites and subsequent exposure of the general population or non-human species.

Disposal and Soil Pathways

Dibutyl phthalate is included on the list of hazardous wastes pursuant to the Resource Conservation and Recovery Act (RCRA) 3001 (40 CFR §§ 261.33) as a listed waste on the U list (U069). 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 (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)[8].

The disposal of dibutyl phthalate as a constituent of produced water primarily falls under the jurisdiction of the Safe Drinking Water Act. Most of the produced water (about 93% in 2012) is injected in Class II wells, which are regulated under the Underground Injection Control Program of the Safe Drinking Water Act (42 U.S.C. § 300f; 40 CFR pt. 146, Subpart C). As a result, EPA is not evaluating exposures of the general population or the environment from the disposal of dibutyl phthalate as a constituent of produced water in Class II wells.

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.

EPA does not plan to evaluate on-site releases to land that go to underground injection or associated exposures to the general population or terrestrial species in its risk evaluation. 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. See 40 CFR part 144.

EPA has identified releases to land from 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 2-5) and 195,503 pounds released to "all other land disposal" 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. See 40 CFR part 264. As a result, EPA does not plan to evaluate on-site releases to land from RCRA Subtitle C hazardous waste landfills or exposures of the general population or terrestrial species

[8] This is not an exclusive list of Subtitle C authority, as it also covers, for example, disposal to surface impoundments, waste piles, and land treatment.

from such releases in the TSCA evaluation. This regulatory coverage is represented by the pink shading in Figure 2-15.

Evaporation ponds, percolation pits and tanks can also be used for the disposal of dibutyl phthalate when it is disposed of as a constituent in produced water. On-site releases of dibutyl phthalate in such a manner fall under the jurisdiction of RCRA subtitle D (see 40 CFR pt. 257). As such, EPA is not evaluating exposures of the general population or terrestrial species from such on-site releases to evaporation ponds, percolation pits, or tanks.

Dibutyl phthalate is present in commercial and consumer products that may be disposed of in Municipal Solid Waste (MSW) landfills. On-site releases from 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. See 40 CFR part 258. As a result, EPA does not plan to evaluate on-site releases to land from RCRA Subtitle D municipal solid waste (MSW) landfills or exposures of the general population or terrestrial species from such releases in the TSCA evaluation. This regulatory coverage is represented by the pink shading in Figure 2-15.

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. See *e.g.*, RCRA Section 3004(c), 4007; 40 CFR part 257. As a result, EPA does not plan to evaluate on-site releases to land from industrial non-hazardous waste and construction/demolition waste landfills or associated exposures to the general population. This regulatory coverage is represented by the pink shading in Figure 2-15.

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

As described in Section 2.6.3.1, some pathways in the conceptual models are covered under the jurisdiction of other environmental statutes administered by EPA. The conceptual model depicted in Figure 2-16 presents the exposure pathways, exposure routes and hazards to general population and environmental receptors from releases and wastes from industrial, commercial, and consumer uses of dibutyl phthalate that EPA plans to evaluate.

The diagram shown in Figure 2-16 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 receptors, and to the general population from emissions to air. EPA plans to evaluate general population exposure to dibutyl phthalate from drinking water via the oral, dermal and inhalation

routes. The supporting basis for environmental pathways considered for dibutyl phthalate are included in Appendix H.

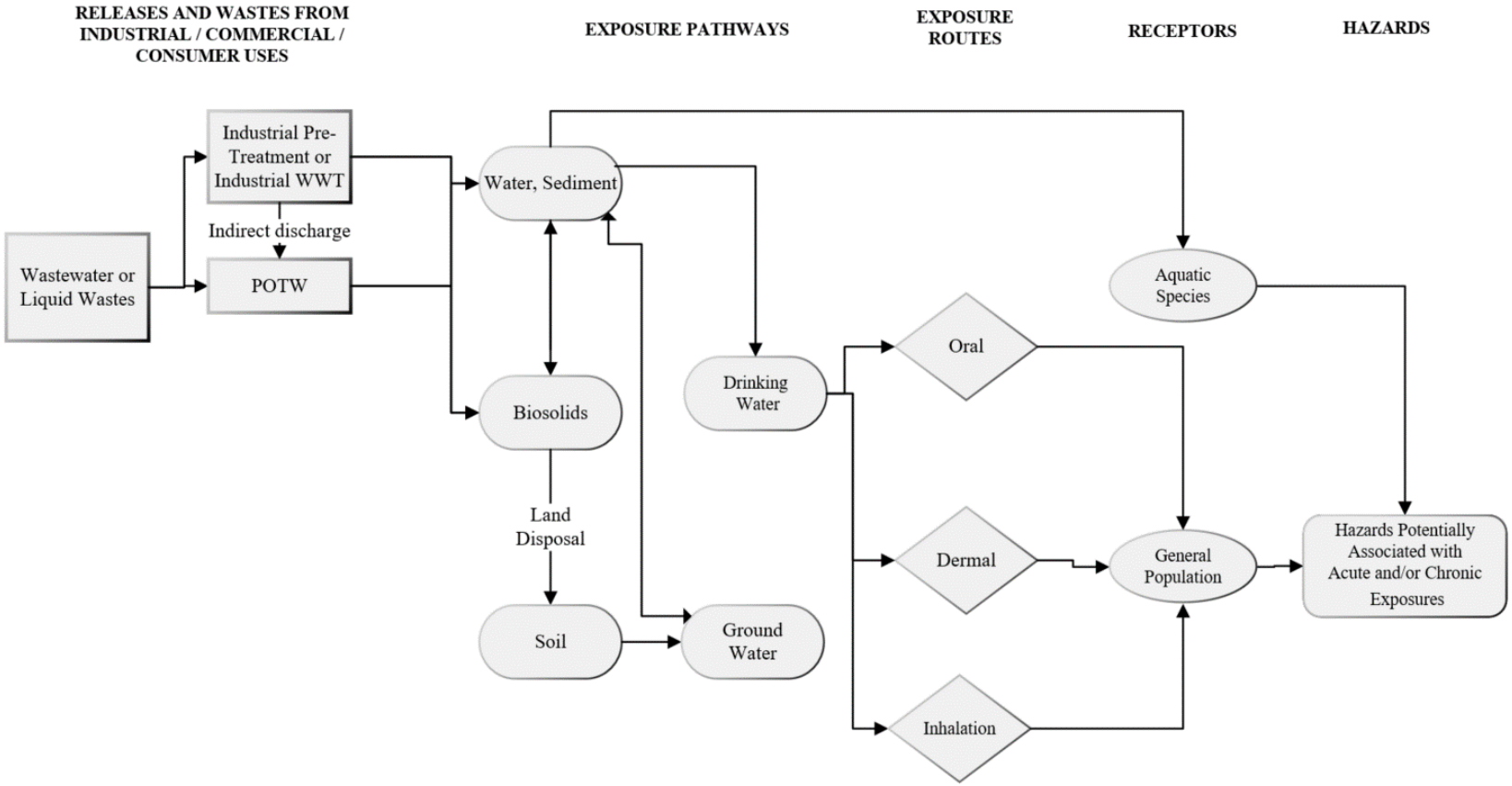

Figure 2-16. Dibutyl Phthalate Conceptual Model for Environmental Releases and Wastes: Environmental and General Population Exposures and Hazards

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.

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 PESS (see Section 2.5).

2.7 Analysis Plan

The analysis plan is based on EPA's knowledge of dibutyl phthalate resulting from the full-text screening of reasonably available information as described in Section 2.1. EPA encourages submission of additional existing data, such as full study reports or workplace monitoring from industry sources, that may be relevant for evaluating conditions of use, exposures, hazards, and PESS during risk evaluation. As discussed in the *Application of Systematic Review in TSCA Risk Evaluations* document (U.S. EPA, 2018a), targeted supplemental searches during the analysis phase may be necessary to identify additional information (*e.g.*, commercial mixtures) for the risk evaluation of dibutyl phthalate. For any additional data needs identified during the risk evaluation, EPA may use the Agency's TSCA authorities under Sections 4, 8 or 11, as appropriate.

2.7.1 Physical and Chemical Properties and Environmental Fate

EPA plans to analyze the physical and chemical properties and environmental fate and transport of dibutyl phthalate as follows:

1) **Review reasonably available measured or estimated physical and chemical and environmental fate endpoint data collected using systematic review procedures and, where reasonably available, environmental assessments conducted by other regulatory agencies.**
   EPA plans to evaluate data and information collected through the systematic review methods and public comments about the physical and chemical properties (Appendix B) and fate endpoints (Appendix C), 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, 2019c). All sources cited in EPA's analysis will be evaluated according to the procedures and metrics described in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018a). Where the systematic review process does not identify experimentally measured chemical property values of sufficiently high quality, testing will be requested under the TSCA Section 4 authority, or 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 physical and chemical 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 physical and chemical 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 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 physical and chemical and environmental fate data, including qualitative and quantitative sources of information.** During risk evaluation, EPA plans to evaluate and integrate the environmental fate evidence identified in the literature inventory using the methods described in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018a).

2.7.2 Exposure

EPA plans to analyze exposure levels for indoor air, surface water, sediment, soil, ground water, dietary food sources, and aquatic biota associated with exposure to dibutyl phthalate. Based on its physical and chemical properties, expected sources, and transport and transformation within the outdoor and indoor environment, dibutyl phthalate is more likely to be present in some of these media and less likely to be present in others. EPA has not yet determined the exposure levels in these media. Exposure level(s) can be characterized through a combination of reasonably available monitoring data and estimated exposure levels from modeling approaches. Exposure scenarios are sources (uses), exposure pathways, and exposed receptors. EPA plans to analyze scenario-specific exposures. Draft exposure scenarios corresponding to various conditions of use for dibutyl phthalate are presented in Appendix F. Appendix G and Appendix H. EPA plans to analyze scenario-specific exposures

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 sources containing information on processes and activities resulting in releases, and the information found is described in Appendix E. EPA plans to review additional data sources identified. Potential sources of environmental release data are summarized in Table 2-6 below:

Table 2-6. Categories and Sources of Environmental Release Data

U.S. EPA TRI Data
U.S. EPA Generic Scenarios
OECD Emission Scenario Documents
EU Risk Assessment Reports
Discharge Monitoring Report (DMR) surface water discharge data from NPDES-permitted facilities
National Emissions Inventory (NEI) data

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 will continue to consider additional reasonably available information and will evaluate it during development of the 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 Exposures and Environmental Releases (ChemSTEER) (U.S. EPA, 2015a).

3) **Review reasonably available release data for surrogate chemicals that have similar uses and physical properties.**
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.

4) **Review reasonably available data that may be used in developing, adapting or applying release 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 and sources (including, for example, regulatory limits, reporting thresholds or disposal requirements) that may be relevant for 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 Formulation (OECD, 2009a), the 2011 ESD on Coating Application via Spray-Painting in the Automotive Refinishing Industry (OECD, 2011a), the 2011 ESD on Chemical Industry (OECD, 2011c), the 2011 ESD on Radiation Curable Coating, Inks and Adhesives (OECD, 2011b), the 2015 ESD on the Use of Adhesives (OECD, 2015), and the 2019 ESD on Plastic Additives (OECD, 2019) may be useful. EPA plans to need 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

If ESDs and GSs are not available, other methods may be considered. EPA may also perform supplemental targeted searches of peer-reviewed or gray literature for applicable models and associated parameters that EPA may use to estimate releases for certain conditions of use. 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 completed an initial mapping of release scenarios to relevant conditions of use as shown in Appendix F. EPA plans to refine the mapping/grouping of release scenarios based on

factors (*e.g.*, process equipment and handling, magnitude of production volume used, and exposure/release sources) corresponding to conditions of use using reasonably available information. EPA may perform supplemental targeted searches of peer-reviewed or gray literature to better understand certain conditions of use to further develop release scenarios.

7) **Evaluate the weight of the scientific evidence of environmental release data.**
During risk evaluation, EPA plans to evaluate and integrate the environmental release evidence identified in the literature inventory using the methods described in the *Application of Systematic Review in TSCA Risk Evaluation* (U.S. EPA, 2018a). EPA plans to integrate the data using 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 EPA plans to analyze are sediment, biosolids, 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.**
EPA plans to analyze and consider reasonably available environmental exposure models that meet the scientific standards TSCA section 26(h) and that estimate air, surface water, groundwater, sediment, and biosolids concentrations alongside reasonably available surface water, groundwater, and sediment monitoring data to characterize environmental exposures. Modeling approaches to estimate surface water concentrations, sediment concentrations may generally include the following inputs: direct release into surface water, or sediment, and indirect release into surface water, sediment, fate and transport (partitioning within media) and characteristics of the environment (*e.g.*, river flow, volume of lake, meteorological data).

3) **Determine applicability of existing additional contextualizing information for any monitored data or modeled estimates during risk evaluation.**
There have been changes to use patterns of dibutyl phthalate over the last few years. EPA plans to review and characterize monitoring data or modeled estimates to determine how representative they are of ongoing use patterns.

   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).**
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, and sediment 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 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 *Application of Systematic Review in TSCA Risk Evaluation* (U.S. EPA, 2018a).

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).

   OSHA has established a PEL of 5 mg/m^3, 8-hour TWA, for dibutyl phthalate. 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 2-7. 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. 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 (OECD, 2015) and the 2009 ESD on Plastic Additives (OECD, 2009b) 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 may conduct industry outreach or perform additional targeted searches of peer-reviewed or gray literature to understand those conditions of use, which may inform identification of exposure scenarios. EPA may also need to perform targeted supplemental searches 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 #2 and #3 are completed, and based on information developed from #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, 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 ONUs.

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. OSHA recommends employers utilize the hierarchy of controls to address hazardous exposures in the workplace. The hierarchy of controls strategy outlines, in descending order of priority, the use of elimination, substitution, engineering controls, administrative controls, and lastly personal protective equipment (PPE). EPA plans to assess worker exposure pre- and post-implementation of EC, using reasonably available information on 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 the fourth column in Table_Apx F-1, EPA has completed an initial mapping of exposure scenarios to conditions of use. EPA plans to refine 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. EPA may perform supplemental targeted searches of peer-reviewed or gray literature to better understand certain conditions of use to further develop exposure scenarios.

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 *Application of Systematic Review in*

TSCA Risk Evaluation (U.S. EPA, 2018a). EPA plans to rely on the weight of the scientific evidence when evaluating and integrating occupational data. EPA plans to integrate the data using systematic review methods to assemble the relevant data, evaluate the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence.

2.7.2.4 Consumer Exposures

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

1) **Group each condition of use to consumer exposure assessment scenario(s).**
   Refine and finalize exposure scenarios for consumers by considering combinations of sources (ongoing consumer uses), exposure pathways including routes, and exposed populations.
   For dibutyl phthalate, the following are noteworthy considerations in constructing consumer exposure scenarios:
   - Conditions of use
   - Duration, frequency and magnitude of exposure
   - Weight fraction of chemical in products
   - Amount of chemical used
2) **Evaluate the potential of indoor exposure pathways based on reasonably available data.**
   Based on physical and chemical properties of dibutyl phthalate and the consumer uses identified, inhalation of particles is expected to be an important indoor exposure pathway for consumers. Other pathways include dust ingestion and dermal contact as a result of indoor use of dibutyl phthalate consumer products. Inhalation of vapor and mist and oral ingestion of liquid and mist are also possible. EPA plans to review all reasonably available information in developing the consumer exposure scenarios and evaluating the exposure pathways in indoor environments.
3) **Review existing indoor exposure models that may be applicable in estimating indoor air exposures.**
   Indoor exposure models that estimate emissions from use of consumer products are available. These models generally consider physical and chemical properties (e.g., vapor pressure, molecular weight), product specific properties (e.g., weight fraction of the chemical in the product), use patterns (e.g., duration and frequency of use), user environment (e.g., room of use, ventilation rates), and receptor characteristics (e.g., exposure factors, activity patterns). The OPPT's Consumer Exposure Model (CEM) and other similar models can be used to estimate indoor air exposures from consumer products.

   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 physical and chemical 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 dust, indoor air).**
The availability of dibutyl phthalate concentration for various conditions of uses will be evaluated. This data provides the source term for any subsequent indoor modeling. EPA plans to analyze source attribution between overall indoor air and dust levels and various indoor sources.

6) **Review reasonably available population- or subpopulation-specific exposure factors and activity patterns to determine if PESS need to be further refined.**
For dibutyl phthalate EPA plans to evaluate exposure scenarios that involve PESS and plans to consider age-specific behaviors, activity patterns and exposure factors unique to those subpopulations. For some exposure scenarios related to consumer uses, EPA plans to consider whether exposures for adults may differ from those of children due to different activities (*e.g.*, children may mouth certain products) or exposure factors (*e.g.*, inhalation rates).

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. EPA plans to integrate the data using 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 the general population by considering sources, conditions of uses, exposure pathways and routes.**
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 modeling approaches 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 and relevant.
- 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 PESS 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 inform exposure scenarios. EPA anticipates that there will be a range in the potential exposures associated with the exposure scenarios identified in Section 2.6.

After refining and finalizing exposure scenarios, EPA plans to quantify concentrations and/or doses. The number of scenarios will depend on the conditions of use, exposure pathways, and receptors. 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 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 include careful consideration of variability and uncertainty.

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, drinking water concentrations, groundwater concentrations, and sediment concentrations

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 physical and chemical 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 PESS 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 PESS will consider age-specific behaviors, activity patterns, and exposure factors unique to those subpopulations.

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 *Application of Systematic Review in TSCA Risk Evaluation* (U.S. EPA, 2018a).

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 organisms, including plants, invertebrates (*e.g.*, insects, arachnids, mollusks, crustaceans), and vertebrates (*e.g.*, mammals, birds, amphibians, fish, reptiles) across exposure durations and conditions if potential environmental hazards are identified through systematic review results and public comments. Additional types of environmental hazard information will also be considered (*e.g.*, analogue and read-across data) when characterizing the potential hazards of dibutyl phthalate to aquatic organisms.

   EPA plans to evaluate environmental hazard data using the evaluation strategies laid out in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018a). The study evaluation results will be documented in the risk evaluation phase and data from acceptable studies will be extracted and integrated in the risk evaluation process.

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

3) **Evaluate the weight of 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 *Application of Systematic Review in TSCA Risk Evaluation* (U.S. EPA, 2018a).

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

5) **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 physical and chemical properties and exposure pathways. EPA plans to assess reasonably available studies collected from the systematic review process relating to bioaccumulation and bioconcentration (*e.g.*, 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).

6) **Conduct an environmental risk estimation and characterization of dibutyl phthalate.**
EPA plans to conduct a risk estimation and characterization of dibutyl phthalate to identify if there are risks to the aquatic environments from the measured and/or predicted concentrations of dibutyl phthalate in environmental media (*e.g.*, water, sediment). Risk quotients (RQs) may be derived by the application of hazard and exposure benchmarks to characterize environmental risk (U.S. EPA, 1998; Barnthouse et al., 1982). Analysis of risk for characterization includes a confidence statement in risk estimation which qualitative judgment describing the certainty of the risk estimate considering the strength the evidence scores for hazard and exposure and the limitations, and relevance.

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 evaluate human health studies using the evaluation strategies laid out in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018a) and updates to the epidemiological data quality criteria released with the first ten risk evaluations. The study evaluation results will be documented in the risk evaluation phase and data from acceptable studies will be extracted and integrated in the risk evaluation process.

   Mechanistic data may include analyses of alternative test data such as novel *in vitro* test methods and high throughput screening. The association between acute and chronic exposure scenarios to the agent and each health outcome will also be integrated. Study results will be extracted and presented in evidence tables or another appropriate format by organ/system.

2) **In evaluating reasonably available data, determine whether particular human receptor groups may have greater susceptibility to the chemical's hazard(s) than the general population.**
Reasonably available human health hazard data will be evaluated to ascertain whether some human receptor groups may have greater susceptibility than the general population to 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 susceptible population and life stages such as pregnant women and infants. Pregnancy (*i.e.*, gestation) and childhood are potential susceptible life stages for dibutyl phthalate exposure. EPA may quantify these differences in the risk evaluation following further evaluation of the reasonably available data and information.

3) **Conduct hazard identification (the qualitative process of identifying non-cancer and cancer endpoints) and dose-response assessment (the quantitative relationship between hazard and exposure) for identified human health hazard endpoints.**
Human health hazards from acute and chronic exposures will be identified by evaluating the human and animal data that meet the systematic review data quality criteria described in the *Application of Systematic Review in TSCA Risk Evaluation* (U.S. EPA, 2018a). 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 the cancer and noncancer endpoints identified in Section 2.4.2.

Dose-response assessment will be performed in accordance with EPA guidance (U.S. EPA, 2012a, 2011b, 1994) developing points of departure (POD) for either margins of exposure (MOEs), cancer slope factors (CSFs), oral slope factors (OSFs), and/or inhalation unit risks (IURs). 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) analyses determine the relevancy of animal data to human risk and how data can be quantitatively evaluated. If cancer hazard is determined to be applicable to dibutyl phthalate, EPA plans to evaluate information on genotoxicity and the MOA 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, 2005a). In accordance with EPA's *Supplemental Guidance for Assessing Susceptibility from Early-life Exposures to Carcinogens* (U.S. EPA, 2005b), EPA plans to determine whether age-dependent adjustment factors (ADAFs) are appropriate for dibutyl phthalate for specific conditions of use based upon potential exposures to children.

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* (U.S. EPA, 2012a). 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 (2011b), 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 *Application of Systematic Review in TSCA Risk Evaluation* (U.S. EPA, 2018a).

6) **Consider the route(s) of exposure (*e.g.*, oral, inhalation, dermal), reasonably available route-to-route extrapolation approaches; biomonitoring data; and approaches to correlate internal and external exposures to integrate exposure and hazard assessment.**
At this stage of review, EPA believes there will be sufficient reasonably available data to conduct a dose-response analysis and/or benchmark dose modeling for the oral route of exposure. EPA plans to also evaluate any potential human health hazards following dermal and inhalation exposure to 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 point of departure can be identified for the dermal and inhalation routes.

If sufficient reasonably available toxicity studies are not identified through the systematic review process to assess risks from inhalation or dermal exposure, then a route-to-route extrapolation may be needed. The preferred approach is to use a PBPK model (U.S. EPA, 2006a). Without an adequate PBPK model, considerations regarding the adequacy of data for route-to-route extrapolation are described in *Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry* (U.S. EPA, 1994). EPA may use these considerations when determining whether to extrapolate from the oral to the inhalation route of exposure. Similar approaches for oral-to-dermal route extrapolation are 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).

If there are acceptable inhalation data after completion of systematic review, EPA may also consider extrapolating from the inhalation to the dermal route if first-pass metabolism through the liver via the oral route is expected because in that case, use of data from the oral route is not recommended (U.S. EPA, 1994). EPA may also consider inhalation-to-dermal route extrapolation if an inhalation toxicity study with a sensitive hazard endpoint is used to evaluate risks. Based on these considerations, EPA extrapolated from the inhalation to the dermal route

for several of the first ten risk evaluations under amended TSCA, including methylene chloride (U.S. EPA, 2020d) and carbon tetrachloride (U.S. EPA, 2020b).

7) **Conduct a human health risk estimation and characterization of dibutyl phthalate.** Analysis of risk for characterization includes a confidence statement in risk estimation. This confidence statement is based on qualitative judgment describing the certainty of the risk estimate considering the strength of the evidence scores for hazard and exposure and the limitations, and relevance. The lowest confidence evaluation for either hazard or exposure will drive the overall confidence estimate.

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." [(U.S. EPA, 2000), Appendix A]. 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, July 20, 2017). As discussed in 40 CFR 702.43, risk characterization has a number of considerations. This is the step where EPA integrates the hazard and exposure assessments into risk estimates for the identified populations (including any PESS) and ecological characteristics and weighs the scientific evidence for the identified hazards and exposures. The risk characterization does not consider costs or other nonrisk factors, and takes into account, "where relevant, the likely duration, intensity, frequency, and number of exposures under the condition(s) of use…." The risk characterization also summarizes the following considerations: (1) uncertainty and variability in each step of the risk evaluation; (2) data quality, and any applicable assumptions used; (3) alternative interpretations of data and analyses, where appropriate; and (4) any considerations for environmental risk evaluations, if necessary (*e.g.*, related to nature and magnitude of effects).

EPA plans to also be guided by EPA's Information Quality Guidelines (U.S. EPA, 2002) as it provides guidance for presenting risk information. Consistent with those guidelines, in the risk characterization, EPA plans to also identify: (1) Each population addressed by an estimate of applicable risk effects; (2) the expected risk or central estimate of risk for the PESS affected; (3) each appropriate upper-bound or lower bound estimate of risk; (4) each significant uncertainty identified in the process of the assessment of risk effects and the studies that would assist in resolving the uncertainty; and (5) peer reviewed studies known to the Agency that support, are directly relevant to, or fail to support any estimate of risk effects and the methodology used to reconcile inconsistencies in the scientific information.

2.8 Peer Review

Peer review will be conducted in accordance with EPA's regulatory procedures for chemical risk evaluations, including using EPA's Peer Review Handbook (U.S. EPA, 2015b) 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 ABBREVIATED METHODS FOR SEARCHING AND SCREENING

A.1 Literature Search of Publicly Available Databases

A.1.1 Search Term Genesis and Chemical Verification

To develop the chemical terms for the subsequent literature search for dibutyl phthalate, several online sources were queried.

- California Department of Pesticide Regulation: https://www.cdpr.ca.gov/docs/chemical/monster2.htm
- USEPA Chemistry Dashboard: https://comptox.epa.gov/dashboard
- University of Hertfordshire PPDB: Pesticide Properties Database: https://sitem.herts.ac.uk/aeru/ppdb/en/search.htm
- USEPA Reregistration Eligibility Decision (RED) documents: https://archive.epa.gov/pesticides/reregistration/web/html/status.html
- Office of Pesticide Programs Pesticide Chemical Search: https://ofmpub.epa.gov/apex/pesticides/f?p=CHEMICALSEARCH:1
- Food and Agriculture Organization of the United Nations: http://www.fao.org/home/en/
- PAN Pesticides Database: http://www.pesticideinfo.org/Search_Chemicals.jsp

Prior to inclusion in the search term string, all forms of chemical names were subjected to verification from several potential sources (*e.g.*, US EPA Chemistry Dashboard, STN International-CAS; see complete list of sources for chemical verification in Table_Apx A-1). From these sources, all chemical names, synonyms, CAS number(s), trade names, etc. were documented and used to generate terms for database searches.

Table_Apx A-1. Sources of Verification for Chemical Names and Structures

CHEMICAL SOURCE	CONTENTS	DOCUMENT LOCATION
Chemistry Dashboard (https://comptox.epa.gov/dashboard)	CAS Numbers, Synonyms, Structures, Properties, Environmental Fate and Transport.	Online
Dictionary of Chemical Names and Synonyms	Wide assortment of chemical compounds by chemical name and synonym, has CAS index and some structure data	ECOTOX
Farm Chemicals Handbook-1992	Pesticide information, CAS numbers and synonyms, some structure data ***Sometimes CAS number presented for a compound is for the main constituent only	ECOTOX
OPPT SMILES Verification Source	Structure Data	Electronic verification
RTECS (Registry of Toxic Effects of chemical substance, 1983-84 ed., 2 vols)	Chemical names, synonyms and CAS numbers	ECOTOX

CHEMICAL SOURCE	CONTENTS	DOCUMENT LOCATION
Sigma – Aldrich website58784 http://www.sigma-aldrich.com	Organic and inorganic Compounds by chemical name, has CAS index and some structure and Physical Property data	Online
STN International (CAS) 1994	***Most complete source of chemical name, synonym and structure information, no physical properties	Online
The Pesticide Manual 10th edition, 1994	Pesticide Compounds by chemical name, synonym, product code, has CAS index and some structure and Physical Property data	ECOTOX
TSCA (Toxic Substances Control Act Chemical Substance Inventory, 1985 ed., 5 vols)	Chemical names, synonyms and CAS numbers	ECOTOX
World Wide Web (misc. web sources) A copy of the verification page is saved to the Attachments tab of the chemical entry. This includes company MSDS sheets or Chemical Labels.	Chemical names, synonyms and CAS numbers	Online
California Department of Pesticide Regulation (http://www.cdpr.ca.gov/dprdatabase.htm)	Multiple databases containing chemicals, pesticides, companies, products, etc.	Online
PAN Pesticide Database (http://www.pesticideinfo.org/Search_Chemicals.jsp)	Pesticides searchable by name or CAS #. Includes CAS #, Name, synonyms, targets, toxicity data, related chemicals and regulatory information.	Online
US EPA Office of Pesticide Programs Pesticide Fate Database – No web access available. An electronic copy of the data file is located at the Contractor site: PFATE_37_Tables.mdb.	Multiple databases containing chemicals, pesticides, companies, products, etc.	Online

A.1.2 Publicly Available Database Searches

The databases listed below were searched for literature containing the chemical search terms. Database searching occurred during April and May of 2019 by an information specialist and the results were stored in the Health and Environmental Research Online (HERO) database and assigned a HERO reference identification number.[9] The present literature search focused only on the chemical name (including synonyms and trade names) with no additional limits. Full details of the search strategy for each database are presented in Appendix A.1.2.1.

After initial deduplication in HERO[10], these studies were imported into SWIFT Review software (Howard et al., 2016) to identify those references most likely to be applicable to each discipline area (*i.e.*

[9]EPA's HERO database provides access to the scientific literature behind EPA science assessments. The database includes more than 600,000 scientific references and data from the peer-reviewed literature used by EPA to develop its regulations.
[10] Deduplication in HERO involves first determining whether a matching unique ID exists (*e.g.*, PMID, WOSid, or DOI). If one matches one that already exists in HERO, HERO will tag the existing reference instead of adding the reference again. Second, HERO checks if the same journal, volume, issue and page number are already in HERO. Third, HERO matches on the title, year, and first author. Title comparisons ignore punctuation and case.

consumer, environmental, and general population exposure, occupational exposure and environmental releases, environmental hazards, human health hazards, and fate and physical chemistry).

A.1.2.1 Query Strings for the Publicly-Available Database Searches on Dibutyl Phthalate

Table_Apx A-2 presents a list of the data sources, the search dates and number of peer-reviewed references resulting from the searches for dibutyl phthalate. The sources are found as online databases and the resulting references were gathered and uploaded into the EPA Health and Environmental Research Online (HERO) database for literature screening.

Table_Apx A-2. Summary of Data Sources, Search Dates and Number of Peer-Reviewed Literature Search Results for Dibutyl Phthalate (DBP)

Source	Date of Search	Number of References
Current Contents	07/08/2019	3391
WOS Core Collection	07/08/2019	4285
ProQuest CSA	07/08/2019	4538
Dissertation Abstracts	07/11/2019	21
Science Direct	07/09/2019	2108
Agricola	07/09/2019	2159
TOXNET	07/09/2019	2259
PubMed	07/09/2019	2434
UNIFY	07/22/2019	358
Totals:		**21,553**

GENERAL:

General search terms were compiled and used in the search strategies for each of the databases/sources listed below. Based upon the online search manuals for the respective databases/sources, it was necessary to construct searches as noted for each of the sources. The search terms are listed below in full for each source and noted if the general search terms or other search terms were used.

"1,2-Benzenedicarboxylic acid dibutyl ester" OR "1,2-Benzenedicarboxylic acid, 1,2-dibutyl ester" OR "1,2-Benzenedicarboxylic acid, Bis(2-methylpropyl) ester" OR "1,2-Benzenedicarboxylic acid, dibutyl ester" OR "Benzenedicarboxylic acid dibutyl ester" OR "Benzene-o-dicarboxylic acid di-n-butyl ester" OR "Bis-n-butyl phthalate" OR "BRN 1914064" OR "Butyl phthalate" OR "Caswell No. 292" OR "Celluflex DPB" OR "Corflex 440" OR "Di(n-butyl) 1,2-benzenedicarboxylate" OR "Di(n-butyl)1,2-benzenedicarboxylate" OR "Di(n-butyl)phthalate" OR "Dibutyl 1,2-benzenedicarboxylate" OR "Dibutyl benzene-1,2-dicarboxylate" OR "Dibutyl ester 1,2-benzenedicarboxylic acid" OR "Dibutyl o-phthalate" OR "Dibutyl phthalate" OR "Dibutyl phthalate" OR "DI-BUTYL PHTHALATE" OR "Dibutyl-o-phthalate" OR "Dibutylphthalat" OR "Dibutylphthalate" OR "Dibutylphthalate" OR "Diisobutyl phthalate" OR "Di-n-butyl phthalate" OR "Di-n-butylorthophthalate" OR "Di-n-butylphtalate" OR "EINECS 201-557-4" OR "Ergoplast FDB" OR "Ersoplast FDA" OR "Genoplast B" OR "Hatco DBP" OR "Hatcol DBP" OR "Hexaplas M/B" OR "Kodaflex DBP" OR "Monocizer DBP" OR "n-Butyl phthalate" OR "n-Butylphthalate" OR "NSC 6370" OR "o-Benzenedicarboxylic acid dibutyl ester" OR "o-Benzenedicarboxylic acid, dibutyl ester" OR "Palatinol C" OR "PHTHALATE, BUTYL" OR

"Phthalate, dibutyl-" OR "Phthalate, di-n-butyl" OR "Phthalic acid dibutyl ester" OR "Phthalic acid di-n-butyl ester"

"Phthalic acid, dibutyl ester" OR "PHTHALIC ACID, DIBUTYL ESTER" OR "Plasthall DBP" OR "Polycizer DBP" OR "RC Plasticizer DBP" OR "RCRA waste number U069" OR "Staflex DBP" OR "Uniflex DBP" OR "UNII-2286E5R2KE" OR "Unimoll DB" OR "Vestinol C" OR "Witcizer 300"

CURRENT CONTENTS CONNECT:
Current Contents Connect may be accessed through EPA Desktop Library (https://intranet.epa.gov/desktop/databases.htm) by clicking on the Current Contents Connect link or by copy and pasting (https://apps.webofknowledge.com).

Date Searched: 07/08/2019
Date Range of Search: 1998 to Present
N = 3391

Current Contents Connect 01:
TS=("1,2-Benzenedicarboxylic acid dibutyl ester" OR "1,2-Benzenedicarboxylic acid, 1,2-dibutyl ester" OR "1,2-Benzenedicarboxylic acid, Bis(2-methylpropyl) ester" OR "1,2-Benzenedicarboxylic acid, dibutyl ester" OR "Benzenedicarboxylic acid dibutyl ester" OR "Benzene-o-dicarboxylic acid di-n-butyl ester" OR "Bis-n-butyl phthalate" OR "BRN 1914064" OR "Butyl phthalate" OR "Caswell No. 292" OR "Celluflex DPB" OR "Corflex 440" OR "Di(n-butyl) 1,2-benzenedicarboxylate" OR "Di(n-butyl)1,2-benzenedicarboxylate" OR "Di(n-butyl)phthalate" OR "Dibutyl 1,2-benzenedicarboxylate" OR "Dibutyl benzene-1,2-dicarboxylate" OR "Dibutyl ester 1,2-benzenedicarboxylic acid" OR "Dibutyl o-phthalate" OR "Dibutyl phthalate" OR "Dibutyl phthalate" OR "DI-BUTYL PHTHALATE" OR "Dibutyl-o-phthalate" OR "Dibutylphthalat" OR "Dibutylphthalate" OR "Dibutylphthalate" OR "Diisobutyl phthalate" OR "Di-n-butyl phthalate" OR "Di-n-butylorthophthalate" OR "Di-n-butylphtalate" OR "EINECS 201-557-4" OR "Ergoplast FDB" OR "Ersoplast FDA" OR "Genoplast B" OR "Hatco DBP" OR "Hatcol DBP" OR "Hexaplas M/B" OR "Kodaflex DBP" OR "Monocizer DBP" OR "n-Butyl phthalate" OR "n-Butylphthalate" OR "NSC 6370" OR "o-Benzenedicarboxylic acid dibutyl ester" OR "o-Benzenedicarboxylic acid, dibutyl ester" OR "Palatinol C" OR "PHTHALATE, BUTYL" OR "Phthalate, dibutyl-" OR "Phthalate, di-n-butyl" OR "Phthalic acid dibutyl ester" OR "Phthalic acid di-n-butyl ester")
N = 3390

Current Contents Connect 02:
TS=("Phthalic acid, dibutyl ester" OR "PHTHALIC ACID, DIBUTYL ESTER" OR "Plasthall DBP" OR "Polycizer DBP" OR "RC Plasticizer DBP" OR "RCRA waste number U069" OR "Staflex DBP" OR "Uniflex DBP" OR "UNII-2286E5R2KE" OR "Unimoll DB" OR "Vestinol C" OR "Witcizer 300")
N = 1

WOS Core Collection: Web of Science Core Collection may be accessed through EPA Desktop Library (https://intranet.epa.gov/desktop/databases.htm) by clicking on the Web of Science Link or copying and pasting (https://apps.webofknowledge.com).

Date Searched: 07/08/2019
Date Range of Search: 1900 to Present

N = 362

WOS Core Collection 01:
TS=("1,2-Benzenedicarboxylic acid dibutyl ester" OR "1,2-Benzenedicarboxylic acid, 1,2-dibutyl ester" OR "1,2-Benzenedicarboxylic acid, Bis(2-methylpropyl) ester" OR "1,2-Benzenedicarboxylic acid, dibutyl ester" OR "Benzenedicarboxylic acid dibutyl ester" OR "Benzene-o-dicarboxylic acid di-n-butyl ester" OR "Bis-n-butyl phthalate" OR "BRN 1914064" OR "Butyl phthalate" OR "Caswell No. 292" OR "Celluflex DPB" OR "Corflex 440" OR "Di(n-butyl) 1,2-benzenedicarboxylate" OR "Di(n-butyl)1,2-benzenedicarboxylate" OR "Di(n-butyl)phthalate" OR "Dibutyl 1,2-benzenedicarboxylate" OR "Dibutyl benzene-1,2-dicarboxylate" OR "Dibutyl ester 1,2-benzenedicarboxylic acid" OR "Dibutyl o-phthalate" OR "Dibutyl phthalate" OR "Dibutyl phthalate" OR "DI-BUTYL PHTHALATE" OR "Dibutyl-o-phthalate" OR "Dibutylphthalat" OR "Dibutylphthalate" OR "Dibutylphthalate" OR "Diisobutyl phthalate" OR "Di-n-butyl phthalate" OR "Di-n-butylorthophthalate" OR "Di-n-butylphtalate" OR "EINECS 201-557-4" OR "Ergoplast FDB" OR "Ersoplast FDA" OR "Genoplast B" OR "Hatco DBP" OR "Hatcol DBP" OR "Hexaplas M/B" OR "Kodaflex DBP" OR "Monocizer DBP" OR "n-Butyl phthalate" OR "n-Butylphthalate" OR "NSC 6370" OR "o-Benzenedicarboxylic acid dibutyl ester" OR "o-Benzenedicarboxylic acid, dibutyl ester" OR "Palatinol C" OR "PHTHALATE, BUTYL" OR "Phthalate, dibutyl-" OR "Phthalate, di-n-butyl" OR "Phthalic acid dibutyl ester" OR "Phthalic acid di-n-butyl ester")
N = 4283

WOS Core Collection 02:
TS=("Phthalic acid, dibutyl ester" OR "PHTHALIC ACID, DIBUTYL ESTER" OR "Plasthall DBP" OR "Polycizer DBP" OR "RC Plasticizer DBP" OR "RCRA waste number U069" OR "Staflex DBP" OR "Uniflex DBP" OR "UNII-2286E5R2KE" OR "Unimoll DB" OR "Vestinol C" OR "Witcizer 300")
N = 2

PROQUEST Agricultural and Environmental Science Database: *ProQuest Agricultural and Environmental Science Database may be accessed through EPA Desktop Library (https://intranet.epa.gov/desktop/databases.htm) by clicking on the Agricultural and Scientific Database link or copying and pasting (https://search.proquest.com/agricenvironm).*

Date Searched: 07/08/2019
Date Range of Search: 1900 to Present
N = 4538

PROQUEST 01:
ALL("1,2-Benzenedicarboxylic acid dibutyl ester" OR "1,2-Benzenedicarboxylic acid, 1,2-dibutyl ester" OR "1,2-Benzenedicarboxylic acid, Bis(2-methylpropyl) ester" OR "1,2-Benzenedicarboxylic acid, dibutyl ester" OR "Benzenedicarboxylic acid dibutyl ester" OR "Benzene-o-dicarboxylic acid di-n-butyl ester" OR "Bis-n-butyl phthalate" OR "BRN 1914064" OR "Butyl phthalate" OR "Caswell No. 292" OR "Celluflex DPB" OR "Corflex 440" OR "Di(n-butyl) 1,2-benzenedicarboxylate" OR "Di(n-butyl)1,2-benzenedicarboxylate" OR "Di(n-butyl)phthalate" OR "Dibutyl 1,2-benzenedicarboxylate" OR "Dibutyl benzene-1,2-dicarboxylate" OR "Dibutyl ester 1,2-benzenedicarboxylic acid" OR "Dibutyl o-phthalate" OR "Dibutyl phthalate" OR "Dibutyl phthalate" OR "DI-BUTYL PHTHALATE" OR "Dibutyl-o-phthalate" OR "Dibutylphthalat" OR "Dibutylphthalate" OR "Dibutylphthalate" OR "Diisobutyl phthalate" OR "Di-n-butyl phthalate" OR "Di-n-butylorthophthalate" OR "Di-n-butylphtalate" OR

"EINECS 201-557-4" OR "Ergoplast FDB" OR "Ersoplast FDA" OR "Genoplast B" OR "Hatco DBP" OR "Hatcol DBP" OR "Hexaplas M/B" OR "Kodaflex DBP" OR "Monocizer DBP" OR "n-Butyl phthalate" OR "n-Butylphthalate" OR "NSC 6370" OR "o-Benzenedicarboxylic acid dibutyl ester" OR "o-Benzenedicarboxylic acid, dibutyl ester" OR "Palatinol C" OR "PHTHALATE, BUTYL" OR "Phthalate, dibutyl-" OR "Phthalate, di-n-butyl" OR "Phthalic acid dibutyl ester" OR "Phthalic acid di-n-butyl ester") AND STYPE("Scholarly Journals" OR Reports OR Thesis OR "Government Documents") AND LA(ENG)
N = 4532

PROQUEST 02:
ALL("Phthalic acid, dibutyl ester" OR "PHTHALIC ACID, DIBUTYL ESTER" OR "Plasthall DBP" OR "Polycizer DBP" OR "RC Plasticizer DBP" OR "RCRA waste number U069" OR "Staflex DBP" OR "Uniflex DBP" OR "UNII-2286E5R2KE" OR "Unimoll DB" OR "Vestinol C" OR "Witcizer 300") AND STYPE("Scholarly Journals" OR Reports OR Thesis OR "Government Documents") AND LA(ENG)
N = 6

PROQUEST Dissertations and Theses @ CIC Institutions: ProQuest Dissertations and Theses may be accessed through the Kathryn A. Martin Library at the University of Minnesota at Duluth (https://libguides.d.umn.edu/az.php) by clicking the Dissertations and Theses link or by copying and pasting (https://search.proquest.com/pqdtlocal1005857/advanced?accountid=8111)

Date Searched: 07/11/2019
Date Range of Search: 1900 to Present
N = 21

Dissertations and Theses 01:
ALL("1,2-Benzenedicarboxylic acid dibutyl ester" OR "1,2-Benzenedicarboxylic acid, 1,2-dibutyl ester" OR "1,2-Benzenedicarboxylic acid, Bis(2-methylpropyl) ester" OR "1,2-Benzenedicarboxylic acid, dibutyl ester" OR "Benzenedicarboxylic acid dibutyl ester" OR "Benzene-o-dicarboxylic acid di-n-butyl ester" OR "Bis-n-butyl phthalate" OR "BRN 1914064" OR "Butyl phthalate" OR "Caswell No. 292" OR "Celluflex DPB" OR "Corflex 440" OR "Di(n-butyl) 1,2-benzenedicarboxylate" OR "Di(n-butyl)1,2-benzenedicarboxylate" OR "Di(n-butyl)phthalate" OR "Dibutyl 1,2-benzenedicarboxylate" OR "Dibutyl benzene-1,2-dicarboxylate" OR "Dibutyl ester 1,2-benzenedicarboxylic acid" OR "Dibutyl o-phthalate" OR "Dibutyl phthalate" OR "Dibutyl phthalate" OR "DI-BUTYL PHTHALATE" OR "Dibutyl-o-phthalate" OR "Dibutylphthalat" OR "Dibutylphthalate" OR "Dibutylphthalate" OR "Diisobutyl phthalate" OR "Di-n-butyl phthalate" OR "Di-n-butylorthophthalate" OR "Di-n-butylphtalate" OR "EINECS 201-557-4" OR "Ergoplast FDB" OR "Ersoplast FDA" OR "Genoplast B" OR "Hatco DBP" OR "Hatcol DBP" OR "Hexaplas M/B" OR "Kodaflex DBP" OR "Monocizer DBP" OR "n-Butyl phthalate" OR "n-Butylphthalate" OR "NSC 6370" OR "o-Benzenedicarboxylic acid dibutyl ester" OR "o-Benzenedicarboxylic acid, dibutyl ester" OR "Palatinol C" OR "PHTHALATE, BUTYL" OR "Phthalate, dibutyl-" OR "Phthalate, di-n-butyl" OR "Phthalic acid dibutyl ester" OR "Phthalic acid di-n-butyl ester") AND LA(ENG)
N = 21

Dissertations and Theses 02:

ALL("Phthalic acid, dibutyl ester" OR "PHTHALIC ACID, DIBUTYL ESTER" OR "Plasthall DBP" OR "Polycizer DBP" OR "RC Plasticizer DBP" OR "RCRA waste number U069" OR "Staflex DBP" OR "Uniflex DBP" OR "UNII-2286E5R2KE" OR "Unimoll DB" OR "Vestinol C" OR "Witcizer 300") AND LA(ENG)
N = 0

SCIENCE DIRECT:
Science Direct may be accessed through the EPA Desktop Library (https://intranet.epa.gov/desktop/databases.htm) by clicking Science Direct or by copying and pasting (https://www.sciencedirect.com/).

Date Searched: 07/09/2019
Date Range of Search: 1823 to Present
N = 2108

Science Direct 01:
"1,2-Benzenedicarboxylic acid dibutyl ester" OR "1,2-Benzenedicarboxylic acid, 1,2-dibutyl ester" OR "1,2-Benzenedicarboxylic acid, Bis(2-methylpropyl) ester" OR "1,2-Benzenedicarboxylic acid, dibutyl ester" OR "Benzenedicarboxylic acid dibutyl ester" OR "Benzene-o-dicarboxylic acid di-n-butyl ester" OR "Bis-n-butyl phthalate" OR "BRN 1914064" OR "Butyl phthalate"
N = 0

Science Direct 02:
"Caswell No. 292" OR "Celluflex DPB" OR "Corflex 440" OR "Di(n-butyl) 1,2-benzenedicarboxylate" OR "Di(n-butyl)1,2-benzenedicarboxylate" OR "Di(n-butyl)phthalate" OR "Dibutyl 1,2-benzenedicarboxylate" OR "Dibutyl benzene-1,2-dicarboxylate" OR "Dibutyl ester 1,2-benzenedicarboxylic acid"
N = 0

Science Direct 03:
"Dibutyl o-phthalate" OR "Dibutyl phthalate" OR "Dibutyl phthalate" OR "DI-BUTYL PHTHALATE" OR "Dibutyl-o-phthalate" OR "Dibutylphthalat" OR "Dibutylphthalate" OR "Dibutylphthalate" OR "Diisobutyl phthalate"
N = 970

Science Direct 04:
"Di-n-butyl phthalate" OR "Di-n-butylorthophthalate" OR "Di-n-butylphtalate" OR "EINECS 201-557-4" OR "Ergoplast FDB" OR "Ersoplast FDA" OR "Genoplast B" OR "Hatco DBP" OR "Hatcol DBP"
N = 459

Science Direct 05:
"Hexaplas M/B" OR "Kodaflex DBP" OR "Monocizer DBP" OR "n-Butyl phthalate" OR "n-Butylphthalate" OR "NSC 6370" OR "o-Benzenedicarboxylic acid dibutyl ester" OR "o-Benzenedicarboxylic acid, dibutyl ester" OR "Palatinol C"
N = 611

Science Direct 06:

"PHTHALATE, BUTYL" OR "Phthalate, dibutyl-" OR "Phthalate, di-n-butyl" OR "Phthalic acid dibutyl ester" OR "Phthalic acid di-n-butyl ester"
N = 66

Science Direct 07:
"Phthalic acid, dibutyl ester" OR "PHTHALIC ACID, DIBUTYL ESTER" OR "Plasthall DBP" OR "Polycizer DBP" OR "RC Plasticizer DBP" OR "RCRA waste number U069" OR "Staflex DBP" OR "Uniflex DBP" OR "UNII-2286E5R2KE"
N = 2

Science Direct 08:
"Unimoll DB" OR "Vestinol C" OR "Witcizer 300"
N = 0

AGRICOLA: Agricola may be accessed through the EPA Desktop Library (https://intranet.epa.gov/desktop/databases.htm) by clicking Agricola or by copying and pasting (https://agricola.nal.usda.gov/) or Agricola may be accessed from within the EndNote environment.

Date Searched: 07/09/2019
Date Range of Search: 15th century to the Present
N = 2159

Agricola 01:
1,2-Benzenedicarboxylic acid dibutyl ester
1,2-Benzenedicarboxylic acid, 1,2-dibutyl ester
1,2-Benzenedicarboxylic acid, Bis(2-methylpropyl) ester
1,2-Benzenedicarboxylic acid, dibutyl ester
Benzenedicarboxylic acid dibutyl ester
Benzene-o-dicarboxylic acid di-n-butyl ester
Bis-n-butyl phthalate
BRN 1914064
Butyl phthalate
Caswell No. 292
N = 415

Agricola 02:
Celluflex DPB
Corflex 440
Di(n-butyl) 1,2-benzenedicarboxylate
Di(n-butyl)1,2-benzenedicarboxylate
Di(n-butyl)phthalate
Dibutyl 1,2-benzenedicarboxylate
Dibutyl benzene-1,2-dicarboxylate
Dibutyl ester 1,2-benzenedicarboxylic acid
Dibutyl o-phthalate
Dibutyl phthalate
N = 644

Agricola 03:
Dibutyl phthalate
DI-BUTYL PHTHALATE
Dibutyl-o-phthalate
Dibutylphthalat
Dibutylphthalate
Dibutylphthalate
Diisobutyl phthalate
Di-n-butyl phthalate
Di-n-butylorthophthalate
Di-n-butylphtalate
N = 713

Agricola 04:
EINECS 201-557-4
Ergoplast FDB
Ersoplast FDA
Genoplast B
Hatco DBP
Hatcol DBP
Hexaplas M/B
Kodaflex DBP
Monocizer DBP
n-Butyl phthalate
N = 325

Agricola 05:
n-Butylphthalate
NSC 6370
o-Benzenedicarboxylic acid dibutyl ester
o-Benzenedicarboxylic acid, dibutyl ester
Palatinol C
PHTHALATE, BUTYL
Phthalate, dibutyl-
Phthalate, di-n-butyl
Phthalic acid dibutyl ester
Phthalic acid di-n-butyl ester
N = 61

Agricola 06:
Phthalic acid, dibutyl ester
PHTHALIC ACID, DIBUTYL ESTER
Plasthall DBP
Polycizer DBP
RC Plasticizer DBP
RCRA waste number U069

Staflex DBP
Uniflex DBP
UNII-2286E5R2KE
Unimoll DB
N = 1

Agricola 07:
Vestinol C
Witcizer 300
N = 0

TOXNET/(Toxline):
TOXNET(Toxline) may be accessed through the EPA Desktop Library (https://intranet.epa.gov/desktop/databases.htm) by clicking the TOXNET link or by copying and pasting (https://toxnet.nlm.nih.gov/newtoxnet/toxline.htm).

Date Searched: 07/09/2019
Date Range of Search: 1900 to Present
N = 2259

TOXNET 01:
84-74-2
N = 2259

PubMed: PubMed may be accessed through the EPA Desktop Library (https://www.ncbi.nlm.nih.gov/pubmed/)

Date Searched: 07/09/2019
Date Range of Search: 1900 to present
N = 2434

PubMed 01:
"1,2-Benzenedicarboxylic acid dibutyl ester" OR "1,2-Benzenedicarboxylic acid, 1,2-dibutyl ester" OR "1,2-Benzenedicarboxylic acid, Bis(2-methylpropyl) ester" OR "1,2-Benzenedicarboxylic acid, dibutyl ester" OR "Benzenedicarboxylic acid dibutyl ester" OR "Benzene-o-dicarboxylic acid di-n-butyl ester" OR "Bis-n-butyl phthalate" OR "BRN 1914064" OR "Butyl phthalate" OR "Caswell No. 292" OR "Celluflex DPB" OR "Corflex 440" OR "Di(n-butyl) 1,2-benzenedicarboxylate" OR "Di(n-butyl)1,2-benzenedicarboxylate" OR "Di(n-butyl)phthalate" OR "Dibutyl 1,2-benzenedicarboxylate" OR "Dibutyl benzene-1,2-dicarboxylate" OR "Dibutyl ester 1,2-benzenedicarboxylic acid" OR "Dibutyl o-phthalate" OR "Dibutyl phthalate" OR "Dibutyl phthalate" OR "DI-BUTYL PHTHALATE" OR "Dibutyl-o-phthalate" OR "Dibutylphthalat" OR "Dibutylphthalate" OR "Dibutylphthalate" OR "Diisobutyl phthalate" OR "Di-n-butyl phthalate" OR "Di-n-butylorthophthalate" OR "Di-n-butylphtalate" OR "EINECS 201-557-4" OR "Ergoplast FDB" OR "Ersoplast FDA" OR "Genoplast B" OR "Hatco DBP" OR "Hatcol DBP" OR "Hexaplas M/B" OR "Kodaflex DBP" OR "Monocizer DBP" OR "n-Butyl phthalate" OR "n-Butylphthalate" OR "NSC 6370" OR "o-Benzenedicarboxylic acid dibutyl ester" OR "o-Benzenedicarboxylic acid, dibutyl ester" OR "Palatinol C" OR "PHTHALATE, BUTYL" OR "Phthalate, dibutyl-" OR "Phthalate, di-n-butyl" OR "Phthalic acid dibutyl ester" OR "Phthalic acid di-n-

butyl ester"
N = 2434

PubMed 02:
"Phthalic acid, dibutyl ester" OR "PHTHALIC ACID, DIBUTYL ESTER" OR "Plasthall DBP" OR "Polycizer DBP" OR "RC Plasticizer DBP" OR "RCRA waste number U069" OR "Staflex DBP" OR "Uniflex DBP" OR "UNII-2286E5R2KE" OR "Unimoll DB" OR "Vestinol C" OR "Witcizer 300"
N = 0

ECOTOX UNIFY: This is an internal EPA database that is not accessible to the public. Results from the ECOTOX Unify search strategy.

Date Searched: 07/22
Date Range of Search: all years
N = 1

A.1.2.2 Data Prioritization for Environmental Hazard, Human Health Hazard, Fate and Physical Chemistry

In brief, SWIFT Review has pre-set literature search strategies ("filters") developed by information specialists that can be applied to identify studies that are more likely to be useful for identifying human health and ecotoxicity content from those that likely do not (*e.g.*, analytical methods). The filters function like a typical search strategy where studies are tagged as belonging to a certain filter if the terms in the filter literature search strategy appear in title, abstract, keyword or medical subject headings (MeSH*)* fields content. The applied SWIFT Review filters focused on lines of evidence: human, animal models for human health, ecological taxa (which includes ecotoxicological animal models, plants, and other taxa), and *in vitro* studies. The details of the search strategies that underlie the filters are available online. Studies not retrieved using these filters were not considered further. Studies that included one or more of the search terms in the title, abstract, keyword, or MeSH fields were exported as a RIS file for screening in Swift-ActiveScreener or DistillerSR[11].

A.1.2.3 Data Prioritization for Occupational Exposures and Environmental Releases and General Population, Consumer and Environmental Exposures

To prioritize references related to occupational exposure, environmental release, general population exposure, consumer exposure, and environmental exposure, EPA used positive and negative seed studies to build a classification model in SWIFT Review. The positive seeds were identified using relevant literature pool for the first ten TSCA risk evaluations, while the negative seeds were identified from a subset of literature for the current high-priority substances. The model was then applied to the unclassified literature to generate a classification score for each reference. Scores above a certain threshold value were then prioritized for further review in SWIFT-ActiveScreener.

A.2 Peer-Reviewed Screening Process

The studies identified from publicly available database searches and SWIFT-Review filtering/ prioritization were housed in HERO system and imported into SWIFT-ActiveScreener or DistillerSR for title/abstract and full-text screening. Both title/abstract and full-text screening were conducted by two independent reviewers. Screening is initiated with a pilot phase of screening (between 10 and 50) studies

[11] DistillerSR is a web-based systematic review software used to screen studies available at https://www.evidencepartners.com/products/distillersr-systematic-review-software.

to identify areas where clarification in screening criteria might be needed or chemical-specific supplemental material tags might be identified. Records that met PECO (or equivalent criteria (Appendix A.2.1) during title and abstract screening were considered for full-text screening. At both the title/abstract and full-text review levels, screening conflicts were resolved by topic-specific experts and/or discussion among the primary screeners. For citations with no abstract, the articles are initially screened based on all or some of the following: title relevance (titles that suggest a record is not relevant can be excluded rather than marked as unclear), and page numbers (articles two pages in length or less were assumed to be conference reports, editorials, or letters). During title/abstract or full-text level screening in DistillerSR, studies that did not meet the PECO criteria, but which could provide supporting information were categorized (or "tagged") as supplemental information.

It is important to emphasize that being tagged as supplemental material does not mean the study would necessarily be excluded from consideration in an assessment. The initial screening level distinctions between a study meeting the PECO criteria and a supplemental study are often made for practical reasons and the tagging structures (as seen in the literature inventory trees and heat maps in Section 2.1 of this document) are designed to ensure the supplemental studies are categorized for easy retrieval if needed while conducting the assessment. The impact on the assessment conclusions of individual studies tagged as supporting material is often difficult to assess during the screening phase of the assessment. These studies may emerge as being critically important to the assessment and need to be evaluated and summarized at the individual study level (*e.g.*, cancer MOA mechanistic or non-English-language studies), or be helpful to provide context (*e.g.*, summarize current levels of exposure, provide hazard evidence from routes or durations of exposure not pertinent to the PECO), or not be cited at all in the assessment (*e.g.*, individual studies that contribute to a well-established scientific conclusion). Studies maybe be tagged as supplemental material during either title and abstract or full-text screening. When tagged as supplemental material during title and abstract screening, it may not be completely clear whether the chemical of interest is reported in the study (*i.e.*, abstracts may not describe all chemicals investigated). In these cases, studies are still tagged with the expectation that if full-text retrieval is pursued, then additional screening would be needed to clarify if the study is pertinent.

A.2.1 Inclusion/Exclusion Criteria

A PECO statement is typically used to focus the research question(s), search terms, and inclusion/exclusion criteria in a systematic review. PECO criteria were developed *a priori* to screening and modified to fit the various discipline areas supporting the TSCA risk evaluations. Variations include the RESO (receptor, exposure, scenario/setting, and outcome) used for the occupational exposure and environmental releases discipline, and PESO (pathways/processes, exposures, setting/scenario, and outcomes) used by the fate and transport discipline. All PECOs and PECO-equivalent criteria can be found in the following sections.

A.2.1.1 PECO for Environmental and Human Health Hazards

The PECO used in this evidence map to identify literature pertinent to dibutyl phthalate effects on human health and environmental hazard is presented in Table_Apx A-3. In addition to the PECO criteria, studies containing potentially relevant supplemental material were tracked and categorized during the literature screening process as outlined in Table_Apx A-4.

Table_Apx A-3. Hazards Title and Abstract and Full-text PECO Criteria for Dibutyl Phthalate

PECO Element	Evidence
P	• **Human:** Any population and life stage (*e.g.*, occupational or general population, including children and other sensitive populations). • **Animal:** Aquatic and terrestrial species (live, whole organism) from any life stage (*e.g.*, preconception, in utero, lactation, peripubertal, and adult stages). Animal models will be inventoried according to the categorization below: • – Human health models: rat, mouse, rabbit, dog, hamster, guinea pig, cat, non-human primate, pig, hen (neurotoxicity only) – Environmental models: invertebrates (*e.g.*, insects, spiders, crustaceans, mollusks, and worms) and vertebrates (*e.g.*, mammals and all amphibians, birds, fish, and reptiles). All hen studies (including neurotoxicity studies) will be included for ecotoxicological models. • **Plants:** All aquatic and terrestrial species (live), including algal, moss, lichen and fungi species. **Screener note:** • To identify human health and environmental hazards, other organisms not listed above in their respective categories can also be used. Non-mammalian model systems are increasingly used to identify potential human health hazards (*e.g.*, *Xenopus*, zebrafish), and traditional human health models (*e.g.*, rodents) can be used to identify potential environmental hazard. Neurotoxicity studies performed in hens (*e.g.*, OECD 418 and 419) are considered relevant to both human and eco hazard • PECO considerations should be directed toward effects on target species only and not on the indirect effects expressed in taxa as a result of chemical treatment (*e.g.*, substance is lethal to a targeted pest species leading to positive effects on plant growth due to diminished presence of the targeted pest species). • Tests of the single toxicants in *in vitro* and *ex vivo* systems or on gametes, embryos, or plant or fungal sections capable of forming whole, new organisms will be tagged as potentially supplemental (mechanistic studies). Bacteria and yeast studies specific for assessing genotoxicity or mutagenicity (*e.g.*, Ames assay) will also be tagged as potentially supplemental (mechanistic studies) but are otherwise excluded. Studies on viruses are excluded.
E	**Relevant forms:** • Dibutyl phthalate (DBP) (CASRN 84-74-2) For synonyms see the EPA Chemistry Dashboard. Also refer to the *List of Synonyms and Isomers* included in this appendix. • No isomers were included for DBP. • **Human:** Any exposure to DBP singularly or in mixture, including exposure as measured by internal concentrations of these chemicals or metabolites of these chemicals in a biological matrix (*i.e.*, urine, blood, semen, etc.). See list of common metabolites for each phthalate below. • **Animal:** Any exposure to DBP including via water (including environmental aquatic exposures), soil or sediment, diet, gavage, injection, dermal, and inhalation. • **Plants:** Any exposure to DBP including via water or soil, or sediment. **Screener note:** • Field studies with media concentrations (surface water, interstitial water, soil, sediment) and/or body/tissue concentrations of animals or plants are to be identified as *Supplemental* if any biological effects are reported.

PECO Element	Evidence
	• Studies involving exposures to mixtures will be *Included* only if they also include exposure to DBP alone. Otherwise, mixture studies will be tagged as supplemental. • Controlled outdoor experimental studies (*e.g.*, controlled crop/greenhouse studies, mesocosm studies, artificial stream studies) are considered to be laboratory studies (not field studies) because there is a known and prescribed exposure dose(s) and an evaluation of hazardous effect(s). Whereas field studies (*e.g.*, biomonitoring) where there is no prescribed exposure dose(s) will be excluded if there is no evaluated hazardous effect, and tagged as supplemental field, if there is an evaluated hazardous effect.
C	• **Human:** A comparison or referent population exposed to lower levels (or no exposure/exposure below detection limits) of DBP, or exposure to DBP for shorter periods of time. • **Animal and Plants:** A concurrent control group exposed to vehicle-only treatment and/or untreated control (control could be a baseline measurement). **Screener note:** • If no control group is explicitly stated or implied (*e.g.* by mention of statistical results that could only be obtained if a control group was present), the study will be marked as *Unclear* during Title/Abstract Screening. • All case series and case studies describing findings in a sample size of less than 20 people in any setting (*e.g.*, occupation, general population) will be tracked as *Supplemental* Case-control, case-crossover, case-referent, case-only, case-specular, case-cohort, case-parent, nested case-control study designs are all *Included*.
O	• **Human:** All health outcomes (cancer and noncancer) at the organ level or higher. • **Animal and Plants:** All apical biological effects (effects measured at the organ level or higher) and bioaccumulation from laboratory studies with concurrently measured media and/or tissue concentrations). Apical endpoints include but are not limited to reproduction, survival, and growth. **Screener note:** • **Measurable biological effects relevant for humans, animals and plants may include but are not limited to**: mortality, behavioral, population, cellular, physiological, growth, reproduction, systemic, point of contact (irritation and sensitization) effects. • Effects measured at the cellular level of biological organization and below are to be tagged as supplemental, mechanistic.

Table_Apx A-4. Major Categories of Potentially Relevant Supplemental Materials for Dibutyl Phthalate

Category	Evidence
Mechanistic studies	All studies that report results at the cellular level and lower in both mammalian and non-mammalian model systems, including *in vitro*, *in vivo*, *ex vivo*, and *in silico* studies. These studies include assays for genotoxicity or mutagenicity using bacteria or yeast.
ADME, PBPK, and toxicokinetic	Studies designed to capture information regarding absorption, distribution, metabolism, and excretion (ADME), toxicokinetic studies, or physiologically based pharmacokinetic (PBPK) models.

Category	Evidence
Case reports or case series	Case reports (n ≤ 3 cases) and case series (non-occupational) will be tracked as potentially relevant supplemental information.
Susceptible populations (no health outcome)	Studies that identify potentially susceptible subgroups; for example, studies that focus on a specific demographic, life stage, or genotype. This tag applies primarily during full-text screening. **Screener note: I**f biological susceptibility issues are clearly present or *strongly* implied in the title/abstract, this supplemental tag may be applied at the title abstract level. If uncertain at title/abstract, do not apply this tag to the reference during title/abstract screening.
Mixture studies	Experimental mixture studies that are not considered PECO-relevant because they do not contain an exposure or treatment group assessing only the chemical of interest. Human health animal model and environmental animal model/plant will be tagged separately for mixture studies.
Records with no original data	Records that do not contain original data, such as other agency assessments, informative scientific literature reviews, editorials or commentaries.
Conference abstracts	Records that do not contain sufficient documentation to support study evaluation and data extraction.
Field Studies	Field studies with media concentrations (*e.g.*, surface water, interstitial water, soil, sediment) and/or body/tissue concentrations of animals or plants if biological effects reported.
Isomer	PECO-relevant studies with an exposure to one of the identified isomers, if any.

A.2.1.2 PECO for Consumer, Environmental, and General Population Exposures.

Table_Apx A-5. Generic Inclusion Criteria for the Data Sources Reporting Exposure Data on General Population, Consumers and Environmental Receptors

PECO Element	Evidence
Population	**Human:** General population; consumers; bystanders in the home; near-facility populations (includes industrial and commercial facilities manufacturing, processing, or using the chemical substance); children; susceptible populations (life stages, preexisting conditions, genetic factors), pregnant women; lactating women, women of childbearing age. Many human population groups may be exposed. No chemical-specific exclusions are suggested at this time.
	Environmental: aquatic species, terrestrial species, terrestrial plants, aquatic plants (field studies only)

PECO Element	Evidence
Exposure	**Expected Primary Exposure Sources, Pathways, Routes:** Pathways: indoor air/vapor/mist; indoor dust; particles; outdoor/ambient air; surface water; biosolids; sediment; breastmilk; food items containing dibutyl phthalate including fish; consumer product uses in the home (including consumer product containing chemical); Routes of Exposure: Inhalation, Oral, Dermal
Comparator (Scenario)	**Human:** Consider media-specific background exposure scenarios and use/source specific exposure scenarios as well as which receptors are and are not reasonably exposed across the projected exposure scenarios.
	Environmental Consider media-specific background exposure scenarios and use/source specific exposure scenarios as well as which receptors are and are not reasonably exposed across the projected exposure scenarios.
Outcomes for Exposure Concentration or Dose	**Human:** Acute, subchronic, and/or indoor air and water concentration estimates (mg/m^3 or mg/L). Both external potential dose and internal dose based on biomonitoring and reverse dosimetry mg/kg/day will be considered. Characteristics of consumer products or articles (weight fraction, emission rates, etc.) containing dibutyl phthalate.
	Environmental: A wide range of ecological receptors will be considered (range depending on available ecotoxicity data) using surface water concentrations, sediment concentrations.

Table_Apx A-6. Pathways Identified as Supplemental for Dibutyl Phthalate[a]

Chemical	Drinking Water	Ambient Air	Air Disposal	Land Disposal	Underground Disposal	Ground Water
Dibutyl phthalate (DBP)	--	X	X	X	X	X

[a] "Supplemental pathways" refer to pathways addressed by other EPA administered statutes (see Section 2.6.3.1). Studies tagged under these pathways provide media information that is not prioritized in the screening process.

A.2.1.3 RESO for Occupational Exposure and Environmental Releases

EPA developed a generic RESO statement to guide the screening of engineering and occupational exposure data or information sources for the TSCA risk evaluations. Data or information sources that comply with the inclusion criteria specified in the RESO statement are eligible for inclusion, considered for evaluation, and possibly included in the environmental release and occupational exposure assessments. On the other hand, data or information sources that fail to meet the criteria in the RESO statement are excluded from further consideration.

Assessors seek information on various chemical-specific engineering and occupational exposure data needs as part of the process of developing the exposure assessment for each risk evaluation. EPA uses the RESO statement (Table_Apx A-7) along with the information in Table_Apx A-8 when screening the engineering and occupational exposure data and information.

Table_Apx A-7. Inclusion Criteria for Data Sources Reporting Engineering and Occupational Exposure Data

RESO Element	Evidence
Receptors	• Humans: Workers, including occupational non-users • Environment: All environmental receptors (relevant release estimates input to Exposure) Please refer to the conceptual models for more information about the environmental and human receptors included in the TSCA risk evaluation.
Exposure	• Worker exposure to and relevant environmental releases of the chemical substance from occupational scenarios: Dermal and inhalation exposure routes (as indicated in the conceptual model) Oral route (as indicated in the conceptual model) Please refer to the conceptual models for more information about the routes and media/pathways included in the TSCA risk evaluation.
Setting or Scenario	• Any occupational setting or scenario resulting in worker exposure and relevant environmental releases (includes all manufacturing, processing, use, disposal.
Outcomes	• Quantitative estimates* of worker exposures and of relevant environmental releases from occupational settings • General information and data related and relevant to the occupational estimates*

* Metrics (*e.g.*, mg/kg/day or mg/m^3 for worker exposures, kg/site/day for releases) are determined by toxicologists for worker exposures and by exposure assessors for releases; also, the Engineering, Release and Occupational Exposure Data Needs (Table_Apx A-8) provides a list of related and relevant general information.
TSCA=Toxic Substances Control Act

Table_Apx A-8. Engineering, Environmental Release and Occupational Data Necessary to Develop the Environmental Release and Occupational Exposure Assessments

Objective Determined during Scoping	Type of Data [a]
General Engineering Assessment (may apply to Occupational Exposures and / or Environmental Releases)	Description of the life cycle of the chemical(s) of interest, from manufacture to end-of-life (*e.g.*, each manufacturing, processing, or use step), and material flow between the industrial and commercial life cycle stages. The total annual U.S. volume (lb/yr or kg/yr) of the chemical(s) of interest manufactured, imported, processed, and used; and the share of total annual manufacturing and import volume that is processed or used in each life cycle step. Description of processes, equipment, and unit operations during each industrial/ commercial life cycle step. Material flows, use rates, and frequencies (lb/site-day or kg/site-day and days/yr; lb/site-batch and batches/yr) of the chemical(s) of interest during each industrial/ commercial life cycle step. Note: if available, include weight fractions of the chemicals (s) of interest and material flows of all associated primary chemicals (especially water). Number of sites that manufacture, process, or use the chemical(s) of interest for each industrial/ commercial life cycle step and site locations. Concentration of the chemical of interest

Objective Determined during Scoping	Type of Data [a]
Occupational Exposures	Description of worker activities with exposure potential during the manufacture, processing, or use of the chemical(s) of interest in each industrial/commercial life cycle stage. Potential routes of exposure (*e.g.*, inhalation, dermal). Physical form of the chemical(s) of interest for each exposure route (*e.g.*, liquid, vapor, mist) and activity. Breathing zone (personal sample) measurements of occupational exposures to the chemical(s) of interest, measured as time-weighted averages (TWAs), short-term exposures, or peak exposures in each occupational life cycle stage (or in a workplace scenario similar to an occupational life cycle stage). Area or stationary measurements of airborne concentrations of the chemical(s) of interest in each occupational setting and life cycle stage (or in a workplace scenario similar to the life cycle stage of interest). For solids, bulk and dust particle size characterization data. Dermal exposure data. Exposure duration (hr/day). Exposure frequency (days/yr). Number of workers who potentially handle or have exposure to the chemical(s) of interest in each occupational life cycle stage. PPE types employed by the industries within scope. EC employed to reduce occupational exposures in each occupational life cycle stage (or in a workplace scenario similar to the life cycle stage of interest), and associated data or estimates of exposure reductions.
Environmental Releases (to relevant environmental media)	Description of sources of potential environmental releases, including cleaning of residues from process equipment and transport containers, involved during the manufacture, processing, or use of the chemical(s) of interest in each life cycle stage. Estimated mass (lb or kg) of the chemical(s) of interest released from industrial and commercial sites to each environmental medium (water) and treatment and disposal methods (POTW), including releases per site and aggregated over all sites (annual release rates, daily release rates) Release or emission factors. Number of release days per year. Waste treatment methods and pollution control devices employed by the industries within scope and associated data on release/emission reductions.

[a] These are the tags included in the full-text screening form. The screener makes a selection from these specific tags, which describe more specific types of data or information.
In addition to the data types listed above, EPA may identify additional data needs for mathematical modeling. These data needs will be determined on a case-by-case basis.

Abbreviations:
hr=Hour
kg=Kilogram(s)
lb=Pound(s)
yr=Year
PV=Particle volume
POTW=Publicly owned treatment works
PPE=Personal protection equipment
PSD=Particle size distribution
TWA=Time-weighted average

A.2.1.4 PESO for Fate and Transport

EPA developed a generic PESO statement to guide the screening of environmental fate data or

information sources for the TSCA risk evaluations. Data or information sources that comply with the inclusion criteria in the PESO statement are eligible for inclusion, considered for evaluation, and possibly included in the environmental fate assessment. On the other hand, data or information sources that fail to meet the criteria in the PESO statement are excluded from further consideration.

Assessors seek information on various chemical-specific fate endpoints and associated fate processes, environmental media and exposure pathways as part of the process of developing the environmental fate assessment for each risk evaluation. EPA uses the PESO statement (Table_Apx A-9) along with the information in Table_Apx A-10 when screening the fate data or information sources to ensure complete coverage of the processes, pathways and data or information relevant to the environmental fate and transport of the chemical substance undergoing risk evaluation.

Table_Apx A-9. Inclusion Criteria for Data or Information Sources Reporting Environmental Fate and Transport Data

PESO Element	Evidence
Pathways and **P**rocesses	Environmental fate, transport, partitioning and degradation behavior across environmental media to inform exposure pathways of the chemical substance of interest Exposure pathways included in the conceptual models: air, surface water, groundwater, wastewater, soil, sediment and biosolids. Processes associated with the target exposure pathways Bioconcentration and bioaccumulation Destruction and removal by incineration Please refer to the conceptual models for more information about the exposure pathways included in each TSCA risk evaluation.
Exposure	Environmental exposure of environmental receptors (*i.e.*, aquatic and terrestrial organisms) to the chemical substance of interest, mixtures including the chemical substance, and/or its degradation products and metabolites Environmental exposure of human receptors, including any PESS to the chemical substance of interest, mixtures including the chemical substance, and/or its degradation products and metabolites Please refer to the conceptual models for more information about the environmental and human receptors included in each TSCA risk evaluation.
Setting or **S**cenario	Any setting or scenario resulting in releases of the chemical substance of interest into the natural or built environment (*e.g.*, buildings including homes or workplaces, or wastewater treatment facilities) that would expose environmental (*i.e.*, aquatic and terrestrial organisms) or human receptors (*i.e.*, general population, and PESS)

PESO Element	Evidence
Outcomes	Fate properties which allow assessments of exposure pathways: Abiotic and biotic degradation rates, mechanisms, pathways, and products Bioaccumulation magnitude and metabolism rates Partitioning within and between environmental media (see Pathways and Processes)

Table_Apx A-10. Fate Endpoints and Associated Processes, Media and Exposure Pathways Considered in the Development of the Environmental Fate Assessment

Fate Data Endpoint	Associated Process(es)	Associated Media/Exposure Pathways			
		Surface Water, Wastewater, Sediment	Soil, Biosolids	Groundwater	Air
Required Environmental Fate Data					
Abiotic reduction rates or half-lives	Abiotic reduction, Abiotic dehalogenation	X			
Aerobic biodegradation rates or half-lives	Aerobic biodegradation	X	X		
Anaerobic biodegradation rates or half-lives	Anaerobic biodegradation	X	X	X	
Aqueous photolysis (direct and indirect) rates or half-lives	Aqueous photolysis (direct and indirect)	X			
Atmospheric photolysis (direct and indirect) rates or half-lives	Atmospheric photolysis (direct and indirect)				X
Bioconcentration factor (BCF), Bioaccumulation factor (BAF)	Bioconcentration, Bioaccumulation	X	X		X
Biomagnification and related information	Trophic magnification	X			
Desorption information	Sorption, Mobility	X	X	X	
Destruction and removal by incineration	Incineration				X
Hydrolysis rates or half-lives	Hydrolysis	X	X	X	
K_{OC} and other sorption information	Sorption, Mobility	X	X	X	
Wastewater treatment removal information	Wastewater treatment	X	X		
Supplemental (or Optional) Environmental Fate Data					
Abiotic transformation products	Hydrolysis, Photolysis, Incineration	X			X
Aerobic biotransformation products	Aerobic biodegradation	X	X		
Anaerobic biotransformation products	Anaerobic biodegradation	X	X	X	

Fate Data Endpoint	Associated Process(es)	Associated Media/Exposure Pathways			
		Surface Water, Wastewater, Sediment	Soil, Biosolids	Groundwater	Air
Atmospheric deposition information	Atmospheric deposition				X
Coagulation information	Coagulation, Mobility	X		X	
Incineration removal information	Incineration				X

A.2.1.5 Generation of Hazard Heat Maps

As stated in Appendix A.1.2.2, SWIFT Review has pre-set literature search strategies ("filters") developed by information specialists that can be applied to identify studies that are more likely to be useful for identifying human health and ecotoxicity content. The filters function like a typical search strategy where studies are tagged as belonging to a certain filter if the terms in the filter literature search strategy appear in title, abstract, keyword or MeSH fields content.

After the completion of full-text screening for hazard data, all references tagged as included (or "PECO-relevant) were uploaded to the SWIFT Review tool for further filtering. The SWIFT Review filters applied at this phase focused on types of health outcomes included: "ADME", "PBPK", "cancer", "cardiovascular", "developmental", "endocrine", "gastrointestinal", "hematological and immune", "hepatic", "mortality", "musculoskeletal", "neurological", "nutritional and metabolic", "ocular and sensory", "renal", "reproductive", "respiratory", and "skin and connective tissue". The details of these health outcome search strategies that underlie the filters are available online. Studies that included one or more of the search terms in the title, abstract, keyword, or MeSH fields were exported and used to populate the Hazard Heat Map (Figure 2-10). Studies that were not retrieved using these filters were tagged as "No Tag". The evidence type listed in the heat map (*e.g.*, human, animal-human health model, animal- environmental model, and plant) was manually assigned to each reference by screeners during the full-text screening.

The health outcome tags were originally designed for vertebrate systems, and as such, did not conform well to plant evidence. Therefore, any plant studies tagged for: "cancer", "cardiovascular", "gastrointestinal", "hematological and immune", "hepatic", "musculoskeletal", "neurological", "ocular and sensory" and "renal and respiratory" were manually reviewed and re-tagged to more appropriate health outcomes.

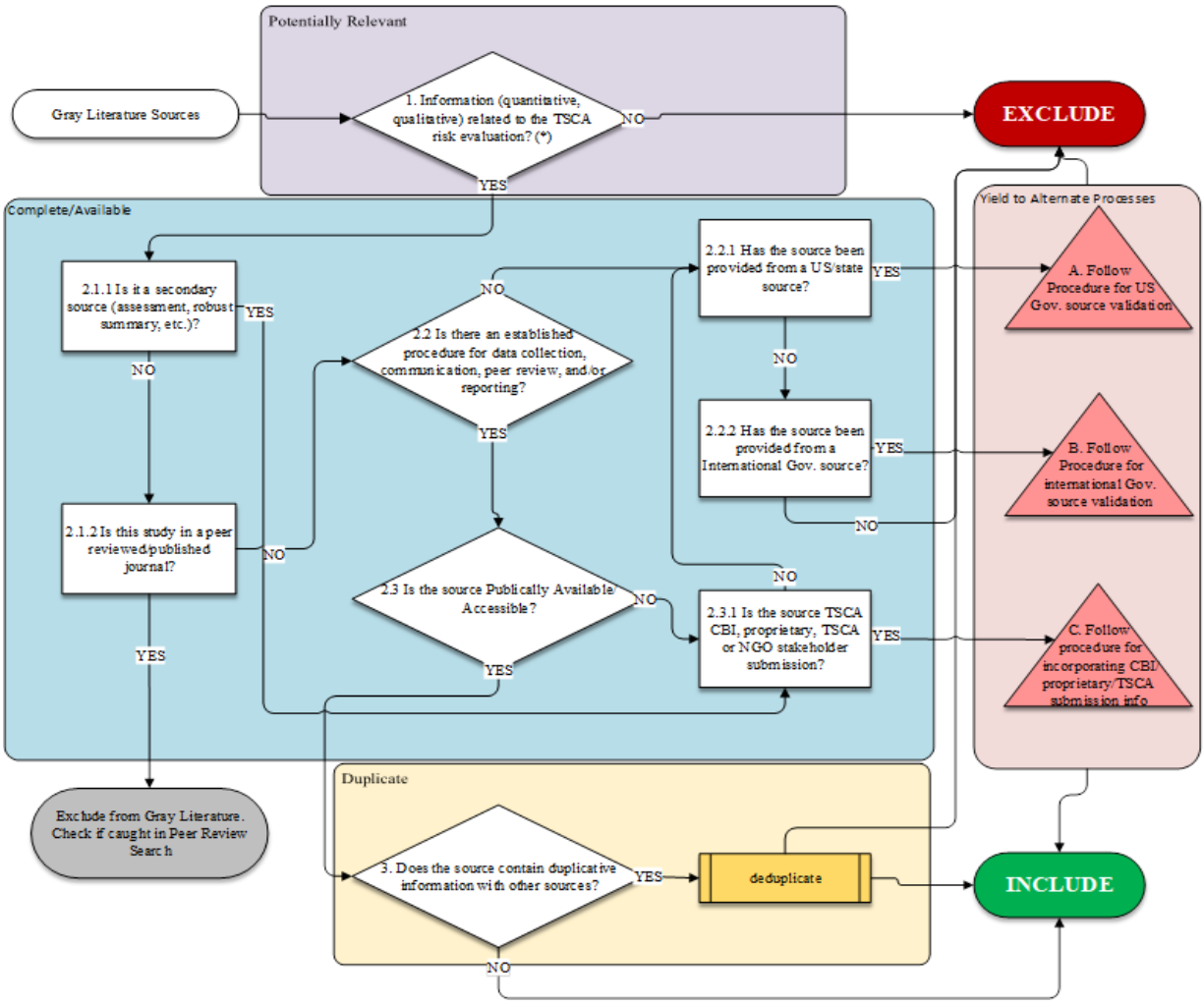
A.3 Gray Literature Search and Screening Strategies

EPA conducted a gray literature search for available information to support the TSCA risk evaluations for the next twenty TSCA risk evaluations. 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. Given the nature of how gray literature is searched and collected, results may not come with a bibliographic citation or abstract and were therefore processed using a decision tree logic described in Appendix A.3.1 for potential relevance prior to entering full text screening where a discipline-specific PECO is applied.

Search terms were variable dependent on source and based on knowledge of a given source to provide discipline-specific information. A summary of sources is provided in Appendix A.3.4. The criteria for determining the potential relevance of documents identified from gray literature sources is described in the following sections for each discipline.

A.3.1 Screening of Gray Literature

To reduce the overall burden of processing gray literature results, EPA developed a screening process to determine the potential relevance of gray literature. This step was introduced prior to collecting the resulting documents**.** Figure_Apx A-1 describes the decision logic used to screen gray literature results.



Figure_Apx A-1. Decision Logic Tree Used to Screen Gray Literature Results

A.3.2 Initial Screening of Sources using Decision Logic Tree

The purpose of the inclusion/exclusion decision logic tree **in** Figure_Apx A-1 **is** to provide a broad, general screening technique to determine whether each gray literature source should be included and further screened or excluded with no additional screening necessary. The diamonds in the decision tree require analysis by the screener, whereas the rectangular boxes are used to classify the type of source. All the questions used in the decision process are provided in Table_Apx A-11**.**

Table_Apx A-11. Decision Logic Tree Overview

Step	Metric	Questions to Consider
1	Potential Relevance	Does the result have information (qualitative or quantitative) related to TSCA risk evaluations? *Apply Discipline relevancy metric
2.1.1	Complete / Available	Is it a secondary data source (assessment, robust summary, TSCA submission databases, etc.)?
2.1.2		Is the document from a peer reviewed/published journal?
2.2		Is there an established procedure for data collection, communication, peer review, and/or reporting?
2.2.1		Has the data been provided by a US governmental/state source?
2.2.2		Has the data been provided by an international governmental source?
2.3		Are these data publicly available/accessible?
2.3.1		Is the source TSCA CBI, proprietary, TSCA or NGO stakeholder submission?
3	Duplicate	Does the result contain any duplicative information found in other sources?

Results of the gray literature search and decision tree process are included in Appendix A.3.4.

A.3.3 TSCA Submission Searching and Title Screening

EPA screens information submitted under TSCA Sections 4, 5, 8(e), and 8(d), as well as for your information (FYI) submissions. In the gray literature process defined in Appendix A.3.2, EPA considers the databases that contain TSCA submissions to be secondary sources (Step 1.1) because the metadata in the databases are secondary. These databases then advance to Step 2.3.1 and then to Process C. The Process C steps are described here.

EPA first screens the titles using two screeners per title. EPA conducts this step primarily to reduce the number of full studies to be obtained because some studies are available only on microfiche or in long-term storage. Screening is done using the inclusion and exclusion criteria within the relevant PECOs, PESOs or RESOs for each topic area (Appendix A.2.1). EPA excludes interim reports (*e.g.*, interim sacrifices for toxicity studies) and only final reports are further considered. If the title is not clear regarding the document's contents, EPA obtains the full text and advances to the next steps.

After full texts were obtained, EPA reviewed some sources (prior to full-text screening) based on whether they have several factors; primary data, an established procedure for peer review, data collection, communication and/or reporting and are publicly available. Sources that have these factors will move on to full text screening. Other sources will go straight to full text screening using PECO-type criteria without going through this extra step.

EPA may decide to initiate a backwards search on sources that are deemed to have secondary data. In situations where parameters such as procedures for peer review and data collection are unclear, EPA may reach out to the authors to retrieve information to gauge whether the source should be included or excluded. Studies that are not publicly available (such as proprietary or CBI sources) may undergo additional screening steps.

During the full-text screening step, two individuals screen each source according to the PECOs, PESOs and RESOs (Appendix A.2.1).

Results of the TSCA submission search and decision tree process are included in Appendix A.3.4.

A.3.4 Gray Literature Search Results for Dibutyl Phthalate

Table_Apx A-12 provides a list of gray literature sources that yielded results for dibutyl phthalate.

Table_Apx A-12. Gray Literature Sources that Yielded Results for Dibutyl Phthalate

Source Agency	Source Name	Source Type	Source Category	Source Website
ATSDR	ATSDR Tox Profile Updates and Addendums	Other US Agency Resources	Assessment or Related Document	https://www.atsdr.cdc.gov/toxprofiles/profilesaddenda.asp
ATSDR	ATSDR Toxicological Profiles (original publication)	Other US Agency Resources	Assessment or Related Document	https://www.atsdr.cdc.gov/toxprofiles/index.asp
Australian Government, Department of Health	NICNAS Assessments (human health, Tier I, II or III)	International Resources	Assessment or Related Document	https://www.nicnas.gov.au/chemical-information/imap-assessments/imap-assessmentshttps://www.industrialchemicals.gov.au/chemical-information/search-assessments
Australian Government, Department of Health	NICNAS Assessments (eco)	International Resources	Assessment or Related Document	https://www.nicnas.gov.au/chemical-information/imap-assessments/imap-assessmentshttps://www.industrialchemicals.gov.au/chemical-information/search-assessments
CAL EPA	Technical Support Documents for regulations: Proposition 65, Reproductive Toxicity	Other US Agency Resources	Assessment or Related Document	https://oehha.ca.gov/chemicals
CPSC	Chronic Hazard Advisory Panel Reports	Other US Agency Resources	Assessment or Related Document	https://www.cpsc.gov/chap

Source Agency	Source Name	Source Type	Source Category	Source Website
CPSC	Technical Reports: Exposure/Risk Assessment	Other US Agency Resources	Assessment or Related Document	https://www.cpsc.gov/Research--Statistics/Chemicals
CPSC	Technical Reports: Toxicity Review	Other US Agency Resources	Assessment or Related Document	https://www.cpsc.gov/Research--Statistics/Chemicals
ECHA	Annex XVII Restriction Reports	International Resources	Assessment or Related Document	https://echa.europa.eu/substances-restricted-under-reach
ECHA	European Union Risk Assessment Report	International Resources	Assessment or Related Document	https://echa.europa.eu/information-on-chemicals/information-from-existing-substances-regulation
ECHA	ECHA Documents	International Resources	Assessment or Related Document	https://echa.europa.eu/information-on-chemicals
ECHA	Annex XVII To REACH - Conditions of Use	International Resources	Assessment or Related Document	https://echa.europa.eu/substances-restricted-under-reach
Env Canada	Priority Substances List Assessment Report; State of Science Report, Environment Canada Assessment	International Resources	Assessment or Related Document	https://www.canada.ca/en/environment-climate-change/services/canadian-environmental-protection-act-registry/substances-list/priority-list.html
Env Canada	Guidelines, Risk Management, Regulations	International Resources	Assessment or Related Document	https://www.canada.ca/en.html
EPA	OPPT: TSCATS database maintained at SRC (TSCA submissions)	US EPA Resources	Database	
EPA	OPPT: Chemview (TSCA submissions - chemical test rule data and substantial risk reports)	US EPA Resources	Database	https://chemview.epa.gov/chemview
EPA	OPPT: 8e database (CBI) (TSCA submissions)	US EPA Resources	Database	
EPA	OPPT: CIS (CBI LAN) (TSCA submissions)	US EPA Resources	Database	
EPA	Office of Air: National Emissions Inventory (NEI) - National Emissions Inventory (NEI) Data (2014, 2011, 2008)	US EPA Resources	Database	https://www.epa.gov/air-emissions-inventories/2014-national-emissions-inventory-nei-data

Source Agency	Source Name	Source Type	Source Category	Source Website
EPA	Office of Water: STORET and WQX	US EPA Resources	Database	https://www.waterqualitydata.us/portal/
EPA	EPA Office of Water: Ambient Water Quality Criteria documents	US EPA Resources	Assessment or Related Document	https://www.epa.gov/wqc
EPA	IRIS Summary	US EPA Resources	Assessment or Related Document	https://cfpub.epa.gov/ncea/iris_drafts/atoz.cfm?list_type=alpha
EPA	Office of Air: TRI	US EPA Resources	Database	https://www.epa.gov/toxics-release-inventory-tri-program/tri-data-and-tools
EPA	IRIS Tox Review	US EPA Resources	Assessment or Related Document	https://cfpub.epa.gov/ncea/iris2/atoz.cfm
EPA	EPA: AP-42	US EPA Resources	Regulatory Document or List	https://www.epa.gov/air-emissions-factors-and-quantification/ap-42-compilation-air-emissions-factors
EPA	Other EPA: Misc sources	US EPA Resources	General Search	https://www.epa.gov/
EPA	Office of Water: CFRs	US EPA Resources	Regulatory Document or List	https://www.epa.gov/eg
EPA	Office of Air: CFRs and Dockets	US EPA Resources	Regulatory Document or List	https://www.epa.gov/stationary-sources-air-pollution
EPA	EPA: Generic Scenario	US EPA Resources	Assessment or Related Document	https://www.epa.gov/tsca-screening-tools/chemsteer-chemical-screening-tool-exposures-and-environmental-releases#genericscenarios
FDA	FDA technical support documents for regulations	Other US Agency Resources	Assessment or Related Document	https://www.fda.gov/
ILO	International Chemical Safety Cards (ICSCs)	International Resources	Database	https://www.ilo.org/safework/info/publications/WCMS_113134/lang--en/index.htm
Japan	Japanese Ministry of the Environment Assessments - Environmental Risk Assessments (Class I Designated Chemical Substances Summary Table)	International Resources	Regulatory Document or List	https://www.env.go.jp/en/chemi/prtr/substances/

Source Agency	Source Name	Source Type	Source Category	Source Website
KOECT	Kirk-Othmer Encyclopedia of Chemical Technology Journal Article	Other Resource	Encyclopedia	https://onlinelibrary.wiley.com/doi/book/10.1002/0471238961
NIOSH	CDC NIOSH - Occupational Health Guideline Documents	Other US Agency Resources	Assessment or Related Document	http://www.cdc.gov/niosh/topics/chemical.html/
NIOSH	CDC NIOSH - Pocket Guide	Other US Agency Resources	Database	https://www.cdc.gov/niosh/npg/default.html
NIOSH	CDC NIOSH - Health Hazard Evaluations (HHEs)	Other US Agency Resources	Assessment or Related Document	https://www2a.cdc.gov/hhe/search.asp
NIOSH	CDC NIOSH - Publications and Products	Other US Agency Resources	Assessment or Related Document	https://www2a.cdc.gov/nioshtic-2/
NLM	National Library of Medicine's PubChem	Other US Agency Resources	Database	https://pubchem.ncbi.nlm.nih.gov/
NTP	Additional NTP Reports	Other US Agency Resources	Assessment or Related Document	https://ntp.niehs.nih.gov/publications/index.html
NTP	OHAT Monographs	Other US Agency Resources	Assessment or Related Document	https://ntp.niehs.nih.gov/pubhealth/hat/noms/evals.html
OECD	OECD Substitution and Alternatives Assessment	International Resources	Assessment or Related Document	http://www.oecdsaatoolbox.org/
OECD	OECD: General Site	International Resources	General Search	https://www.oecd.org/
OECD	OECD Emission Scenario Documents	International Resources	Assessment or Related Document	http://www.oecd.org/document/46/0,2340,en_2649_201185_2412462_1_1_1_1,00.html
OSHA	OSHA Chemical Exposure Health Data	Other US Agency Resources	Database	http://www.osha.gov/opengov/healthsamples.html/
RIVM	RIVM Reports: Risk Assessments	International Resources	Assessment or Related Document	https://www.rivm.nl/en
TERA	Toxicology Excellence for Risk Assessment	Other Resources	Assessment or Related Document	http://www.tera.org/

Appendix B PHYSICAL AND CHEMICAL PROPERTIES OF DIBUTYL PHTHALATE

Table_Apx B-1 summarizes statistics for the physical and chemical property values identified through systematic review as of June 2020. The "N" column indicates the number of unique primary sources of data for that endpoint. That is, if multiple sources presented equivalent values and cited the same primary source, only one of those was included in these statistics and included in the statistical calculations. All physical and chemical property values that were extracted and evaluated as of June 2020 are presented in the supplemental file *Data Extraction and Data Evaluation Tables for Physical and Chemical Property Studies* (EPA-HQ-OPPT-2018-0503).

Table_Apx B-1. Summary Statistics for Reviewed Physical Properties

Property or Endpoint	N	Unit	Mean	Standard Deviation	Min	Max
Molecular formula	-	-	NA	NA	NA	NA
Molecular weight	-	g/mol	NA	NA	NA	NA
Physical state	3	-	NA	NA	NA	NA
Physical properties	5	-	NA	NA	NA	NA
Melting point	11	°C	-40.5	18.3	-95.75	-35
Boiling point	13	°C	332.6	25.2	248.85	340.7
Density	9	g/cm^3	1.0453	0.0030	1.0402	1.0501
Vapor pressure	6	mm Hg	9.97×10^{-5}	8.27×10^{-5}	2.01×10^{-5}	2.5×10^{-4}
Vapor density	1	-	9.58		9.58	9.58
Water solubility	12	mg/L	6.58	5.72	6.35×10^{-7}	14.6
Octanol/water partition coefficient (log Kow)	10	-	4.46	0.34	3.74	4.825
Henry's Law constant	3	atm-m^3/mol	2.49	4.31	8.83×10^{-7}	7.47
Flash point	8	°C	165.4	7.0	157	171
Auto flammability	0	cP	-	-	-	-

Property or Endpoint	N	Unit	Mean	Standard Deviation	Min	Max
Viscosity	8	-	6502.2	18343.5	12.9	51900
Refractive index	7	-	1.49	0.12	1.266	1.646
Dielectric constant	2	°C	6.36	0	6.36	6.36

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. This information was presented in the in the *Proposed Designation of Dibutyl Phthalate (CASRN 84-74-2) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019c) and may be updated as EPA collects additional information through systematic review methods.

Table_Apx C-1. Environmental Fate Characteristics of Dibutyl Phthalate

Property or Endpoint	Value[a]	Reference
Direct Photodegradation	$t_{1/2}$ = 3 hours	Mackay et al. (2006) citing Jin et al. (1999)
Indirect Photodegradation	$t_{1/2}$ = 18.4 hours with reaction with •OH radical	Mackay et al. (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 et al. (2006)
	Sediment: $t_{1/2}$ = 1.0–23 days reported by multiple sources in Mackay et al., 2006	Mackay et al. (2006)
Biodegradation (Anaerobic)	Water: $t_{1/2}$ = 1.19–27.2 days reported by multiple sources in Mackay et al., 2006	Mackay et al. (2006)

Property or Endpoint	Value[a]	Reference
	Soil: $t_{1/2}$ = 1–20 days reported by multiple sources in Mackay et al., 2006	Mackay et al. (2006)
	Sediment: $t_{1/2}$ = 7–30 days reported by multiple sources in Mackay et al., 2016	Mackay et al. (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 (2012b)
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 et al. (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 et al. (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 Statutes/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 (85 FR 20122, April 9, 2020).
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, 2018b). 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, January 9, 1989). 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, 2018b). 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.C. 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 statute 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. (40 CFR 401.15). 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 Statutes/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 (8:59 N.J. Admin. Code § 9.1) 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 726/2004,

Country/ Organization	Requirements and Restrictions
	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 as a component of finished products or mixtures and also as a raw material for

Country/ Organization	Requirements and Restrictions
	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 As referenced in the National Institute for National Institute for 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.

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, 2019a). 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, 2019a).

E.1.1.1 Domestic Manufacturing

Dibutyl phthalate is manufactured through the esterification of the carboxyl groups phthalic anhydride 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, 2019a).

E.1.2 Processing and Distribution

E.1.2.1 Processing as a Reactant

Processing as a reactant 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, 2019a).

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, 2019a; NLM, 2015). Dibutyl phthalate is used as a functional fluid in printing activities and a solvent in other chemical manufacturing (U.S. EPA, 2019a; NLM, 2015; Kosaric et al., 2011; Ash and Ash, 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, 2019a). Dibutyl phthalate may also be used as a plasticizer in ceramic and in textiles and apparel (NLM, 2015).

A commenter (EPA-HQ-OPPT-2018-0503-0035) provided descriptions of their use of dibutyl phthalate as a plasticizer in solvent-based processes for tape casting ceramic powders, which the commenter also indicated was a critical use, further informing EPA's understanding of this condition of use.

EPA plans to further investigate processing uses of dibutyl phthalate during risk evaluation.

E.1.2.4 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.1.2.5 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, 2019a). 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, 2019a; NLM, 2015; GoodGuide, 2011; Streitberger et al., 2011). 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).

A commenter (EPA-HQ-OPPT-2018-0503-0035) provided descriptions of their use of dibutyl phthalate in pedigreed adhesive used in testing test articles and human-rated spaceflight hardware, which the commenter also indicated was a critical use, further informing EPA's understanding of this condition of use.

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, 2019a). 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) (Whelton et al., 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 (Whelton et al., 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, 2019a; 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, 2019a; 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, 2019a; 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, 2019a), in explosives and propellants (Akhavan, 2018; NLM, 2015; Ash and Ash, 2009), and in chemiluminescent light sticks, inspection penetrant kit, and lubricants (EPA-HQ-OPPT-2018-0503-0036). Dibutyl phthalate is also used as a laboratory chemical (Akhavan, 2018; NLM, 2015; Kosaric et al., 2011; Ash and Ash, 2009). Laboratory procedures are generally done within a fume hood, on a bench with local exhaust ventilation, or under general ventilation.

A commenter (EPA-HQ-OPPT-2018-0503-0035) provided reported their use of dibutyl phthalate in laboratory use including such applications as analytical standards, research, equipment calibration, sample preparation and as a component of a variety of other common off the shelf materials, including anti-seize compound.

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. The presence of dibutyl phthalate in the reuse of produced waters is included in the disposal condition of use. 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 wastewater and solid waste.

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 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).

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[a]

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 Silk screening
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	HHE 80-094-840	Automobile Manufacture and Assembly
1977	HHE 76-92-363	Acrylic Furniture Manufacture

[a] Table includes HHEs identified to date. HHEs can be found at https://www.cdc.gov/niosh/hhe/.

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 [a]
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

[a] Number of data points in Table_Apx E-2 was populated from data found at https://www.osha.gov/opengov/healthsamples.html.

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	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
	Import	Import	Repackaging of import containers	Liquid Contact	Dermal	Workers	Yes	2016 CDR references import in liquid form. Thus, the potential for exposures to workers exists during manufacturing.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
				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	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
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 = 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

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
								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	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
	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; petrochemical manufacturing; rubber product 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 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

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
		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						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	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
	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 = 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
								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	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
	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.
				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

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
								dibutyl phthalate may be incorporated into products in solid form.
				Liquid/Solid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
	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	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
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

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
								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	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
	Non-incorporative solvent use; Ink, toner, and colorant products; laboratory chemical; Inspection penetrant kits; lubricants	Non-incorporative solvent use; Ink, toner, and colorant products; laboratory chemical; Inspection penetrant kits; lubricants	Use of solvents containing dibutyl phthalate in non-incorporative activities Use of ink, toner, and colorant products (*e.g.*, printing) Use of laboratory chemicals Use of inspection penetrant kits Use of lubricants	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	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

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
								these products because they are in liquid form.
				Liquid/Solid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
	Explosive materials; Floor coverings; furniture and furnishings not covered elsewhere; plastic and rubber products not covered elsewhere; Chemiluminescent light sticks	Explosive materials; Floor coverings; furniture and furnishings not covered elsewhere; plastic and rubber products not covered elsewhere; Chemiluminescent light sticks	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.
				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 /

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
								other machining operations occur.
				Liquid/Solid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
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
				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	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.

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,	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
			Abrasion, Transfer to Dust					
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 Products	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	Direct contact through handling of articles	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
		not Covered Elsewhere (Article)	containing chemical					
			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	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
			application or use of products					
			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	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 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 and/or surface water	Oral Inhalation	General Population	Yes	EPA plans to analyze the pathway from biosolids to the general population, aquatic species.
				TBD	Aquatic Receptors	Yes	
		Underground injection	Migration to groundwater, potential	Oral Dermal Inhalation	General Population	No	Dibutyl phthalate is released to Class I Underground Injection Wells which are covered by RCRA and SDWA.

Life Cycle Stage	Category	Release	Exposure Pathway / Media	Exposure Routes	Receptor / Population	Plans to Evaluate	Rationale
			surface/drinking water	TBD	Aquatic and Terrestrial Species		
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		