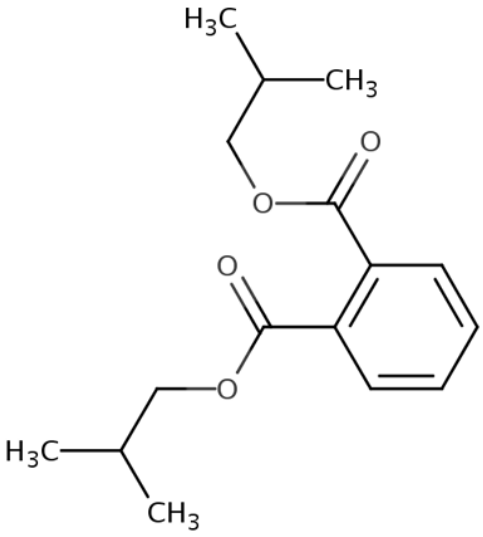
EPA Document# EPA-740-R-20-018
August 2020
Office of Chemical Safety and
Pollution Prevention

United States
Environmental Protection Agency

Final Scope of the Risk Evaluation for Di-isobutyl Phthalate (1,2-Benzenedicarboxylic acid, 1,2-bis(2-methylpropyl) ester)

CASRN 84-69-5



August 2020

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF APPENDIX TABLES

LIST OF APPENDIX FIGURES

ACKNOWLEDGEMENTS

This report was developed by the United States Environmental Protection Agency (U.S. EPA), Office of Chemical Safety and Pollution Prevention (OCSPP), Office of Pollution Prevention and Toxics (OPPT).

Acknowledgements

The OPPT Assessment Team gratefully acknowledges participation or input from intra-agency reviewers that included multiple offices within EPA, inter-agency reviewers that included multiple federal agencies, and assistance from EPA contractors GDIT (Contract No. HHSN316201200013W), ERG (Contract No. EP-W-12-006), Versar (Contract No. EP-W-17-006), ICF (Contract No. 68HERC19D0003), Abt Associates (Contract No. EP-W-16-009) and SRC (Contract No. 68HERH19F0213). EPA also acknowledges the contributions of technical experts from EPA's Office of Research and Development.

Docket

Supporting information can be found in public docket: EPA-HQ-OPPT-2018-0434.

Disclaimer

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

ABBREVIATIONS AND ACRONYMS

ACGIH	American Conference of Governmental Industrial Hygienists
ADME	Absorption, Distribution, Metabolism, and Excretion
BBP	Butylbenzyl Phthalate
BCF	Bioconcentration Factor
BMF	Biomagnification factor
BP	Boiling point
$BW^{3/4}$	Body weight scaling to the 3/4 power
CAA	Clean Air Act
CASRN	Chemical Abstracts Service Registry Number
CBI	Confidential Business Information
CDR	Chemical Data Reporting
CEHD	Chemical Exposure Health Data
CFR	Code of Federal Regulations
CHRIP	Chemical Risk Information Platform
ChemSTEER	Chemical Screening Tool for Exposure and Environmental Releases
COC	Concentration of Concern
CPCat	Chemical and Product Categories
CPSC	Consumer Product Safety Commission
CPSIA	Consumer Product Safety Improvement Act
CSCL	Chemical Substances Control Law
CWA	Clean Water Act
DMR	Discharge Monitoring Report
EC	Engineering Controls
EC_x	Effective Concentration
ECHA	European Chemicals Agency
EPA	Environmental Protection Agency
ERG	Eastern Research Group
ESD	Emission Scenario Document
EU	European Union
FDA	Food and Drug Administration
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
HAWC	Health Assessment Workplace Collaborative
Hg	Mercury
HHE	Health Hazard Evaluation
HSDB	Hazardous Substances Data Bank
ICF	ICF is a global consulting services company
IECCU	Indoor Environmental Concentrations in Buildings with Conditioned and Unconditioned Zones

IMAP	Inventory Multi-Tiered Assessment and Prioritisation (Australia)
IMIS	Integrated Management Information System
KOECT	Kirk-Othmer Encyclopedia of Chemical Technology
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
MOA	Mode of Action
MP	Melting point
MRSA	Maine Revised Statutes Annotated
NESHAP	National Emission Standards for Hazardous Air Pollutants
NHANES	National Health and Nutrition Examination Survey
NICNAS	National Industrial Chemicals Notification and Assessment Scheme (Australia)
NIOSH	National Institute for Occupational Safety and Health
NITE	National Institute of Technology and Evaluation
NLM	National Library of Medicine
NOAEL	No Observed Adverse Effect Level
NOEC	No Observed Effect Concentration
NPDES	National Pollutant Discharge Elimination System
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
PECO	Population, Exposure, Comparator and Outcome
PESO	Pathways and Processes, Exposure, Setting or Scenario, and Outcomes
PESS	Potentially Exposed Susceptible Populations
POD	Point of Departure
POTW	Publicly Owned Treatment Works
PPE	Personal Protective Equipment
PVC	Polyvinyl chloride
RCRA	Resource Conservation and Recovery Act
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals (European Union)
RESO	Receptors, Exposure, Setting or Scenario, and Outcomes
RQ	Risk Quotient
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
SMILES	Simplified molecular-input line-entry system
SRC	SRC Inc., formerly Syracuse Research Corporation
SVOC	Semi-volatile organic compound
$T_{1/2}$	Half-Life

TBD	To be determined
TIAB	Title and Abstract
TMF	Trophic Magnification Factors
TRI	Toxic Release Inventory
TSCA	Toxic Substances Control Act
U.S.C.	United States Code
VP	Vapor Pressure
WHO	World Health Organization
WS	Water solubility
WWT	Wastewater Treatment
WWTP	Wastewater Treatment Plant

EXECUTIVE SUMMARY

In December 2019, EPA designated di-isobutyl phthalate (CASRN 85-69-5) 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 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 Di-isobutyl Phthalate* CASRN 84-69-5 (EPA Document No. 740-D-20-018) (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-2018-0434) 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 di-isobutyl 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 di-isobutyl phthalate includes the following information: the conditions of use, potentially exposed or susceptible subpopulations (PESS), hazards, and exposures that EPA plans to consider in the 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. Di-isobutyl phthlate is a colorless liquid with a total production volume in the United States of less than one million pounds.

Reasonably Available Information. EPA leveraged the data and information sources already described in the *Proposed Designation of Di-isobutyl Phthalate (DIBP) (CASRN 84-69-5) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019d) to inform the development of this 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 di-isobutyl 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 di-isobutyl phthalate in the risk evaluation. Di-isobutyl phthalate is manufactured (including imported) in the United States. The chemical is incorporated into formulation, mixture, or reaction products and incorporated into articles. The identified processing activities also include the recycling of di-isobutyl phthalate. Several industrial and commercial uses were identified that ranged from use in plastic and rubber products to use in adhesives and sealants. Consumer uses varied from inks, toner, and colorant products to adhesives and sealants. EPA identified these conditions of use from information reported to EPA through CDR, published literature, public comments and consultation with stakeholders for both uses currently in

production and uses whose production may have ceased. 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-2018-0434) on the draft scope document for di-isobutyl phthalate. EPA is aware of information listing use of di-isobutyl phthalate in food packaging material; however, they are not conditions of use for the chemical substance as defined in TSCA § 3(2) and (4). Section 2.2 provides details about the conditions of use within the scope of the risk evaluation.

Conceptual Model. The conceptual models for di-isobutyl 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 di-isobutyl 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 di-isobutyl 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 di-isobutyl phthalate that EPA plans to consider in risk evaluation. Exposures for di-isobutyl 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 di-isobutyl phthalate in media pathways falling under the jurisdiction of those authorities. Di-isobutyl phthalate does not have pathways covered under the jurisdiction of other EPA-administered laws. In Section 2.6.3, EPA presents the conceptual model describing the identified exposures (pathways and routes), receptors and hazards associated with the conditions of use of di-isobutyl phthalate within the scope of the risk evaluation.

  EPA considered reasonably available information and comments received on the draft scope for di-isobutyl 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 exposure:* EPA plans to evaluate exposures to workers and occupational non-users (ONUs) via the inhalation route and exposures to worker via the dermal route associated with the manufacturing, processing, industrial/commercial use, and disposal of di-isobutyl phthalate. EPA plans to analyze dermal exposure for workers and ONUs to mists and dust that deposit on surfaces.
  - *Consumer and bystander exposure pathways:* EPA plans to evaluate the inhalation, oral and dermal exposure to di-isobutyl phthalate for consumers and bystanders from the use and/or handling of adhesives and sealants; air care products; fabric, textile, and leather products; floor coverings; ink, toner, and colorant products; other; paints and coatings; plastic and rubber products not covered elsewhere; and toys, playground, and sporting

equipment; and mouthing of products/articles containing di-isobutyl phthalate for consumers.
  - *General population exposure:* EPA plans to evaluate general population exposure to di-isobutyl phthalate via drinking water, surface water, groundwater, ambient air, soil, biosolids, and fish ingestion. EPA plans to evaluate general population exposure to di-isobutyl phthalate via the oral route from drinking water, fish ingestion, human breast milk and soil, via the inhalation route from ambient air and via dermal route from contact with drinking water and soil.
  - *PESS:* EPA plans to evaluate children, women of reproductive age (*e.g.*, pregnant women), workers and consumers as PESS in the risk evaluation.
  - *Environmental exposure*: EPA plans to evaluate exposure to di-isobutyl phthalate for aquatic and terrestrial receptors.

- *Hazards.* Hazards for di-isobutyl 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 di-isobutyl phthalate as part of the prioritization (U.S. EPA, 2019d) 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 di-isobutyl phthalate in determining the broad categories of environmental and human health hazard effects to be evaluated in the risk evaluation. EPA plans to use systematic review methods to evaluate the epidemiological and toxicological literature for di-isobutyl phthalate.

  EPA plans to evaluate all potential environmental and human health hazard effects identified for di-isobutyl 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, developmental, endocrine, mortality, musculoskeletal, neurological, and reproductive for di-isobutyl phthalate. Similarly, the potential human health hazard effects and related information identified through prioritization and the data screening phase of systematic review for di-isobutyl 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 di-isobutyl 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 di-isobutyl 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 di-isobutyl 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 di-isobutyl 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-2018-0131) (84 FR 71924, December 30, 2019), as required by TSCA § 6(b)(2)(B), which initiated the risk evaluation process for those chemical substances. Di-isobutyl 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 Di-isobutyl Phthalate CASRN 84-69-5 (EPA Document No. EPA-740-D-20-018) (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-2018-0434) 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 di-isobutyl 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] *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).

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

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

Search terms were used to search each of the literature streams and gather di-isobutyl 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 60 search results relevant to EPA's risk evaluation needs for di-isobutyl phthalate. Appendix A.3.4 lists the gray literature sources that yielded 60 discrete data or information sources relevant to di-isobutyl 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 plans to 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.

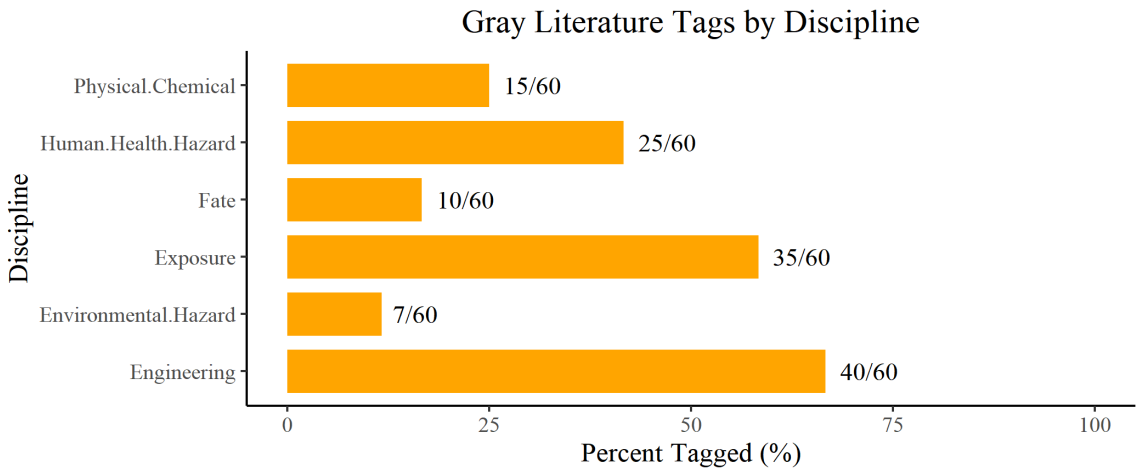


Figure 2-1. Gray Literature Search Results for Di-isobutyl Phthalate
The percentages across disciplines do not add up to 100%, as each source may provide data or information for various topic areas (or disciplines).

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

EPA has begun the systematic review process and has conducted a systematic review 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 di-isobutyl 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 2-6, Figure 2-7,

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.

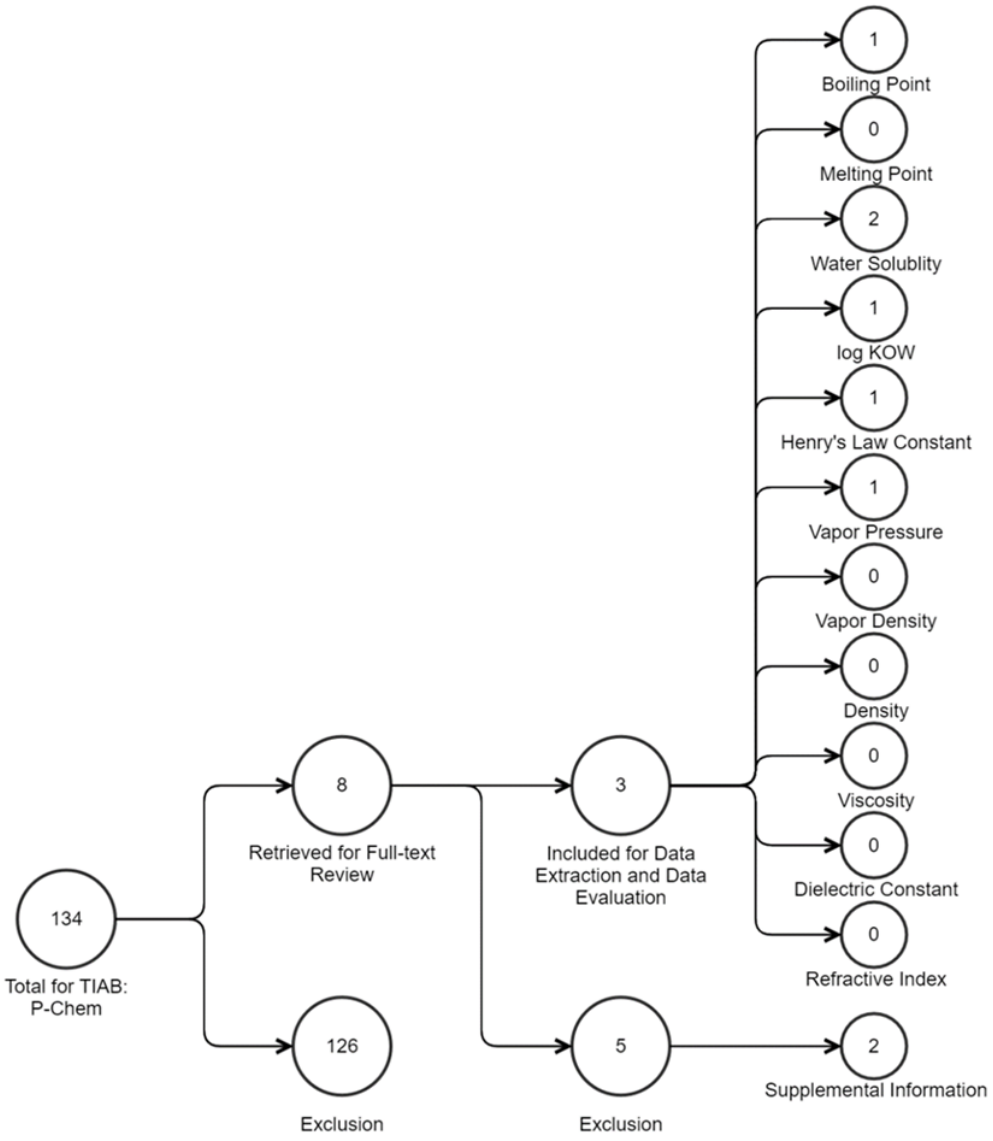


Figure 2-2. Peer-reviewed Literature Inventory Tree – Physical and Chemical Properties Search Results for Di-isobutyl Phthalate
Data in this static figure represent references obtained from the publicly available databases search (see A.1.2) that were included during full-text screening as of June 2, 2020. TIAB refers to “title and abstract” screening.

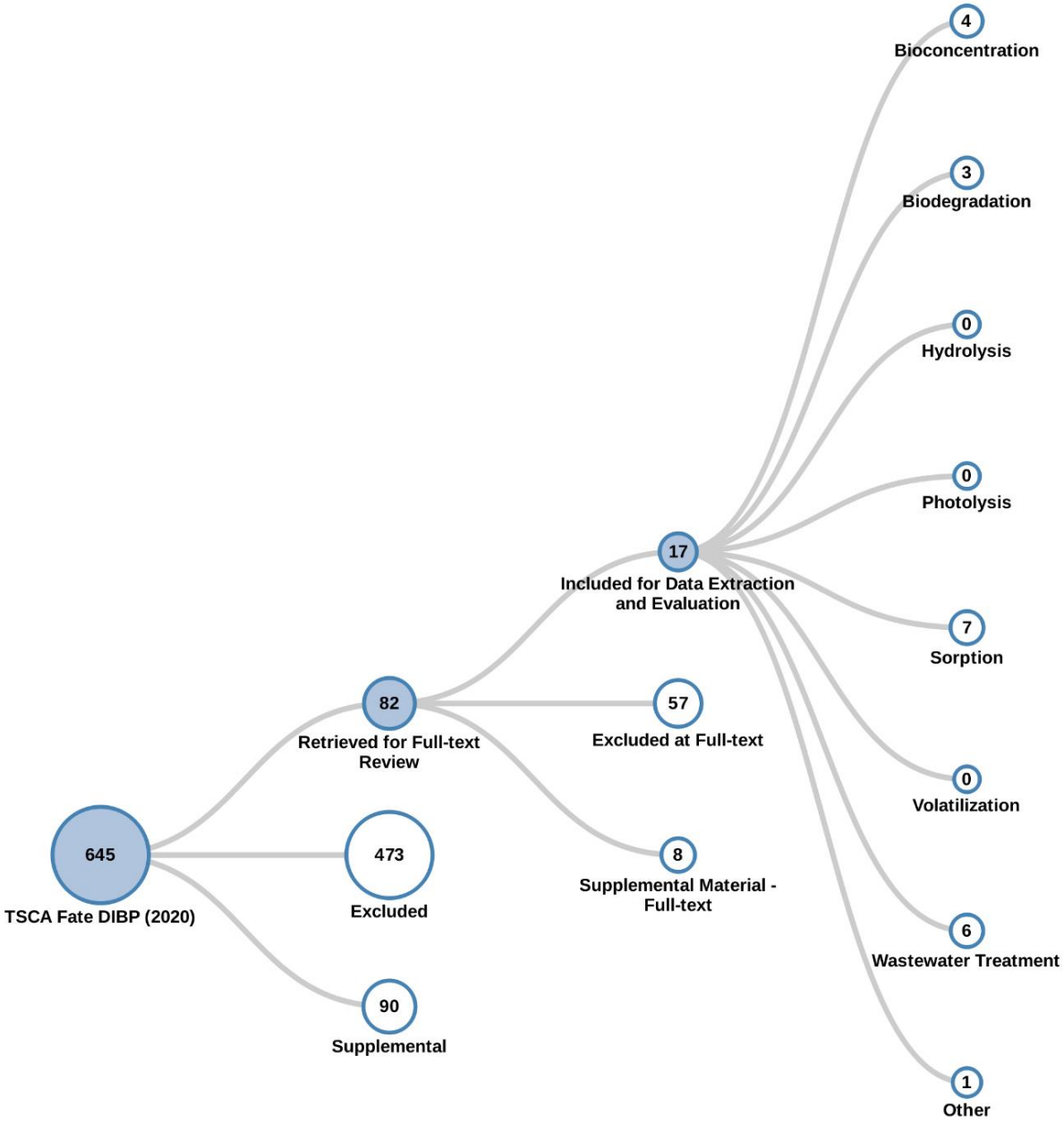


Figure 2-3. Peer-reviewed Literature Inventory Tree – Fate and Transport Search Results for Di-isobutyl Phthalate

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		4		4		4
Biodegradation		2	1	2		3
Hydrolysis						
Photolysis						
Sorption		7		7		7
Volatilization						
Wastewater Treatment		3	5	5		6
Other		1	1	1		1
Grand Total		14	6	16		17

Figure 2-4. Peer-reviewed Literature Inventory Heat Map – Fate and Transport Search Results for Di-isobutyl 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.

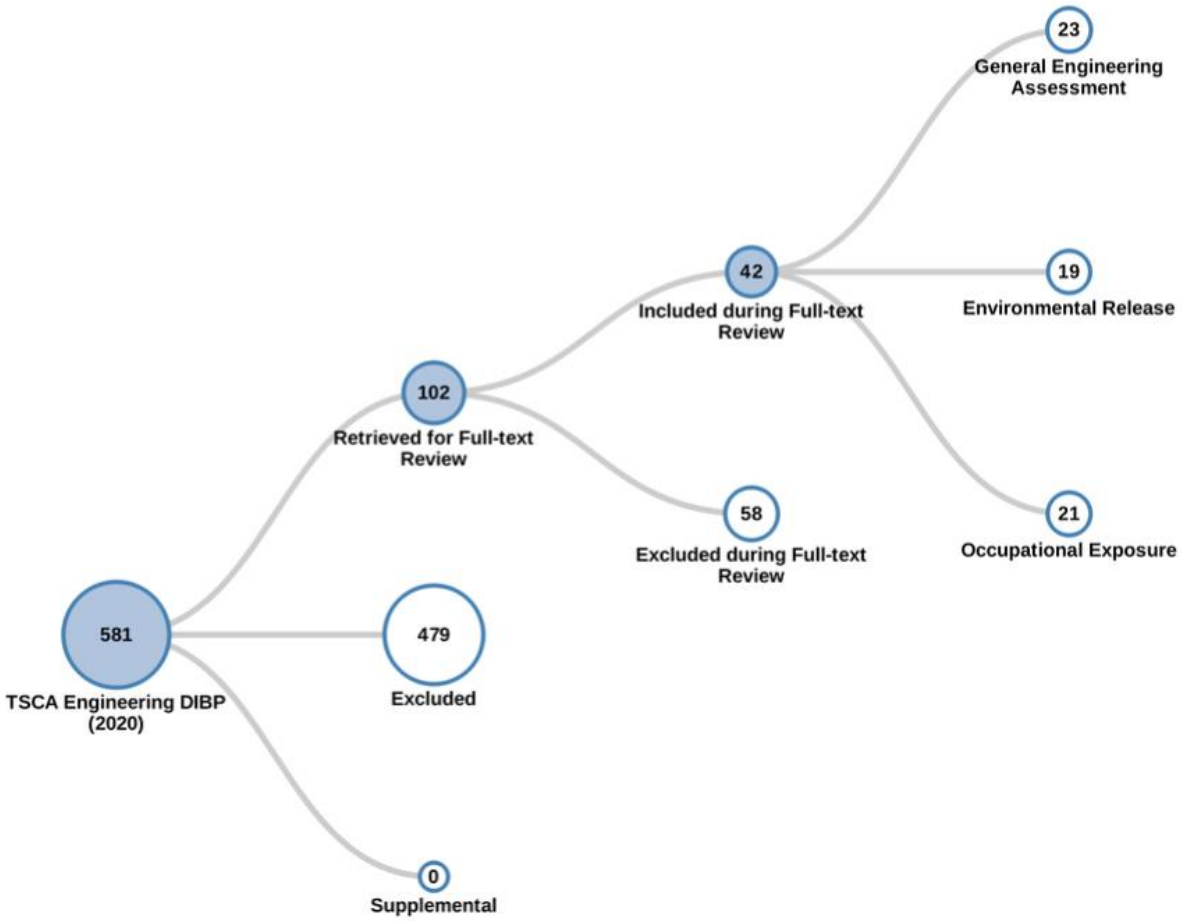


Figure 2-5. Peer-reviewed Literature Inventory Tree – Engineering Search Results for Di-isobutyl Phthalate

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 this interactive version as they become available.

Data Type	Evidence Tags	
Environmental Releases	Description of release source	14
	Release frequency	2
	Release or emission factors	12
	Release quantity	8
	Waste treatment methods and pollution control	5
	Total	19
General Engineering Assessment	Chemical concentration	15
	Life cycle description	4
	Number of sites	6
	Process description	13
	Production, import, or use volume	8
	Throughput	5
	Total	23
Occupational Exposures	Area sampling data	9
	Dermal exposure data	5
	Engineering control	4
	Exposure duration	5
	Exposure frequency	3
	Exposure route	14
	No evidence tag	1
	Number of workers	5
	Particle size characterization	
	Personal protective equipment	4
	Personal sampling data	6
	Physical form	5
	Worker activity description	8
	Total	21
Grand Total		42

Figure 2-6. Peer-reviewed Literature Inventory Heat Map – Engineering Search Results for Di-isobutyl Phthalate

Click here to view the interactive version for additional study details. Data in this static 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.

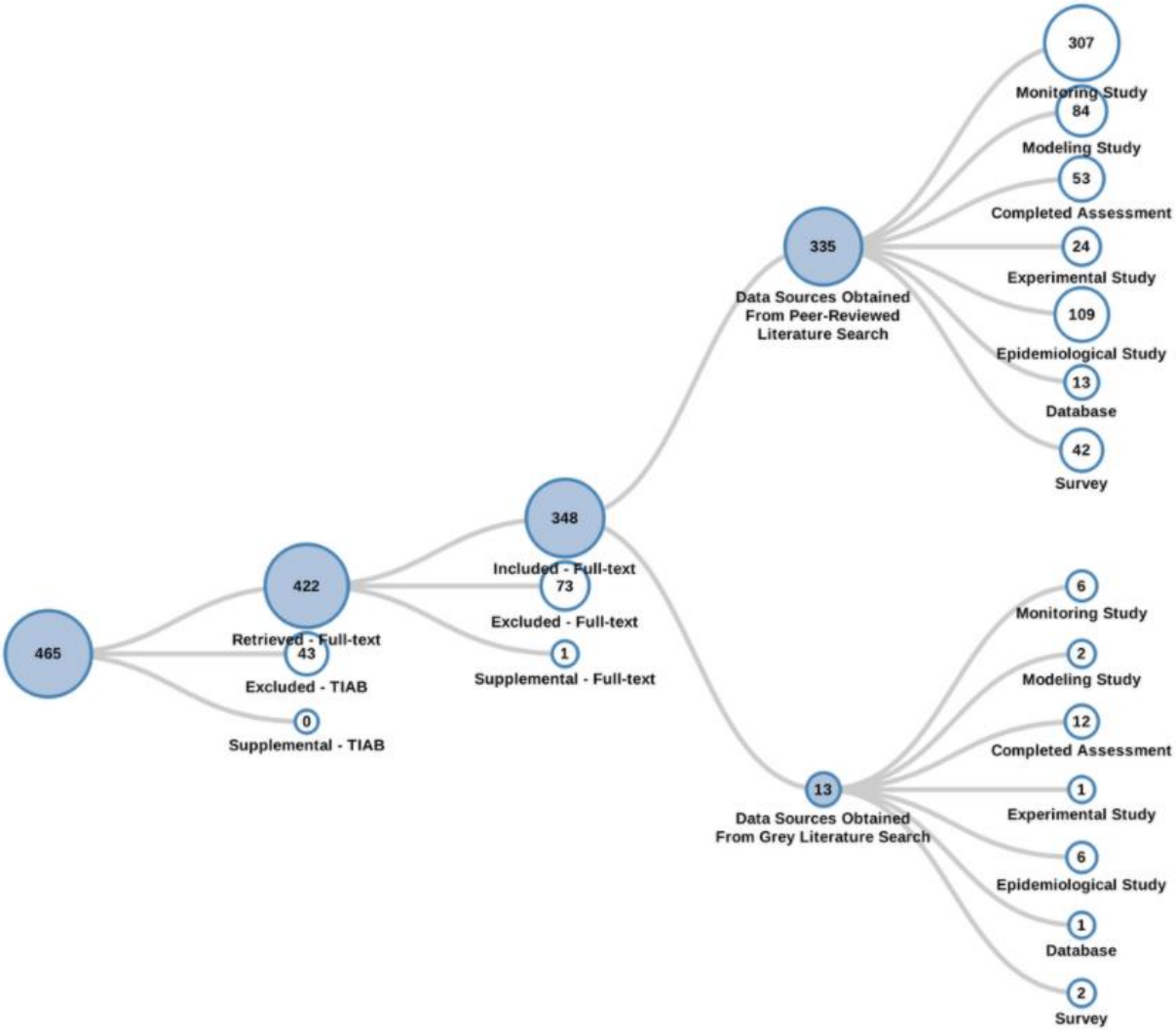


Figure 2-7. Peer-reviewed and Gray Literature Inventory Tree – Exposure Search Results for Di-isobutyl Phthalate

Click here to view the interactive literature inventory tree. Data in this static 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	9	5	4	3	2		2	11
Biosolids/Sludge	3		1	1				3
Drinking Water	5	2	2	3	1		2	5
Groundwater	1							1
Land Disposal/ Landfill								
Sediment	3	1	1	2				4
Soil	9	4	7	1	2		1	12
Surface Water								
Wastewater								
Aquatic Species	2	2	2	1	1		1	2
Terrestrial Species								
Consumer	31	14	19	18	6		8	45
Dietary	28	20	16	9	3	1	4	38
Dust	58	29	28	3	14		11	72
Exposure Factors	15	14	7	3	6		1	19
Exposure Pathway	10	6	6	2	4		4	14
Human Biomonitoring	222	50	28	4	104	14	35	230
Indoor Air	41	20	16	6	5		3	48
Isomers								
Use Information	5	4	10	1	3		3	13
No Evidence Type	2		1		1		1	2
Grand Total	313	86	65	25	115	14	44	348

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

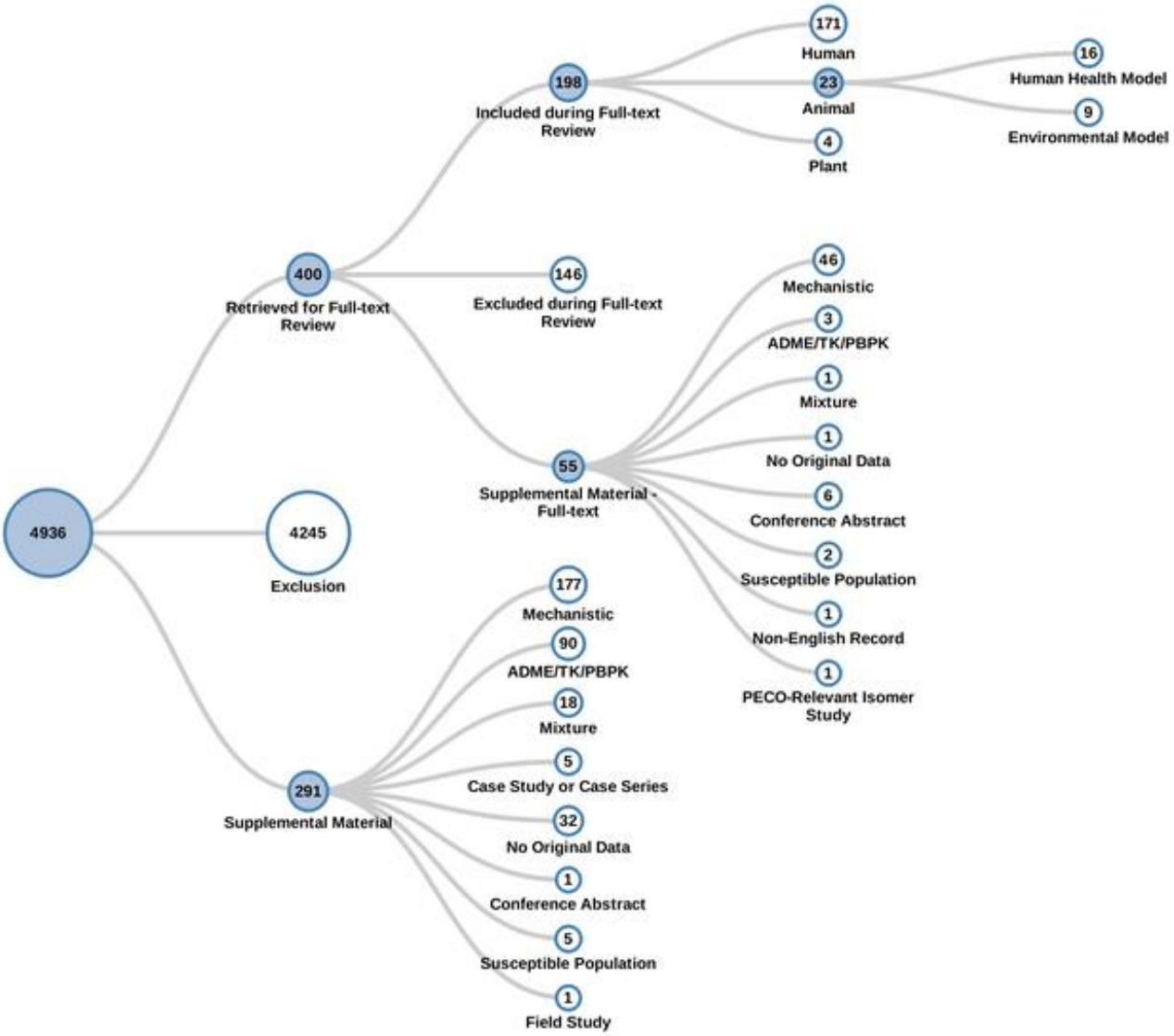


Figure 2-9. Peer-reviewed Literature Inventory Tree – Human Health and Environmental Hazards Search Results for Di-isobutyl Phthalate

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	159	5	2	2	167
Cancer	9				9
Cardiovascular	13				13
Developmental	117	11	2		128
Endocrine	61	12	1		73
Gastrointestinal	1				1
Hematological and Immune	70	2			72
Hepatic		2			2
Mortality	8	1	1		10
Musculoskeletal	10	3	2		13
Neurological	30	1	2		33
Nutritional and Metabolic	59	2			61
Ocular and Sensory	19				19
PBPK	2				2
Renal	90	1			91
Reproductive	105	14	2	1	120
Respiratory	20				20
Skin and Connective Tissue	13				13
No Tag	1	2	3	2	8
Grand Total	171	16	9	4	198

Figure 2-10. Peer-reviewed Literature Inventory Heat Map – Human Health and Environmental Hazards Search Results for Di-isobutyl 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 particular health outcome, not the number of studies that observed an association with di-isobutyl phthalate. 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 of TSCA Submissions

Table 2-1 presents the results of screening the titles of data sources and reports submitted to EPA under various sections of TSCA. EPA screened a total of 13 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 eleven submissions that met the inclusion criteria in these statements and identified zero submissions with supplemental data. EPA excluded two submissions[3] 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
Physical and Chemical Properties	0	0
Environmental Fate and Transport	0	0
Environmental and General Population Exposure	1	0
Occupational Exposure/Release Information	1	0
Environmental Hazard	1	0
Human Health Hazard	8	0

[a]Individual submissions may be relevant to multiple disciplines.

2.2 Conditions of Use

As described in the *Proposed Designation of Di-isobutyl Phthalate (DIBP) (CASRN 84-69-5) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019d), EPA assembled information from the CDR program 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 plans to utilize the most recent CDR information. EPA also consulted a variety of other sources to identify uses of di-isobutyl phthalate, including published literature, company websites, and government and commercial trade databases and publications. To identify formulated products containing di-isobutyl phthalate, EPA searched for safety data sheets (SDS) using internet searches, EPA Chemical and Product Categories (CPCat) (U.S. EPA, 2019c) 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, and public comments (Docket ID: EPA-HQ-OPPT-2018-0434) to supplement the use information.

[3] EPA may further consider some excluded references depending on the reasons the exclusions.
[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)).

EPA identified and described the categories and subcategories of conditions of use that EPA plans to consider in the risk evaluation (Section 2.2.1; Table 2-2). The conditions of use included in the scope of the risk evaluation are those reflected in the life cycle diagrams and conceptual models.

After gathering reasonably available information related to the manufacture, processing, distribution in commerce, use and disposal of di-isobutyl phthalate, EPA identified those activities for di-isobutyl phthalate the Agency determined not to be conditions of use or are otherwise excluded from the scope of the risk evaluation. These excluded activities 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 [d, e, f, h, i, j, k]

Life-Cycle Stage [a]	Category [b]	Subcategory [c]	References
Manufacturing	Domestic Manufacturing	Domestic Manufacturing	U.S. EPA (2020a)
	Import	Import	U.S. EPA (2020a)
Processing	Incorporation into article	Plasticizers in: -Construction; plastic product manufacturing; transportation equipment manufacturing	U.S. EPA (2020a)
	Processing – incorporation into formulation, mixture, or reaction product	Plasticizers in: - Adhesive manufacturing; Plastic product manufacturing	U.S. EPA (2020a)
		Solvents (which become part of product formulations or mixture) – Plastic material and resin manufacturing -Paints and Coatings	U.S. EPA (2020a) Lanxess Corporation (2015)
		Fuels and Related Products (*e.g.*, Fuel additives)	Lanxess Corporation (2015)
		Processing aids, not otherwise listed	Lanxess Corporation (2015)

Life-Cycle Stage [a]	Category [b]	Subcategory [c]	References
		Inks, Toner, and Colorant Products (*e.g.*, Toner/ printer cartridge)	Lanxess Corporation (2015)
		Repackaging (*e.g.*, laboratory chemicals	EPA-HQ-OPPT-2018-0434-0020
		Plastic and rubber products not covered elsewhere	Lanxess Corporation (2015); EPA-HQ-OPPT-2018-0434-0014
		Fabric, textile, and leather products not covered elsewhere (*e.g.*, Textile (fabric) dyes)	Dow Chemical Company (2013)
	Recycling	Recycling	EPA-HQ-OPPT-2018-0434-0014
Distribution in commerce	Distribution in commerce	NA	NA
Industrial	Paints and Coatings	Paints and Coatings	Lanxess Corporation (2015)
	Fuels and Related Products	Fuels and Related Products	Lanxess Corporation (2015)
	Plastic and rubber products not covered elsewhere	Plastic and rubber products not covered elsewhere	EPA-HQ-OPPT-2018-0434-0014
	Adhesives and Sealants	Adhesives and Sealants -Two-component glues and adhesives -Transportation equipment manufacturing	Azon USA Inc (2015); Glue 360 Inc (2018); EPA-HQ-OPPT-2018-0434-0007; EPA-HQ-OPPT-2019-0434-0015
	Fabric, textile, and leather products not covered elsewhere	Fabric, textile, and leather products not covered elsewhere (*e.g.*, Textile (fabric) dyes)	Dow Chemical Company (2013)
	Inks, Toner, and Colorant Products	Inks, Toner, and Colorant Products (*e.g.*, Toner/printer cartridge)	Lanxess Corporation (2015)

Life-Cycle Stage [a]	Category [b]	Subcategory [c]	References
	Building/construction materials not covered elsewhere	Building/construction materials not covered elsewhere	Lanxess Corporation (2015)
	Floor coverings	Floor coverings	EPA-HQ-OPPT-2018-0434-0014
Commercial	Adhesives and Sealants	-Adhesives and Sealants -Two-component glues and adhesives	U.S. EPA (2019b); Glue 360 Inc (2018)
	Paints and Coatings	Paints and Coatings	Lanxess Corporation (2015)
	Plastic and rubber products not covered elsewhere	Plastic and rubber products not covered elsewhere	U.S. EPA (2020a); Lanxess Corporation (2015); EPA-HQ-OPPT-2018-0434-0014
	Inks, Toner, and Colorant Products	Inks, Toner, and Colorant Products (*e.g.*, Toner/printer cartridge)	Lanxess Corporation (2015)
	Laboratory chemicals	Laboratory chemicals	EPA-HQ-OPPT-2018-0434-0040; Sigma Aldrich (2020)
	Air Care Products	Air Care Products (*e.g.*, Air Freshener)	CPSC (2015a)
	Floor coverings	Floor coverings	EPA-HQ-OPPT-2018-0434-0014
Consumer	Air Care Products	Air Care Products (*e.g.*, Air Freshener)	CPSC (2015a)
	Floor coverings	Floor coverings	EPA-HQ-OPPT-2018-0434-0014
	Toys, playground, and sporting equipment	Toys, playground, and sporting equipment	EPA-HQ-OPPT-2018-0434-0014
	Paints and Coatings	Paints and Coatings	Lanxess Corporation (2015)
	Fabric, textile, and leather products not covered elsewhere	Fabric, textile, and leather products not covered	Dow Chemical Company (2013)

Life-Cycle Stage [a]	Category [b]	Subcategory [c]	References
		elsewhere (*e.g.*, Textile (fabric) dyes)	
	Inks, Toner, and Colorant Products	Inks, Toner, and Colorant Products (*e.g.*, Toner/printer cartridge)	Lanxess Corporation (2015)
	Plastic and rubber products not covered elsewhere	Plastic and rubber products not covered elsewhere	Lanxess Corporation (2015); EPA-HQ-OPPT-2018-0434-0014
	Adhesives and Sealants	Adhesives and Sealants	U.S. EPA (2019b); ITW Performance Polymers (2015)
	Other	Consumer articles that contain di-isobutyl phthalate from: - Inks, toner and colorants - Paints and coatings - Adhesives and sealants (*e.g.*, paper products) [g]	CPSC (2015a)
Disposal	Disposal	Disposal	

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 di-isobutyl phthalate in industrial and/or commercial settings.

c. These subcategories reflect more specific conditions of use of di-isobutyl phthalate.

d. In the draft scope of the risk evaluation, a condition of use was included for both industrial and commercial uses for di-isobutyl phthalate in food packaging material. EPA has determined that the use of di-isobutyl phthalate in food packaging material falls outside TSCA's definition of a "chemical substance." (See Section 2.2.2 for more information).

e. In the final scope, EPA removed commercial use of lubricants based on additional stakeholder outreach with a trade association (EPA-HQ-OPPT-2018-0434-0021) and insufficient information indicating that these uses are not intended, known, or reasonably foreseen.

f. In the final scope, EPA revised and removed processing- incorporation into formulation, mixture, or reaction product as well as industrial and consumer uses of paper products based on additional stakeholder outreach with a trade association (EPA-HQ-OPPT-2018-0434-0042) and further research.

Life-Cycle Stage [a]	Category [b]	Subcategory [c]	References
g. In the final scope, EPA added consumer use – other – consumer articles that contain di-isobutyl phthalate from: inks, toner and colorants; paints and coatings; adhesives and sealants (*e.g.*, paper products) due to a recategorizing of conditions of use based on further outreach with a stakeholder trade association (EPA-HQ-OPPT-2018-0434-0042). h. In the proposed designation and draft scope documents, a condition of use was included for di-isobutyl phthalate for commercial use as a catalyst solvent. The industry that reported this use has removed this use from the 2012 reporting cycle. This condition of use has been removed in the final scope. i. In the final scope, EPA removed use under processing- incorporation into formulation, mixture, or reaction product- viscosity adjusters based on insufficient information indicating that these uses are not intended, known, or reasonably foreseen. j. In the final scope, EPA removed commercial and consumer uses in furnishing, cleaning, treatment/ care products based on insufficient information indicating that these uses are not intended, known, or reasonably foreseen. k. In the final scope, EPA removed commercial use in explosive materials based on insufficient information indicating that these uses are not intended, known, or reasonably foreseen.			

2.2.2 Activities Excluded from the Scope of the Risk Evaluation

As explained in the final rule for 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 33736, 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[5]. As a result, EPA does not plan to include in this scope or in the risk evaluation 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 di-isobutyl phthalate are non-TSCA uses:

[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 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)).

The U.S. Consumer Product Safety Commission lists use of di-isobutyl phthalate in food packaging materials (CPSC, 2015a). 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.

2.2.3 Production Volume

As reported to EPA during the 2016 CDR submission period and described here as a range to protect production volumes that were claimed as confidential business information (CBI), total production volume of di-isobutyl phthalate in 2015 was less than one million pounds. (U.S. EPA, 2020a). EPA also uses pre-2015 CDR production volume information, as detailed in the *Proposed Designation of Di-isobutyl Phthalate (DIBP) (CASRN 84-69-5) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019d) and will include more recent production volume information from the 2020 CDR reporting period in the risk evaluation to support the exposure assessment.

2.2.4 Overview of Conditions of Use and Lifecycle Diagram

Figure 2-11 provides the lifecycle diagram for di-isobutyl 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.

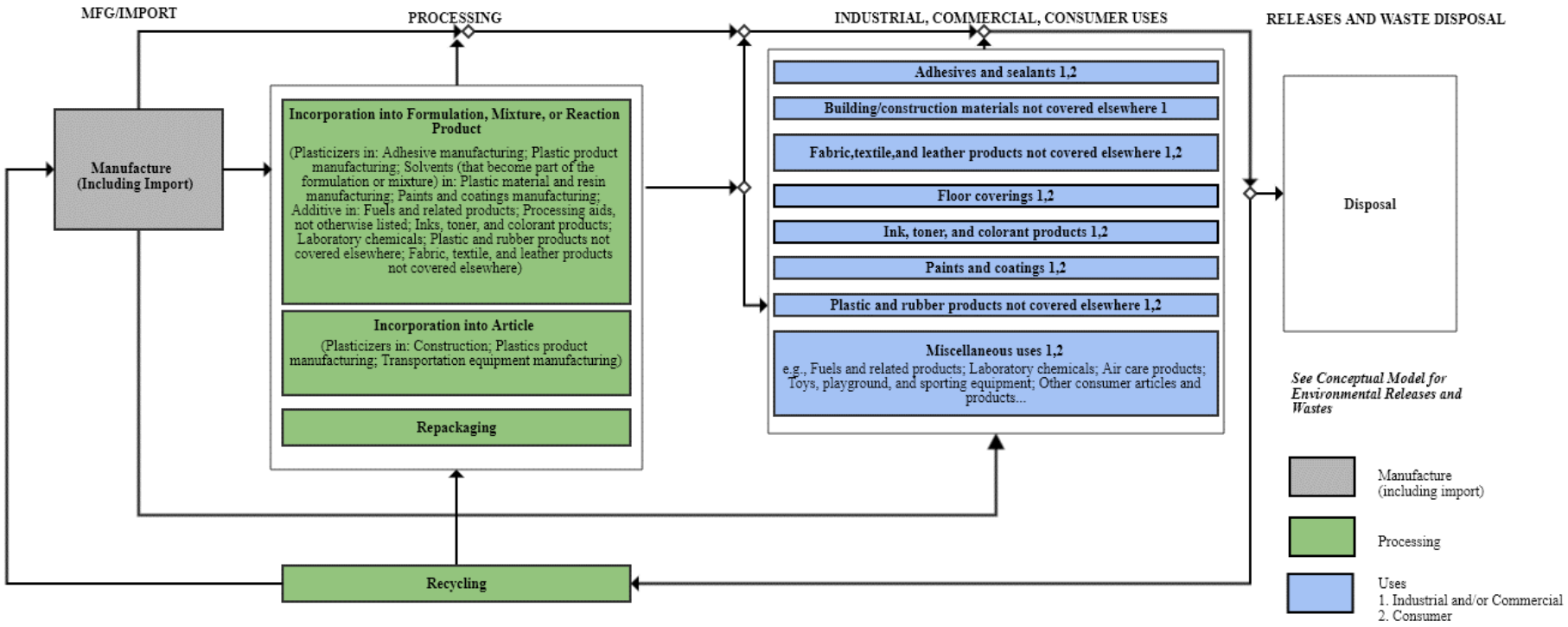


Figure 2-11. Di-isobutyl Phthalate Life Cycle Diagram

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 di-isobutyl 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 di-isobutyl 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 Di-isobutyl Phthalate (DIBP) (CASRN 84-69-5) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019d) 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-2018-0434).

Table 2-3. Physical and Chemical Properties of Di-isobutyl Phthalate

Property or Endpoint	Value[a]	Reference	Data Quality Rating
Molecular formula	$C_{16}H_{22}O_4$	NA	NA
Molecular weight	278.35 g/mol	NA	NA
Physical state	Liquid	NLM (2013)	High
Physical properties	Colorless	Elsevier (2019)	High
Melting point	-64°C	NLM (2013)	High
Boiling point	296.5°C	NLM (2013)	High
Density	1.036 - 1.0412 g/cm^3 at 20°C	Elsevier (2019)	High
Vapor pressure	4.76×10^{-5} mm Hg at 25°C	NLM (2013)	High
Vapor density	Not available		
Water solubility	6.2 mg/L at 24°C	NLM (2013)	High

Property or Endpoint	Value[a]	Reference	Data Quality Rating
Octanol/water partition coefficient (Log Kow)	4.34	Ishak et al. (2016)	High
Henry's Law constant	1.83×10^{-7} atm-m^3/mol	Elsevier (2019)	High
Flash point	169°C	RSC (2019)	Medium
Auto flammability	Not available		
Viscosity	41 cP at 20°C	NLM (2013)	High
Refractive index	1.4900	NLM (2013)	High
Dielectric constant	6.56	Elsevier (2019)	High

[a] Measured unless otherwise noted.

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.

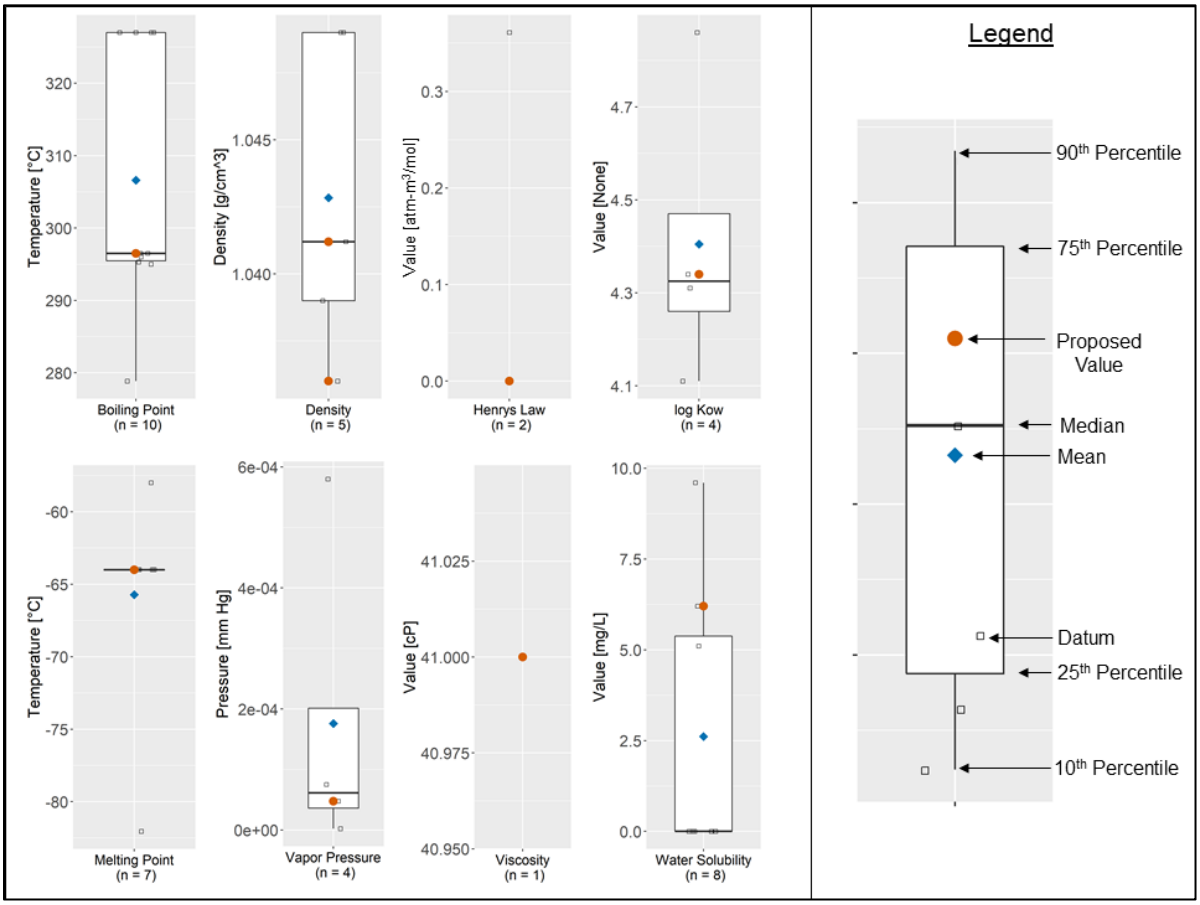


Figure 2-12. Box and Whisker Plots of Reported Physical and Chemical Property Values

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 di-isobutyl phthalate. EPA plans to use the environmental fate characteristics described in Appendix C to support the development of the risk evaluation for di-isobutyl 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.

Di-isobutyl phthalate is not reported to the Toxics Release Inventory (TRI). There may be releases of di-isobutyl phthalate from industrial sites to wastewater treatment plants (WWTP), surface water, air and landfill. Articles that contain di-isobutyl phthalate may release di-isobutyl phthalate to the environment during use or through recycling and disposal.

2.3.4 Environmental Exposures

The manufacturing, processing, distribution, use and disposal of di-isobutyl phthalate can result in releases to the environment and exposure to aquatic and terrestrial receptors (biota). Environmental exposures to biota are informed by releases into the environment, overall persistence, degradation, and bioaccumulation, and partitioning across different media. Concentrations of chemical substances in biota provide evidence of exposure.

Monitoring data were identified in the EPA's data search for di-isobutyl 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. Preliminary data review indicates evidence of available environmental monitoring data (MDI Biological Laboratory, 2002). EPA plans to review reasonably available environmental monitoring data for di-isobutyl 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 plans 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 di-isobutyl phthalate that EPA may analyze include, but are not limited to:

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

Di-isobutyl phthalate is a liquid at room temperature and has a vapor pressure of 4.76×10^{-5} mm Hg at 25 ºC (NLM, 2013) and inhalation exposure to vapor is expected to be low when working with di-isobutyl phthalate at room temperature. However, EPA plans to analyze inhalation exposure for workers and ONUs in occupational scenarios where di-isobutyl 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, di-isobutyl 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.

Occupational exposure limits have not been established for di-isobutyl phthalate by the Occupational Safety and Health Administration (OSHA), the National Institute for Occupational Safety and Health (NIOSH), or the American Conference of Governmental Industrial Hygienists (ACGIH).

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 dust 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 plans to 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.

2.3.6 Consumer Exposures

CDR reporting and conversations with industry indicate the presence of di-isobutyl phthalate in a number of consumer products and articles including: adhesives and sealants; air care products; fabric, textile, and leather products not covered elsewhere; floor coverings; ink, toner, and colorant products; other; 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 information on consumer conditions of use, inhalation of di-isobutyl phthalate is possible through either inhalation of vapor/mist during product usage or indoor air/dust. Oral exposure of di-isobutyl phthalate is possible through ingestion through product use via transfer from hand to mouth, through mouthing of articles containing di-isobutyl 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 di-isobutyl 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 di-isobutyl phthalate from certain conditions of use, such as manufacturing, processing, distribution, use, or disposal activities, may result in general population exposures via drinking water ingestion, dermal contact, and inhalation from air releases (CPSC, 2010). Available assessments reviewed indicate that diet has been reported as the primary source of exposure to di-isobutyl phthalate with indoor air also contributing to total di-isobutyl phthalate exposure (CPSC, 2014). There is some evidence of environmental concentration data present based on preliminary review of reasonably available data (MDI Biological Laboratory, 2002).

Available assessments reviewed indicate that diet has been reported as the primary source of exposure to di-isobutyl phthalate with indoor air also contributing to total di-isobutyl phthalate exposure (CPSC, 2014). In the United States, urinary di-isobutyl phthalate levels have increased over the past four

National Health and Nutrition Examination Survey (NHANES) surveys (2001–2002; 2003–2004; 2005–2006; 2007–2008) in all age groups, genders, and races, and in total (CPSC, 2014).

The presence in environmental media and biomonitoring data suggest that general population exposures are occurring. The general population pathways in the scope of this evaluation are described in Sections 2.6.3 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 di-isobutyl phthalate as well as public comments received on the *Proposed Designation of Di-isobutyl Phthalate (DIBP) (CASRN 84-69-5) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019d) and draft scope for di-isobutyl 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, developmental, endocrine, mortality, musculoskeletal, neurological and reproductive (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 di-isobutyl phthalate as well as public comments received on *Proposed Designation of Di-isobutyl Phthalate (DIBP) (CASRN 84-69-5) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019d) and draft scope for di-isobutyl 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 of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly." General population is "the total of individuals inhabiting an area or making up a whole group" and refers here to the U.S. general population (U.S. EPA, 2011a).

EPA identified the PESS based on CDR information, public comments received on the draft scope for di-isobutyl phthalate (Docket ID: EPA-HQ-OPPT-2018-0434) and studies reporting developmental and reproductive effects: children, women of reproductive age (*e.g.,* pregnant women), workers, including ONUs and users, and consumers (U.S. EPA, 2019a). 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 di-isobutyl 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 in the conceptual model shown in Section 2.6.3. Pathways and routes of exposure associated with environmental releases and wastes, excluding those pathways that are under the jurisdiction of other EPA-administered laws, are presented in the conceptual model shown in Section 2.6.3.

2.6.1 Conceptual Model for Industrial and Commercial Activities and Uses

There is potential for exposures to workers and ONUs via inhalation routes and exposures to workers via dermal routes. The conceptual model also includes potential worker and ONU dermal exposure to di-isobutyl 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 is presented in Appendix F.

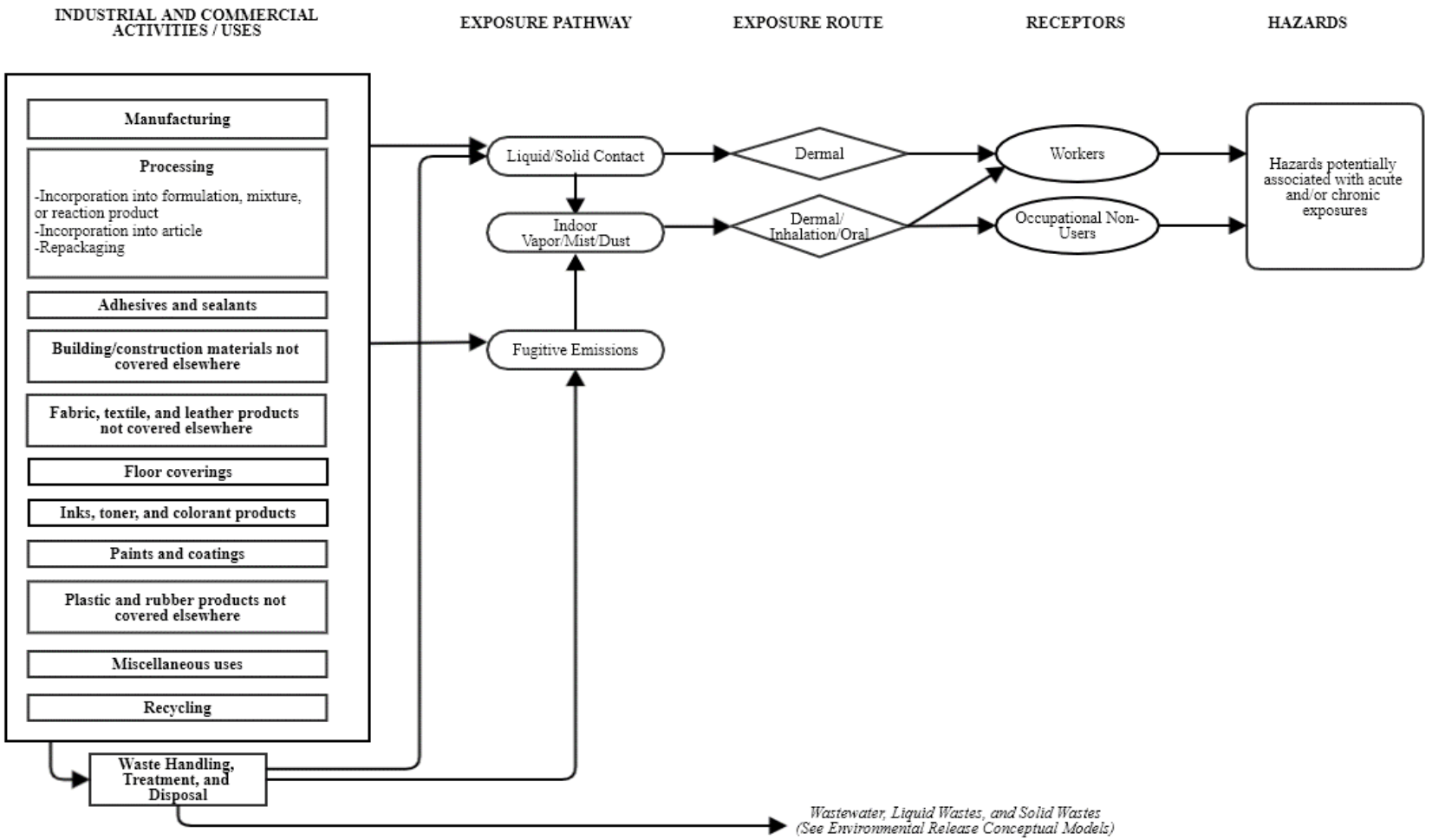


Figure 2-13. Di-isobutyl Phthalate Conceptual Model for Industrial and Commercial Activities and Uses: Worker and Occupational Non-User Exposures and Hazards

The conceptual model presents the exposure pathways, exposure routes, and hazards to human receptors from industrial and commercial activities and uses of di-isobutyl 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 di-isobutyl phthalate. EPA expects that consumers and bystanders may be exposed through product use or articles or via dust containing di-isobutyl 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 analyze pathways and routes of exposure that may occur during the varied identified consumer activities and uses. The supporting rationale for consumer pathways considered for di-isobutyl phthalate are included in Appendix G.

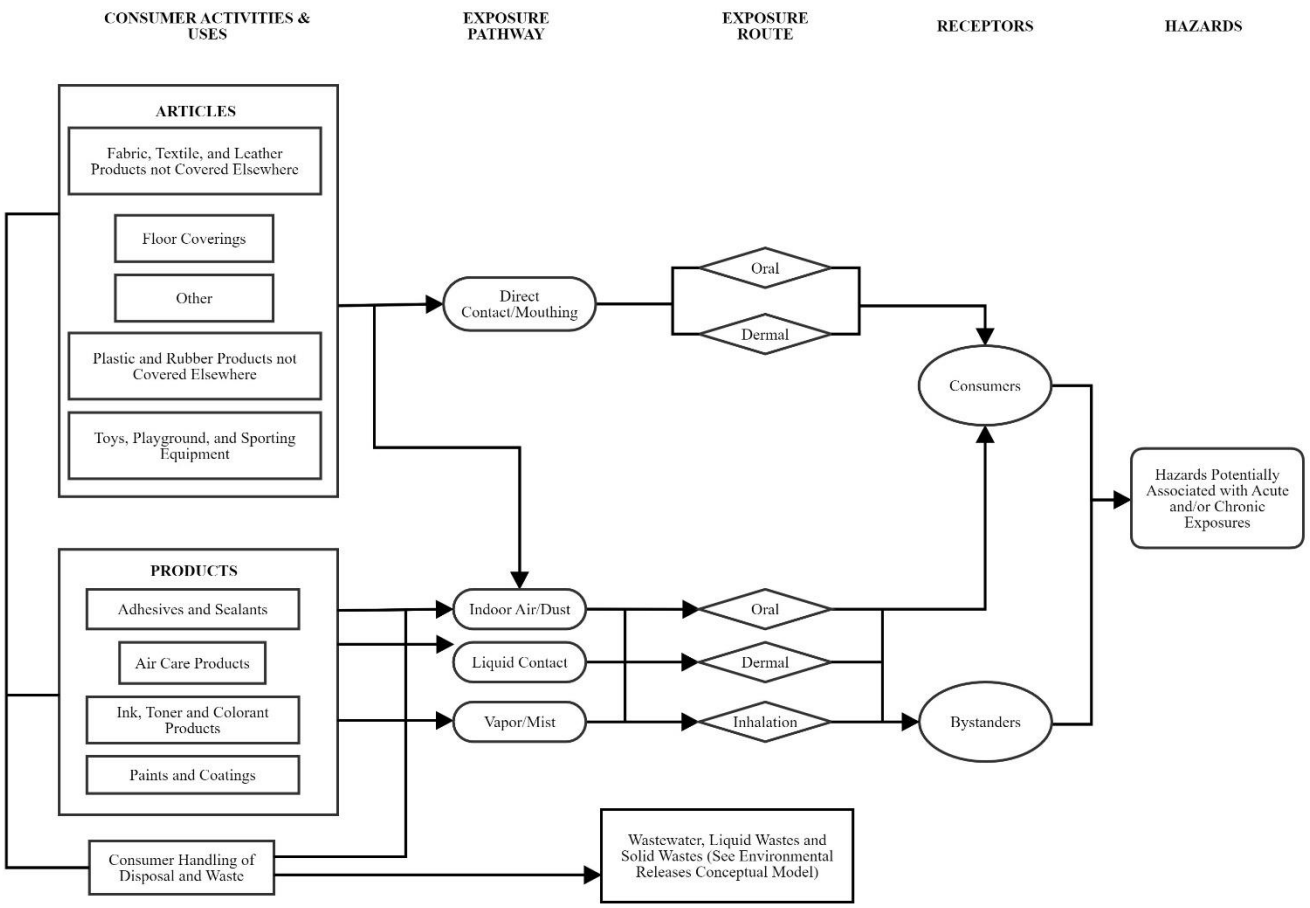


Figure 2-14. Di-isobutyl Phthalate Conceptual Model for Consumer Activities and Uses: Consumer Exposures and Hazards
The conceptual model presents the exposure pathways, exposure routes, and hazards to human receptors from consumer activities and uses of di-isobutyl phthalate.

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 di-isobutyl 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 exposure pathways, exposure routes and hazards to human and environmental receptors from releases and wastes from industrial, commercial and consumer uses of di-isobutyl phthalate that EPA plans to consider in the risk evaluation. There are no pathways covered under the jurisdiction of other EPA-administered laws. EPA expects humans to be exposed to di-isobutyl phthalate from air emissions via inhalation as well as from water, liquid, and solid waste releases and orally via drinking water, fish and soil ingestion, and dermally from contact with drinking water and soil. The supporting rationale for general population and environmental pathways considered for di-isobutyl phthalate are included in Appendix H.

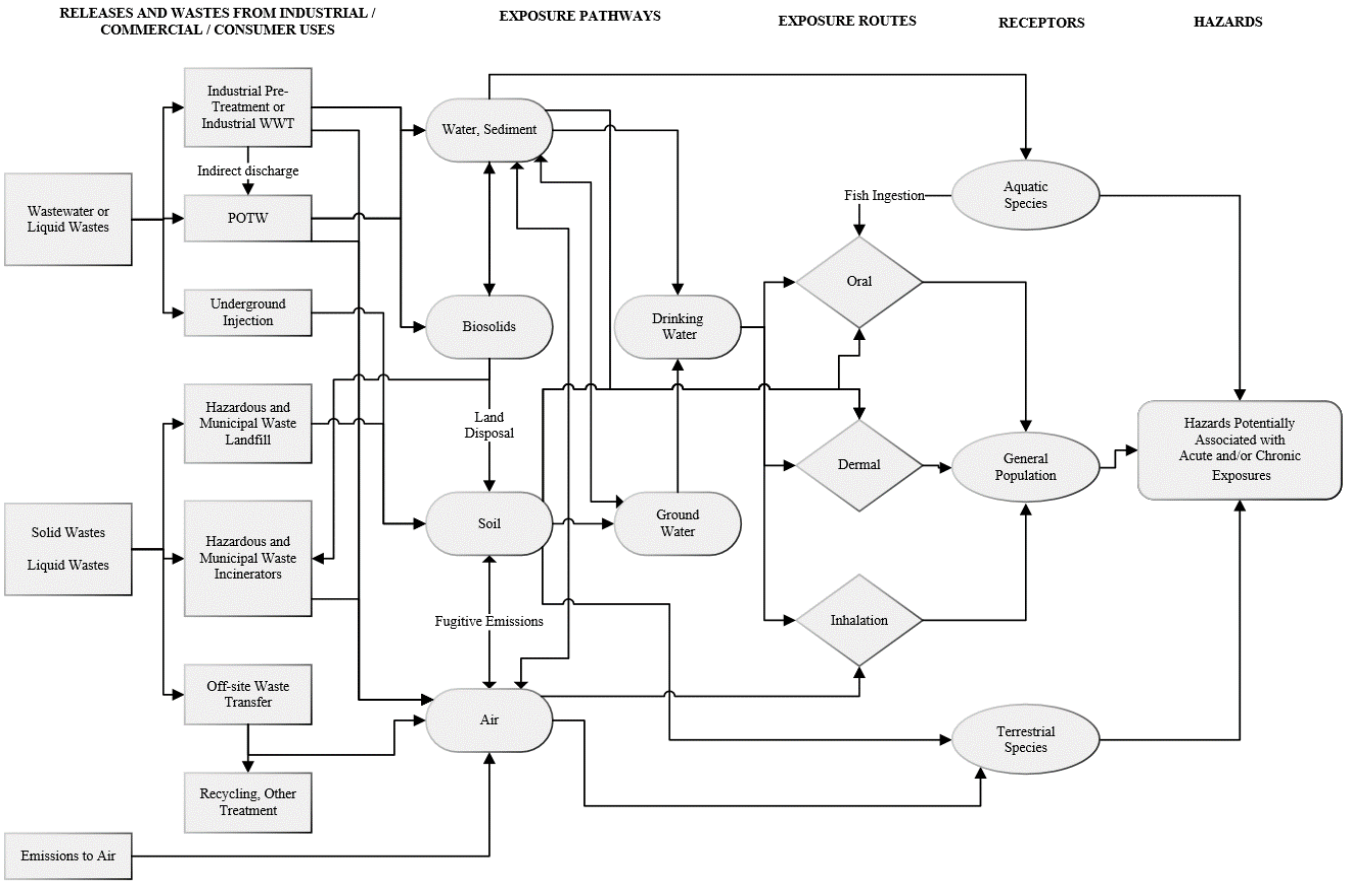


Figure 2-15. Di-isobutyl Phthalate Conceptual Model for Environmental Releases and Wastes: Environmental and General Population Exposures and Hazards.

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 Di-isobutyl 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 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).

2.7 Analysis Plan

The analysis plan is based on EPA's knowledge of di-isobutyl 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 to EPA's evaluation of 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, 2018), targeted supplemental searches during the analysis phase may be necessary to identify additional information (*e.g.,* commercial mixtures) for the risk evaluation of di-isobutyl 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 di-isobutyl phthalate as follows:

1) **Review reasonably available measured or estimated physical and chemical properties 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 (Docket ID: EPA-HQ-OPPT-2018-0434) about the physical and chemical properties (Appendix B) and fate endpoints (Appendix C), some of which appeared in the *Proposed Designation of Di-isobutyl Phthalate (DIBP) (CASRN 84-69-5) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019d). 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, 2018). 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 di-isobutyl phthalate within and across environmental media. The fate endpoints of interest include volatilization, sorption to organic matter in soil and sediments, water solubility, aqueous and atmospheric photolysis rates, aerobic and anaerobic biodegradation rates, and potential bioconcentration and bioaccumulation. These endpoints will be used in exposure calculations.

3) **Conduct a weight of the scientific evidence evaluation of physical and chemical properties 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, 2018).

2.7.2 Exposure

EPA plans to analyze exposure levels for indoor air, ambient air, surface water, drinking water, groundwater, sediment, soil, biosolids, fish ingestion aquatic biota, and terrestrial biota associated with exposure to di-isobutyl phthalate. Based on its physical and chemical properties, expected sources, and transport and transformation within the outdoor and indoor environment, di-isobutyl 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 combinations of sources (uses), exposure pathways, and exposed receptors. Draft exposure scenarios corresponding to various conditions of use for di-isobutyl 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 2-4 below:

   Table 2-4. Categories and Sources of Environmental Release Data

U.S. EPA Generic Scenarios
OECD Emission Scenario Documents

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 plans to consider additional reasonably available information and will evaluate it during development of the draft risk evaluation. EPA plans to match identified data to applicable conditions of use and identify data gaps where no data are found for particular conditions of use. EPA plans to attempt to address data gaps identified as described in steps 3 and 4 below by considering potential surrogate data and models.

   Additionally, for conditions of use where no measured data on releases are 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 to release estimation. EPA plans to further consider relevant regulatory requirements in estimating releases during risk evaluation.

5) **Review and determine applicability of OECD Emission Scenario Documents (ESDs) and EPA Generic Scenarios to estimation of environmental releases.**
EPA has identified potentially relevant OECD Emission Scenario Documents (ESDs) and EPA Generic Scenarios (GS) that correspond to some conditions of use; for example, the 2009 ESD on Adhesive 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 2009 ESD on Plastic Additives (OECD, 2009b), 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/chemsteer-chemical-screening-tool-exposures-and-environmental-releases#genericscenarios

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 Evaluations* (U.S. EPA, 2018). 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 di-isobutyl phthalate:

1) **Review reasonably available environmental and biological monitoring data for all media relevant to environmental exposure.** For di-isobutyl phthalate, environmental media which EPA plans to analyze are sediment, soil, biosolids, air, drinking water, 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 consider reasonably available environmental exposure models that meet the scientific standards under TSCA Section 26(h) and that estimate air, surface water, groundwater, sediment, biosolids, and soil concentrations alongside reasonably available air, surface water, groundwater, sediment, and soil monitoring data to characterize environmental exposures. Modeling approaches to estimate air concentrations, surface water concentrations, sediment concentrations. biosolids concentrations, and soil concentrations consider the following inputs: direct release into air, groundwater, surface water, sediment, or soil, indirect release into air, groundwater, surface water, sediment, or soil *(i.e.*, air deposition), fate and transport (partitioning within media) and characteristics of the environment (*e.g.*, river flow, volume of lake, meteorological data).

3) **Determine applicability of existing additional contextualizing information for any monitored data or modeled estimates during risk evaluation.**
Any studies which relate levels of di-isobutyl 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 di-isobutyl phthalate, the following are noteworthy considerations in constructing exposure scenarios for environmental receptors:

    - Estimates of surface water concentrations, sediment concentrations and soil concentrations near industrial point sources based on reasonably available monitoring data.
    - Consider the following modeling inputs: release into the media of interest, fate and transport and characteristics of the environment.

- Reasonably available biomonitoring data. Monitoring data could be used to compare with species or taxa-specific toxicological benchmarks.
- Applicability of existing additional contextualizing information for any monitored data or modeled estimates during risk evaluation. Review and characterize the spatial and temporal variability, to the extent that data are reasonably available, and characterize exposed aquatic and terrestrial populations.
- Weight of the scientific evidence of environmental occurrence data and modeled estimates.

5) **Evaluate the weight of the scientific evidence of environmental occurrence data and modeled estimates.** During risk evaluation, EPA plans to evaluate and integrate the exposure evidence identified in the literature inventory using the methods described in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018).

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 monitoring data found in published literature (including both personal exposure monitoring data (direct exposures) and area monitoring data (indirect exposures)). EPA has searched for reasonably available monitoring data collected by OSHA and NIOSH and neither collected data for di-isobutyl phthalate exposures.

   The most recent submissions to CDR for di-isobutyl phthalate will be used to identify manufacturing and processing information for di-isobutyl phthalate where occupational exposure may occur. CDR may also identify potential uses of di-isobutyl phthalate that would indicate occupational exposure. Additionally, systematic review will identify published reports containing worker exposure monitoring data that will inform the occupational exposure assessment of di-isobutyl phthalate. EPA plans to continue to review data sources identified in Appendix A for di-isobutyl phthalate using systematic review evaluation strategies for environmental releases and occupational exposure data sources.

2) **Review reasonably available exposure data for surrogate chemicals that have uses, volatility and physical and chemical properties similar to di-isobutyl 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 di-isobutyl phthalate may serve as surrogates for di-isobutyl 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. EPA may conduct industry outreach or perform additional supplemental 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 Evaluations* (U.S. EPA, 2018). 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 di-isobutyl 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 di-isobutyl 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 di-isobutyl 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 also available. These models generally consider indoor fate and transport properties such as 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 di-isobutyl 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 di-isobutyl 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 di-isobutyl phthalate in specific media (*e.g.,* indoor dust, indoor air).**
The availability of di-isobutyl phthalate concentration for various conditions of use 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 refined.**
For di-isobutyl 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 use, exposure pathways, and routes.** For di-isobutyl 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 di-isobutyl phthalate, media where exposure models will be considered for general population exposure include models that estimate ambient air concentrations, surface water concentrations, drinking water concentrations, sediment concentrations, soil concentrations, and uptake from aquatic and terrestrial environments into edible aquatic and terrestrial organisms.

3) **Review reasonably available exposure modeled estimates. For example, existing models developed for a previous di-isobutyl 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 di-isobutyl 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 may change over time. Any modeled concentrations based on recent release estimates will be 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 di-isobutyl phthalate, exposure scenarios that involve PESS will consider age-specific behaviors, activity patterns, and exposure factors unique to those subpopulations. For example, children will have different intake rates for soil than adults.

6) **Evaluate the weight of the scientific evidence of general population exposure estimates based on different approaches.**
During risk evaluation, EPA plans to evaluate and integrate the exposure evidence identified in the literature inventory using the methods described in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018).

2.7.3 Hazards (Effects)

2.7.3.1 Environmental Hazards

EPA plans to conduct an environmental hazard assessment of di-isobutyl 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 di-isobutyl phthalate to aquatic and terrestrial organisms, including plants, invertebrates (*e.g.*, insects, arachnids, mollusks, crustaceans), and vertebrates (*e.g.*, mammals, birds, amphibians, fish, reptiles) across exposure durations and conditions if potential environmental hazards are identified through systematic review results and public comments. Additional types of environmental hazard information will also be considered (*e.g.*, analogue and read-across data) when characterizing the potential hazards of di-isobutyl phthalate to aquatic and terrestrial 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, 2018). 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 and terrestrial organisms.**
Depending on the robustness of the evaluated data for a particular organism or taxa (*e.g.*, aquatic invertebrates), environmental hazard values (*e.g.*, EC_x, LC_x, NOEC, LOEC) may be derived and used to further understand the hazard characteristics of di-isobutyl phthalate to aquatic and terrestrial species. Identified environmental hazard thresholds may be used to derive concentrations of concern (COC), based on endpoints that may affect populations of organisms or taxa analyzed.

3) **Evaluate the weight of 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 Evaluations* (U.S. EPA, 2018).

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

5) **Consider a persistent, bioaccumulative, and toxic (PBT) assessment of di-isobutyl phthalate.**
EPA plans to consider the persistence, bioaccumulation, and toxic (PBT) potential of di-isobutyl phthalate after reviewing relevant physical and chemical properties and exposure pathways. EPA plans to assess the reasonably available studies collected from the systematic review process relating to bioaccumulation and bioconcentration (*e.g.*, BAF, BCF) of di-isobutyl 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 di-isobutyl phthalate with the fate parameters (*e.g.*, BAF, BCF, BMF, TMF).

6) **Conduct an environmental risk estimation and characterization of di-isobutyl phthalate.**
EPA plans to conduct a risk estimation and characterization of di-isobutyl phthalate to identify if there are risks to the aquatic and terrestrial environments from the measured and/or predicted concentrations of di-isobutyl phthalate in environmental media (*e.g.*, water, sediment, soil). Risk quotients (RQs) may be derived by the application of hazard and exposure benchmarks to characterize environmental risk (U.S. EPA, 1998; Barnthouse et al., 1982). 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, 2018) 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 di-isobutyl phthalate hazard(s). Susceptibility of particular human receptor groups to di-isobutyl phthalate will be determined by evaluating information on factors that influence susceptibility.

EPA has reviewed some sources containing hazard information associated with susceptible populations and lifestages such as pregnant women and infants. Pregnancy (*i.e.*, gestation) and childhood are potential susceptible lifestages for di-isobutyl 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 Evaluations* (U.S. EPA, 2018). 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 di-isobutyl 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 di-isobutyl 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 Evaluations* (U.S. EPA, 2018).

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 di-isobutyl 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, 2020e) and carbon tetrachloride (U.S. EPA, 2020b).

7) **Conduct a human health risk estimation and characterization of di-isobutyl 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 along with their 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). 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 non-risk 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 di-isobutyl phthalate will be peer reviewed.

REFERENCES

Azon USA Inc. (2015). Azo-Grout 443 Safety Data Sheet. https://azonintl.com/wp-content/uploads/2015/06/Azo-Grout-443-Rev.-1.1-42015.pdf

Barnthouse, LW; DeAngelis, DL; Gardner, RH; O'Neill, RV; Suter, GW; Vaughan, DS. (1982). Methodology for environmental risk analysis. (ORNL/TM-8167). Oak Ridge, TN: Oak Ridge National Laboratory.

Cadogan, DF; Howick, CJ. (2000). Plasticizers [Type of Work]. https://onlinelibrary.wiley.com/doi/abs/10.1002/0471238961.1612011903010415.a01

Cherrie, JW; Semple, S; Christopher, Y; Saleem, A; Hughson, GW; Philips, A. (2006). How important is inadvertent ingestion of hazardous substances at work? Ann Occup Hyg 50: 693-704. http://dx.doi.org/10.1093/annhyg/mel035

CPSC (U.S. Consumer Product Safety Commission). (2010). Toxicity Review for Diisobutyl phthalate (DIBP). Bethesda, MD. http://www.cpsc.gov/PageFiles/125773/dibp.pdf

CPSC (U.S. Consumer Product Safety Commission). (2014). Chronic hazard advisory panel on phthalates and phthalate alternatives. Bethesda, Maryland: U.S. Consumer Product Safety Commission, Directorate for Health Sciences. https://web.archive.org/web/20170202160318/https://www.cpsc.gov/s3fs-public/CHAP-REPORT-With-Appendices.pdf

CPSC (U.S. Consumer Product Safety Commission). (2015a). Exposure assessment: Composition, production, and use of phthalates. Cincinnati, OH: Prepared by: Toxicology Excellence for Risk Assessment Center at the University of Cincinnati. https://web.archive.org/web/20190320060357/https://www.cpsc.gov/s3fs-public/pdfs/TERAReportPhthalates.pdf

CPSC (U.S. Consumer Product Safety Commission). (2015b). Exposure assessment: Potential for the presence of phthalates in selected plastics. . Cincinnati, OH: Prepared by: Toxicology Excellence for Risk Assessment Center at the University of Cincinnati. https://web.archive.org/web/20190320060355/https://www.cpsc.gov/s3fs-public/pdfs/ReportonPhthalatesinFourPlastics.pdf

Dow Chemical Company. (2013). ICOPOR I-105 (P) Black Pigment Paste Product Safety Assessment. http://msdssearch.dow.com/PublishedLiteratureDOWCOM/dh_08d7/0901b803808d77a8.pdf?filepath=productsafety/pdfs/noreg/233-01019.pdf&fromPage=GetDoc

ECHA (European Chemicals Agency). (2019). Registration dossier: Diisobutyl phthalate (CASRN 84-69-5). Helsinki, Finland. https://echa.europa.eu/registration-dossier/-/registered-dossier/13519/7/1

Elsevier. (2019). Reaxys: physical-chemical property data for Di(2-ethylhexyl) phthalate. CAS Registry Number: 117-81-7 [Website].

Glue 360 Inc. (2018). Glue 360 2-Componenet Solid Surfacing Adhesive (10:1 Ratio) - All Colors Safety Data Sheet. https://domainindustries.com/media/PDF/SDS%20GLUE%20360%202-Component%20Solid%20Surfacing%20Adhesive.pdf

Hattori, Y; Kuge, Y; Nakagawa, S. (1975). Microbial decomposition of phthalate esters in environmental water (pp. 951-954). Osaka Prefecture, Japan: Environmental Pollution Control Center, Mizu Shori Gijutsu.

Howard, BE; Phillips, J; Miller, K; Tandon, A; Mav, D; Shah, MR; Holmgren, S; Pelch, KE; Walker, V; Rooney, AA; Macleod, M; Shah, RR; Thayer, K. (2016). SWIFT-Review: a text-mining workbench for systematic review. Syst Rev 5: 87. http://dx.doi.org/10.1186/s13643-016-0263-z

Ishak, H; Stephan, J; Karam, R; Goutaudier, C; Mokbel, I; Saliba, C; Saab, J. (2016). Aqueous solubility, vapor pressure and octanol-water partition coefficient of two phthalate isomers dibutyl phthalate and di-isobutyl phthalate contaminants of recycled food packages. Fluid Phase Equilibria 427: 362-370. http://dx.doi.org/10.1016/j.fluid.2016.07.018

ITW Performance Polymers. (2015). MA 685 50 ml 10:1 Cartridge Safety Data Sheet. https://static.rshughes.com/wm/p/wm-asis/7e417bc0534b68c6d2f2daede0787f5e72a88e22.pdf?uf=

Lanxess Corporation. (2015). Product Safety Assessment: Diisobutyl phthalate. http://lanxess4you.com/psra/summaries/Diisobutyl%20phthalate.pdf

Madsen, T; Rasmussen, HB; Nilsson, L. (1995). Anaerobic biodegradation potentials in digested sludge, a freshwater swamp and a marine sediment. Chemosphere 31: 4243-4258. http://dx.doi.org/10.1016/0045-6535(95)00300-W

MDI Biological Laboratory. (2002). Comparitive Toxicogenomics Database [Database]. http://ctdbase.org

NLM (U.S. National Library of Medicine). (2013). PubChem: Hazardous Substance Data Bank: Diisobutyl phthalate, 84-69-5. Available online at https://pubchem.ncbi.nlm.nih.gov/compound/6782#source=HSDB

OECD (Organisation for Economic Co-operation and Development). (2009a). Emission scenario document on adhesive formulation. (JT03263583). Paris, France.

OECD (Organisation for Economic Co-operation and Development). (2009b). Emission scenario document on plastic additives. Paris: OECD Environmental Health and Safety Publications. http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2004)8/rev1&doclanguage=en

OECD (Organisation for Economic Co-operation and Development). (2010). Emission scenario document on formulation of radiation curable coatings, inks and adhesives. Paris, France: OECD Environmental Health and Safety Publications. http://www.oecd-ilibrary.org/docserver/download/9714171e.pdf?expires=1497031714&id=id&accname=guest&checksum=E5B188BBD13C6D7100D39B8643ABA020

OECD (Organisation for Economic Co-operation and Development). (2011a). Emission scenario document on coating application via spray-painting in the automotive refinishing industry. In OECD Series on Emission Scenario Documents No 11. (ENV/JM/MONO(2004)22/REV1). Paris, France: Organization for Economic Co-operation and Development. http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2004)22/rev1&doclanguage=en

OECD (Organisation for Economic Co-operation and Development). (2011b). Emission scenario document on radiation curable coating, inks and adhesives. Paris: OECD Environmental Health and Safety Publications. http://www.oecd-ilibrary.org/docserver/download/9714111e.pdf?expires=1497031939&id=id&accname=guest&checksum=C794B2987D98D1D145225EAF9B482280

OECD (Organisation for Economic Co-operation and Development). (2011c). Emission Scenario Document on the Chemical Industry. (30). http://www.oecd.org/env/ehs/risk-assessment/48774702.pdf

OECD (Organisation for Economic Co-operation and Development). (2015). Emission scenario document on use of adhesives. In Series on Emission Scenario Documents No 34. (Number 34). Paris, France. http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/JM/MONO(2015)4&doclanguage=en

OECD (Organization for Economic Co-operation and Development). (2019). Emission scenario documents [Website]. http://www.oecd.org/env/ehs/risk-assessment/emissionscenariodocuments.htm

RSC (Royal Society of Chemistry). (2019). ChemSpider: Diisobutyl phthalate. Available online at http://www.chemspider.com/Chemical-Structure.6524.html?rid=9f7ae5a5-b027-4789-be5c-adb367568a72

Sabljic, A; Gusten, H; Verhaar, H; Hermens, J. (1995). QSAR modelling of soil sorption. Improvements and systematics of log Koc vs. log Kow correlations. Chemosphere 32: 4489-4514.

Sedykh, A; Klopman, G. (2007). Data analysis and alternative modelling of MITI-I aerobic biodegradation. SAR QSAR Environ Res 18: 693-709.

Sigma Aldrich. (2020). Diisobutyl phthalate safety data sheet. https://www.sigmaaldrich.com/MSDS/retriever.do?country=US&language=EN&productNumber=152641&brand=ALDRICH

Tomer, A; Kane, J. (2015). The great port mismatch. U.S. goods trade and international transportation. The Global Cities Initiative. A joint project of Brookings and JPMorgan Chase. https://www.brookings.edu/wp-content/uploads/2015/06/brgkssrvygcifreightnetworks.pdf

U.S. EPA (U.S. Environmental Protection Agency). (1994). Methods for derivation of inhalation reference concentrations and application of inhalation dosimetry [EPA Report]. (EPA/600/8-90/066F). Research Triangle Park, NC: U.S. Environmental Protection Agency, Office of Research and Development, Office of Health and Environmental Assessment, Environmental Criteria and Assessment Office. https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=71993&CFID=51174829&CFTOKEN=25006317

U.S. EPA (U.S. Environmental Protection Agency). (1998). Guidelines for ecological risk assessment [EPA Report]. (EPA/630/R-95/002F). Washington, DC: U.S. Environmental Protection Agency, Risk Assessment Forum. https://www.epa.gov/risk/guidelines-ecological-risk-assessment

U.S. EPA (U.S. Environmental Protection Agency). (2000). Science policy council handbook: Risk characterization handbook. (EPA/100/B-00/002). Washington, DC: U.S. Environmental Protection Agency, Science Policy Council. https://www.epa.gov/risk/risk-characterization-handbook

U.S. EPA (U.S. Environmental Protection Agency). (2002). Guidelines for ensuring and maximizing the quality, objectivity, utility, and integrity of information disseminated by the Environmental Protection Agency. (EPA/260/R-02/008). Washington, DC: U.S. Environmental Protection Agency, Office of Environmental Information. https://www.epa.gov/sites/production/files/2017-03/documents/epa-info-quality-guidelines.pdf

U.S. EPA (U.S. Environmental Protection Agency). (2004). Risk Assessment Guidance for Superfund (RAGS), Volume I: Human health evaluation manual, (Part E: Supplemental guidance for dermal risk assessment). (EPA/540/R/99/005). Washington, DC: U.S. Environmental Protection Agency, Risk Assessment Forum. http://www.epa.gov/oswer/riskassessment/ragse/index.htm

U.S. EPA (U.S. Environmental Protection Agency). (2005a). Guidelines for carcinogen risk assessment [EPA Report]. (EPA/630/P-03/001B). Washington, DC: U.S. Environmental Protection Agency, Risk Assessment Forum. https://www.epa.gov/sites/production/files/2013-09/documents/cancer_guidelines_final_3-25-05.pdf

U.S. EPA (U.S. Environmental Protection Agency). (2005b). Supplemental guidance for assessing susceptibility from early-life exposure to carcinogens [EPA Report]. (EPA/630/R-03/003F). Washington, DC: U.S. Environmental Protection Agency, Risk Assessment Forum. https://www3.epa.gov/airtoxics/childrens_supplement_final.pdf

U.S. EPA. (U.S. Environmental Protection Agency). (2006a). Approaches for the application of physiologically based pharmacokinetic (PBPK) models and supporting data in risk assessment (Final Report) [EPA Report] (pp. 1-123). (EPA/600/R-05/043F). Washington, DC: U.S. Environmental Protection Agency, Office of Research and Development, National Center for Environmental Assessment. http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=157668

U.S. EPA (U.S. Environmental Protection Agency). (2006b). A framework for assessing health risk of environmental exposures to children (pp. 1-145). (EPA/600/R-05/093F). Washington, DC: U.S. Environmental Protection Agency, Office of Research and Development, National Center for Environmental Assessment. http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=158363

U.S. EPA (U.S. Environmental Protection Agency). (2010). Draft generic scenario on manufacture and use of printing inks. https://www.epa.gov/tsca-screening-tools/chemsteer-chemical-screening-tool-exposures-and-environmental-releases#genericscenarios

U.S. EPA (U.S. Environmental Protection Agency). (2011a). Exposure factors handbook: 2011 edition [EPA Report]. (EPA/600/R-090/052F). Washington, DC. http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=236252

U.S. EPA (U.S. Environmental Protection Agency). (2011b). Recommended use of body weight 3/4 as the default method in derivation of the oral reference dose (pp. 1-50). (EPA/100/R-11/0001). Washington, DC: U.S. Environmental Protection Agency, Risk Assessment Forum, Office of the Science Advisor. https://www.epa.gov/sites/production/files/2013-09/documents/recommended-use-of-bw34.pdf

U.S. EPA (U.S. Environmental Protection Agency). (2012a). Benchmark dose technical guidance. (EPA/100/R-12/001). Washington, DC: U.S. Environmental Protection Agency, Risk Assessment Forum. https://www.epa.gov/risk/benchmark-dose-technical-guidance

U.S. EPA (U.S. Environmental Protection Agency). (2012b). PhysProp database. Estimation Programs Interface Suite for Microsoft Windows, v 4.11: (CAS RN: 84-69-5) [Fact Sheet]. Washington, DC. https://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface

U.S. EPA (U.S. Environmental Protection Agency). (2015a). ChemSTEER user guide - Chemical screening tool for exposures and environmental releases. Washington, DC. https://www.epa.gov/sites/production/files/2015-05/documents/user_guide.pdf

U.S. EPA (U.S. Environmental Protection Agency). (2015b). Peer review handbook [EPA Report] (4th ed.). (EPA/100/B-15/001). Washington, DC: U.S. Environmental Protection Agency, Science Policy Council. https://www.epa.gov/osa/peer-review-handbook-4th-edition-2015

U.S. EPA (U.S. Environmental Protection Agency). (2018). Application of systematic review in TSCA risk evaluations. (740-P1-8001). Washington, DC: U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention. https://www.epa.gov/sites/production/files/2018-06/documents/final_application_of_sr_in_tsca_05-31-18.pdf

U.S. EPA (U.S. Environmental Protection Agency). (2019a). Chemical data reporting (2012 and 2016 CBI CDR database). U.S. Environmental Protection Agency, Office of Pollution Prevention and Toxics.

U.S. EPA (U.S. Environmental Protection Agency). (2019b). Chemical data reporting (2012 and 2016 Public CDR database) [Database]. Washington, DC: U.S. Environmental Protection Agency, Office of Pollution Prevention and Toxics. http://www.epa.gov/cdr/

U.S. EPA. (U.S. Environmental Protection Agency). (2019c). CPCat: Chemical and Product Categories. https://actor.epa.gov/cpcat/faces/home.xhtml

U.S. EPA (U.S. Environmental Protection Agency). (2019d). Proposed designation of di-isobutyl phthalate (DIBP) (CASRN 84-69-5) as high-priority substance for risk evaluation. Washington,

DC: U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention. https://www.epa.gov/sites/production/files/2019-08/documents/diisobutylphthalate_84-69-5_high-priority_proposeddesignation_082319_0.pdf

U.S. EPA (U.S. Environmental Protection Agency). (2020a). Chemical data reporting (2012 and 2016 Public CDR database). Washington, DC: U.S. Environmental Protection Agency, Office of Pollution Prevention and Toxics. ChemView: July 2020. https://chemview.epa.gov/chemview

U.S. EPA. (U.S. Environmental Protection Agency). (2020b). Draft risk evaluation for carbon tetrachloride (methane, tetrachloro-); CASRN: 56-23-5 (pp. 1-301). (EPA-740-R1-8014). Office of Chemical Safety and Pollution Prevention, U.S. Environmental Protection Agency. https://nepis.epa.gov/Exe/ZyPDF.cgi/P100YHUW.PDF?Dockey=P100YHUW.PDF

U.S. EPA. (U.S. Environmental Protection Agency). (2020c). Draft Scope of the Risk Evaluation for Di-isobutyl Phthalate (1,2-Benzenedicarboxylic acid, 1,2-bis(2-methylpropyl) ester) CASRN 84-69-5. (EPA-740-D-20-018). https://www.epa.gov/sites/production/files/2020-04/documents/casrn-84-69-5_diisobutyl_phthalate_draft_scope_4-15-2020.pdf

U.S. EPA (U.S. Environmental Protection Agency). (2020d). Generic scenarios documents for occupational exposure and release assessment. https://www.epa.gov/tsca-screening-tools/chemsteer-chemical-screening-tool-exposures-and-environmental-releases#genericscenarios

U.S. EPA. (U.S. Environmental Protection Agency). (2020e). Risk evaluation for methylene chloride (dichloromethane, dcm); CASRN: 75-09-2 (pp. 1-753). (EPA-740-R1-8010). Office of Chemical Safety and Pollution Prevention, U.S. Environmental Protection Agency. https://www.epa.gov/sites/production/files/2020-06/documents/1_mecl_risk_evaluation_final.pdf

Wolfe, NL; Steen, WC; Burns, LA. (1980). Phthalate ester hydrolysis: Linear free energy relationships. Chemosphere 9: 403-408.

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 di-isobutyl 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.[6] 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[7], 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.*, consumer, environmental, and general population exposure, occupational exposure and environmental releases, environmental hazards, human health hazards, and fate and physical chemistry).

[6]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.

[7] 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.

A.1.2.1 Query Strings for the Publicly-Available Database Searches on Di-isobutyl 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 di-isobutyl 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 Di-isobutyl Phthalate (DIBP) - (1,2-Benzene- dicarboxylic acid, 1,2-bis-(2methylpropyl) ester)

Source	Date of Search	Number of References
Current Contents	07/09/2019	2108
WOS Core Collection	09/11/2019	2707
ProQuest CSA	07/09/2019	3040
Dissertation Abstracts	07/11/2019	13
Science Direct	07/10/2019	1096
Agricola	07/11/2019	703
TOXNET	07/10/2019	211
PubMed	07/10/2019	1476
UNIFY	07/23/2019	28
Totals:		**11,382**

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 bis(2-methylpropyl) ester" OR "1,2-benzenedicarboxylic acid di(2-methylpropyl) ester" OR "1,2-Benzenedicarboxylic acid diisobutyl ester" OR "1,2-Benzenedicarboxylic acid, 1,2-bis(2-methylpropyl) ester" OR "1,2-Benzenedicarboxylic acid, 1,2-Dibutyl ester" OR "1,2-Benzenedicarboxylic acid, bis-(2-methoxypropyl)ester" OR "1,2-Benzenedicarboxylic acid, bis(2-methylpropyl) ester" OR "1,2-Benzenedicarboxylic acid, di(2-methylpropyl) ester" OR "1,2-Benzenedicarboxylic acid, dibutyl ester" OR "1,2-bis(2-methylpropyl) benzene-1,2-dicarboxylate" OR "Bis(2-methylpropyl) benzene-1,2-dicarboxylate" OR "Bis(2-methylpropyl) o-phthalate" OR "Bis(2-methylpropyl) phthalate" OR "BRN 2054802" OR "Di(2-methylpropyl) phthalate" OR "di(i-butyl)phthalate" OR "Di(isobutyl) 1,2-benzenedicarboxylate" OR "Di(isobutyl)-1,2-benzenedicarboxylate" OR "di-2-methylpropyl phthalate" OR "Dibutyl phthalate" OR "Dibutylphthalate" OR "Diisobutyl phthalate" OR "Di-isobutyl phthalate" OR "Di-iso-Butyl phthalate" OR "Diisobutylester kyseliny ftalove" OR "Diisobutylphthalat" OR "di-l-butyl phthalate" OR "EINECS 201-553-2" OR "Hatcol DIBP" OR "Hexaplas M/1B" OR "Isobutyl phthalate" OR "isobutyl-o-phthalate" OR "Kodaflex DIBP" OR "NSC 15316" OR "Palatinol IC" OR "PHTHALATE, DIISOBUTYL" OR "Phthalic acic, diisobutyl ester" OR "Phthalic acid, diisobutyl ester" OR "Reomol DiBP" OR "UNII-IZ67FTN290"

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: 07/09/2019
Date Range of Search: 1998 to Present
N = 2108

TS=("1,2-benzenedicarboxylic acid bis(2-methylpropyl) ester" OR "1,2-benzenedicarboxylic acid di(2-methylpropyl) ester" OR "1,2-Benzenedicarboxylic acid diisobutyl ester" OR "1,2-Benzenedicarboxylic acid, 1,2-bis(2-methylpropyl) ester" OR "1,2-Benzenedicarboxylic acid, 1,2-Dibutyl ester" OR "1,2-Benzenedicarboxylic acid, bis-(2-methoxypropyl)ester" OR "1,2-Benzenedicarboxylic acid, bis(2-methylpropyl) ester" OR "1,2-Benzenedicarboxylic acid, di(2-methylpropyl) ester" OR "1,2-Benzenedicarboxylic acid, dibutyl ester" OR "1,2-bis(2-methylpropyl) benzene-1,2-dicarboxylate" OR "Bis(2-methylpropyl) benzene-1,2-dicarboxylate" OR "Bis(2-methylpropyl) o-phthalate" OR "Bis(2-methylpropyl) phthalate" OR "BRN 2054802" OR "Di(2-methylpropyl) phthalate" OR "di(i-butyl)phthalate" OR "Di(isobutyl) 1,2-benzenedicarboxylate" OR "Di(isobutyl)-1,2-benzenedicarboxylate" OR "di-2-methylpropyl phthalate" OR "Dibutyl phthalate" OR "Dibutylphthalate" OR "Diisobutyl phthalate" OR "Di-isobutyl phthalate" OR "Di-iso-Butyl phthalate" OR "Diisobutylester kyseliny ftalove" OR "Diisobutylphthalat" OR "di-l-butyl phthalate" OR "EINECS 201-553-2" OR "Hatcol DIBP" OR "Hexaplas M/1B" OR "Isobutyl phthalate" OR "isobutyl-o-phthalate" OR "Kodaflex DIBP" OR "NSC 15316" OR "Palatinol IC" OR "PHTHALATE, DIISOBUTYL" OR "Phthalic acic, diisobutyl ester" OR "Phthalic acid, diisobutyl ester" OR "Reomol DiBP" OR "UNII-IZ67FTN290")
N = 2108

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: 09/11/2019
Date Range of Search: 1998 to Present
N = 2707

TS=("1,2-benzenedicarboxylic acid bis(2-methylpropyl) ester" OR "1,2-benzenedicarboxylic acid di(2-methylpropyl) ester" OR "1,2-Benzenedicarboxylic acid diisobutyl ester" OR "1,2-Benzenedicarboxylic acid, 1,2-bis(2-methylpropyl) ester" OR "1,2-Benzenedicarboxylic acid, 1,2-Dibutyl ester" OR "1,2-Benzenedicarboxylic acid, bis-(2-methoxypropyl)ester" OR "1,2-Benzenedicarboxylic acid, bis(2-methylpropyl) ester" OR "1,2-Benzenedicarboxylic acid, di(2-methylpropyl) ester" OR "1,2-Benzenedicarboxylic acid, dibutyl ester" OR "1,2-bis(2-methylpropyl) benzene-1,2-dicarboxylate" OR "Bis(2-methylpropyl) benzene-1,2-dicarboxylate" OR "Bis(2-methylpropyl) o-phthalate" OR "Bis(2-methylpropyl) phthalate" OR "BRN 2054802" OR "Di(2-methylpropyl) phthalate" OR "di(i-butyl)phthalate" OR "Di(isobutyl) 1,2-benzenedicarboxylate" OR "Di(isobutyl)-1,2-benzenedicarboxylate" OR "di-2-methylpropyl phthalate" OR "Dibutyl phthalate" OR "Dibutylphthalate" OR "Diisobutyl phthalate" OR "Di-isobutyl phthalate" OR "Di-iso-Butyl phthalate"

OR "Diisobutylester kyseliny ftalove" OR "Diisobutylphthalat" OR "di-l-butyl phthalate" OR "EINECS 201-553-2" OR "Hatcol DIBP" OR "Hexaplas M/1B" OR "Isobutyl phthalate" OR "isobutyl-o-phthalate" OR "Kodaflex DIBP" OR "NSC 15316" OR "Palatinol IC" OR "PHTHALATE, DIISOBUTYL" OR "Phthalic acic, diisobutyl ester" OR "Phthalic acid, diisobutyl ester" OR "Reomol DiBP" OR "UNII-IZ67FTN290")
N = 2707

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: 07/09/2019
Date Range of Search: 1900 to Present
N = 3040

ALL("1,2-benzenedicarboxylic acid bis(2-methylpropyl) ester" OR "1,2-benzenedicarboxylic acid di(2-methylpropyl) ester" OR "1,2-Benzenedicarboxylic acid diisobutyl ester" OR "1,2-Benzenedicarboxylic acid, 1,2-bis(2-methylpropyl) ester" OR "1,2-Benzenedicarboxylic acid, 1,2-Dibutyl ester" OR "1,2-Benzenedicarboxylic acid, bis-(2-methoxypropyl)ester" OR "1,2-Benzenedicarboxylic acid, bis(2-methylpropyl) ester" OR "1,2-Benzenedicarboxylic acid, di(2-methylpropyl) ester" OR "1,2-Benzenedicarboxylic acid, dibutyl ester" OR "1,2-bis(2-methylpropyl) benzene-1,2-dicarboxylate" OR "Bis(2-methylpropyl) benzene-1,2-dicarboxylate" OR "Bis(2-methylpropyl) o-phthalate" OR "Bis(2-methylpropyl) phthalate" OR "BRN 2054802" OR "Di(2-methylpropyl) phthalate" OR "di(i-butyl)phthalate" OR "Di(isobutyl) 1,2-benzenedicarboxylate" OR "Di(isobutyl)-1,2-benzenedicarboxylate" OR "di-2-methylpropyl phthalate" OR "Dibutyl phthalate" OR "Dibutylphthalate" OR "Diisobutyl phthalate" OR "Di-isobutyl phthalate" OR "Di-iso-Butyl phthalate" OR "Diisobutylester kyseliny ftalove" OR "Diisobutylphthalat" OR "di-l-butyl phthalate" OR "EINECS 201-553-2" OR "Hatcol DIBP" OR "Hexaplas M/1B" OR "Isobutyl phthalate" OR "isobutyl-o-phthalate" OR "Kodaflex DIBP" OR "NSC 15316" OR "Palatinol IC" OR "PHTHALATE, DIISOBUTYL" OR "Phthalic acic, diisobutyl ester" OR "Phthalic acid, diisobutyl ester" OR "Reomol DiBP" OR "UNII-IZ67FTN290") AND STYPE("Scholarly Journals" OR Reports OR Thesis OR "Government Documents") AND LA(ENG)
N = 3040

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 = 13

ALL("1,2-benzenedicarboxylic acid bis(2-methylpropyl) ester" OR "1,2-benzenedicarboxylic acid di(2-methylpropyl) ester" OR "1,2-Benzenedicarboxylic acid diisobutyl ester" OR "1,2-Benzenedicarboxylic

acid, 1,2-bis(2-methylpropyl) ester" OR "1,2-Benzenedicarboxylic acid, 1,2-Dibutyl ester" OR "1,2-Benzenedicarboxylic acid, bis-(2-methoxypropyl)ester" OR "1,2-Benzenedicarboxylic acid, bis(2-methylpropyl) ester" OR "1,2-Benzenedicarboxylic acid, di(2-methylpropyl) ester" OR "1,2-Benzenedicarboxylic acid, dibutyl ester" OR "1,2-bis(2-methylpropyl) benzene-1,2-dicarboxylate" OR "Bis(2-methylpropyl) benzene-1,2-dicarboxylate" OR "Bis(2-methylpropyl) o-phthalate" OR "Bis(2-methylpropyl) phthalate" OR "BRN 2054802" OR "Di(2-methylpropyl) phthalate" OR "di(i-butyl)phthalate" OR "Di(isobutyl) 1,2-benzenedicarboxylate" OR "Di(isobutyl)-1,2-benzenedicarboxylate" OR "di-2-methylpropyl phthalate" OR "Dibutyl phthalate" OR "Dibutylphthalate" OR "Diisobutyl phthalate" OR "Di-isobutyl phthalate" OR "Di-iso-Butyl phthalate" OR "Diisobutylester kyseliny ftalove" OR "Diisobutylphthalat" OR "di-l-butyl phthalate" OR "EINECS 201-553-2" OR "Hatcol DIBP" OR "Hexaplas M/1B" OR "Isobutyl phthalate" OR "isobutyl-o-phthalate" OR "Kodaflex DIBP" OR "NSC 15316" OR "Palatinol IC" OR "PHTHALATE, DIISOBUTYL" OR "Phthalic acic, diisobutyl ester" OR "Phthalic acid, diisobutyl ester" OR "Reomol DiBP" OR "UNII-IZ67FTN290") AND LA(ENG)
N = 13

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: 07/10/2019
Date Range of Search: 1823 to Present
N = 1096

Science Direct 01:
"1,2-benzenedicarboxylic acid bis(2-methylpropyl) ester" OR "1,2-benzenedicarboxylic acid di(2-methylpropyl) ester" OR "1,2-Benzenedicarboxylic acid diisobutyl ester" OR "1,2-Benzenedicarboxylic acid, 1,2-bis(2-methylpropyl) ester" OR "1,2-Benzenedicarboxylic acid, 1,2-Dibutyl ester" OR "1,2-Benzenedicarboxylic acid, bis-(2-methoxypropyl)ester" OR "1,2-Benzenedicarboxylic acid, bis(2-methylpropyl) ester" OR "1,2-Benzenedicarboxylic acid, di(2-methylpropyl) ester" OR "1,2-Benzenedicarboxylic acid, dibutyl ester"
N = 0

Science Direct 02:
"1,2-bis(2-methylpropyl) benzene-1,2-dicarboxylate" OR "Bis(2-methylpropyl) benzene-1,2-dicarboxylate" OR "Bis(2-methylpropyl) o-phthalate" OR "Bis(2-methylpropyl) phthalate" OR "BRN 2054802" OR "Di(2-methylpropyl) phthalate" OR "di(i-butyl)phthalate" OR "Di(isobutyl) 1,2-benzenedicarboxylate" OR "Di(isobutyl)-1,2-benzenedicarboxylate"
N = 0

Science Direct 03:
"di-2-methylpropyl phthalate" OR "Dibutyl phthalate" OR "Dibutylphthalate" OR "Diisobutyl phthalate" OR "Di-isobutyl phthalate" OR "Di-iso-Butyl phthalate" OR "Diisobutylester kyseliny ftalove" OR "Diisobutylphthalat" OR "di-l-butyl phthalate"
N = 992

Science Direct 04:
"EINECS 201-553-2" OR "Hatcol DIBP" OR "Hexaplas M/1B" OR "Isobutyl phthalate" OR "isobutyl-o-phthalate" OR "Kodaflex DIBP" OR "NSC 15316" OR "Palatinol IC" OR "PHTHALATE, DIISOBUTYL"
N = 104

Science Direct 05:
"Phthalic acic, diisobutyl ester" OR "Phthalic acid, diisobutyl ester" OR "Reomol DiBP" OR "UNII-IZ67FTN290"
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: 07/11/2019
Date Range of Search: 15th century to the Present
N = 703

Agricola 01:
1,2-benzenedicarboxylic acid bis(2-methylpropyl) ester
1,2-benzenedicarboxylic acid di(2-methylpropyl) ester
1,2-Benzenedicarboxylic acid diisobutyl ester
1,2-Benzenedicarboxylic acid, 1,2-bis(2-methylpropyl) ester
1,2-Benzenedicarboxylic acid, 1,2-Dibutyl ester
1,2-Benzenedicarboxylic acid, bis-(2-methoxypropyl)ester
1,2-Benzenedicarboxylic acid, bis(2-methylpropyl) ester
1,2-Benzenedicarboxylic acid, di(2-methylpropyl) ester
1,2-Benzenedicarboxylic acid, dibutyl ester
1,2-bis(2-methylpropyl) benzene-1,2-dicarboxylate
N = 0

Agricola 02:
Bis(2-methylpropyl) benzene-1,2-dicarboxylate
Bis(2-methylpropyl) o-phthalate
Bis(2-methylpropyl) phthalate
BRN 2054802
Di(2-methylpropyl) phthalate
di(i-butyl)phthalate
Di(isobutyl) 1,2-benzenedicarboxylate
Di(isobutyl)-1,2-benzenedicarboxylate
di-2-methylpropyl phthalate
Dibutyl phthalate
N = 492

Agricola 03:

Dibutylphthalate
Diisobutyl phthalate
Di-isobutyl phthalate
Di-iso-Butyl phthalate
Diisobutylester kyseliny ftalove
Diisobutylphthalat
di-l-butyl phthalate
EINECS 201-553-2
Hatcol DIBP
Hexaplas M/1B
N = 157

Agricola 04:
Isobutyl phthalate
isobutyl-o-phthalate
Kodaflex DIBP
NSC 15316
Palatinol IC
PHTHALATE, DIISOBUTYL
Phthalic acic, diisobutyl ester
Phthalic acid, diisobutyl ester
Reomol DiBP
UNII-IZ67FTN290
N = 54

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: 07/10/2019
Date Range of Search: 1900 to Present
N = 211

TOXNET 01:
84-69-5
N = 211

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

Date Searched: 07/10/2019
Date Range of Search: 1900 to present
N = 1476

"1,2-benzenedicarboxylic acid bis(2-methylpropyl) ester" OR "1,2-benzenedicarboxylic acid di(2-methylpropyl) ester" OR "1,2-Benzenedicarboxylic acid diisobutyl ester" OR "1,2-Benzenedicarboxylic

acid, 1,2-bis(2-methylpropyl) ester" OR "1,2-Benzenedicarboxylic acid, 1,2-Dibutyl ester" OR "1,2-Benzenedicarboxylic acid, bis-(2-methoxypropyl)ester" OR "1,2-Benzenedicarboxylic acid, bis(2-methylpropyl) ester" OR "1,2-Benzenedicarboxylic acid, di(2-methylpropyl) ester" OR "1,2-Benzenedicarboxylic acid, dibutyl ester" OR "1,2-bis(2-methylpropyl) benzene-1,2-dicarboxylate" OR "Bis(2-methylpropyl) benzene-1,2-dicarboxylate" OR "Bis(2-methylpropyl) o-phthalate" OR "Bis(2-methylpropyl) phthalate" OR "BRN 2054802" OR "Di(2-methylpropyl) phthalate" OR "di(i-butyl)phthalate" OR "Di(isobutyl) 1,2-benzenedicarboxylate" OR "Di(isobutyl)-1,2-benzenedicarboxylate" OR "di-2-methylpropyl phthalate" OR "Dibutyl phthalate" OR "Dibutylphthalate" OR "Diisobutyl phthalate" OR "Di-isobutyl phthalate" OR "Di-iso-Butyl phthalate" OR "Diisobutylester kyseliny ftalove" OR "Diisobutylphthalat" OR "di-l-butyl phthalate" OR "EINECS 201-553-2" OR "Hatcol DIBP" OR "Hexaplas M/1B" OR "Isobutyl phthalate" OR "isobutyl-o-phthalate" OR "Kodaflex DIBP" OR "NSC 15316" OR "Palatinol IC" OR "PHTHALATE, DIISOBUTYL" OR "Phthalic acic, diisobutyl ester" OR "Phthalic acid, diisobutyl ester" OR "Reomol DiBP" OR "UNII-IZ67FTN290"
N = 1476

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

Date Searched: 07/23/2019
Date Range of Search: all years
N = 28

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.[8]

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

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

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 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 di-isobutyl 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 Di-isobutyl 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:** • Di-isobutyl phthalate (DIBP) (CASRN 84-69-5) For synonyms see the EPA Chemistry Dashboard. • No isomers were included for DIBP. • **Human:** Any exposure to DIBP 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 DIBP including via water (including environmental aquatic exposures), soil or sediment, diet, gavage, injection, dermal, and inhalation. • **Plants:** Any exposure to DIBP including via water or soil, or sediment. **Screener note:**

PECO Element	Evidence
	• 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 <u>*Supplemental*</u> if any biological effects are reported. • Studies involving exposures to mixtures will be <u>*Included* only</u> if they also include exposure to DIBP 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 DIBP, or exposure to DIBP 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). **<u>Screener note</u>:** • 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. **<u>Screener note</u>:** • **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 Di-isobutyl 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 child bearing 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)
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 di-isobutyl 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 di-isobutyl 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 Di-isobutyl Phthalate[a]

Chemical	Drinking Water	Ambient Air	Air Disposal	Land Disposal	Underground Disposal	Ground Water
Di-isobutyl phthalate (DIBP)	--	--	--	--	--	--

[a] "Supplemental pathways" refer to pathways addressed by other EPA administered statutes. 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. RESO stands for **R**eceptors,

Exposure, **S**etting or Scenario, and **O**utcomes. 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
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.	

Objective Determined during Scoping	Type of Data [a]
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:** PV=Particle volume POTW=Publicly owned treatment works 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. PESO stands for **P**athways and **P**rocesses, **E**xposure, **S**etting or Scenario, and **O**utcomes. 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)
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

Fate Data Endpoint	Associated Process(es)	Associated Media/Exposure Pathways			
		Surface Water, Wastewater, Sediment	Soil, Biosolids	Groundwater	Air
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	
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.

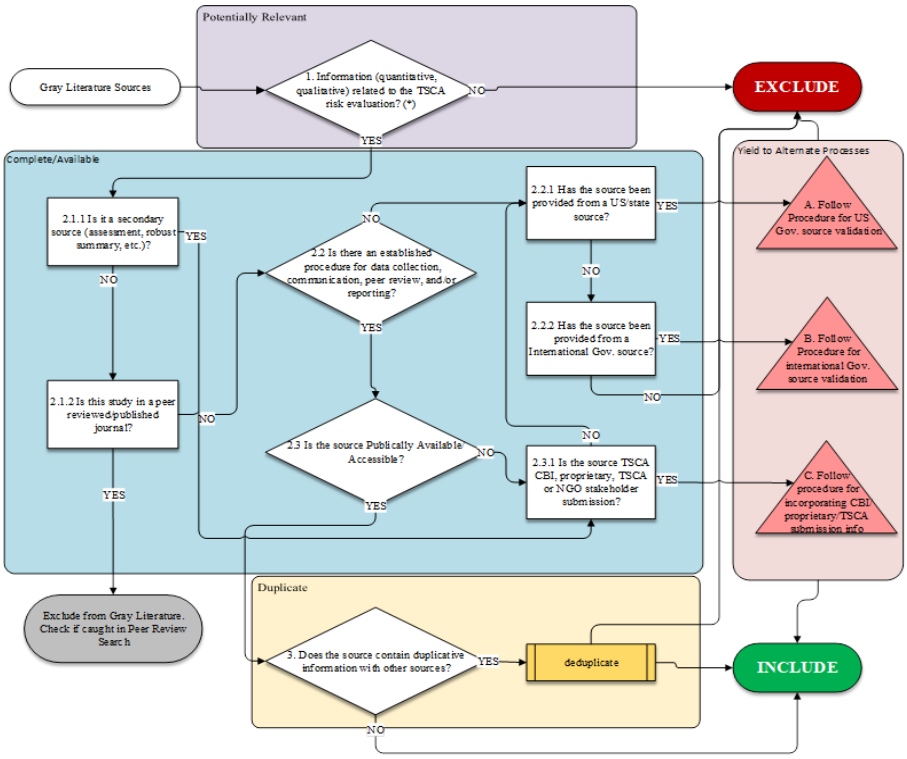
A.3 Gray Literature Search and Screening Strategies

EPA conducted a gray literature search for reasonably 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 are provided in Appendix A.3.3. 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. Results of the gray literature search and decision tree process are included in Appendix A.3.4.

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?

Step	Metric	Questions to Consider
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?

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 are obtained, EPA reviews 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 Di-isobutyl Phthalate

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

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

Source Agency	Source Name	Source Type	Source Category	Source Website
Australian Government, Department of Health	NICNAS Assessments (human health, Tier I, II or III)	International Resources	Assessment or Related Document	https://www.industrialchemicals.gov.au/chemical-information/search-assessments
Australian Government, Department of Health.	NICNAS Assessments (eco)	International Resources	Assessment or Related Document	https://www.industrialchemicals.gov.au/chemical-information/search-assessments
CPSC	Chronic Hazard Advisory Panel Reports	Other US Agency Resources	Assessment or Related Document	https://www.cpsc.gov/chap
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	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
ECHA	European Union Risk Assessment Report	International Resources	Assessment or Related Document	https://echa.europa.eu/information-on-chemicals/information-from-existing-substances-regulation
Env Canada	Canada Substance Grouping Pages	International Resources	Assessment or Related Document	http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=D7A631FF-1
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	

Source Agency	Source Name	Source Type	Source Category	Source Website
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	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

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 - Publications and Products	Other US Agency Resources	Assessment or Related Document	https://www2a.cdc.gov/niosh tic-2/
NIOSH	CDC NIOSH – Pocket Guide	Other US Agency Resources	Database	https://www.cdc.gov/niosh/npg/default.html
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

Appendix B PHYSICAL AND CHEMICAL PROPERTIES OF DI-ISOBUTYL 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-2018-0434).

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	1	-	NA	NA	NA	NA
Physical properties	5	-	NA	NA	NA	NA
Melting point	7	°C	-65.7	7.54	-82.05	-58
Boiling point	10	°C	306.6	18.3	278.85	327
Density	5	g/cm^3	1.043	0.0059	1.036	1.049
Vapor pressure	4	mm Hg	1.76×10^{-4}	2.71×10^{-4}	2.00×10^{-6}	5.8×10^{-4}
Vapor density	0	-	-	-	-	-
Water solubility	8	mg/L	2.61	3.81	7.05×10^{-7}	9.60
Octanol/water partition coefficient (log Kow)	4	-	4.41	0.32	4.11	4.86
Henry's Law constant	2	$atm\text{-}m^3/mol$	0.181	0.255	1.83×10^{-7}	0.361
Flash point	0	°C	-	-	-	-
Auto flammability	0	cP	-	-	-	-
Viscosity	1	-	41	0	41	41
Refractive index	3	-	1.490	0.00058	1.490	1.491
Dielectric constant	1	°C	6.56	0	6.56	6.56

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 di-isobutyl phthalate. This information was presented in the *Proposed Designation of Di-isobutyl Phthalate (DIBP) (CASRN 84-69-5) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019d) and may be updated as EPA collects additional information through systematic review methods.

Table_Apx C-1. Environmental Fate Characteristics of Di-isobutyl Phthalate

Property or Endpoint	Value*	Reference
Direct Photodegradation	May be susceptible due to potential absorption	NLM (2013)
Indirect Photodegradation	$t_{1/2}$ = 1.2 days (12-hour day at 1.5 × 10^6 OH/cm^3) based on OH rate constant of 9.3 × 10^{-12} cm^3/molecule-second at 25 ºC; estimated)^	U.S. EPA (2012b)
Hydrolysis	$t_{1/2}$ = 5,730 days (at pH = 8, based on a rate constant of 0.0014 M^{-1} $second^{-1}$)	Wolfe et al. (1980)
Biodegradation (Aerobic)	98%/4 weeks (OECD 302C)	NLM (2013) citing Sedykh and Klopman (2007)
	100%/6 days (die-away tests)	NLM (2013) citing Hattori et al. (1975)
	40%/28 days OECD 301B (CO_2 evolution)	ECHA (2019)
Biodegradation (Anaerobic)	0–30%/96 days (sewage sludge and swamp water) 0–30%/56 days (marine sediment)	NLM (2013) citing Madsen et al. (1995)
Wastewater Treatment	99.5% total removal (92% by biodegradation, 7.5% by sludge adsorption, and 0% by volatilization to air; estimated)^	U.S. EPA (2012b)
Bioconcentration Factor	240 (log BCF = 2.4; estimated)^	U.S. EPA (2012b)
	26 (log BAF = 1.4; estimated)^	U.S. EPA (2012b)
Soil Organic Carbon:Water Partition Coefficient (Log K_{OC})	3.14	NLM (2013) citing Sabljic et al. (1995)

* Measured unless otherwise noted

^ EPI Suite™ physical property inputs: Log K_{OW} = 4.11, BP = 296.5 ºC, MP = -64 ºC, VP = 4.76 × 10^{-5} mm Hg, WS = 6.2 mg/L, BioP = 4, BioA = 1, Bio S = 1 SMILES O=C(OCC(C)C)c(c(ccc1)C(=O)OCC(C)C)c1

Bioconcentration factor = BCF; Bioaccumulation factor = BAF

Appendix D REGULATORY HISTORY

The chemical substance, di-isobutyl 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 di-isobutyl 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.	Di-isobutyl 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 di-isobutyl 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.	Di-isobutyl phthalate manufacturing (including importing), processing and use information is reported under the CDR rule (76 FR 50816, August 16, 2011).
Toxic Substances Control Act (TSCA) – Section 8(b)	EPA must compile, keep current and publish a list (the TSCA Inventory) of each chemical substance manufactured (including imported) or processed in the United States.	Di-isobutyl 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(d)	Provides EPA with authority to issue rules requiring producers, importers, and (if specified) processors of a chemical substance or mixture to submit lists and/or copies of ongoing and completed, unpublished health and safety studies.	Zero health and safety studies received for di-isobutyl phthalate (1982-1992) (U.S. EPA, ChemView. Accessed April 25, 2019). Di-isobutyl phthalate is listed under the category "Alkyl phthalates — all alkyl esters of 1, 2-benzenedicarboxylic acid (ortho -phthalic acid)" (40 CFR 716.120).
Toxic Substances Control Act (TSCA) – Section 8(e)	Manufacturers (including importers), processors, and distributors must immediately notify EPA if they obtain	Two risk reports received for di-isobutyl phthalate (2003: 88030000106; 2010: 88100000438)

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	information that supports the conclusion that a chemical substance or mixture presents a substantial risk of injury to health or the environment.	(U.S. EPA, ChemView. Accessed April 9, 2019).
Clean Water Act (CWA) – Sections 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-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.	As a phthalate ester, di-isobutyl phthalate is designated as a toxic pollutant under Section 307(a)(1) of the CWA, and as such is subject to effluent limitations. Specifically, di-isobutyl phthalate is categorized as an "aromatic organic chemical," as applicable to the process wastewater discharges resulting from the manufacture of bulk organic chemicals (40 CFR 414.70).
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.	Di-isobutyl 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. (21 CFR § 177.1200).
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,	The use of di-isobutyl phthalate at concentrations greater than 0.1 percent is banned in toys and child care articles (16 CFR part 1307.3). Di-isobutyl phthalate is considered "toxic" under the FHSA. (CPSC Toxicity Review of di-isobutyl phthalate, Oct. 24, 2010). See also

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	butyl benzyl phthalate, diisononyl phthalate, diisobutyl phthalate, di-n-pentyl phthalate, di-n-hexyl phthalate and dicyclohexyl phthalate.	CPSC, Exposure Assessment: Potential for the Presence of Phthalates in Selected Plastics, October 1, 2015.

D.2 State Laws and Regulations

Table_Apx D-2. State Laws and Regulations

State Actions	Description of Action
State Water Pollution Discharge Programs	Several states have adopted water pollution discharge programs which categorize di-isobutyl phthalate as an "aromatic organic chemical," as applicable to the process wastewater discharges resulting from the manufacture of bulk organic chemicals, including Illinois (35 Ill. Adm. Code 307-2406); and Wisconsin (Wis. Adm. Code § NR 235.60).
Chemicals of High Concern to Children	Several states have adopted reporting laws for chemicals in children's products containing di-isobutyl phthalate, including: Maine which lists di-isobutyl phthalate as a "chemical of concern" (38 MRSA Chapter 16-D); Minnesota which lists di-isobutyl phthalate as a "chemical of high concern" (Toxic Free Kids Act Minn. Stat. 116.9401 to 116.9407); and Washington State which lists di-isobutyl phthalate as a "chemical of high concern to children" (Wash. Admin. Code 173-334-130).
Other	Di-isobutyl phthalate is listed as a Candidate Chemical under California's Safer Consumer Products Program established under Health and Safety Code § 25252 and 25253 (California, Candidate Chemicals List. Accessed April 17, 2019). Di-isobutyl phthalate is listed as a "nonfunctional constituent" under California's Cleaning Product Right to Know Act of 2017 (California Health & Safety Code § 108952). California lists di-isobutyl phthalate as a designated priority chemical for biomonitoring under criteria established by California SB 1379 (Biomonitoring California, Priority Chemicals, February 2019).

D.3 International Laws and Regulations

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

Country/Tribe/ Organization	Requirements and Restrictions
Canada	Di-isobutyl phthalate is on the Domestic Substances List (Government of Canada. Managing substances in the environment. Substances search. Database accessed April 17, 2019).
European Union	In February 2012, di-isobutyl phthalate was added to Annex XIV of REACH (Authorisation List) with a sunset date of February 21, 2015. After the sunset date, only persons with approved authorization applications may continue to use the chemical. No requests for authorization were submitted by any user. There is a recommendation for amending the authorization list under review, with a deadline for commenting on December 3, 2019, which would revise the allowable concentration of the chemical for use in mixtures from 0.3% to 0.1%. (European Chemicals Agency (ECHA) database. Accessed April 26, 2019). In March 2015, di-isobutyl phthalate was added to Annex II of Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (EEE) (RoHS 2). The Directive sets a maximum concentration value tolerated by weight in homogenous materials for di-isobutyl phthalate of 0.1%. The restriction applies 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 does 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 (Commission Delegated Directive (EU) 2015/863). Di-isobutyl 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	Di-isobutyl phthalate was assessed under Human Health Tier II of the Inventory Multi-Tiered Assessment and Prioritisation (IMAP) as part of the C4-6 side chain transitional phthalates. Uses reported include as a plasticizer for rubber and PVC, and in adhesives (NICNAS, 2016, *Human Health Tier II assessment for* C4-6 side chain transitional phthalates). In addition, di-isobutyl phthalate was assessed under Environment Tier II of IMAP as part of the phthalate esters.

Country/Tribe/ Organization	Requirements and Restrictions
Japan	Di-isobutyl 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) (National Institute of Technology and Evaluation (NITE) Chemical Risk Information Platform (CHRIP). Accessed April 17, 2019).
World Health Organization (WHO)	WHO International Programme on Chemical Safety identified an acute hazard for di-isobutyl phthalate as combustible and recommended prevention and fire-fighting techniques (ICSC: 0829, October 2006).
Denmark, Ireland, Latvia, New Zealand, United Kingdom	Occupational exposure limits for di-isobutyl phthalate (GESTIS International limit values for chemical agents (Occupational exposure limits, OELs) database. Accessed April 17, 2019). Ireland, New Zealand and the United Kingdom have an eight-hours limit of 5 mg/m^3. Latvia has an eight-hours limit of 1 mg/m^3. Denmark has an eight-hours limit of 3 mg/m^3 and a short-term limit of 6 mg/m^3.

Appendix E PROCESS, RELEASE, AND OCCUPATIONAL EXPOSURE INFORMATION

This appendix provides information and data found in preliminary data gathering for di-isobutyl 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 two facilities that submitted activity data for 2015. One of these facilities stated that they imported di-isobutyl phthalate in 2015 and the other stated that they manufactured di-isobutyl phthalate in 2015 (U.S. EPA, 2020a). According to 2016 public CDR data, di-isobutyl phthalate is imported into the United States in solid form and manufactured in liquid form (U.S. EPA, 2020a).

E.1.1.1 Domestic Manufacturing

Di-isobutyl phthalate is classified as part of the phthalate ester grouping of compounds predominantly used as plasticizers in the production of varied plastic products. Di-isobutyl phthalate is typically termed a "specialty" plasticizer, as it is a fast-fusing, low-carbon-number phthalate that can be used for varying applications (Cadogan and Howick, 2000). Di-isobutyl phthalate is typically manufactured through catalytic esterification of phthalic anhydride with isobutanol. Manufacturing operations take place in closed systems either via batch or more automated continuous operations and will typically involve the purification of di-isobutyl phthalate product streams via either vacuum distillation or by passing over activated charcoal as a means of recovering unreacted alcohols (CPSC, 2010).

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. Di-isobutyl phthalate is shipped in solid form according to 2016 CDR. The facility in the 2016 CDR that imported di-isobutyl phthalate in 2015 imported di-isobutyl phthalate directly to their site for on-site processing or use (U.S. EPA, 2020a).

E.1.2 Processing and Distribution

E.1.2.1 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 di-isobutyl phthalate into a chemical formulation, mixture, or reaction product are dependent on the specific manufacturing process or processes involved. One company reported to 2016 CDR that di-isobutyl phthalate is used as a plasticizer in the formulation of adhesives and one company reported that di-isobutyl phthalate is used as a plasticizer in plastic products (U.S. EPA, 2020a). Di-isobutyl phthalate is also used as an additive to ink, toner, and colorant products, automotive care products, and other miscellaneous products (U.S. EPA, 2020a, 2019a; CPSC, 2015a; Lanxess Corporation, 2015). The exact processes used to formulate products containing di-isobutyl phthalate are not known at this time; however, several ESDs published by the OECD (OECD, 2019) and Generic

Scenarios published by EPA (U.S. EPA, 2020d) have been identified that provide general process descriptions for these types of products. EPA plans to evaluate processing uses of di-isobutyl phthalate during risk evaluation.

E.1.2.2 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 di-isobutyl phthalate-containing formulations or reaction products are dependent on the article. One company reported to 2016 CDR that di-isobutyl phthalate is used as a plasticizer in plastic products and another company reported that di-isobutyl phthalate is used as a plasticizer in construction and transportation equipment manufacturing (U.S. EPA, 2020a). EPA plans to evaluate processing uses of di-isobutyl phthalate during risk evaluation.

E.1.2.3 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.1.2.4 Recycling

The 2016 CDR reports that no companies reported recycling (U.S. EPA, 2020a). A public commenter indicated that di-isobutyl phthalate may be recycled (EPA-HQ-OPPT-2018-0434-0014). EPA plans to evaluate the potential for recycling of di-isobutyl phthalate during risk evaluation.

E.1.3 Uses

E.1.3.1 Adhesives, Sealants, Paints, and Coatings

Di-isobutyl phthalate is used in a variety of adhesive, sealant, paint, and coating products. Specifically, di-isobutyl phthalate is used in adhesives and sealants used in transportation equipment manufacturing, adhesives and sealants used in construction, two-component high-strength anchoring adhesive, surface adhesives and seam adhesive for solid surfacing, motor vehicle paints, paints, lacquers, and varnishes ((U.S. EPA, 2020a); EPA-HQ-OPPT-2019-0434-0015; EPA-HQ-OPPT-2018-0434-0007; (Glue 360 Inc, 2018; Azon USA Inc, 2015; CPSC, 2015a; ITW Performance Polymers, 2015; Lanxess Corporation, 2015). The application procedure depends on the type of adhesive, sealant, paint, or coating formulation and the type of substrate. The formulation is loaded into the application reservoir or apparatus and applied to the substrate via brush, spray, roll, dip, curtain, or syringe or bead application. Application may be manual or automated. After application, the adhesive, sealant, paint, or coating is allowed to dry or cure (OECD, 2015). The drying/curing process may be promoted through the use of heat or radiation (radiation can include ultraviolet (UV) and electron beam radiation (OECD, 2010).

E.1.3.2 Building/Construction Materials Not Covered Elsewhere

Di-isobutyl phthalate is a constituent of building and construction materials used for brick laying (U.S. EPA, 2020a), concrete (Lanxess Corporation, 2015), and construction adhesives (U.S. EPA, 2020a), and other materials (CPSC, 2015a; Lanxess Corporation, 2015). EPA plans to evaluate these uses of di-isobutyl phthalate during risk evaluation.

E.1.3.3 Ink, Toner, and Colorant Products

Di-isobutyl phthalate is used in coloring agents, dyes, pigments (as a dispersing agent), and printing inks (CPSC, 2015a; Lanxess Corporation, 2015). Printing inks are comprised 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.1.3.4 Plastic and Rubber Products

As described in Section E.1.2.2, di-isobutyl phthalate is used to increase the flexibility of plastic and rubber products, which may be used industrially, commercially, and by consumers. Di-isobutyl phthalate is used in plastics used in the building and construction industry, floor coverings, and toys (EPA-HQ-OPPT-2018-0434-0014); (CPSC, 2015b; Lanxess Corporation, 2015). Di-isobutyl phthalate is likely entrained in the products; however, DIBP 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 evaluate these uses of di-isobutyl phthalate during risk evaluation.

E.1.3.5 Other Uses

Di-isobutyl phthalate is also used in fuels and related products (CPSC, 2015a; Lanxess Corporation, 2015) and air care products (CPSC, 2015a). Di-isobutyl phthalate is also used in laboratory settings (Sigma Aldrich, 2020). 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-2018-0434-0040) provided descriptions of their use of di-isobutyl phthalate in laboratory use including such applications as analytical standards, research, equipment calibration and sample preparation, further informing EPA's understanding of this condition of use.

EPA plans to evaluate these uses of di-isobutyl phthalate during risk evaluation.

E.1.4 Disposal

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

Di-isobutyl phthalate may be contained in wastewater discharged to POTW or other, non-public treatment works for treatment. Industrial wastewater containing di-isobutyl 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 di-isobutyl 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).

E.2 Preliminary Occupational Exposure Data

NIOSH HHEs have not been conducted with a focus on di-isobutyl phthalate monitoring and/or workplace exposure to date. Di-isobutyl phthalate does not have an OSHA IMIS code. As such, OSHA has not collected monitoring data for this chemical.

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

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

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / 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 reference manufacture in solid form.
				Vapor	Inhalation	Workers, ONU	No	Due to di-isobutyl phthalate's vapor pressure (VP) (VP = 4.76 × 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 does not reference manufacture 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.
	Import	Import	Repackaging of import containers	Liquid Contact	Dermal	Workers	No	2016 CDR does not reference import in liquid form.
				Solid Contact	Dermal	Workers	Yes	2016 CDR references import in solid form. The potential for exposures to workers exists during import, but exposure will only occur in the event the imported material is repackaged.
				Vapor	Inhalation	Workers, ONU	No	Due to di-isobutyl phthalate's vapor pressure (VP) (VP = 4.76 × 10-5 mm

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
								Hg) at room temperature, potential for vapor generation is low.
				Mist	Inhalation/ Dermal	Workers, ONU	No	Mist generation is not expected during repackaging of import containers.
				Dust	Inhalation/ Dermal	Workers, ONU	Yes	2016 CDR references solid form, which may create dust. The potential for dust exposures to workers and ONUs exists during import, but exposure will only occur in the event the imported material is repackaged.
				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	Incorporated into formulation, mixture or reaction product	Plasticizers in: Adhesive manufacturing; Plastic product manufacturing Solvents (which become part of product formulations or mixture): Plastic material and resin manufacturing; Paints and Coatings Fuels and Related Products (*e.g.*, Fuel additives) Processing aids, not otherwise listed	Processing into formulations, mixtures, or reaction product	Liquid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during processing (incorporation into formulation, mixture, or reaction product), as di-isobutyl phthalate may be 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 di-isobutyl phthalate may be in solid form.
				Vapor	Inhalation	Workers, ONU	Yes	Due to di-isobutyl phthalate's vapor pressure (VP) (VP = 4.76 × 10-5 mm Hg) at room temperature, potential for vapor generation is low. However, some of these operations may occur at elevated temperatures, which increase the potential for vapor generation.
				Mist	Inhalation/ Dermal	Workers, ONU	No	Mist generation is not expected during processing (incorporation into formulation, mixture, or reaction product).

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
		Inks, Toner, and Colorant Products (*e.g.*, Toner/ printer cartridge) Plastic and rubber products not covered elsewhere Fabric, textile, and leather products not covered elsewhere		Dust	Inhalation/ Dermal	Workers, ONU	Yes	The potential for dust exposures to workers and ONUs exists during processing as di-isobutyl phthalate may be 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.
	Incorporated into articles	Plasticizers in: Construction; plastic product manufacturing; transportation equipment 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 di-isobutyl phthalate may be in liquid form.
				Solid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during processing (incorporation into articles), as di-isobutyl phthalate may be in solid form, such as for resins.
				Vapor	Inhalation	Workers, ONU	Yes	Due to di-isobutyl phthalate's vapor pressure (VP) (VP = 4.76 × 10-5 mm Hg) at room temperature, potential for vapor generation is low. However, some of these operations may occur at elevated temperatures, which increase the potential for vapor generation.
				Mist	Inhalation/ Dermal	Workers, ONU	No	Mist generation is not expected during incorporation into article.
				Dust	Inhalation/ Dermal	Workers, ONU	Yes	The potential for exposures to workers exists during processing (incorporation into articles), as di-isobutyl phthalate may be in solid form, such as for resins.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
				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 repackaging, as di-isobutyl phthalate may be in liquid form.
				Solid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during repackaging, as di-isobutyl phthalate may be incorporated into products in solid form.
				Vapor	Inhalation	Workers, ONU	No	Due to di-isobutyl phthalate's vapor pressure (VP) (VP = 4.76 × 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 di-isobutyl 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 di-isobutyl phthalate and products containing di-isobutyl 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.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
				Vapor	Inhalation	Workers, ONU	No	Due to di-isobutyl phthalate's vapor pressure (VP) (VP = 4.76 × 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	Paints and coatings; adhesives and sealants; Air Care Products (*e.g.*, Air Freshener)	Paints and coatings; adhesives and sealants; Air Care Products (*e.g.*, Air Freshener)	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 di-isobutyl phthalate used in these products.
				Solid Contact	Dermal	Workers	No	The potential for exposures to solid di-isobutyl phthalate is not expected during the use of these products because they are in liquid form.
				Vapor	Inhalation	Workers, ONU	No	Due to di-isobutyl phthalate's vapor pressure (VP) (VP = 4.76 × 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 di-isobutyl phthalate is not expected 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

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
								they are not expected to directly handle the chemical.
	Fuels and related products; Fabric, textile, and leather products not covered elsewhere (*e.g.*, Textile (fabric) dyes); Inks, Toner, and Colorant Products (*e.g.*, Toner/printer cartridge);Laboratory chemicals	Fuels and related products; Fabric, textile, and leather products not covered elsewhere (*e.g.*, Textile (fabric) dyes); Inks, Toner, and Colorant Products (*e.g.*, Toner/printer cartridge); Laboratory chemicals	Use of fuels and related products Use of fabric dyes Use of inks, toner, and colorant products (*e.g.*, printing) Use of laboratory chemicals	Liquid Contact	Dermal	Workers	Yes	These products are in liquid form; therefore, exposures to workers exists for di-isobutyl phthalate used in these products.
				Solid Contact	Dermal	Workers	No	The potential for exposures to solid di-isobutyl phthalate is not expected during the use of these products because they are in liquid form.
				Vapor	Inhalation	Workers, ONU	No	Due to di-isobutyl phthalate's vapor pressure (VP) (VP = 4.76 × 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 di-isobutyl 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.
	Plastic and rubber products not covered elsewhere; Building/ construction materials not covered elsewhere; floor coverings	Plastic and rubber products not covered elsewhere; Building/ construction materials not covered elsewhere; floor coverings	Use of articles made using di-isobutyl phthalate	Liquid Contact	Dermal	Workers	No	The potential for exposures to liquid di-isobutyl 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 di-isobutyl phthalate is entrained; therefore, di-isobutyl phthalate exposures to workers is unlikely but may occur if cutting

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
								/sawing / other machining operations occur.
				Vapor	Inhalation	Workers, ONU	No	Due to di-isobutyl phthalate's vapor pressure (VP) (VP = 4.76 × 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	Yes	These products may include solid articles in which di-isobutyl phthalate is entrained; therefore, di-isobutyl phthalate exposures to workers and ONUs is unlikely but may occur if cutting /sawing / 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 di-isobutyl 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 di-isobutyl phthalate's vapor pressure (VP) (VP = 4.76 × 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.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
				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 - CONCEPTUAL MODEL FOR CONSUMER ACTIVITIES AND USES

Table_Apx G-1. Consumer Exposure Conceptual Model Supporting Table

Life Cycle Stage	Category	Subcategory	Release from source	Exposure Pathway	Route	Receptor	Plans to Evaluate	Rationale
Consumer Use	Furnishing, Cleaning, Treatment/Care Products	Fabric, Textile and Leather Products no 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, dermal exposure will be analyzed.
			Direct contact through mouthing of articles containing chemical	Mouthing	Oral	Consumers	Yes	Oral exposure may occur for this condition of use and will be analyzed.
			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 and will be analyzed
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, dermal exposure will be analyzed.
			Direct contact through mouthing of articles containing chemical	Mouthing	Oral	Consumers	Yes	Oral exposure may occur for this condition of use and will be analyzed.

Life Cycle Stage	Category	Subcategory	Release from source	Exposure Pathway	Route	Receptor	Plans to Evaluate	Rationale
			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 and will be analyzed
Consumer Use	Other	Other (Article)	Direct contact through handling of articles containing chemical	Direct Contact	Dermal	Consumers	Yes	Dermal exposure may occur for this condition of use, dermal exposure will be analyzed.
			Direct contact through mouthing of articles containing chemical	Mouthing	Oral	Consumers	Yes	Oral exposure may occur for this condition of use and will be analyzed.
			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 and will be analyzed
Consumer Use	Packaging, Paper, Plastic, Hobby Products	Plastic and Rubber Products not Covered Elsewhere (Article)	Direct contact through handling of articles containing chemical	Direct Contact	Dermal	Consumers	Yes	Dermal exposure may occur for this condition of use, dermal exposure will be analyzed.
			Direct contact through mouthing of articles containing chemical	Mouthing	Oral	Consumers	Yes	Oral exposure may occur for this condition of use and will be analyzed

Life Cycle Stage	Category	Subcategory	Release from source	Exposure Pathway	Route	Receptor	Plans to Evaluate	Rationale
			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 and will be analyzed
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, dermal exposure will be analyzed.
			Direct contact through mouthing of articles containing chemical	Mouthing	Oral	Consumers	Yes	Oral exposure may occur for this condition of use and will be analyzed
			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 and will be analyzed
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 and will be analyzed
			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 and will be analyzed
			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 and analyzed
Consumer Use	Furnishing, Cleaning, Treatment/Care Products	Air 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 and will be analyzed
			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 and will be analyzed
			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 and analyzed
Consumer Use	Packaging, Paper, Plastic, Hobby Products	Ink, Toner and Colorant 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 and will be analyzed

Life Cycle Stage	Category	Subcategory	Release from source	Exposure Pathway	Route	Receptor	Plans to Evaluate	Rationale
			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 and will be analyzed
			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 and analyzed
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 and will be analyzed
			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 and will be analyzed
			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 and analyzed

Life Cycle Stage	Category	Subcategory	Release from source	Exposure Pathway	Route	Receptor	Plans to Evaluate	Rationale
Consumer Handling of Disposal and Waste	Wastewater, Liquid wastes and solid wastes	Wastewater, Liquid wastes and solid wastes	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 and will be analyzed
			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 Supporting Table

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	Yes	Di-isobutyl phthalate deposition to nearby bodies of water and soil are expected exposure pathways, not covered under other EPA regulations, and, therefore in scope.
			Indirect deposition to nearby bodies of water and soil catchments	Oral Dermal	General Population	Yes	
				TBD	Aquatic and Terrestrial Receptors	Yes	
	Wastewater or Liquid Wastes	Industrial pre-treatment and wastewater treatment, or POTW	Direct release into surface water and indirect partitioning to sediment	TBD	Aquatic and Terrestrial Receptors	Yes	Release of di-isobutyl phthalate into surface water and indirect partitioning to sediment exposure pathways to aquatic and terrestrial receptors will be analyzed
				Oral Dermal	General Population	Yes	Release of di-isobutyl phthalate into surface water and indirect partitioning to sediment and bioaccumulation exposure pathways to the general population will be analyzed.
			Drinking Water via Surface or Ground Water	Oral Dermal and Inhalation (*e.g.*, showering)	General Population	Yes	Release of di-isobutyl phthalate into surface water and indirect partitioning to drinking water is an expected exposure pathway.

Life Cycle Stage	Category	Release	Exposure Pathway / Media	Exposure Routes	Receptor / Population	Plans to Evaluate	Rationale
			Biosolids: application to soil and/or migration to groundwater and/or surface water	Oral (*e.g.*, ingestion of soil) Inhalation	General Population	Yes	EPA plans to analyze the pathway from biosolids to the general population, aquatic and terrestrial species.
				TBD	Aquatic and Terrestrial Receptors	Yes	
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	Yes	EPA plans to analyze the pathway from municipal landfills and other land disposal to the general population, aquatic and terrestrial receptors.
				TBD	Aquatic and Terrestrial Receptors		