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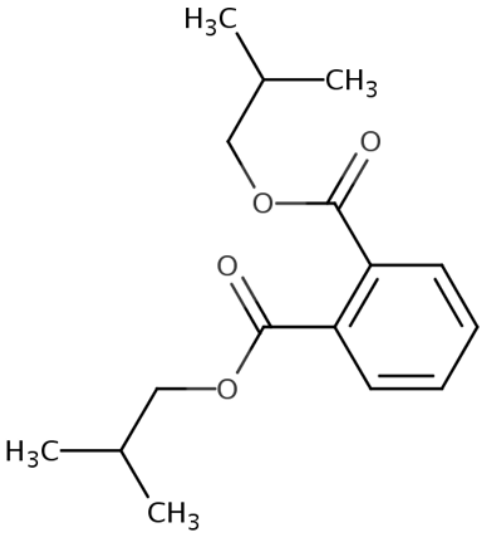
Office of Chemical Safety and
Pollution Prevention

United States
Environmental Protection Agency

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

CASRN 84-69-5



April 2020

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ACKNOWLEDGEMENTS

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Docket

Supporting information can be found in public docket: [Docket ID: 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
DBP	Dibutyl Phthalate
DCHP	Dicyclohexyl Phthalate
DEHP	Di-ethylhexyl Phthalate
DHEXP	Di-n-hexyl Phthalate
DIBP	Di-isobutyl Phthalate
DINP	Di-isononyl Phthalate
DPENP	Di-n-pentyl Phthalate
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
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
ILO	International Labor Organization
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
NEI	National Emissions Laboratory
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

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)
RQ	Risk Quotient
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
SDWA	Safe Drinking Water Act
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 84-69-5) 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 Part 702) (Docket ID: EPA-HQ-OPPT-2018-0434). The first step of the risk evaluation process is the development of the scope document and this document fulfills the TSCA regulatory requirement to issue a draft scope document as described in 40 CFR 702.41(c)(7). The draft scope for 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 this risk evaluation, along with a description of the reasonably available information, conceptual model, analysis plan and science approaches, and plan for peer review for this chemical substance. EPA is providing a 45-day comment period on the draft scope. Comments received on this draft scope document will help inform development of the final scope document and the risk evaluation.

General Information. Di-isobutyl phthlate is a colorless liquid with a total production volume in the United States up to 500,000 pounds (U.S. EPA 2019b).

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

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 within, as well as imported into, 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 Chemical Data Reporting (CDR), published literature, and consultation with stakeholders for both uses currently in production and uses whose production may have ceased. EPA is aware of information reporting di-isobutyl phthalate used in personal care products such as perfume and nail polish as well as in dentistry settings; however, they are not conditions of use as defined in TSCA § 3(4). Section 2.2

provides details about the conditions of use within – and outside – the scope of the risk evaluation. In addition, EPA plans to analyze distribution in commerce and disposal as part of the risk evaluation.

Conceptual Model. The conceptual models for 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—from manufacturing, processing, distribution in commerce, storage, use, to release or disposal. EPA plans to focus the risk evaluation for di-isobutyl phthalate on the following exposures, hazards and receptors, however, EPA also plans to consider comments received on this draft scope and other reasonably available information when finalizing this scope document, and to adjust the exposure pathways, exposure routes and hazards included in the scope document as needed.

- *Exposures (Pathways and Routes), Receptors and PESS.* EPA plans to analyze both human and environmental exposures resulting from the conditions of use of di-isobutyl phthalate that EPA plans to consider in the risk evaluation. Exposures for di-isobutyl phthalate are discussed in Section 2.3. Additional information gathered through systematic review searches will also inform expected exposures.

  In Section 2.6.3, 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 within the scope of the risk evaluation.

  Preliminarily, EPA plans to evaluate the following human and environmental exposure pathways, routes, receptors and PESS in the scope of the risk evaluation. However, EPA plans to consider comments received on this draft scope and other reasonably available information when finalizing this scope document, and to adjust the exposure pathways, exposure routes and hazards included in the scope document as needed.
  - *Occupational exposures associated with industrial and commercial conditions of use:* EPA plans to evaluate exposures to workers and occupational non-users (ONUs) via the inhalation route and exposures to workers via the dermal route associated with the manufacturing, processing, use or disposal of di-isobutyl phthalate.
  - *Consumer and bystander exposures associated with consumer conditions of use:* EPA plans to evaluate the inhalation and dermal exposure to di-isobutyl phthalate for consumers and bystanders from use of adhesives and sealants; air care products; cleaning and furnishing care products; fabric, textile, and leather products; floor coverings; ink, toner, and colorant products; paints and coatings; paper products; plastic and rubber products not covered elsewhere; and toys, playground, and sporting equipment.
  - *General population exposures:* EPA plans to evaluate exposure to di-isobutyl phthalate via drinking water, surface water, groundwater, ambient air, soil, and fish ingestion for the general population.
  - *Receptors and PESS:* EPA plans to evaluate children, women of reproductive age (e.g., pregnant women), workers and consumers as receptors and PESS in the risk evaluation.
  - *Environmental exposures*: EPA plans to evaluate exposure to 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 from peer-reviewed assessments and databases to identify potential environmental and human health hazards for di-isobutyl phthalate as part of the prioritization process. Environmental hazard effects were identified EPA for aquatic and terrestrial organisms. Information collected through systematic review methods and public comments may identify additional environmental hazards that warrant inclusion in the environmental hazard assessment of the risk evaluation.

  EPA plans to use systematic review methods to evaluate the epidemiological and toxicological literature for di-isobutyl phthalate. Relevant mechanistic evidence will also be considered, if reasonably available, to inform the interpretation of findings related to potential human health effects and the dose-response assessment. EPA plans to evaluate all the potential human health hazards for di-isobutyl phthalate identified in Section 2.4.2. The broad health effect categories include reproductive and developmental, immunological, nervous system, and irritation effects.

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 information streams (i.e., chemistry, fate, release and engineering, exposure, hazard) supporting the risk evaluation. The analysis plan is based on EPA's knowledge of di-isobutyl phthalate to date which includes a partial, but ongoing, review of identified information as described in Section 2.1. EPA plans to continue to consider new information submitted by the public. Should additional data or approaches become reasonably available, EPA may update its analysis plan in the final scope document.

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

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 and other methods consistent with Section 26 of TSCA (See 40 CFR 702.45).

1 INTRODUCTION

This document presents for comment the draft scope of the risk evaluation to be conducted for 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 the Toxic Substances Control Act (TSCA) on June 22, 2016. The new law includes statutory requirements and deadlines for actions related to conducting risk evaluations of existing chemicals.

TSCA § 6(b) and 40 CFR Part 702, Subpart A require the Environmental Protection Agency (EPA) to designate chemical substances as high-priority substances for risk evaluation or low-priority substances for which risk evaluations are not warranted at the time, and upon designating a chemical substance as a high-priority substance, initiate a risk evaluation on the substance. TSCA § 6(b)(4) directs EPA, in conducting risk evaluations for existing chemicals, to "determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use."

TSCA § 6(b)(4)(D) and implementing regulations require that EPA publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use and potentially exposed or susceptible subpopulations that the Administrator expects to consider within 6 months after the initiation of a risk evaluation. In addition, a draft scope is to be published pursuant to 40 CFR 702.41. In December 2019, EPA published a list of 20 chemical substances that have been designated high-priority substances for risk evaluations (84 FR 71924), as required by TSCA § 6(b)(2)(B), which initiated the risk evaluation process for those chemical substances. Di-isobutyl phthalate is one of the chemicals designated as a high-priority substance for risk evaluation.

2 SCOPE OF THE EVALUATION

2.1 Reasonably Available Information

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

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

[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).

Following the comprehensive search, EPA performed a title and abstract screening to identify information potentially relevant for the risk evaluation process. This step also classified the references into useful categories or tags to facilitate the sorting of information through the systematic review process. The search and screening processes were conducted based on EPA's general expectations for the planning, execution and assessment activities outlined in the *Application of Systematic Review in TSCA Risk Evaluations* document (U.S. EPA, 2018a). EPA plans to publish supplemental documentation on the systematic review methods supporting the di-isobutyl phthalate risk evaluation to explain the literature and screening process presented in this document in the form of literature inventory trees. Please note that EPA focuses on the data collection phase (consisting of data search, data screening, and data extraction) during the preparation of the TSCA scope document, whereas the data evaluation and integration stages will occur during the development of the draft risk evaluation and thus are not part of the scoping activities described in this document.

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

2.1.1 Search of Gray Literature

EPA surveyed the gray literature[2] and identified 70 search results relevant to EPA's risk assessment needs for di-isobutyl phthalate. Appendix A lists the gray literature sources that yielded 70 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-chemical (p-chem) properties, environmental fate, environmental hazard, human health hazard, exposure, engineering) and the breakdown is shown in Figure 2-1. EPA is currently identifying additional reasonably available information (e.g., public comments), and the reported numbers in Figure 2-1 may change.

[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.

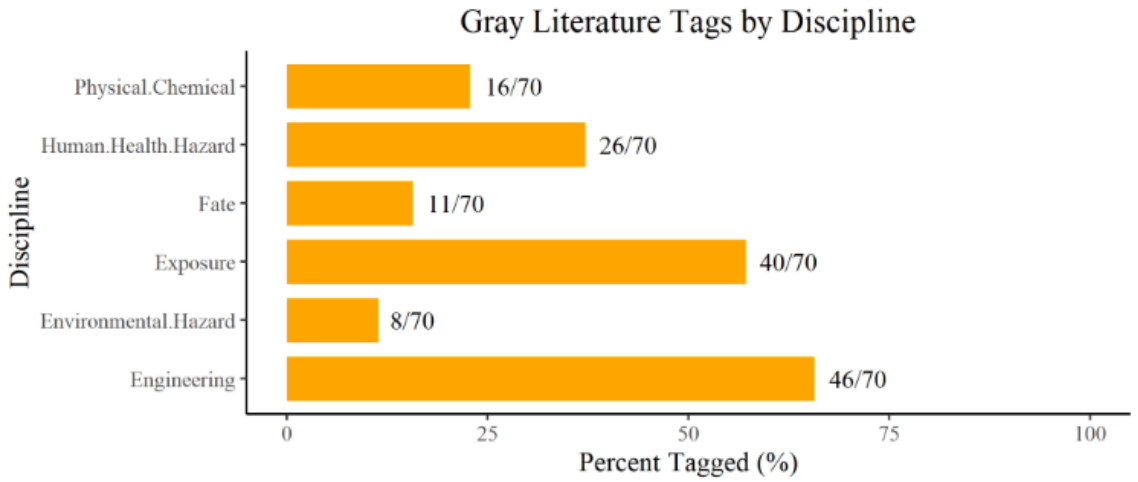

Figure 2-1. Gray Literature Search Results for Di-isobutyl Phthalate
The percentages across disciplines do not add up to 100%, as each source may provide data or information for various topic areas (or disciplines).

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

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

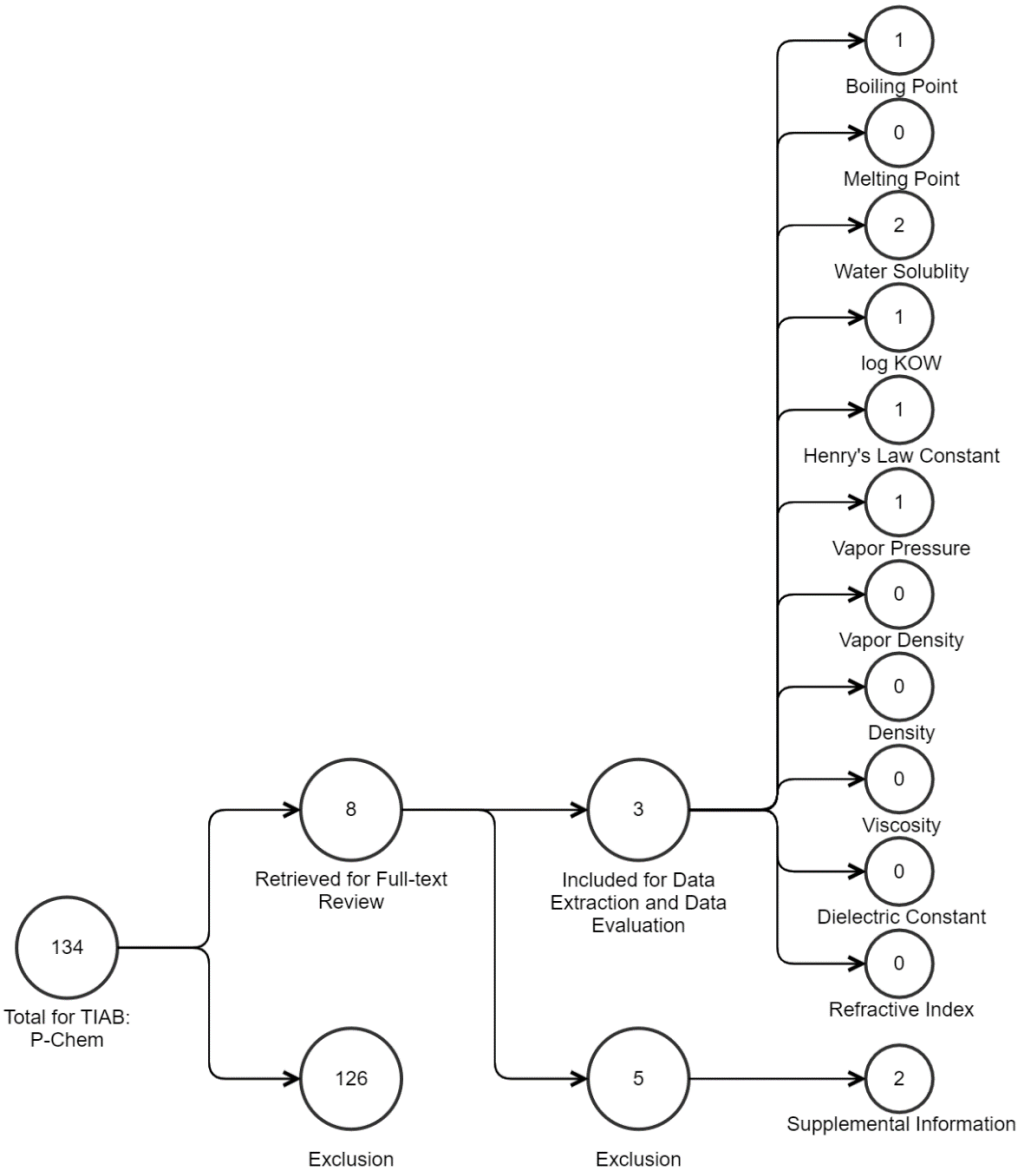

Figure 2-2. Peer-reviewed Literature - Physical-Chemical Properties Search Results for Di-isobutyl Phthalate

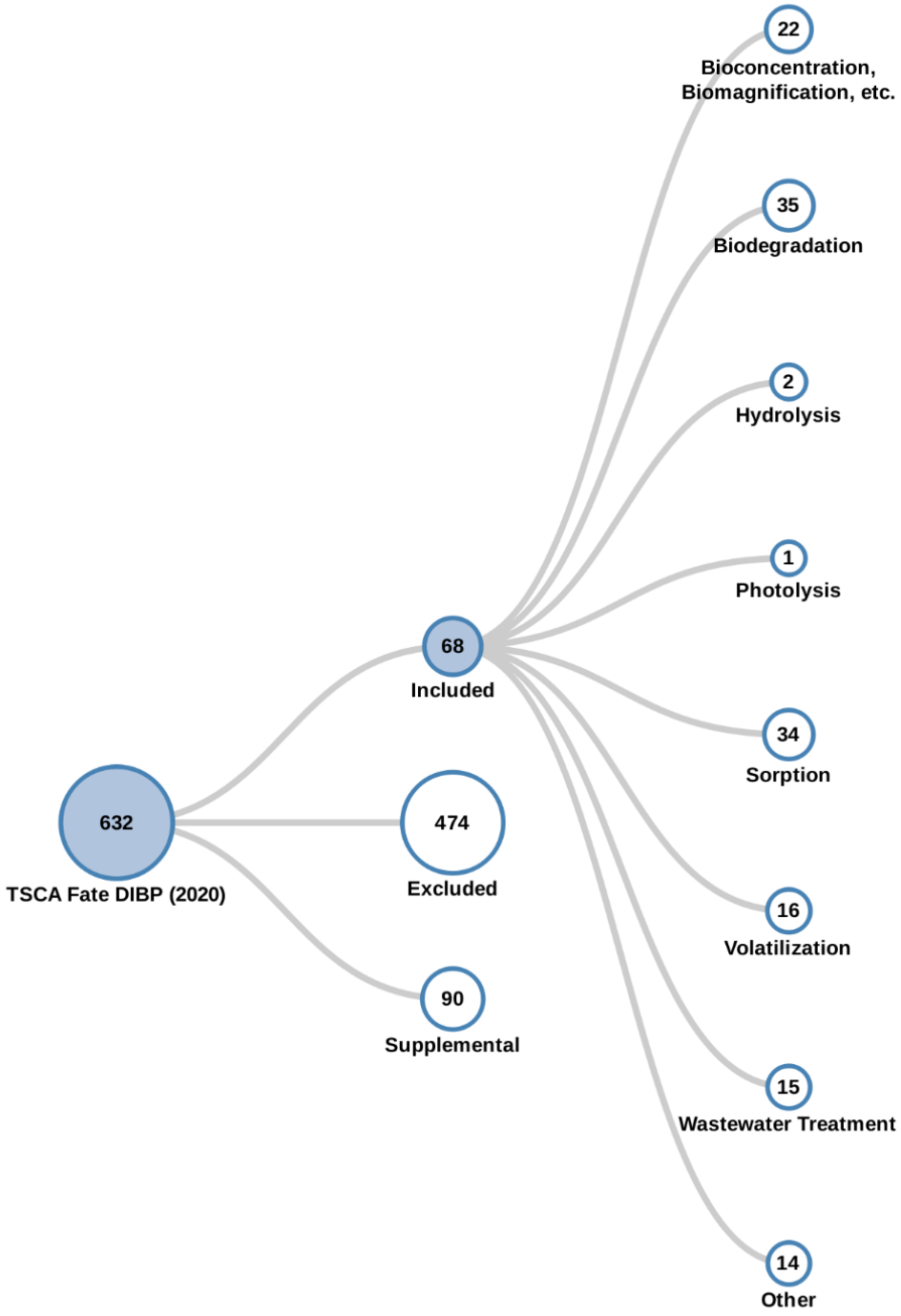

Figure 2-3. Peer-reviewed Literature - Fate and Transport Search Results for Di-isobutyl Phthalate

Click here for interactive Health Assessment Workplace Collaborative (HAWC) Diagram.

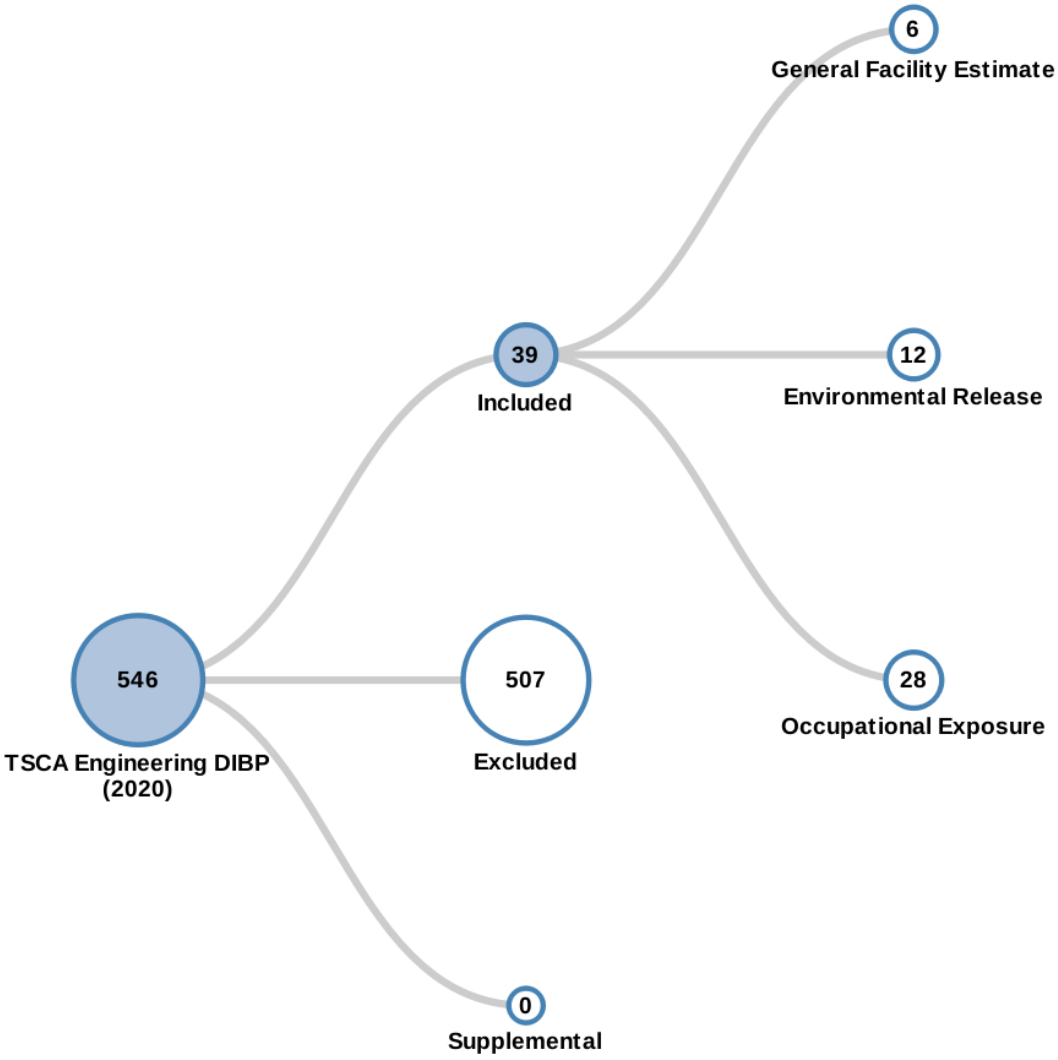

Figure 2-4. Peer-reviewed Literature - Engineering Search Results for Di-isobutyl Phthalate
Click here for interactive HAWC Diagram.

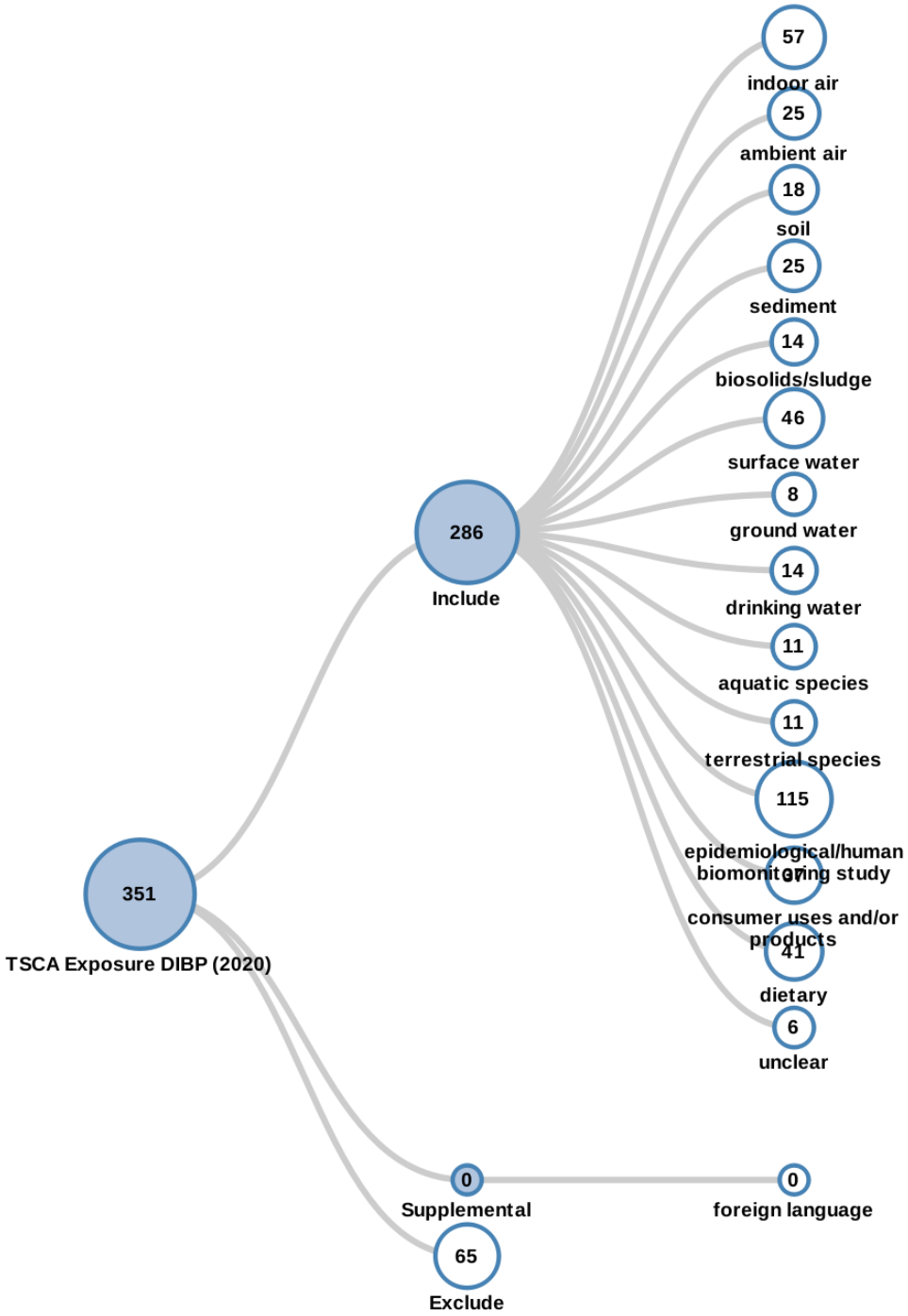

Figure 2-5. Peer-reviewed Literature - Exposure Search Results for Di-isobutyl Phthalate
Click here for interactive HAWC Diagram.

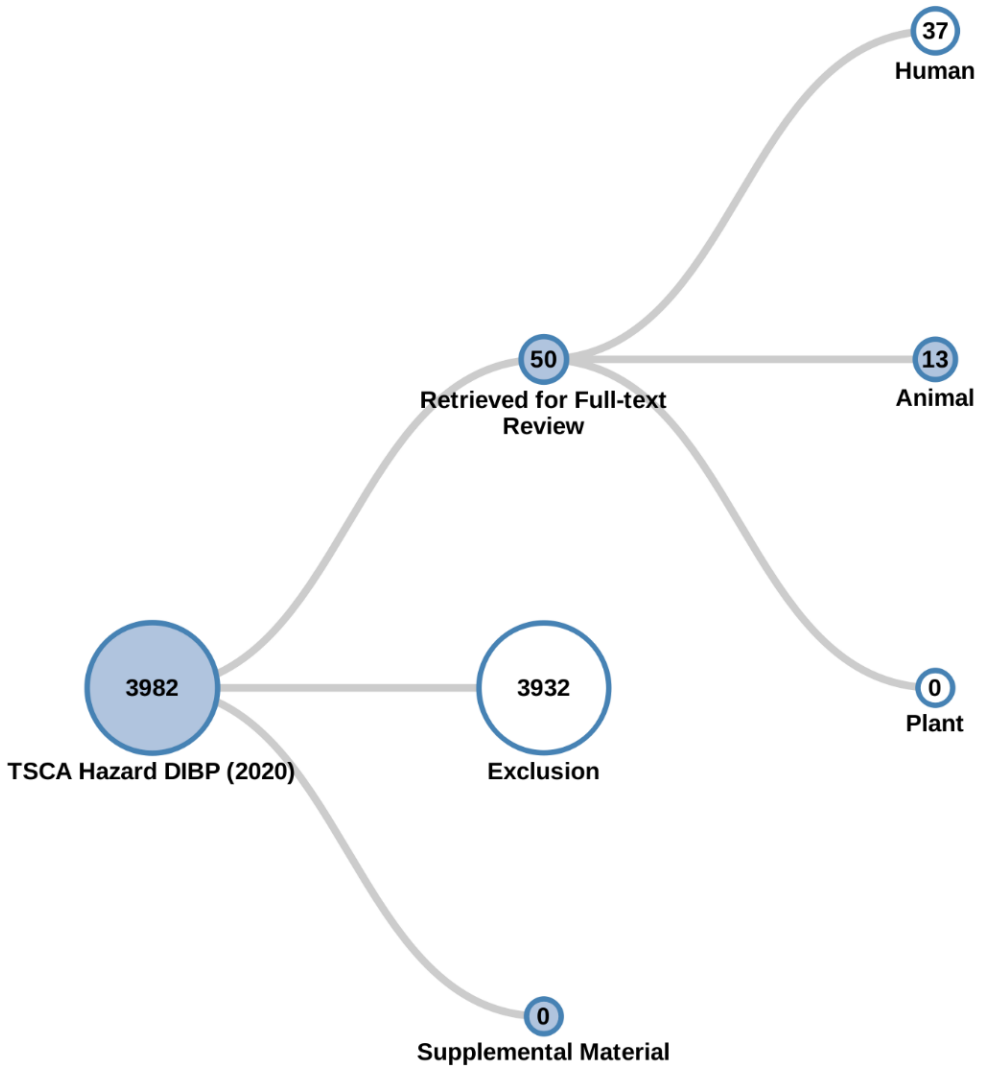

Figure 2-6. Peer-reviewed Literature - Hazard Search Results for Di-isobutyl Phthalate
Click here for interactive HAWC Diagram.

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 criteria specific to individual disciplines (see Table 2-1 for the list of disciplines). The details about the criteria are not part of this document but will be provided in a supplemental document that EPA anticipates releasing prior to the finalization of the scope document. EPA identified eleven submissions that met the inclusion criteria in these statements and identified zero submissions with supplemental data. EPA excluded two submissions because the reports were identified as one of the following:

- Record of telephone communication
- Letter with no data

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

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

Discipline	Included	Supplemental
P-Chem Properties	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

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, 2019b), EPA assembled information from the CDR program to determine conditions of use[3] or significant changes in conditions of use of the chemical substance. EPA also consulted a variety of other sources to identify uses of 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) 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 to supplement the use information.
EPA identified and described the categories and subcategories of conditions of use that will be included in the scope of the risk evaluation (Section 2.2.1; Table 2-2). The conditions of use included in the scope are those reflected in the life cycle diagrams and conceptual models.

After gathering the conditions of use, EPA identified those categories or subcategories of use activities for di-isobutyl phthalate the Agency determined not to be conditions of use or will otherwise be excluded during scoping. These categories and subcategories are described in Section 2.2.2.

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

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

[3] *Conditions of use* means the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of (15 U.S.C. § 2602(4)).

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

Life Cycle Stage	Category	Subcategory	References
Manufacturing	Domestic Manufacturing	Domestic Manufacturing	U.S. EPA (2019a)
	Import	Import	U.S. EPA (2019a)
Processing	Incorporation into article	Plasticizers in: -Construction; plastic product manufacturing; transportation equipment manufacturing	U.S. EPA (2019a)
	Processing – incorporation into formulation, mixture, or reaction product	Plasticizers in: - Adhesive manufacturing; Plastic product manufacturing	U.S. EPA (2019a)
		Solvents (which become part of product formulations or mixture) – Plastic material and resin manufacturing	U.S. EPA (2019a)
		-Paints and Coatings	CPSC (2015); Lanxess Corporation (2015)
		-Viscosity Adjusters	CPSC (2015)
		Fuels and Related Products (e.g., Fuel additives)	CPSC (2015); Lanxess Corporation (2015)
		Processing aids, not otherwise listed	Lanxess Corporation (2015)
		Inks, Toner, and Colorant Products (e.g., Toner/ printer cartridge)	CPSC (2015); Lanxess Corporation (2015)
		Repackaging (e.g., laboratory chemicals	EPA-HQ-OPPT-2018-0504-0019
		Paper Products	CPSC (2015)

Life Cycle Stage	Category	Subcategory	References
		Plastic and rubber products not covered elsewhere	Lanxess Corporation (2015); EPA-HQ-OPPT-2018-0434-0014
		Fabric, textile, and leather products not covered elsewhere	Dow Chemical Company (2013); CPSC (2015)
	Recycling	Recycling	EPA-HQ-OPPT-2018-0434-0014
Distribution in commerce	Distribution in commerce		
Industrial	Paints and Coatings	Paints and Coatings	CPSC (2015); Lanxess Corporation (2015)
	Fuels and Related Products	Fuels and Related Products	(U.S. CPSC, 2015); 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); CPSC (2015)
	Inks, Toner, and Colorant Products	Inks, Toner, and Colorant Products (e.g., Toner/printer cartridge)	CPSC (2015); Lanxess Corporation (2015)

Life Cycle Stage	Category	Subcategory	References
	Building/construction materials not covered elsewhere	Building/construction materials not covered elsewhere	CPSC (2015); Lanxess Corporation (2015)
	Floor coverings	Floor coverings	EPA-HQ-OPPT-2018-0434-0014; CPSC (2015)
	Food packaging material	Food packaging material	CPSC (2015)
	Paper Products	Paper Products	CPSC (2015)
Commercial	Adhesives and sealants	-Adhesives and sealants -Two-component glues and adhesives	U.S. EPA (2019a) Glue 360 Inc. (2018)
	Catalyst solvent	Catalyst solvent	U.S. EPA (2019a)
	Paints and Coatings	Paints and Coatings	CPSC (2015); Lanxess Corporation (2015)
	Plastic and rubber products not covered elsewhere	Plastic and rubber products not covered elsewhere	U.S. EPA (2019a); Lanxess Corporation (2015); EPA-HQ-OPPT-2018-0434-0014
	Inks, Toner, and Colorant Products	Inks, Toner, and Colorant Products (e.g., Toner/printer cartridge)	CPSC (2015); Lanxess Corporation (2015)
	Laboratory chemicals	Laboratory chemicals	Sigma-Aldrich Inc. (2020)
	Furnishing, Cleaning, Treatment/Care Products	Furnishing, Cleaning, Treatment/Care Products (e.g., Laundry and dishwashing products)	CPSC (2015)
	Explosive Materials	Explosive Materials	CPSC (2015)
	Air Care Products	Air Care Products (e.g., Air Freshener)	CPSC (2015)
	Floor coverings	Floor coverings	EPA-HQ-OPPT-2018-0434-0014); CPSC (2015)
	Lubricants	Lubricants	CPSC (2015)

Life Cycle Stage	Category	Subcategory	References
	Food packaging material	Food packaging material	CPSC (2015)
Consumer	Air Care Products	Air Care Products (e.g., Air Freshener)	CPSC (2015)
	Floor coverings	Floor coverings	EPA-HQ-OPPT-2018-0434-0014); CPSC (2015)
	Toys, playground, and sporting equipment	Toys, playground, and sporting equipment	EPA-HQ-OPPT-2018-0434-0014); CPSC (2015)
	Paints and Coatings	Paints and Coatings	CPSC (2015); Lanxess Corporation (2015)
	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)	CPSC (2015); Lanxess Corporation (2015)
	Furnishing, Cleaning, Treatment/Care Products	Furnishing, Cleaning, Treatment/Care Products (e.g., Laundry and dishwashing products)	CPSC (2015)
	Plastic and rubber products not covered elsewhere	Plastic and rubber products not covered elsewhere	Lanxess Corporation (2015); EPA-HQ-OPPT-2018-0434-0014
	Paper Products	Paper Products	CPSC (2015)
	Adhesives and sealants	Adhesives and sealants	U.S. EPA (2019a); ITW Performance Polymers (2015)
Disposal	Disposal	Disposal	

Life Cycle Stage Use Definitions
- "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.

Life Cycle Stage	Category	Subcategory	References
– "Consumer use" means the use of a chemical or a mixture containing a chemical (including as part of an article, such as furniture or clothing) when sold to or made available to consumers for their use.			

2.2.2 Activities Excluded from the Scope of the Risk Evaluation

As explained in the final rule, *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act*, TSCA Section 6(b)(4)(D) requires EPA to identify the hazards, exposures, conditions of use, and the PESS the Administrator expects to consider in a risk evaluation, suggesting that EPA may exclude certain activities that it determines to be conditions of use on a case-by-case basis (82 FR 33726, 33729; July 20, 2017). As a result, EPA plans not to include in this scope or in the risk evaluation the activities described below that the Agency has concluded do not constitute conditions of use.

The U.S. Consumer Product Safety Commission lists use of Di-isobutyl phthalate in perfume, nail polish and dentistry settings (U.S. CPSC, 2015), but these activities and releases associated with consumer uses are not TSCA conditions of use and will not be evaluated during the risk evaluation. Perfume, nail polish and dentistry settings uses are covered by the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321 and are therefore outside the scope of the definition of chemical substance[4] as regulated by TSCA. However, processing and industrial uses of these products are covered by TSCA and will be considered a condition of use.

2.2.3 Production Volume

Production volume of di-isobutyl phthalate in 2011, as reported to EPA during the 2012 CDR reporting period, was up to 500,000 pounds (U.S. EPA, 2017). Production volume reported to EPA during the 2016 CDR reporting period is CBI. EPA also uses pre-2011 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, 2019b) and will include future production volume information as it becomes available to support the exposure assessment.

2.2.4 Overview of Conditions of Use and Lifecycle Diagram

The life cycle diagram provided in Figure 2-8 depicts the conditions of use that are considered within the scope of the risk evaluation for the various life cycle stages as presented in Section 2.2.1. This

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

section provides a brief overview of the industrial, commercial and consumer use categories included in the life cycle diagram, which does not include the activities that EPA determined are out of scope. 0 contains more detailed descriptions (e.g., process descriptions, worker activities, process flow diagrams) for each manufacture, processing, distribution in commerce, use and disposal category.

The information in the life cycle diagram is grouped according to the CDR processing codes and use categories (including functional use codes for industrial uses and product categories for industrial, commercial and consumer uses). The production volume of di-isobutyl phthalate in 2011 is included in the lifecycle diagram, as reported to EPA during the 2016 CDR reporting period, as a range between 1 and 500,000 pounds (U.S. EPA, 2017) to protect production volumes that were claimed as CBI.

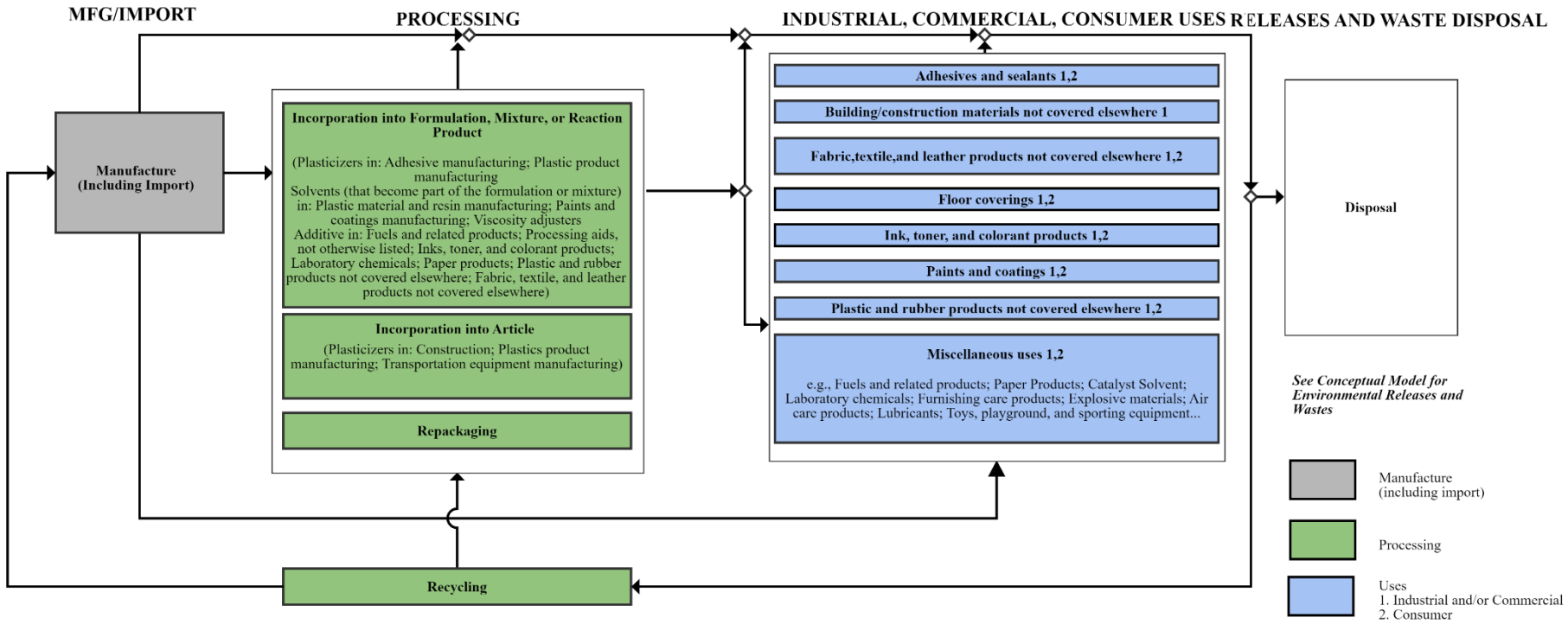

Figure 2-7. Di-isobutyl Phthalate Life Cycle Diagram

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

2.3 Exposures

For TSCA exposure assessments, EPA plans to analyze exposures and releases to the environment resulting from the conditions of use within the scope of the risk evaluation for di-isobutyl phthalate. Release pathways and routes will be described to characterize the relationship or connection between the conditions of use of the chemical and the exposure to human receptors, including 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 p-chem properties are essential for a thorough understanding or prediction of environmental fate (i.e., transport and transformation) and the eventual environmental concentrations. They can also inform the hazard assessment. EPA plans to use the physical and chemical properties described in the *Proposed Designation of Di-isobutyl Phthalate (DIBP) (CASRN 84-69-5) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019b) to support the development of the risk evaluation for di-isobutyl phthalate. The values for the physical and chemical properties (Appendix B) may be updated as EPA collects additional information through systematic review methods.

2.3.2 Environmental Fate and Transport

Understanding of environmental fate and transport processes assists in the determination of the specific exposure pathways and potential human and environmental receptors that need to be assessed in the risk evaluation for di-isobutyl phthalate. EPA plans to use the environmental fate characteristics 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, 2019b) to support the development of the risk evaluation for di-isobutyl phthalate. The values for the environmental fate properties (Appendix C) may be updated as EPA collects additional information through systematic review methods.

2.3.3 Releases to the Environment

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

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. EPA plans to review reasonably available environmental exposure data in biota in the risk evaluation.

There is some evidence of environmental concentration data present based on preliminary review of reasonably available data (MDI (2002). Relevant and reliable monitoring studies provide information that can be used in an exposure assessment. Monitoring studies that measure environmental concentrations or concentrations of chemical substances in biota provide evidence of exposure. EPA plans to review reasonably available information on environmental exposures in biota to inform the development of the environmental exposure assessment for di-isobutyl phthalate.

2.3.5 Occupational Exposures

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

Worker activities associated with these conditions of use that will be analyzed include, but are not limited to:

- Unloading and transferring di-isobutyl phthalate to and from storage containers to process vessels;
- Handling, transporting 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;

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 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. 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 does not plan to analyze dermal exposure for ONUs that do not directly handle di-isobutyl phthalate.

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

where there is information and data on incidental ingestion of inhaled dust. EPA will consider ingestion of inhaled dust as an inhalation exposure for di-isobutyl phthalate.

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; cleaning and furnishing care products; fabric, textile, and leather products not covered elsewhere; floor coverings; ink, toner, and colorant products; paints and coatings; paper products; plastic and rubber products not covered elsewhere; and toys, playground, and sporting equipment (See Section 2.6.2 and Figure 2-8). 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 either ingestion through product use via transfer from hand to mouth or via through mouthing of articles containing di-isobutyl phthalate. Dermal exposure may occur via contact with vapor or mist deposition onto the skin, via direct liquid contact during use, or direct dermal contact of articles containing di-isobutyl phthalate. Based on these potential sources and pathways of exposure, EPA plans to analyze oral, dermal and inhalation exposures to consumers and inhalation exposures to bystanders that may result from the conditions of use of di-isobutyl phthalate.

2.3.7 General Population Exposures

Releases of di-isobutyl phthalate from certain conditions of use, such as manufacturing, processing, or disposal activities, may result in general population exposures via drinking water ingestion, dermal contact, and inhalation from air releases (CPSC 2010b). Available assessments reviewed indicate that diet has been reported 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 (2002)). EPA plans to review the reasonably available information for the presence of di-isobutyl phthalate in environmental media relevant to general population exposure.

Available assessments reviewed indicate that diet has been reported 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 occuring. EPA plans to review reasonably available data related to general population exposures in the risk evaluation.

2.4 Hazards (Effects)

2.4.1 Environmental Hazards

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, 2019b), EPA considered reasonably available information from peer-reviewed assessments and databases to identify potential environmental hazards for di-isobutyl phthalate. EPA considers all the potential environmental hazards for di-isobutyl phthalate identified during prioritization (U.S. EPA 2019b) to be relevant for the risk evaluation and thus they remain within the scope of the evaluation. EPA is in the process of identifying additional reasonably available information through systematic review methods and public comments, which may update the list of potential environmental hazards associated with di-isobutyl phthalate. If necessary, EPA plans to update the list of potential hazards in the final scope document of di-isobutyl phthalate. Based on information identified during prioritization, environmental hazard effects were identified for aquatic and terrestrial organisms.

2.4.2 Human Health Hazards

As described in the *Proposed Designation of Di-isobutyl Phthalate (DIBP) (CASRN 84-69-5) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019b), EPA considered reasonably available information from peer-reviewed assessments and databases to identify potential human health hazards for di-isobutyl phthalate. EPA plans to evaluate all the potential human health hazards for di-isobutyl phthalate identified during prioritization. The health effect categories screened for during prioritization included acute toxicity, irritation/corrosion, dermal sensitization, respiratory sensitization, genetic toxicity, repeated dose toxicity, reproductive toxicity, developmental toxicity, immunotoxicity, neurotoxicity, carcinogenicity, epidemiological or biomonitoring studies and ADME (absorption, distribution, metabolism, and excretion).

The broad health effect categories included for further evaluation from designation are developmental and reproductive effects. EPA is in the process of identifying additional reasonably available information through systematic review methods and public input, which may update the list of potential human health hazards under the scope of the risk evaluation. If necessary, EPA plans to update the list of potential hazards in the final scope document of the di-isobutyl phthalate risk evaluation.

2.5 Potentially Exposed or Susceptible Subpopulations

TSCA § 6(b)(4) requires EPA to determine whether a chemical substance presents an unreasonable risk to "a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation." TSCA §3(12) states that "the term 'potentially exposed or susceptible subpopulation', or PESS, means a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population for adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly." General population is "the total of individuals inhabiting an area or making up a whole group" and refers here to the U.S. general population (U.S. EPA, 2011).

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

In developing exposure scenarios, EPA plans to analyze reasonably available data to ascertain whether some human receptor groups may be exposed via exposure pathways that may be distinct to a particular subpopulation or life stage (e.g., children's crawling, mouthing or hand-to-mouth behaviors) and whether some human receptor groups may have higher exposure via identified pathways of exposure due to unique characteristics (e.g., activities, duration or location of exposure) when compared with the general population (U.S. EPA, 2006a). Likewise, EPA plans to evaluate reasonably available human health hazard information to ascertain whether some human receptor groups may have greater susceptibility than the general population to the chemical's hazard(s).

2.6 Conceptual Models

In this section, EPA presents the conceptual models describing the identified exposures (pathways and routes), receptors and hazards associated with the conditions of use of 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 are discussed and depicted the conceptual model shown in Section 2.6.3.

2.6.1 Conceptual Model for Industrial and Commercial Activities and Uses

Figure 2-8 illustrates the conceptual model for the pathways of exposure from industrial and commercial activities and uses of di-isobutyl phthalate that EPA plans to include in the risk evaluation. There is potential for exposures to workers and/or ONU's via inhalation routes and exposures to workers via dermal routes. EPA plans to evaluate activities resulting in exposures associated with distribution in commerce (e.g., loading, unloading) throughout the various lifecycle stages and conditions of use (e.g., manufacturing, processing, industrial use, commercial use, and disposal) rather than a single distribution scenario. For each condition of use identified in Table 2-2, an initial determination was made as to whether or not each unique combination of exposure pathway, route, and receptor will be analyzed in the risk evaluation. The supporting rationale is presented in Appendix F.

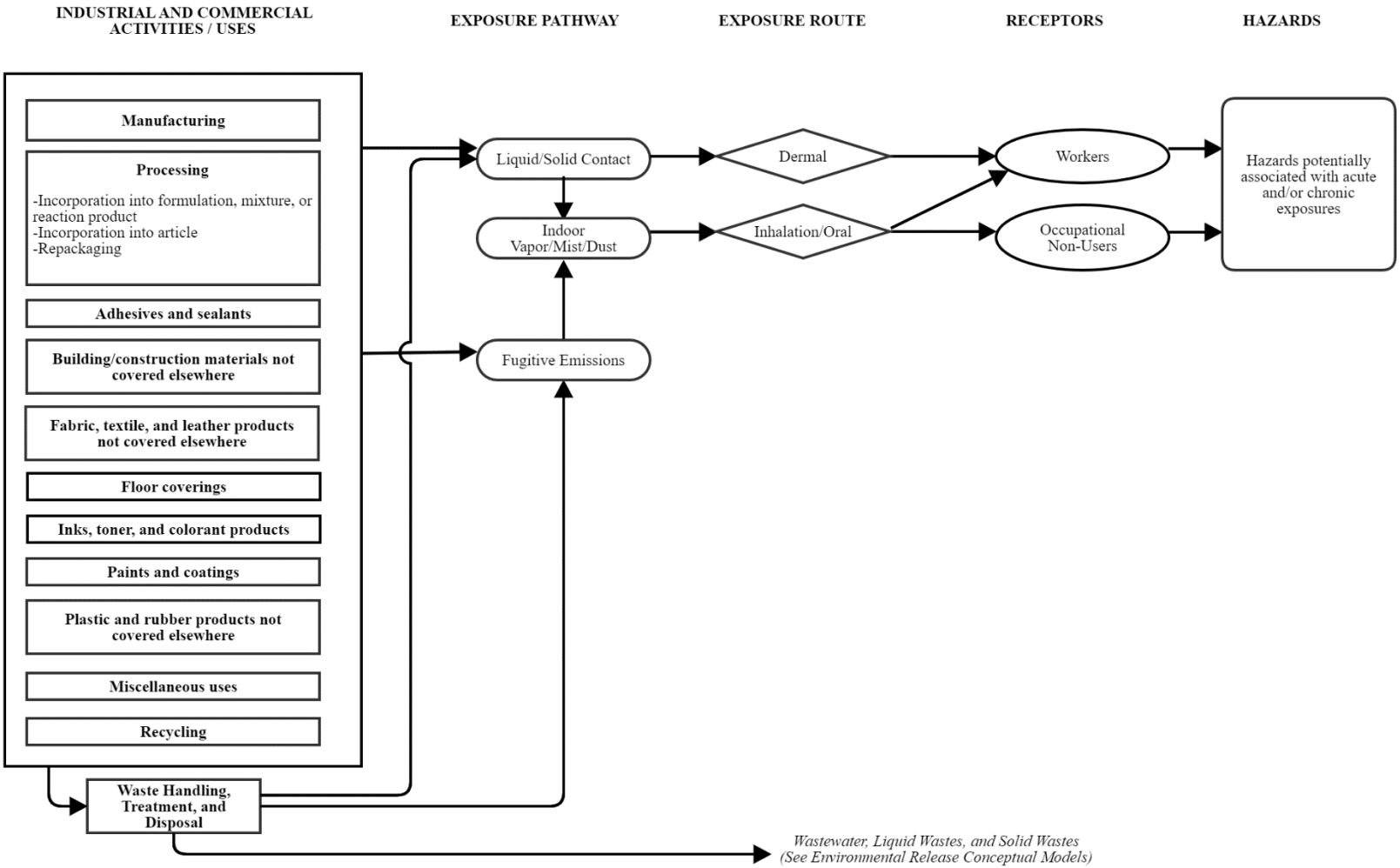

Figure 2-8. Di-isobutyl Phthalate Conceptual Model for Industrial and Commercial Activities and Uses: Worker and Occupational Non-User Exposures and Hazards

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 2-9 presents the exposure pathways, exposure routes and hazards to human receptors from consumer activities and uses of di-isobutyl phthalate. EPA expects that consumers may be exposed through product use or articles 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. Bystanders are expected to be exposed through product use via inhalation. It should be noted that some consumers may purchase and use products primarily intended for commercial use. EPA plans to 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.

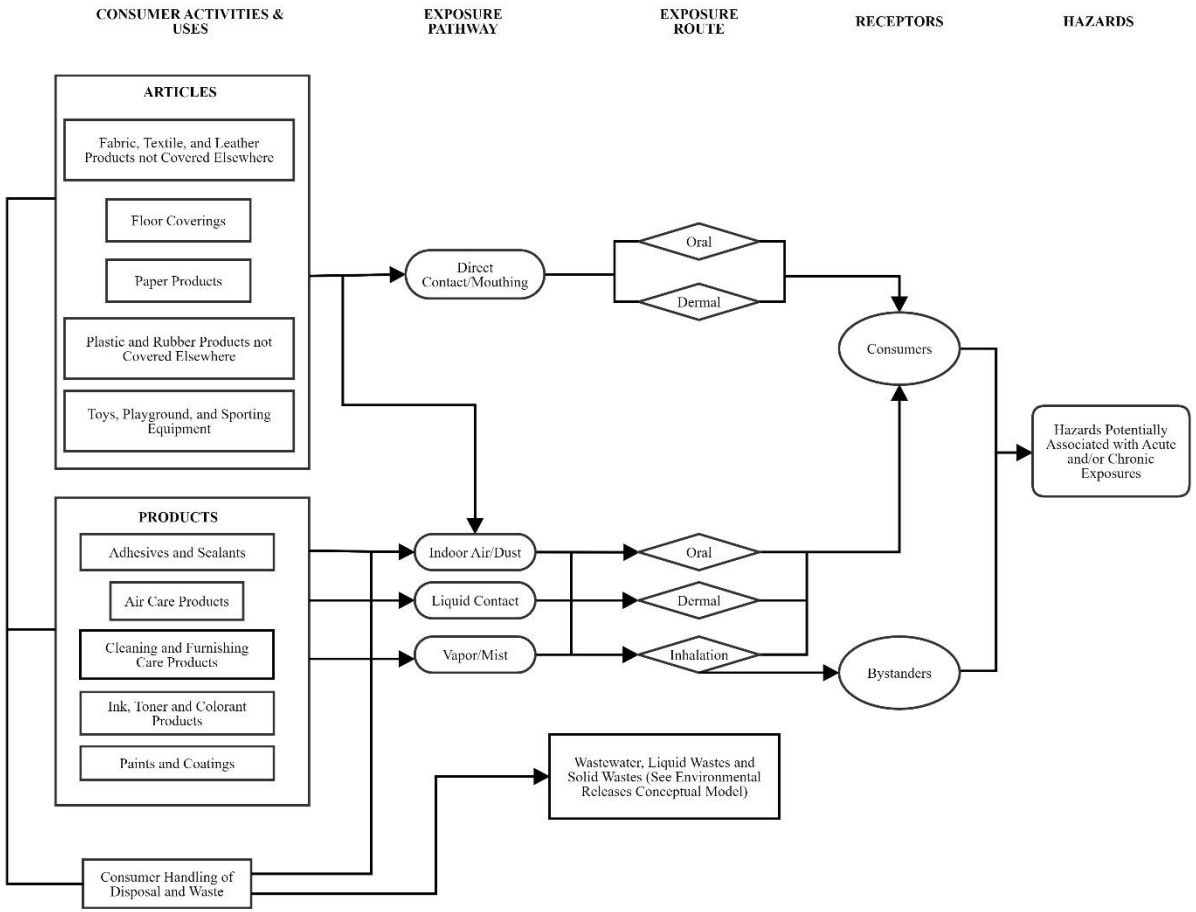

Figure 2-9. Di-isobutyl Phthalate Conceptual Model for Consumer Activities and Uses: Consumer Exposures and Hazards
The conceptual model presents the exposure pathways, exposure routes, and hazards to human receptors from consumer activities and uses of di-isobutyl phthlate.

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

Figure 2-10 presents the potential exposure pathways, exposure routes and hazards to human and environmental receptors from releases and waste streams associated with industrial, commercial and consumer uses of di-isobutyl phthalate. EPA plans to evaluate exposures to receptors (e.g., general population, aquatic, terrestrial species) that may occur from industrial and/or commercial and consumer releases to air, water or land, including biosolids and soil, and other conditions of use. 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; orally via drinking water, fish and soil ingestion; and dermally from contact with groundwater and soil. The supporting rationale for general population and environmental pathways considered for di-isobutyl phthalate are included in Appendix H.

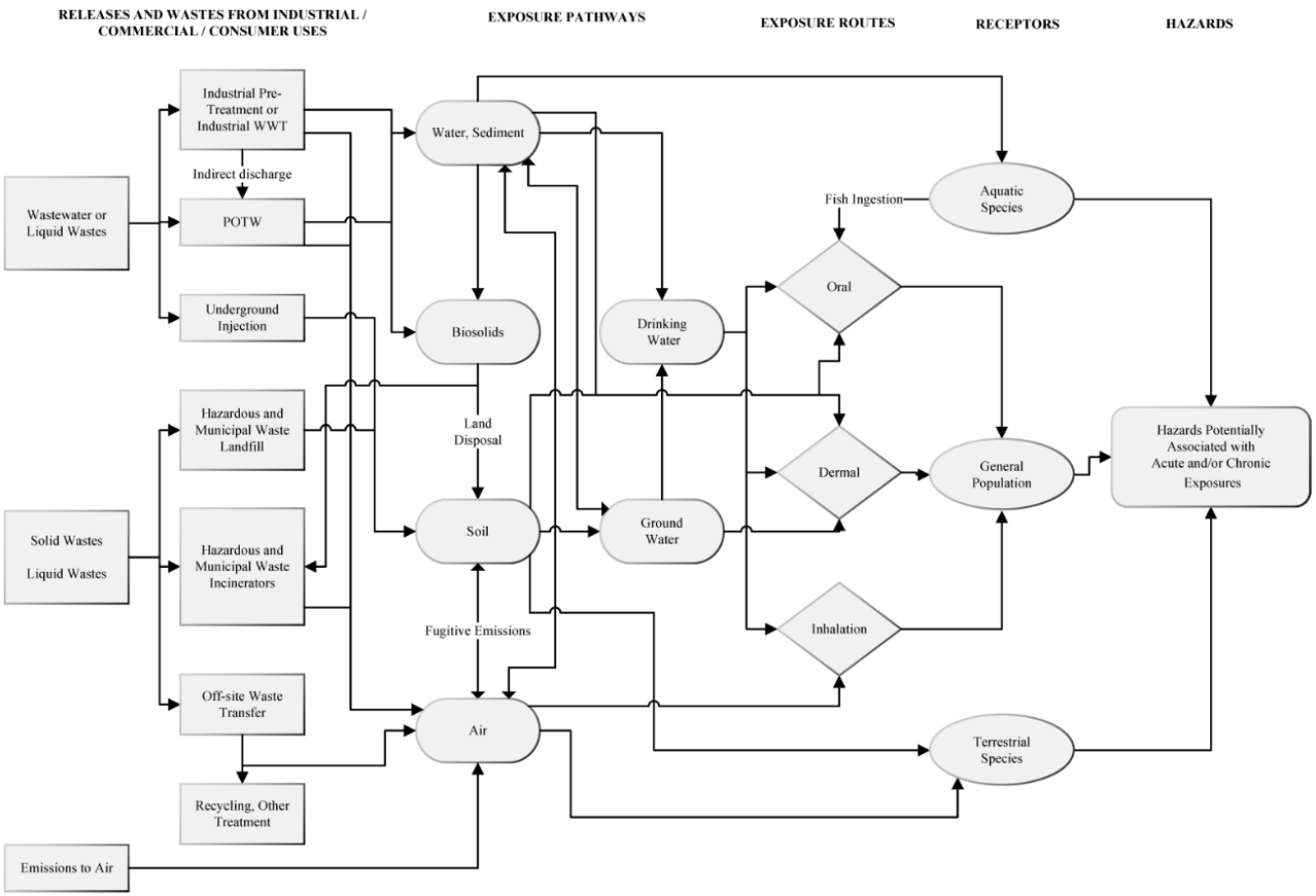

Figure 2-10. Di-isobutyl Phthalate Conceptual Model for Environmental Releases and Wastes: Environmental and General Population Exposures and Hazards.

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

2.7.1 Physical and Chemical Properties and Environmental Fate

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

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

2) **Using measured data and/or modeling, determine the influence of p-chem properties and environmental fate endpoints (e.g., persistence, bioaccumulation, partitioning, transport) on exposure pathways and routes of exposure to human and environmental receptors.** Measured data and, where necessary, model predictions of p-chem properties and environmental fate endpoints will be used to characterize the persistence and movement of 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 p-chem and environmental fate data, including qualitative and quantitative sources of information.** During risk evaluation, EPA plans to evaluate and integrate the p-chem and environmental fate evidence identified in the literature inventory using the methods described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document.

2.7.2 Exposure

EPA plans to analyze exposure levels for indoor air, surface water, drinking water, sediment, soil, aquatic biota, and terrestrial biota associated with exposure to di-isobutyl phthalate. EPA has not yet determined the exposure levels in these media or how they may be used in the risk evaluation. Exposure scenarios are

sources (uses), exposure pathways, and exposed receptors. EPA plans to analyze scenario-specific exposures. Based on their p-chem properties, expected sources, and transport and transformation within the outdoor and indoor environment, chemical substances are more likely to be present in some media and less likely to be present in others. Exposure level(s) can be characterized through a combination of reasonably available monitoring data and modeling approaches.

2.7.2.1 Environmental Releases

EPA plans to analyze releases to environmental media as follows:

1) **Review reasonably available published literature and other reasonably available information on processes and activities associated with the conditions of use to analyze the types of releases and wastes generated.** EPA has reviewed some key data sources containing information on processes and activities resulting in releases, and the information found is described in Appendix D. EPA plans to continue to review data sources during risk evaluation using the evaluation strategy in the systematic review documentation that EPA plans to publish prior to finalizing the scope document. Potential sources of environmental release data are summarized in Table 2-3 below:

Table 2-3. 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 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 Occupational Exposures and Releases ChemSTEER (U.S. EPA, 2013).

3) **Review reasonably available measured or estimated release data for surrogate chemicals that have similar uses and physical properties.** If surrogate data are identified, these data will be matched with applicable conditions of use for potentially filling data gaps. Measured or estimated release data for other phthalate esters may be considered as surrogates for di-isobutyl phthalate.

4) **Review reasonably available data that may be used in developing, adapting or applying exposure models to the particular risk evaluation.** This item will be performed after completion of #2 and #3 above. EPA plans to evaluate relevant data to determine whether the data can be used to develop, adapt or apply models for specific conditions of use (and corresponding release scenarios). EPA has identified information from various EPA statutes (including, for example, regulatory limits, reporting thresholds or disposal requirements) that may be relevant to release estimation. EPA plans to 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, the 2011 ESD on Coating Application via Spray-Painting in the Automotive Refinishing Industry, the 2011 ESD on Chemical Industry, the 2011 ESD on Radiation Curable Coating, Inks and Adhesives, the 2015 ESD on the Use of Adhesives, and the 2009 ESD on Plastic Additives may be useful to assess potential releases. EPA plans to critically review these generic scenarios and ESDs to determine their applicability to the conditions of use.

   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

   EPA may also need to perform targeted research for applicable models and associated parameters that EPA may use to estimate releases for certain conditions of use. If ESDs and GSs are not available, other methods may be considered. Additionally, for conditions of use where no measured data on releases are available, EPA may use a variety of methods including the application of default assumptions such as standard loss fractions associated with drum cleaning (3%) or single process vessel cleanout (1%).

6) **Map or group each condition of use to a release assessment scenario(s).** EPA has identified release scenarios and mapped (i.e., grouped) them to relevant conditions of use as shown in Appendix F. EPA may refine the mapping of release scenarios based on factors (e.g., process equipment and handling, magnitude of production volume used, and release sources and usage rates of di-isobutyl phthalate and articles and formulations containing di-isobutyl phthalate, or professional judgment) corresponding to conditions of use as additional information is identified during risk evaluation.

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

2.7.2.2 Environmental Exposures

EPA plans to analyze the following in developing its environmental exposure assessment of 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 will be analyzed are sediment, soil, and water.

2) **Review reasonably available information on releases to determine how modeled estimates of concentrations near industrial point sources compare with reasonably available monitoring data.**
Reasonably available environmental exposure models that meet the TSCA Science Standards and that estimate water, sediment, and soil concentrations will be analyzed and considered alongside reasonably available water, sediment, and soil monitoring data to characterize environmental exposures. Modeling approaches to estimate surface water concentrations, sediment concentrations and soil concentrations generally will include the following inputs: direct release into 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.
    - Modeling inputs for release into the media of interest, fate and transport and characteristics of the environment.
    - Reasonably available biomonitoring data. Monitoring data could be used to compare with species or taxa-specific toxicological benchmarks.
    - Applicability of existing additional contextualizing information for any monitored data or modeled estimates during risk evaluation. Review and characterize the spatial and temporal variability, to the extent that data are reasonably available, and characterize exposed aquatic and terrestrial populations.
    - Weight of the scientific evidence of environmental occurrence data and modeled estimates.

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

2.7.2.3 Occupational Exposures

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

1) **Review reasonably available exposure monitoring data for specific condition(s) of use.** EPA plans to review exposure monitoring data found in published literature (including both personal exposure monitoring data (direct exposures) and area monitoring data (indirect exposures)). EPA has reviewed 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 chemical and physical 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. EPA believes 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 and the 2009 ESD on Plastic Additives, the are some of the ESDs and GS's that EPA may use to estimate occupational exposures. EPA plans to critically review these generic scenarios and ESDs to determine their applicability to the conditions of use assessed. EPA plans to perform additional targeted research to understand those conditions of use where ESDs or GS's were not identified, which may inform the exposure scenarios. EPA may also need to perform targeted research to identify applicable models that EPA may use to estimate exposures for certain conditions of use.

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

5) **Consider and incorporate applicable EC and/or PPE into exposure scenarios.** EPA plans to review potentially relevant data sources on EC and PPE to determine their applicability and

incorporation into exposure scenarios during risk evaluation. EPA plans to assess worker exposure pre- and post-implementation of EC, using reasonably available information on available control technologies and control effectiveness. For example, EPA may assess worker exposure in industrial use scenarios before and after implementation of local exhaust ventilation.

6) **Map or group each condition of use to occupational exposure assessment scenario(s).** EPA has identified occupational exposure scenarios and mapped them to relevant conditions of use (see Appendix F). As presented in Table_Apx F-1, EPA has grouped the scenarios into representative release/exposure scenarios. EPA was not able to identify occupational scenarios corresponding to some conditions of use. EPA plans to perform targeted research to understand those uses which may inform identification of occupational exposure scenarios. EPA may refine the mapping of occupational exposure scenarios based on factors (e.g., process equipment and handling, magnitude of production volume used, and exposure/release sources) corresponding to conditions of use as additional information is identified during risk evaluation.

7) **Evaluate the weight of the scientific evidence of occupational exposure data, which may include qualitative and quantitative sources of information.** During risk evaluation, EPA plans to evaluate and integrate the exposure evidence identified in the literature inventory using the methods described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document. EPA plans to rely on the weight of the scientific evidence when evaluating and integrating occupational data. The data integration strategy will be designed to be fit-for-purpose in which EPA plans to use systematic review methods to assemble the relevant data, evaluate the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence.

2.7.2.4 Consumer Exposures

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

1) **Group each condition of use to consumer exposure assessment scenario(s).** 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 and type of consumer product
   - Duration, frequency and magnitude of exposure
   - Weight fraction of chemical in products
   - Amount of chemical used

2) **Evaluate the relative potential of indoor exposure pathways based on reasonably available data.** Indoor exposure pathways may include inhalation of indoor air during di-isobutyl phthalate use and disposal, dermal contact to liquids or articles and mouthing of articles. The data sources associated with these respective pathways have not yet been comprehensively evaluated, so quantitative comparisons across exposure pathways or in relation to toxicity thresholds are not yet available.

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

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

4) **Review reasonably available empirical data that may be used in developing, adapting or applying exposure models to a particular risk evaluation scenario. For example, existing models developed for a chemical assessment may be applicable to another chemical assessment if model parameter data are available.** To the extent other organizations have already modeled a 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 air).** The availability of di-isobutyl phthalate concentration for various ongoing uses will be evaluated. This data provides the source term for any subsequent indoor modeling. Source attribution between overall indoor air levels and various indoor sources will be analyzed.

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

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

2.7.2.5 General Population

EPA plans to analyze general population exposures as follows:

1) **Refine and finalize exposure scenarios for general population by considering combinations of sources and uses, exposure pathways including routes, and exposed populations.** For 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 models that may be applicable in estimating exposure levels.
    - Consider and incorporate applicable media-specific regulations into exposure scenarios or modeling.
    - Review reasonably available data that may be used in developing, adapting or applying exposure models to the particular risk evaluation. For example, existing models developed for a chemical assessment may be applicable to another chemical assessment if model parameter data are reasonably available.
    - Review reasonably available information on releases to determine how modeled estimates of concentrations near industrial point sources compare with reasonably available monitoring data.
    - Review reasonably available population- or subpopulation-specific exposure factors and activity patterns to determine if 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).
    - Environmental Exposure pathways regulated by non-TSCA EPA laws and regulations will be excluded from analysis

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

    After refining and finalizing exposure scenarios, EPA plans to quantify concentrations and/or doses for these scenarios. The number of scenarios will depend on how combinations of uses, exposure pathways, and receptors are characterized. The number of scenarios is also dependent upon the

reasonably available data and approaches to quantify scenarios. When quantifying exposure scenarios, EPA plans to use a tiered approach. First-tier analysis is based on data that is reasonably available without a significant number of additional inputs or assumptions, and may be qualitative, semi-quantitative, or quantitative. First-tier analyses were conducted during problem formulation and are expected to continue during risk evaluation. The results of first tier analyses inform whether scenarios require more refined analysis. Refined analyses will be iterative and require careful consideration of variability and uncertainty. Should data become reasonably available that summarily alters the overall conclusion of a scenario through iterative tiering, EPA can refine its analysis during risk evaluation.

2) **For exposure pathways where empirical data is not reasonably available, review existing exposure models that may be applicable in estimating exposure levels.** For di-isobutyl phthalate, media where exposure models will be considered for general population exposure include models that estimate, surface water concentrations, sediment concentrations, soil concentrations, and uptake from aquatic and terrestrial environments into edible aquatic and terrestrial organisms.

3) **Review reasonably available exposure modeled estimates. For example, existing models developed for a previous 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 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 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 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 systematic review documentation that EPA plans to publish prior to finalizing the scope document.

2.7.3 Hazards (Effects)

2.7.3.1 Environmental Hazards

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

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

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

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

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

4) **Consider the route(s) of exposure, based on reasonably available monitoring and modeling data and other reasonably available approaches to integrate exposure and hazard assessments.** EPA plans to consider 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) **Conduct an environmental risk characterization of di-isobutyl phthalate.** EPA plans to conduct a risk characterization of di-isobutyl phthalate to identify if there are risks to the aquatic and/or terrestrial environments from the measured and/or predicted concentrations of di-isobutyl phthalate in environmental media (i.e., water, sediment, soil). Risk quotients (RQs) may be derived by the application of hazard and exposure benchmarks to characterize environmental risk (U.S. EPA, 1998; Barnthouse et al., 1982).

6) **Consider a Persistent, Bioaccumulative, and Toxic (PBT) Assessment of di-isobutyl phthalate.** EPA plans to consider the persistence, bioaccumulation, and toxic (PBT) potential of di-isobutyl phthalate after reviewing relevant p-chem 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).

2.7.3.2 Human Health Hazards

EPA plans to analyze human health hazards as follows:

1) **Review reasonably available human health hazard data, including data from alternative test methods (e.g., computational toxicology and bioinformatics; high-throughput screening methods; data on categories and read-across; *in vitro* studies; systems biology).** EPA plans to use systematic review methods to evaluate the epidemiological and toxicological literature for di-isobutyl phthalate. EPA plans to publish the systematic review documentation prior to finalizing the scope document.

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

2) **Conduct hazard identification (the qualitative process of identifying non-cancer and cancer endpoints) and dose-response assessment (the quantitative relationship between hazard and exposure) for identified human health hazard endpoints.** Human health hazards from acute and chronic exposures will be identified by evaluating the human and animal data that meet the systematic review data quality criteria described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document. Hazards identified by studies meeting data quality criteria will be grouped by routes of exposure relevant to humans (oral, dermal, inhalation) and by cancer and noncancer endpoints.

   Dose-response assessment will be performed in accordance with EPA guidance (U.S. EPA, 2012a, 2011, 1994). Dose-response analyses may be used if the data meet data quality criteria and if additional information on the identified hazard endpoints are not reasonably available or would not alter the analysis.

   The cancer mode of action (MOA) determines how cancer risks can be quantitatively evaluated. If cancer hazard is determined to be applicable to di-isobutyl phthalate, EPA plans to evaluate information on genotoxicity and the mode of action for all cancer endpoints to determine the appropriate approach for quantitative cancer assessment in accordance with the U.S. EPA Guidelines for Carcinogen Risk Assessment (U.S. EPA, 2005).

3) **In evaluating reasonably available data, determine whether particular human receptor groups may have greater susceptibility to the chemical's hazard(s) than the general population.** Reasonably available human health hazard data will be evaluated to ascertain whether some human receptor groups may have greater susceptibility than the general population to 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 PESS and lifestages such as pregnant women and infants. Pregnancy (i.e., gestation) and childhood are potential susceptible lifestages for di-isobutyl phthalate exposure. EPA plans to review the current state of the literature in order to potentially quantify these differences for risk evaluation purposes.

4) **Derive points of departure (PODs) where appropriate; conduct benchmark dose modeling depending on the reasonably available data. Adjust the PODs as appropriate to conform (e.g., adjust for duration of exposure) to the specific exposure scenarios evaluated.** Hazard data will be evaluated to determine the type of dose-response modeling that is applicable. Where modeling is feasible, a set of dose-response models that are consistent with a variety of potentially underlying biological processes will be applied to empirically model the dose-response relationships in the range of the observed data consistent with EPA's *Benchmark Dose Technical Guidance Document*. Where dose-response modeling is not feasible, NOAELs or LOAELs will be identified. Non-quantitative data will also be evaluated for contribution to weight of the scientific evidence or for evaluation of qualitative endpoints that are not appropriate for dose-response assessment.

   EPA plans to evaluate whether the reasonably available PBPK and empirical kinetic models are adequate for route-to-route and interspecies extrapolation of the POD, or for extrapolation of the POD to standard exposure durations (e.g., lifetime continuous exposure). If application of the PBPK model is not possible, oral PODs may be adjusted by $BW^{3/4}$ scaling in accordance with U.S. EPA (2011), and inhalation PODs may be adjusted by exposure duration and chemical properties in accordance with U.S. EPA (1994).

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

6) **Consider the route(s) of exposure (oral, inhalation, dermal), available route-to-route extrapolation approaches, reasonably available biomonitoring data and available approaches to correlate internal and external exposures to integrate exposure and hazard assessment.** At this stage of review, EPA believes there will be sufficient data to conduct 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. This may include using route-to-route extrapolation methods where appropriate and depending on the nature of reasonably available data.

   If sufficient toxicity studies are not identified in the literature search to assess risks from dermal and inhalation exposures, then a route-to-route extrapolation from oral toxicity studies would be needed to assess systemic risks from dermal or inhalation exposures. Without an adequate PBPK model, the approaches described in EPA guidance document *Risk Assessment Guidance for Superfund Volume I: Human Health Evaluation Manual (Part E, Supplemental Guidance for Dermal Risk Assessment)*

(U.S. EPA, 2004) could be applied to extrapolate from oral to dermal exposure. These approaches may be able to further inform the relative importance of dermal exposures compared with other routes of exposure. Similar methodology may also be used for assessing inhalation exposures

2.7.4 Summary of Risk Approaches for Characterization

Risk characterization is an integral component of the risk assessment process for both environmental and human health risks. EPA plans to derive the risk characterization in accordance with EPA's *Risk Characterization Handbook* (U.S. EPA, 2000). As defined in EPA's Risk Characterization Policy, "the risk characterization integrates information from the preceding components of the risk evaluation and synthesizes an overall conclusion about risk that is complete, informative and useful for decision makers." Risk characterization is considered to be a conscious and deliberate process to bring all important considerations about risk, not only the likelihood of the risk but also the strengths and limitations of the assessment, and a description of how others have assessed the risk into an integrated picture.

The level of information contained in each risk characterization varies according to the type of assessment for which the characterization is written. Regardless of the level of complexity or information, the risk characterization for TSCA risk evaluations will be prepared in a manner that is transparent, clear, consistent, and reasonable (U.S. EPA, 2000) and consistent with the requirements of the *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act* (82 FR 33726). For instance, in the risk characterization summary, EPA plans to further carry out the obligations under TSCA Section 26; for example, by identifying and assessing uncertainty and variability in each step of the risk evaluation, discussing considerations of data quality such as the reliability, relevance and whether the methods utilized were reasonable and consistent, explaining any assumptions used, and discussing information generated from independent peer review.

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

2.8 Peer Review

Peer review will be conducted in accordance with EPA's regulatory procedures for chemical risk evaluations, including using EPA's Peer Review Handbook and other methods consistent with Section 26 of TSCA (See 40 CFR 702.45). As explained in the 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.

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APPENDICES

Appendix A LIST OF GRAY LITERATURE SOURCES

Table_Apx A-1. Gray Literature Sources for Di-isobutyl Phthalate

Source/Agency	Source Name	Source Type	Source Category
Australian Government, Department of Health	NICNAS Assessments (eco)	International Resources	Assessment or Related Document
Australian Government, Department of Health	NICNAS Assessments (human health, Tier I, II or III)	International Resources	Assessment or Related Document
CPSC	Chronic Hazard Advisory Panel Reports	Other US Agency Resources	Assessment or Related Document
CPSC	Technical Reports: Exposure/Risk Assessment	Other US Agency Resources	Assessment or Related Document
CPSC	Technical Reports: Toxicity Review	Other US Agency Resources	Assessment or Related Document
ECHA	ECHA Documents	International Resources	Assessment or Related Document
ECHA	Annex XVII To REACH - Conditions of Use	International Resources	Assessment or Related Document
ECHA	European Union Risk Assessment Report	International Resources	Assessment or Related Document
Env Canada	Canada Substance Grouping Pages	International Resources	Assessment or Related Document
Env Canada	Priority Substances List Assessment Report; State of Science Report, Environment Canada Assessment	International Resources	Assessment or Related Document

Source/Agency	Source Name	Source Type	Source Category
Env Canada	Guidelines, Risk Management, Regulations	International Resources	Assessment or Related Document
EPA	Other EPA: Misc sources	US EPA Resources	General Search
EPA	EPA: AP-42	US EPA Resources	Regulatory Document or List
EPA	TRI: Envirofacts Toxics Release Inventory 2017 Updated Dataset	US EPA Resources	Database
EPA	Chemical Data Reporting (2012 and 2016 non-CBI CDR database)	US EPA Resources	Database
EPA	Chemical Data Reporting (2012 and 2016 CBI CDR database)	US EPA Resources	Database
EPA	EPA: Generic Scenario	US EPA Resources	Assessment or Related Document
EPA	EPA Discharge Monitoring Report Data	US EPA Resources	Database
EPA	IRIS Tox Review	US EPA Resources	Assessment or Related Document
EPA	Office of Water: CFRs	US EPA Resources	Regulatory Document or List
EPA	Office of Air: National Emissions Inventory (NEI) - National Emissions Inventory (NEI) Data (2014, 2011, 2008)	US EPA Resources	Database
EPA	Office of Air: CFRs and Dockets	US EPA Resources	Regulatory Document or List
FDA	FDA technical support documents for regulations	Other US Agency Resources	Assessment or Related Document
KOECT	Kirk-Othmer Encyclopedia of Chemical Technology Journal Article	Other Resource	Encyclopedia
NIOSH	CDC NIOSH - Publications and Products	Other US Agency Resources	Assessment or Related Document

Source/Agency	Source Name	Source Type	Source Category
NLM	National Library of Medicine's Hazardous Substance Databank	Other US Agency Resources	Database
NLM	National Library of Medicine's HazMap	Other US Agency Resources	Database
OECD	OECD Emission Scenario Documents	International Resources	Assessment or Related Document
OECD	OECD: General Site	International Resources	General Search
OSHA	U.S. OSHA Chemical Exposure Health Data (CEHD) program data [ERG]	Other US Agency Resources	Database

Appendix B PHYSICAL AND CHEMICAL PROPERTIES OF DI-ISOBUTYL PHTHALATE

This appendix provides p-chem information and data found in preliminary data gathering for di-isobutyl phthalate. Table_Apx B-1 summarizes the p-chem property values preliminarily selected for use in the risk evaluation from among the range of reported values collected as of March 2020. This table differs from that presented in the *Proposed Designation of Di-isobutyl Phthalate (CASRN 84-69-5) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019b) and may be updated as EPA collects additional information through systematic review methods. All p-chem property values that were extracted and evaluated as of March 2020 are presented in the supplemental file *Data Extraction and Data Evaluation Tables for Physical Chemical Property Studies* (EPA-HQ-OPPT-2018-0434).

Table_Apx B-1. Physical and Chemical Properties of Di-isobutyl Phthalate

Property or Endpoint	Value*	Reference	Data Quality Rating
Molecular formula	$C_{16}H_{22}O_4$	NA	NA
Molecular weight	278.35 g/mol	NA	NA
Physical state	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
Log Octanol/water partition coefficient (Log Kow)	4.34	Ishak, 2016	High
Henry's Law constant	1.83×10^{-7} atm·m^3/mol	Elsevier, 2019	High
Flash point	169°C	RSC, 2019	Medium

Property or Endpoint	Value*	Reference	Data Quality Rating
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

* Measured unless otherwise noted.
NA = Not applicable

Appendix C ENVIRONMENTAL FATE AND TRANSPORT PROPERTIES

Table Apx C-1 provides the environmental fate characteristics that EPA identified and considered in developing the scope for di-isobutyl phthalate.

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	HSDB (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 (1980)
Biodegradation (Aerobic)	98%/4 weeks (OECD 302C)	HSDB (2013) citing Sedykh and Klopman (2007)
	100%/6 days (die-away tests)	HSDB (2013) citing Hattori (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)	HSDB (2013) citing Madsen (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	HSDB (2013) citing Sabljic (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 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 information that supports the	Two risk reports received for di-isobutyl phthalate (2003: 88030000106; 2010: 88100000438**)** (U.S. EPA, ChemView. Accessed April 9, 2019).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	conclusion that a chemical substance or mixture presents a substantial risk of injury to health or the environment.	
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 statue specifies a list of families of toxic pollutants also listed in the Code of Federal Regulations at 40 CFR Part 401.15. The "priority pollutants" specified by those families are listed in 40 CFR Part 423 Appendix A. These are pollutants for which best available technology effluent limitations must be established on either a national basis through rules (Sections 301(b), 304(b), 307(b), 306) or on a case-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).
Clean Air Act (CAA) – Section 112(d)	Directs EPA to establish, by rule, NESHAPs for each category or subcategory of listed major sources and area sources of HAPs (listed pursuant to Section 112(c)). For major sources, the standards must require the maximum degree of emission reduction that EPA determines is achievable by each particular source category. This is generally referred to as maximum achievable control technology (MACT). For area sources, the standards must require generally achievable control technology (GACT) though may require MACT.	EPA has established NESHAPs for a number of source categories that emit di-isobutyl phthalate to air. (See https://www.epa.gov/stationary-sources-air-pollution/national-emission-standards-hazardous-air-pollutants-neshap-9)
Other Federal Regulations		

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
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, butyl benzyl phthalate, diisononyl phthalate, diisobutyl phthalate, di-n-pentyl phthalate, di-n-hexyl phthalate and dicyclohexyl 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 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).

State Actions	Description of Action
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

Country/Tribe/ Organization	Requirements and Restrictions
	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. In 2015, di-isobutyl phthalate was also assessed as a Priority Existing Chemical (Assessment Report No. 40) (National Industrial Chemicals Notification and Assessment Scheme (NICNAS). Chemical inventory. Database accessed April 3, 2019).
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 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. EPA plans to consider this information in combination with available monitoring data and estimation methods and models, as appropriate, to quantify occupational exposure and releases for the various conditions of use in the risk evaluation.

E.1.1 Manufacture (Including Import)

The 2016 CDR reports 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, 2019a). 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, 2019a).

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 & 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 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, 2019a).

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, 2019a). 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, 2019a; U.S. CPSC, 2015; UNIPLEX, 155). The exact processes used to formulate products containing di-isobutyl phthalate are not known at this time; however, several ESDs published by the OECD and Generic Scenarios published by EPA have been identified that provide

general process descriptions for these types of products. EPA plans to 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, 2019a). 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, 2019a). A public commenter indicated that di-isobutyl phthalate may be recycled (Earth Justice 2019). 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, food packaging adhesives, two-component high-strength anchoring adhesive, surface adhesives and seam adhesive for solid surfacing, motor vehicle paints, paints, lacquers, and varnishes (U.S. EPA, 2019a; Auto Alliance 2019; Aerospace Industries Association 2019; U.S. CPSC, 2015; Lanxess 2015; Azon USA 2015; Glue 360 Inc. 2018; ITW Performance Polymers 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, 2019a), concrete (Lanxess 2015), and construction adhesives (U.S. EPA, 2019a), and other materials (U.S. CPSC, 2015; Lanxess 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 (U.S. CPSC, 2015; Lanxess 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, toys, and food packaging (Earth Justice 2019; U.S. CPSC, 2015; Lanxess 2015). Di-isobutyl phthalate is likely entrained in the products; however, DIHP 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.1.4 Other Uses

Di-isobutyl phthalate is also used in fuels and related products (U.S. CPSC, 2015; Lanxess 2015), paper products (U.S. CPSC, 2015), catalyst solvent (US EPA, 2019a), explosive materials (U.S. CPSC, 2015), air care products (U.S. CPSC, 2015), and lubricants (U.S. CPSC, 2015). 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.

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

E.1.5 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 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 following:

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

regulated under the more stringent requirements of Subtitle C of RCRA, whereas non-hazardous solid wastes are regulated under the less stringent requirements of Subtitle D of RCRA.

Di-isobutyl phthalate is not a listed hazardous waste under RCRA.

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

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.

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 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; Viscosity Adjusters	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.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
		Fuels and Related Products (e.g., Fuel additives) Processing aids, not otherwise listed Inks, Toner, and Colorant Products (e.g., Toner/ printer cartridge) Paper Products Plastic and rubber products not covered elsewhere Fabric, textile, and leather products not covered elsewhere		Mist	Inhalation/ Dermal	Workers, ONU	No	Mist generation is not expected during processing (incorporation into formulation, mixture, or reaction product).
				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;	Plastics and Rubber product manufacturing (Plastic Converting)	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.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
		transportation equipment manufacturing	Other article manufacturing	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.
				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.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
				Mist	Inhalation/ Dermal	Workers, ONU	No	Mist generation is not expected during repackaging.
				Dust	Inhalation/ Dermal	Workers, ONU	Yes	The potential for dust exposures to workers and ONUs exists during processing (repackaging), as 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.
				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.
	Paints and coatings;	Paints and coatings; adhesives and		Liquid Contact	Dermal	Workers	Yes	These products are in liquid form; therefore, exposures to workers exists for

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
Industrial/ Commercial Use	adhesives and sealants; Furnishing, Cleaning, Treatment/Care Products; Air Care Products (e.g., Air Freshener)	sealants; Furnishing, Cleaning, Treatment/Care Products; Air Care Products (e.g., Air Freshener)	Spray, brush, roll, dip, and other forms of application					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 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	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	Use of fuels and related products Use of fabric dyes Use of inks, toner, and colorant products (e.g., printing)	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)

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
	Products (e.g., Toner/printer cartridge); catalyst solvent; lubricants	cartridge); catalyst solvent; lubricants	Use of catalyst solvents Use of lubricants					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; food packaging material; paper products; explosive materials	Plastic and rubber products not covered elsewhere; Building/ construction materials not covered elsewhere; floor coverings; food packaging material; paper products; explosive materials	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 /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

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
								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.
				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	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
			articles containing chemical					
			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
	Packaging, Paper, Plastic, Hobby Products	Paper Products (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	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.

Life Cycle Stage	Category	Subcategory	Release from source	Exposure Pathway	Route	Receptor	Plans to Evaluate	Rationale
		(Article)	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	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

Life Cycle Stage	Category	Subcategory	Release from source	Exposure Pathway	Route	Receptor	Plans to Evaluate	Rationale
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.
			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.

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	Cleaning and Furnishing Care Products (Product)	Long-term emission/mass-transfer, Abrasion, Transfer to Dust	Dust	Dermal, Inhalation, Oral	Consumers, Bystanders	Yes	Dermal, oral and inhalation exposure from this condition of use may occur 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 evaluated

Life Cycle Stage	Category	Subcategory	Release from source	Exposure Pathway	Route	Receptor	Plans to Evaluate	Rationale
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
			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.

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 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.

Life Cycle Stage	Category	Release	Exposure Pathway / Media	Exposure Routes	Receptor / Population	Plans to Evaluate	Rationale
			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.
			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 and terrestrial species.
				TBD	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		