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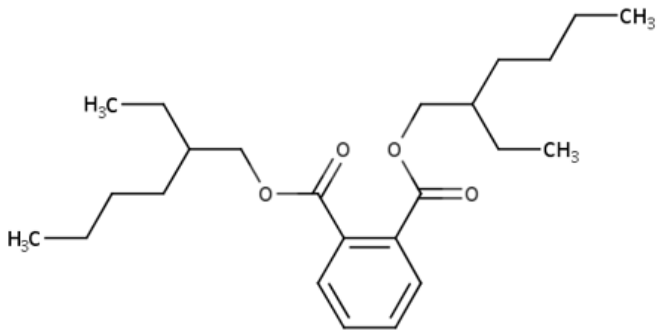
Office of Chemical Safety and
Pollution Prevention

United States
Environmental Protection Agency

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

CASRN 117-81-7



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Docket

Supporting information can be found in public docket: [Docket ID: EPA-HQ-OPPT-2018-0433].

Disclaimer

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

ABBREVIATIONS AND ACRONYMS

ACGIH	American Conference of Governmental Industrial Hygienists
ADME	Absorption, Distribution, Metabolism, and Excretion
ATSDR	Agency for Toxic Substances and Disease Registry
AWQC	Ambient Water Quality Criteria
BAF	Bioaccumulation Factor
BBP	Butylbenzyl Phthalate
BCF	Bioconcentration Factor
BMF	Biomagnification Factor
BP	Boiling point
BW	Body weight
CAA	Clean Air Act
CASRN	Chemical Abstracts Service Registry Number
CBI	Confidential Business Information
CDR	Chemical Data Reporting
CEHD	Chemical Exposure Health Data
CERCLA	Comprehensive Environmental Response, Compensation and Liability Act
CFR	Code of Federal Regulations
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
DCHP	Dicyclohexyl Phthalate
DEHP	Di-ethylhexyl Phthalate
DIBP	Di-isobutyl Phthalate
DINP	Di-isononyl Phthalate
DHEXP	Di-n-hexyl 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
EPCRA	Emergency Planning and Community Right-to-Know Act
ERG	Eastern Research Group
ESD	Emission Scenario Document
EU	European Union
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FR	Federal Register
GACT	Generally Available Control Technology
GDIT	General Dynamics Information Technology
GESTIS	International Occupational Exposure Limit Database
GS	Generic Scenario

HAP	Hazardous Air Pollutant
Hg	Mercury
HHE	Health Hazard Evaluation
HMTA	Hazardous Materials Transportation Act
HSDB	Hazardous Substances Data Bank
ICF	ICF is a global consulting services company
IDLH	Immediately Dangerous to Life and Health
IECCU	Indoor Environmental Concentrations in Buildings with Conditioned and Unconditioned Zones
IMAP	Inventory Multi-Tiered Assessment and Prioritisation (Australia)
ISHA	Industrial Safety and Health Act
JECFA	Joint Expert Committee on Food Additives
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
MCL	Maximum Contaminant Level
MCLG	Maximum Contaminant Level Goal
MOA	Mode of Action
MP	Melting point
MSW	Municipal Solid Waste
NAICS	North American Industry Classification System
NEI	National Emissions Laboratory
NESHAP	National Emission Standards for Hazardous Air Pollutants
NICNAS	National Industrial Chemicals Notification and Assessment Scheme (Australia)
NIOSH	National Institute for Occupational Safety and Health
NLM	National Library of Medicine
NOAEL	No Observed Adverse Effect Level
NOEC	No Observed Effect Concentration
NPDES	National Pollutant Discharge Elimination System
NPDWR	National Primary Drinking Water Regulations
NPL	National Priorities List
NPRI	National Pollutant Release Inventory
NTP	National Toxicology Program
OCSPP	Office of Chemical Safety and Pollution Prevention
OECD	Organisation for Economic Co-operation and Development
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
PEL	Permissible Exposure Limit

PESS	Potentially Exposed or Susceptible Populations
POD	Point of Departure
POTW	Publicly Owned Treatment Works
PPE	Personal Protective Equipment
PVC	Polyvinyl chloride
RCRA	Resource Conservation and Recovery Act
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals (European Union)
REL	Recommended Exposure Limit
RIVM	Dutch Risk Assessment Agency
RQ	Risk Quotient
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
SDWA	Safe Drinking Water Act
SOC	Synthetic Organic Chemical
SRC	SRC Inc., formerly Syracuse Research Corporation
STEL	Short-term Exposure Limit
STORET	STORage and RETrieval (water quality data warehouse)
SVHC	Substance of Very High Concern
TIAB	Title and Abstract
TBD	To be determined
TLV	Threshold Limit Value
TMF	Trophic Magnification Factors
TRI	Toxic Release Inventory
TSCA	Toxic Substances Control Act
TTO	Total Toxic Organics
TURA	Toxics Use Reduction Act (Massachusetts)
TWA	Time-weighted average
VOC	Volatile Organic Compound
VP	Vapor Pressure
WHO	World Health Organization
WQX	Water Quality Exchange
WS	Water solubility
WWT	Wastewater Treatment

EXECUTIVE SUMMARY

In December 2019, EPA designated di-ethylhexyl phthalate (CASRN 117-81-7) as a high-priority substance for risk evaluation following the prioritization process as required by Section 6(b) of the Toxic Substances Control Act (TSCA) and implementing regulations (40 CFR 702) (Docket ID: EPA-HQ-OPPT-2018-0433). The first step of the risk evaluation process is the development of the scope document and this document fulfills the TSCA requirement to issue a draft scope document as required in 40 CFR 702.41(c)(7). The draft scope for di-ethylhexyl 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-ethylhexyl phthalate is a colorless liquid with almost no odor. It does not dissolve in water or evaporate easily and attaches strongly to soil particles.

Reasonably Available Information. EPA leveraged the data and information sources already described in the document supporting the High-Priority Substance designation for di-ethylhexyl 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-ethylhexyl phthalate

Conditions of Use. EPA plans to evaluate manufacturing, including importing; processing; distribution in commerce; industrial, commercial and consumer uses; and disposal of di-ethylhexyl phthalate in the risk evaluation. Di-ethylhexyl phthalate is manufactured within the United States as well as imported into the United States. The chemical is processed as a reactant, incorporated into a formulation, mixture, or reaction products, and incorporated into articles. The identified processing activities also include the repackaging and recycling of di-ethylhexyl phthalate. Section 2.2 provides details about the conditions of use within the scope of the risk evaluation.

Conceptual Model. The conceptual models for di-ethylhexyl 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-ethylhexyl 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-ethylhexyl phthalate that EPA plans to consider in the risk evaluation. Exposures for di-ethylhexyl phthalate are discussed in Section 2.3. EPA identified environmental monitoring data reporting the presence of di-ethylhexyl phthalate in air, water, sediment, soil, surface water and biomonitoring samples. Di-ethylhexyl phthalate is subject to reporting to EPA's Toxics Release Inventory (TRI) and EPA plans to use TRI information as reasonably available information to inform di-ethylhexyl phthalate's environmental release assessment. For the 2018 reporting year (Table 2-3) 118 facilities reported to EPA releases of di-ethylhexyl phthalate to air, water, and via land disposal. Additional information gathered through the results of systematic review searches will also inform expected exposures.

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

  Preliminarily, EPA plans to evaluate the following human and environmental exposure pathways, routes, receptors and PESS in the scope of the risk evaluation. However, EPA plans to consider comments received on this draft scope and other reasonably available information when finalizing this scope document, and to adjust the exposure pathways, exposure routes and hazards included in the scope document as needed.
  - *Occupational exposures associated with industrial and commercial conditions of use:* EPA plans to evaluate exposures to workers and/or occupational non-users (ONUs) via the inhalation route and exposures to workers via the dermal route associated with the manufacturing, processing, use or disposal of di-ethylhexyl phthalate.
  - *Consumer and bystander exposures associated with consumer conditions of use:* EPA plans to evaluate oral, inhalation and dermal exposure routes to di-ethylhexyl phthalate when consumers and bystanders are exposed via the use and/or handling of consumer adhesives and sealants, arts, crafts and hobby materials; automotive care products; building/construction materials; electrical and electronic products; fabric, textile and leather products, furniture and furnishings; ink, toner and colorant products; lawn and garden care products; paints and coatings; plastic and rubber products and toys, playground and sporting equipment.
  - *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-ethylhexyl phthalate for aquatic and terrestrial receptors.

- *Hazards.* Hazards for di-ethylhexyl 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-ethylhexyl phthalate as part of the prioritization process. Environmental hazard effects were identified for aquatic and terrestrial organisms. Information collected through systematic review methods and public comments may identify additional environmental hazards that warrant inclusion in the environmental hazard assessment of the risk evaluation.

EPA plans to use systematic review methods to evaluate the epidemiological and toxicological literature for di-ethylhexyl 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-repose assessment. EPA plans to evaluate all of the potential human health hazards for di-ethylhexyl phthalate identified in Section 2.4.2. The broad health effect categories include reproductive and developmental, immunological, nervous system, and irritation effects. Studies were identified reporting information on genotoxicity, carcinogenicity and Absorption, Distribution, Metabolism, and Excretion (ADME).

Analysis Plan. The analysis plan for di-ethylhexyl phthalate is presented in Section 2.7. The analysis plan outlines the general science approaches that EPA plans to use for the various evidence streams (i.e., chemistry, fate, release and engineering, exposure, hazard) supporting the risk evaluation. The analysis plan is based on EPA's knowledge of di-ethylhexyl 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 will seek public comments on the systematic review methods supporting the risk evaluation for di-ethylhexyl phthalate, including the methods for assessing the quality of data and information and the approach for evidence synthesis and evidence integration supporting the exposure and hazard assessments. The details will be provided in a supplemental document that EPA anticipates releasing for public comment prior to the finalization of the scope document.

Peer Review. The draft risk evaluation for di-ethylhexyl 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-ethylhexyl phthalate (DEHP) 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.

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

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. EPA conducted the search and screening process based on 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-ethylhexyl 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-ethylhexyl 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 100 search results relevant to EPA's risk assessment needs for diethylhexyl phthalate. Appendix A lists the gray literature sources that yielded 100 discrete data or information sources relevant to di-ethylhexyl phthalate. EPA further categorized the data and information into the various topic areas (or disciplines) supporting the risk evaluation (e.g., physical chemistry, environmental fate, environmental hazard, human health hazard, exposure, engineering) and

[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).

[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

the breakdown is shown in Figure 2-1. EPA is currently identifying additional reasonably available information (e.g., public comments), and the reported numbers in Figure 2-1 may change.

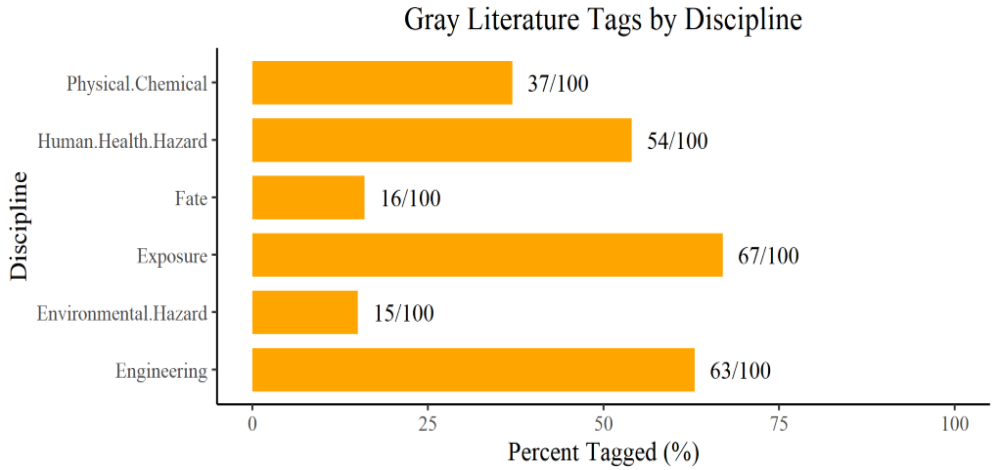

Figure 2-1. Gray Literature Tags by Discipline for Di-ethylhexyl Phthalate
The percentages across disciplines do not add up to 100%, as each source may provide data or information for various topic areas (or disciplines).

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 physical-chemical (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-ethylhexyl 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 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.

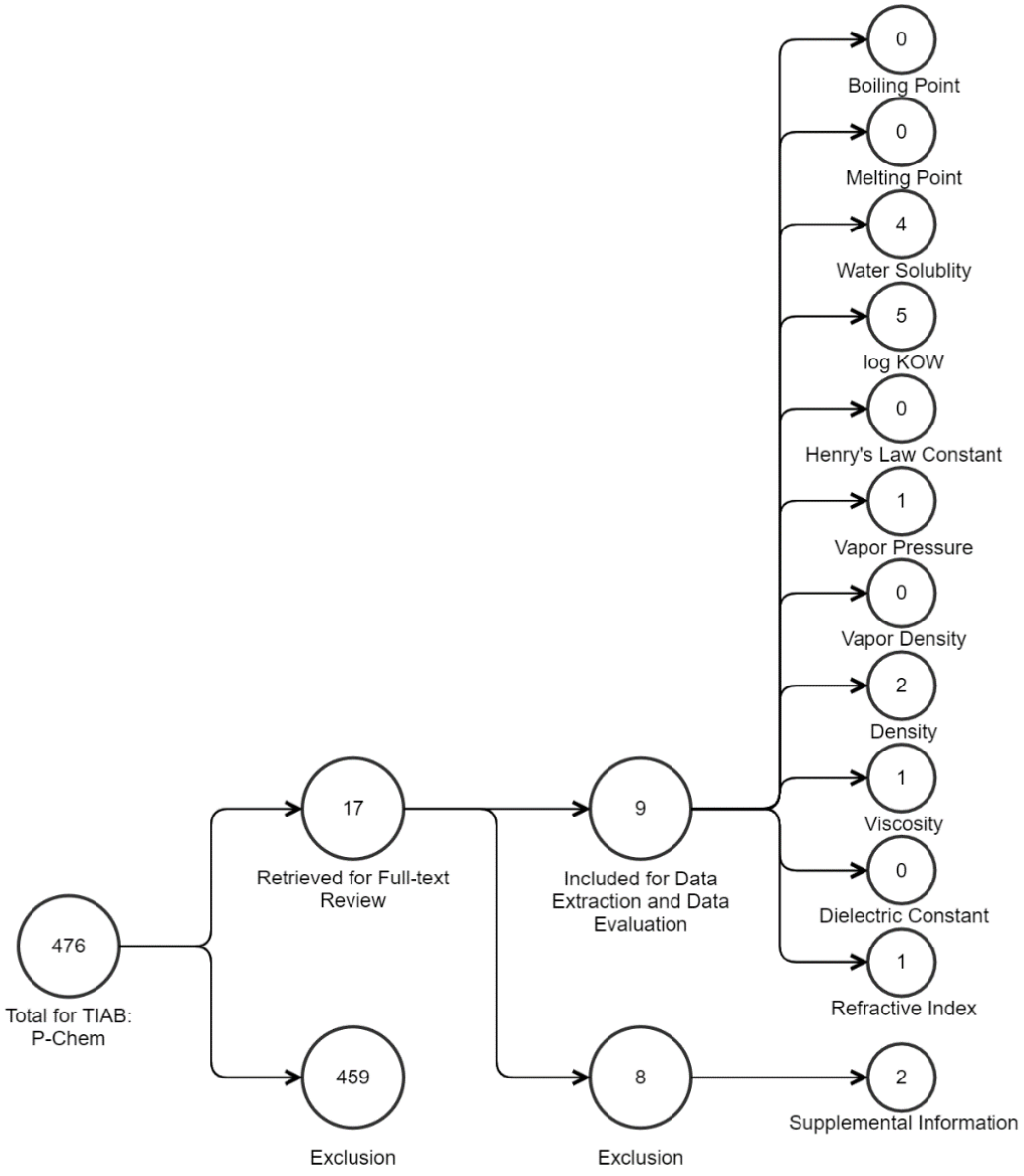

Figure 2-2. Peer-reviewed Literature - Physical-Chemical Properties Search Results for Di-ethylhexyl Phthalate

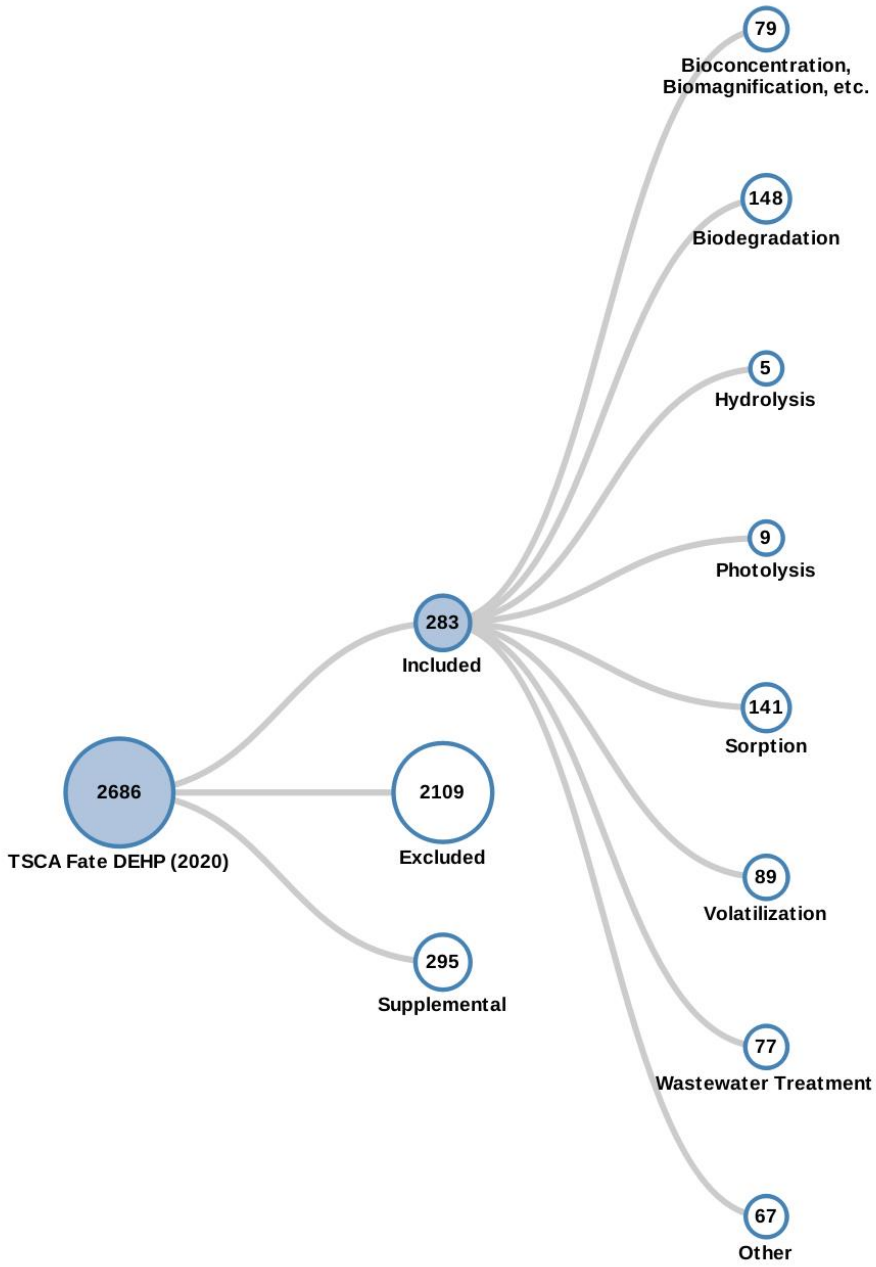

Figure 2-3. Peer-reviewed Literature – Fate and Transport Search Results for Di-ethylhexyl Phthalate

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

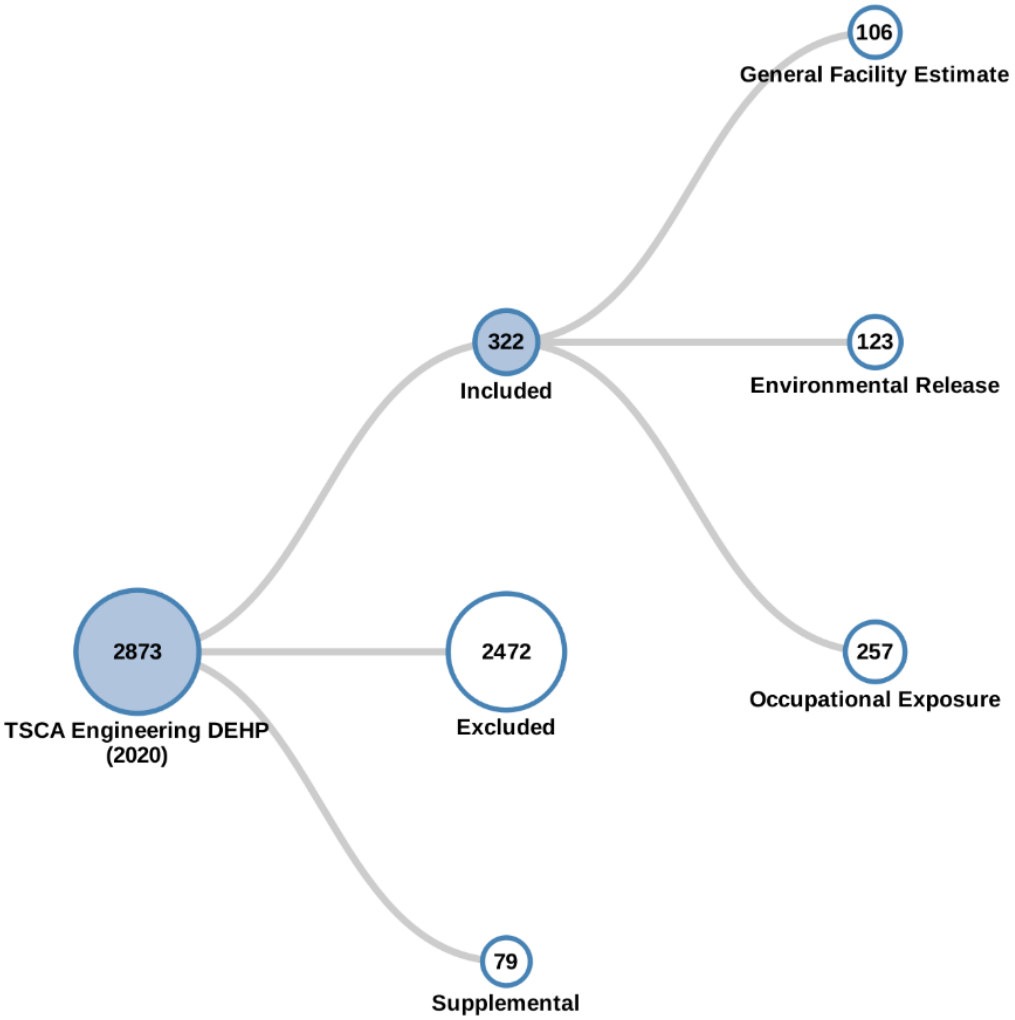

Figure 2-4. Peer-reviewed Literature - Engineering Search Results for Di-ethylhexyl Phthalate
Click here for interactive HAWC Diagram.

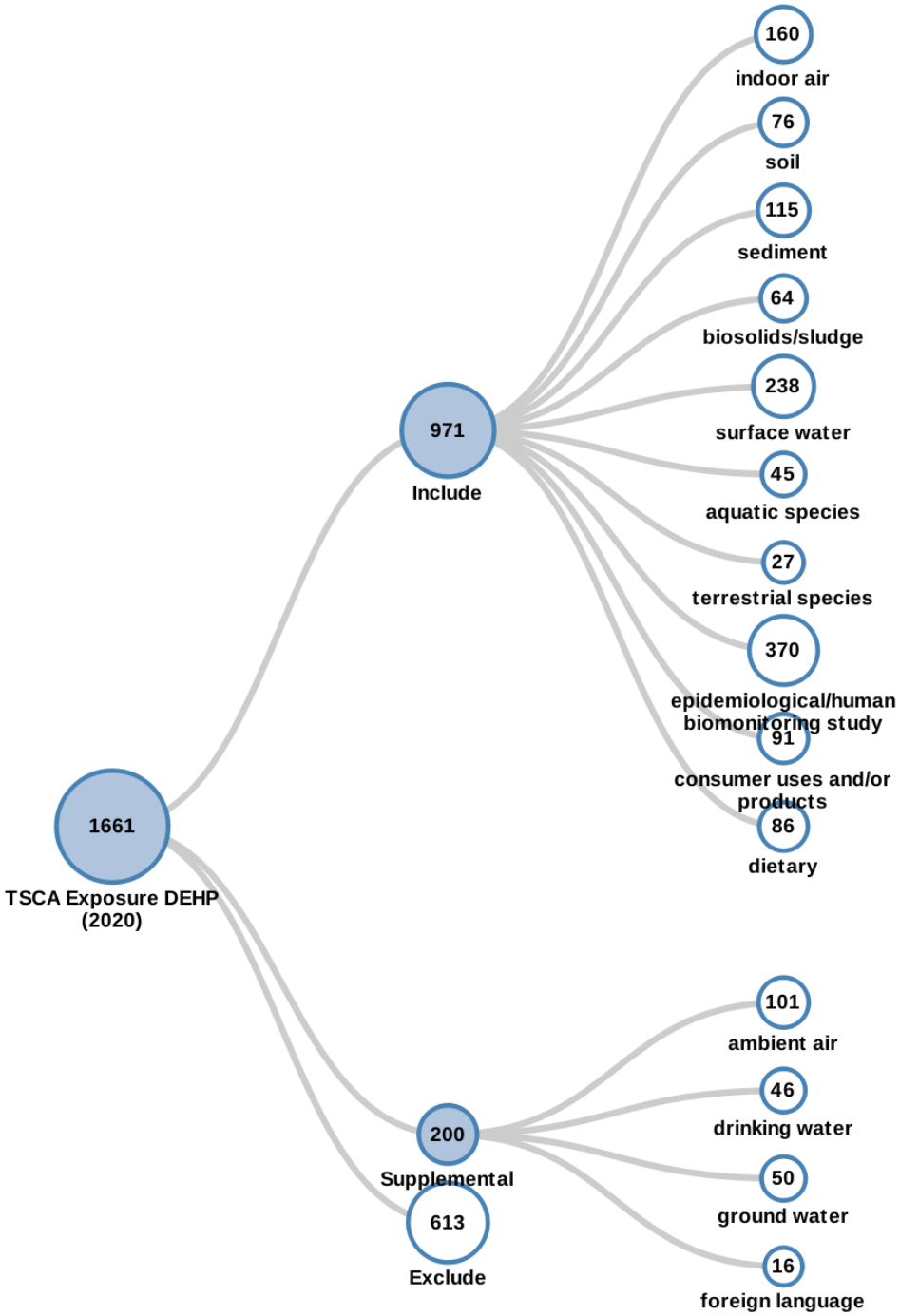

Figure 2-5. Peer-reviewed Literature – Exposure Search Results for Di-ethylhexyl Phthalate
Click here for interactive HAWC Diagram.

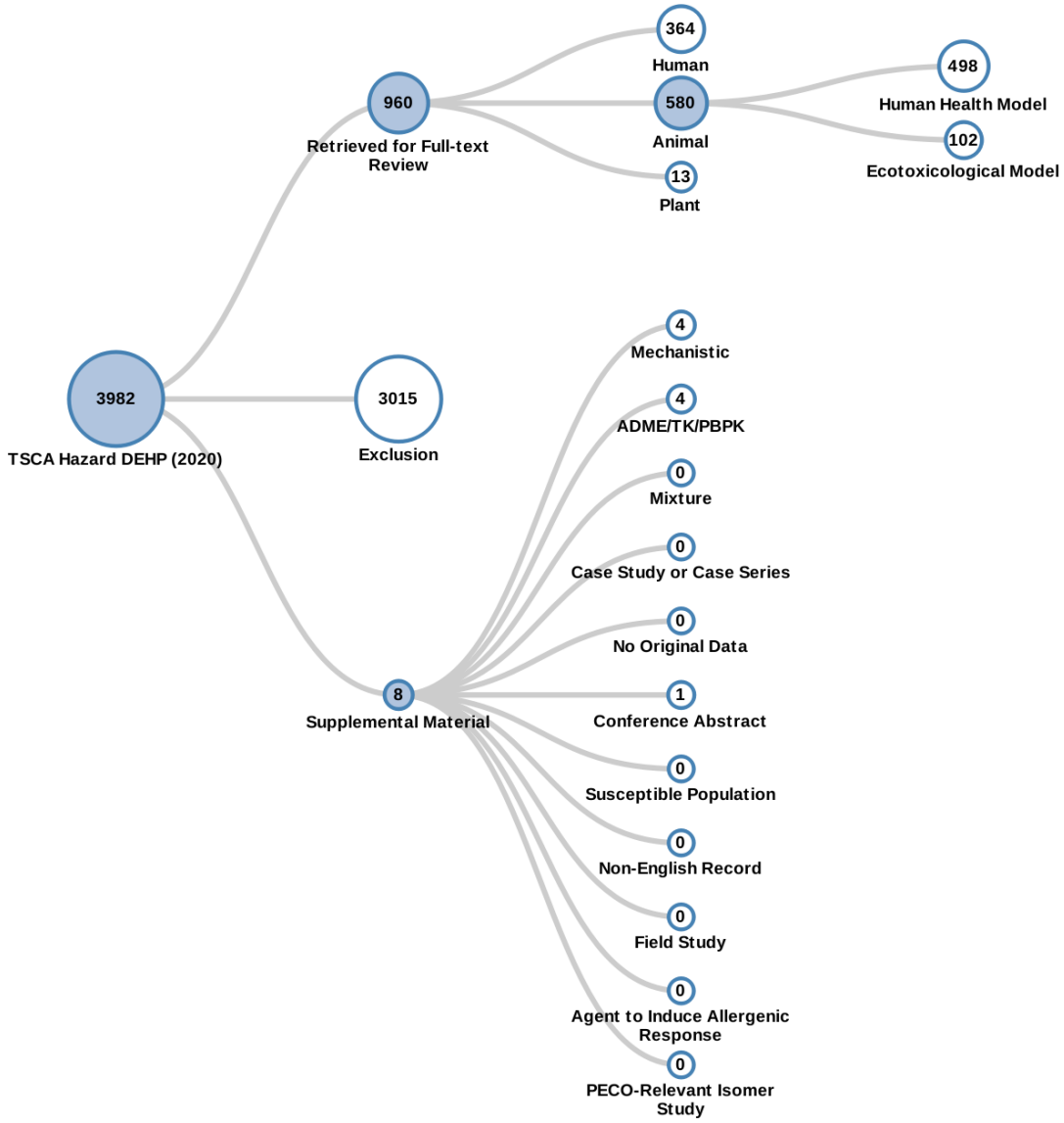

Figure 2-6. Peer-reviewed Literature - Hazard Search Results for Di-ethylhexyl Phthalate
Click here for interactive HAWC Diagram.

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 various sections of TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act. EPA screened a total of 279 submissions using inclusion/exclusion criteria specific to individual disciplines (see Table 2-1 for the list of disciplines). The details about the criteria are not part of this document but will be provided in a supplemental document that EPA anticipates releasing prior to the finalization of the scope document. EPA identified 182 submissions that met the inclusion criteria in these statements and identified 76 submissions with supplemental data. EPA excluded 21 submissions because the reports were identified as one of the following:

- Submission on a different chemical
- Study summaries with limited information
- Commentary on a published study

- Meeting notes
- Ranking of chemicals for proposed evaluation
- Letter of notification with no data
- NTP annual plan
- Cover sheet of a study
- Preliminary results of a final available submitted study

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	13	0
Environmental Fate and Transport	23	3
Environmental and General Population Exposure	54	0
Occupational Exposure/Release Information	22	0
Environmental Hazard	42	10
Human Health Hazard	54	66

2.2 Conditions of Use

As described in the *Proposed Designation of Di-ethylhexyl Phthalate (CASRN 117-81-7) as a High-Priority Substance for Risk Evaluation* (U.S. EPA 2019a), EPA assembled information from the CDR and TRI programs to determine conditions of use[3] or significant changes in conditions of use of the chemical substance. EPA also consulted a variety of other sources to identify uses of di-ethylhexyl phthalate including published literature, company websites, and government and commercial trade databases and publications. To identify formulated products containing di-ethylhexyl 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, environmental organizations, and public comments to supplement the use information.

EPA identified and described the categories and subcategories of conditions of use that will be included in the scope of the risk evaluation (Section 2.2.1; Table 2-2). The conditions of use 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-ethylhexyl 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
Manufacture	Domestic Manufacture	Domestic Manufacture	EPA (2017, 2014b), Acros Organics N.V. (2002), Eastman (2019), Harwick Standard. (2015), Spectrum (2008), Tenoit Co., Ltd. (n.d.)
	Import	Import	EPA (2017, 2014b), Comet Chemical Company (2016)
Processing	As a reactant	Plasticizer in plastic material and resin manufacturing, rubber product manufacturing, and synthetic rubber manufacturing.	EPA (2017), Natrochem (2016)
		Adhesive and sealant chemical in adhesive manufacturing.	EPA (2014b), Morgan Advanced Materials. (2016a)
	Incorporation into article	Plasticizer in all other basic organic chemical manufacturing, plastics product manufacturing	EPA (2017, 2014b), Victor Technologies (2012)
		Plasticizer in food, beverage, and tobacco product manufacturing; medical devices; plastic material and resin manufacturing.	EPA (2017), 3M. (2018)
		Plasticizer in custom compounding of purchased resin	EPA (2014b)
	Incorporation into formulation, mixture, or reaction product	Plasticizer in all other basic organic chemical manufacturing; custom compounding of purchased resins; miscellaneous manufacturing; paint and coating manufacturing; plastics material and resin manufacturing; plastics product manufacturing.	EPA (2017, 2014b)

Life Cycle Stage	Category	Subcategory	References
		Plasticizer in adhesive manufacturing; all other basic inorganic chemical manufacturing; rubber product manufacturing; and services.	EPA (2017)
		Plasticizer in all other chemical product and preparation manufacturing.	EPA (2014b)
	Intermediate	Intermediate in plastics product manufacturing.	EPA (2014b)
	Recycling	Recycling	
	Repackaging	Other functional use in wholesale and retail trade.	EPA (2017)
Distribution	Distribution		
Industrial Use	Hydraulic fracturing chemicals	Hydraulic fracturing chemicals	U.S. House of Representatives (2011); NYSDEC (2011)
	Paints and Coatings	Paints and Coatings (e.g., Industrial Polish)	3M. (2019a)
	Laboratory chemicals	Reference material and/or laboratory reagent	UltraScientific (2014), Restek (2019)
	Transportation Equipment Manufacturing	(e.g., formulations for diffusion bonding and manufacture of aero engine fan blades)	Morgan Advanced Materials. (2016a)
Commercial Use	Adhesives and sealants	Adhesives and sealants	EPA (2014b), NLM (2019), Airserco (n.d.), 3M. (2011), Imperial Tools (2012) Valspar (2017, 2019), Tremco (2015), StatSpin, Inc (2004).
	Arts, crafts, and hobby materials	Arts, crafts, and hobby materials	EPA (2014b)

Life Cycle Stage	Category	Subcategory	References
	Automotive care products	Automotive and interior car care products	EPA (2019); American Chemistry Council (2019); Danish EPA (2010), 3M (2017)
	Batteries	Batteries (e.g., Digital camera)	Amazon (n.d.)
	Building/construction materials not covered elsewhere	Building/construction materials not covered elsewhere	EPA (2017, 2014b)
	Dyes and pigments	Dyes, pigments, and fixing agents	EPA (2019); EPA (1999); Identity Group (2016), SPIN (2019)
	Electrical and electronic products	Electrical and electronic products	EPA (2017, 2014b), 3M (2011, 2019b), Rakuten (2019)
	Fabric, textile, and leather products not covered elsewhere	Fabric, textile, and leather products not covered elsewhere	EPA (2017, 2014b), Office Stock USA. (2019)
	Furniture and furnishings not covered elsewhere	Furniture and furnishings not covered elsewhere	EPA (2017, 2014b)
	Lawn and garden care products	Lawn and garden care products	EPA (2014b)
	Paints and coatings	Paints and coatings (e.g., sealer for decorative concrete as waterproof polyurethane)	EPA (2017, 2014b), CETCO, (2014) Chemsol (n.d.), Dupli-Color Products Company. (2017). Glidden Co (1999), LORD Corporation. (2015, 2019), Pacific Coast Lacquer (2016) Ramuc (2011), Republic Powdered Metals, Inc. (2002), The Sherwin-Williams Company (2019)
	Plastic and rubber products not covered elsewhere	Plastic and rubber products not covered elsewhere	EPA (2017, 2014b), Lighthouse Office Supply (2018) Quad City Safety Inc (2019a, b)

Life Cycle Stage	Category	Subcategory	References
	Toys, playground, and sporting equipment	Toys, playground, and sporting equipment	EPA (2017, 2014b)
Consumer Use	Adhesives and sealants	Adhesives and sealants	EPA (2014b), U.S. Library of Medicine (2019), Airserco (n.d.), 3M. (2011), Imperial Tools (2012) Valspar (2017, 2019), Tremco (2015), StatSpin, Inc (2004).
	Arts, crafts, and hobby materials	Arts, crafts, and hobby materials	EPA (2014b)
	Automotive care products	Automotive and interior car care products	EPA (2019); American Chemistry Council (2019); Danish EPA (2010), 3M (2017)
	Batteries	Batteries (e.g., Digital camera)	Amazon (2020)
	Building/construction materials not covered elsewhere	Building/construction materials not covered elsewhere	EPA (2017, 2014b)
	Dyes and pigments	Dyes, pigments, and fixing agents	EPA (2019); EPA (1999); Identity Group (2016), SPIN (2019)
	Electrical and electronic products	Electrical and electronic products	EPA (2017, 2014b), 3M (2011, 2019b), Rakuten (2019)
	Fabric, textile, and leather products not covered elsewhere	Fabric, textile, and leather products not covered elsewhere	EPA (2017, 2014b), Office Stock USA. (2019)
	Furniture and furnishings not covered elsewhere	Furniture and furnishings not covered elsewhere	EPA (2017, 2014b)
	Lawn and garden care products	Lawn and garden care products	EPA (2014b)
	Paints and coatings	Paints and coatings	EPA (2017, 2014b), CETCO, (2014) Chemsol (n.d.), Dupli-Color

Life Cycle Stage	Category	Subcategory	References
		(e.g., sealer for decorative concrete as waterproof polyurethane)	Products Company. (2017). Glidden Co (1999), LORD Corporation. (2015a,b), Pacific Coast Lacquer (2016) Ramuc (2011), Republic Powdered Metals, Inc. (2002), Sherwin-Williams Company. (2019)
	Plastic and rubber products not covered elsewhere	Plastic and rubber products not covered elsewhere	EPA (2017, 2014b), Lighthouse Office Supply (2018) Quad City Safety Inc (2019a), Quad City Safety Inc. (2019b)
	Toys, playground, and sporting equipment	Toys, playground, and sporting equipment	EPA (2017, 2014b)
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.
  - "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 does not plan to include in this scope or in the risk evaluation the activities described below that the Agency has concluded do not constitute conditions of use under TSCA.

EPA has determined that the following uses of di-ethylhexyl phthalate are non-TSCA uses:

- EPA determined that di-ethylhexyl phthalate is used in fragrances which meets the definition of cosmetics under Section 201 of the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 321, and are therefore excluded from the definition of "chemical substance" in TSCA § 3(2)(B)(vi). Activities and releases associated with such cosmetics are therefore not "conditions of use"

(defined as circumstances associated with "a chemical substance," TSCA § 3(4)) and will not be evaluated during risk evaluation. However, manufacturing, processing, and industrial uses of these products are covered by TSCA and will be considered a condition of use.

- Baby products and pharmaceuticals also fall under 21 U.S.C. § 321 of the FFDCA and are non-TSCA uses beyond the scope of the risk evaluation for di-ethylhexyl phthalate. However, manufacturing, processing, and industrial uses of these products are covered by TSCA and will be considered a condition of use.
- Pesticide/Fumigant. NLM's HSDB confirms that di-ethylhexyl phthalate is not registered for current use in the United States, but approved pesticide uses may change periodically and so federal, state and local authorities must be consulted for currently approved uses. However, manufacturing, processing, and industrial uses of these products are covered by TSCA and will be considered a condition of use.

2.2.3 Production Volume

As reported to EPA during the 2016 CDR reporting period and described here as a range to protect production volumes that were claimed as confidential business information (CBI), aggregate production volume of di-ethylhexyl phthalate in 2015 was between 100 million and 250 million pounds (U.S. EPA 2017). EPA also uses pre-2015 CDR production volume information, as detailed in the *Proposed Designation of Di-ethylhexyl Phthalate (CASRN 117-81-7) as a High-Priority Substance for Risk Evaluation* (U.S. EPA 2019a) and will include future production volume information as it becomes available to support the exposure assessment.

2.2.4 Overview of Conditions of Use and Lifecyle Diagram

The life cycle diagram provided in Figure 2-7 depicts the conditions of use that EPA plans to consider in the risk evaluation for the various life cycle stages. This section provides a brief overview of the industrial, commercial, and consumer use categories included in the life cycle diagram. Appendix E contains more detailed descriptions (e.g., process descriptions, worker activities) for each manufacturing, processing, distribution in commerce, use, and disposal category based on preliminary information.

The information in the life cycle diagram is grouped according to the CDR processing codes and use categories (including functional use codes for industrial uses and product categories for commercial and consumer uses). The production volume of di-ethylhexyl phthalate in 2015 is included in the lifecycle diagram, as reported to EPA during the 2016 CDR reporting period and described here as an aggregate range between 100 million and 250 million pounds (U.S. EPA 2017) to protect production volumes that were claimed as CBI.

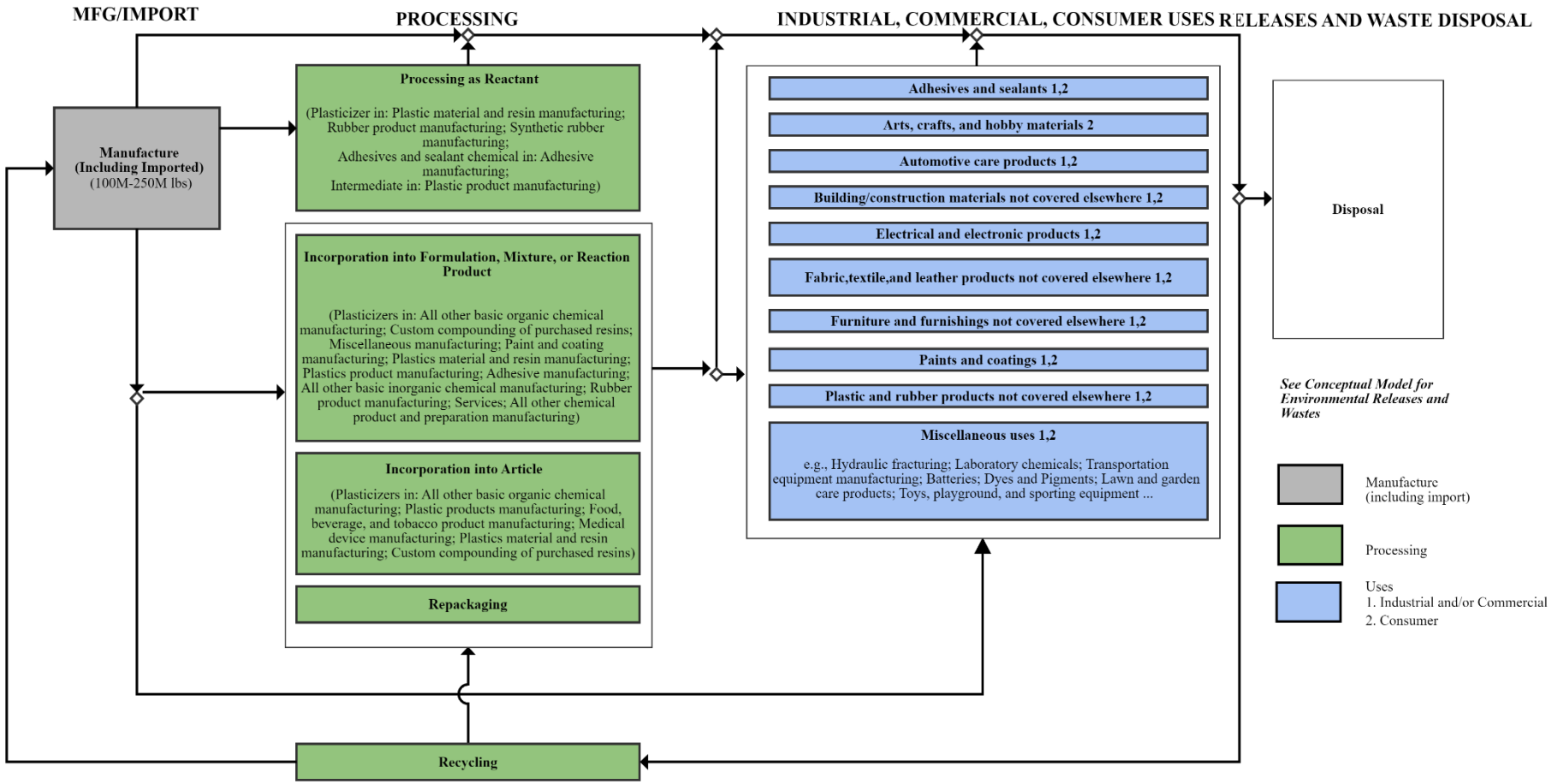

Figure 2-7. Di-ethylhexyl Phthalate Life Cycle Diagram

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, is withheld pursuant to TSCA Section §14, or is unknown.

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-ethylhexyl 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-ethylhexyl phthalate.

2.3.1 Physical and Chemical Properties

Consideration of physical and chemical properties is essential for a thorough understanding or prediction of environmental fate (i.e., transport and transformation) and the eventual environmental concentrations. They can also inform the hazard assessment. EPA plans to use the physical and chemical properties described in the *Proposed Designation of Di-ethylhexyl Phthalate (CASRN 117-81-7) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019a) to support the development of the risk evaluation for di-ethylhexyl 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-ethylhexyl phthalate. EPA plans to use the environmental fate characteristics described in the *Proposed Designation of Di-ethylhexyl Phthalate (CASRN 117-81-7) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019a) to support the development of the risk evaluation for di-ethylhexyl 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.

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

Under Section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA), di-ethylhexyl phthalate is a TRI-reportable substance effective January 1, 1987 (40 CFR 372.65). For TRI reporting[4], facilities in covered sectors in the United States are required to disclose release and other waste management activity quantities of di-ethylhexyl phthalate under the CASRN 106-99-0 if they manufacture (including import) or process more than 25,000 pounds or otherwise use more than 10,000 pounds of the chemical in a given year by July 1 of the following year.

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

Table 2-3 provides production-related waste management data for di-ethylhexyl phthalate reported by facilities to the TRI program for reporting year 2018.[5] As shown in the table, 118 facilities managed, in total, nearly 8 million pounds of di-ethylhexyl phthalate as waste. Of this total: more than 6.5 million pounds were recycled; over 600,000 pounds were treated; nearly 80,000 pounds were burned for energy recovery, and just over 710,000 pounds were released to the environment. Most (82%) of the total quantity of production-related waste was managed by recycling. Roughly 60% of all the production-related waste was managed on site. For recycling and energy recovery, the portions managed on site were higher at 67% and 82%, respectively. The inverse was true for treatment-related quantities; approximately ¾ of the total quantity was treated off-site. A relatively small portion (710,000 pounds, 9%) of the total quantity of production-related waste was released to the environment, and most (90%) of this amount was disposed of or otherwise released off-site.

Table 2-3. Summary of Di-ethylhexyl Phthalate Production-Related Waste Managed in 2018

Year	Number of Facilities	Recycled (lbs)	Recovered for Energy (lbs)	Treated (lbs)	Released[a,b,c] (lbs)	Total Production Related Waste (lbs)
2018	118	6,541,493	79,746	607,502	710,514	7,939,256

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

Table 2-4 provides a summary of the di-ethylhexyl phthalate disposed of or otherwise released to the environment during 2018.[5] Very little di-ethylhexyl phthalate (less than 31 lbs) was released to water. Disposal to land, however, accounted for approximately 90% of the total quantity of di-ethylhexyl phthalate released to the environment. Of the total quantity of di-ethylhexyl phthalate released (disposed of) to land, 96% was reported as "all other land disposal". This includes di-ethylhexyl phthalate sent off-site to Class II-V underground injection wells (62% of total land disposal), as well as di-ethylhexyl phthalate sent off-site for disposal in non-RCRA Subtitle C landfills (34% of total land disposal). Quantities of di-ethylhexyl phthalate released on site to air totaled nearly 47,000 pounds, which accounted for 6.6% of the total quantity of di-ethylhexyl phthalate released to the environment during 2018. Nearly ¾ of these air releases were in the form of stack emissions, with fugitive air releases accounting for the remaining ¼. The majority of "other releases" occurred off-site.

Table 2-4. Summary of Releases of Di-ethylhexyl Phthalate to the Environment During 2018

Year	Number of Facilities	Air Releases (lbs)		Water Releases (lbs)	Land Disposal (lbs)			Other Releases [a] (lbs)	Total Releases [b, c] (lbs)
		Stack Air Releases	Fugitive Air Releases		Class I Under-ground Injection	RCRA Subtitle C Landfills	All other Land Disposal [a]		
2018	118	33,879	12,795	30.57	5	22,909	619,423		710,694

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

Year	Number of Facilities	Air Releases (lbs)		Water Releases (lbs)	Land Disposal (lbs)			Other Releases [a] (lbs)	Total Releases [b, c] (lbs)
		Stack Air Releases	Fugitive Air Releases		Class I Under-ground Injection	RCRA Subtitle C Landfills	All other Land Disposal [a]		
		46,674			642,337			21,651.88	

Data source: 2018 TRI Data (Updated November 2019)

[a] Terminology used in these columns may not match the more detailed data element names used in the TRI public data and analysis access points.

[b] These release quantities include releases due to one-time events not associated with production such as remedial actions or earthquakes.

[c] Counts release quantities once at final disposition, accounting for transfers to other TRI reporting facilities that ultimately dispose of the chemical waste.

The total production-related waste managed quantity shown in Table 2-3 does not include any quantities reported as catastrophic or one-time releases or otherwise not associated with production. Release quantities shown in Table 2-4 include both production-related and non-production-related quantities. Total release quantities differ by 180 pounds between Table 2-3 and Table 2-4 due to differences in TRI calculation methods for reported release range estimates (U.S. EPA, 2017d). Table 2-3 includes quantities transferred off-site to receiving facilities for release or disposal and, if the receiving facilities are subject to the TRI reporting requirements, they would report these quantities as on-site releases, and these same quantities would be included in the total release aggregate. This is referred to as "double counting", because the quantities are counted twice. This is done because total production-related waste values in the TRI database considers all instances of where and how the waste is managed (first as a quantity sent off-site for disposal and next as a quantity disposed of on-site), and reflects both the off-site transfer and the on-site disposal quantities, In processing the data, the TRI program recognizes that this is the same quantity of the chemical and includes it only once in the total releases value, such as in Table 2-4. The production-related waste value in the TRI database, however, considers all instances where the waste is managed (first as a quantity sent off-site for disposal and next as a quantity disposed of on-site), and reflects both the off-site transfer and the on-site disposal. In the case of di-ethylhexyl phthalate, the similarity in the total release quantities shown in Table 2-3 and Table 2-4 indicates that di-ethylhexyl phthalate waste quantities transferred off-site for disposal to land are received by facilities not required to report to TRI.

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

2.3.4 Environmental Exposures

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

Environmental monitoring data were identified in EPA's data search for di-ethylhexyl phthalate and can be used in the exposure assessment. Relevant and reliable monitoring studies provide(s) information that can be used in an exposure assessment. Environmental monitoring studies that measure environmental concentrations or concentrations of chemical substances in biota provide evidence of exposure.

Environmental monitoring data shows that di-ethylhexyl phthalate has been identified in various environmental compartments including air, water, soil/sediment and other environmental media (NICNAS 2019, NTP 2016, IARC 2013, ECB 2008, NTP-CERHR 2006, ATSDR 2002, OEHHA 1997). EPA anticipates possible presence of di-ethylhexyl phthalate in soil, sediment, and water (NICNAS 2019, NTP 2016). Di-ethylhexyl phthalate has been found in in aquatic invertebrates, fish, and monkeys (IARC 2013, ECB 2008, ATSDR 2002). EPA plans to review available environmental monitoring data in the risk evaluation.

2.3.5 Occupational Exposures

EPA plans to analyze worker activities where there is a potential for exposure under the various conditions of use described in Section 2.2.2. In addition, EPA plans to analyze exposure to occupational non-users (i.e., workers, who do not directly handle the chemical but perform work in an area where the chemical is present). EPA also plans to consider the effect(s) that engineering controls (EC) and/or personal protective equipment (PPE) have on occupational exposure levels as part of the draft risk evaluation.

Worker activities associated with the conditions of use within the scope of the risk evaluation for di-ethylhexyl phthalate that will be analyzed, include, but are not limited to:

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

Di-ethylhexyl phthalate is a liquid at room temperature and has a vapor pressure of 1.42×10^{-7} mm Hg at 25 ºC (NLM, 2015) and inhalation exposure to vapor is expected to be low when working with the material at room temperature. However, EPA plans to analyze inhalation exposure in occupational scenarios where di-ethylhexyl phthalate is applied via spray or roll application methods or is handled as a dry powder or at elevated temperatures.

Di-ethylhexyl phthalate has an Occupational Safety and Health Administration (OSHA) permissible exposure limit (PEL) (OSHA 2009). The PEL is 5 mg/m^3 over an 8-hour workday, time weighted average (TWA). The National Institute for Occupational Safety and Health (NIOSH) has set the Recommended Exposure Limit (REL) of 5 mg/m^3 TWA, set the short-term exposure limit (STEL) of 10 mg/m^3, set the Immediately Dangerous to Life and Health (IDLH) at 5000 mg/m^3, and designated it as a potential occupational carcinogen (NIOSH 2005).The American Conference of Governmental Industrial Hygienists (ACGIH) set the threshold limit value (TLV) at 5 mg/m^3 TWA.

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

EPA generally does not evaluate occupational exposures through the oral route. Workers may inadvertently transfer chemicals from their hands to their mouths or ingest inhaled particles that deposit in the upper respiratory tract. The frequency and significance of this exposure route are dependent on several factors including the p-chem properties of the substance during expected worker activities, workers' awareness of the chemical hazards, the visibility of the chemicals on the hands while working,

workplace practices, and personal hygiene that is difficult to predict (Cherrie et al., 2006). However, EPA will consider oral exposure on a case-by-case basis for certain COUs and worker activities where there is information and data on incidental ingestion of inhaled dust. EPA will consider ingestion of inhaled dust as an inhalation exposure for di-ethylhexyl phthalate.

2.3.6 Consumer Exposures

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

Based on reasonably available information on consumer conditions of use, inhalation of di-ethylhexyl phthalate is possible through either inhalation of vapor/mist during product usage or indoor air/dust. Oral exposure of di-ethylhexyl phthalate is possible through either ingestion through product use via transfer from hand to mouth or via through mouthing of articles containing di-ethylhexyl 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-ethylhexyl 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-ethylhexyl phthalate.

2.3.7 General Population Exposures

Releases of di-ethylhexyl phthalate from certain conditions of use, such as manufacturing, processing, or disposal activities, may result in general population exposures. General population exposures are primarily via drinking water ingestion and inhalation from air releases. Exposure can also occur orally through consumption of food containing di-ethylhexyl phthalate, either through contamination from environmental sources or as a result of leaching from food packaging materials (TERA 2015, ATSDR 2002, OEHHA 1997) Environmental monitoring data indicates that di-ethylhexyl phthalate has been identified in various environmental compartments including air, water, soil/sediment and other environmental media (NICNAS 2019, NTP 2016, IARC 2013, ECB 2008, NTP-CERHR 2006, ATSDR 2002, OEHHA 1997). EPA plans to review the reasonably available information for the presence of di-ethylhexyl phthalate in environmental media relevant to general population exposure

In human matrices, di-ethylhexyl phthalate has been detected in serum, breast milk, adipose tissue, cord blood and stored blood (NTP 2016, IARC 2013, ECB 2008, NTP-CERHR 2006, OEHHA 2005, ATSDR 2002, OEHHA 1997, NTP 1982), whereas metabolites of di-ethylhexyl phthalate have been detected in urine, saliva, breast milk, cord blood, and serum (NTP 2016, CPSC 2014, IARC 2013, NICNAS 2010, ECHA 2010, ECB 2008, NTP-CERHR 2006, ATSDR 2002).

The presence in environmental media and biomonitoring data suggest that general population exposures are occurring. 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-Ethylhexyl Phthalate (CASRN 117-81-7) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019a), EPA considered reasonably available information from peer-reviewed assessments and databases to identify potential environmental hazards for di-ethylhexyl phthalate. EPA considers all the potential environmental hazards for di-ethylhexyl phthalate identified during prioritization (U.S. EPA 2019) 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-ethylhexyl phthalate. If necessary, EPA plans to update the list of potential hazards in the final scope document of di-ethylhexyl 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-ethylhexyl Phthalate (CASRN 117-81-7) as a High-Priority Substance for Risk Evaluation* (U.S. EPA 2019a), EPA considered reasonably available information from peer-reviewed assessments and databases to identify potential human health hazards for di-ethylhexyl phthalate. EPA plans to evaluate all of the potential human health hazards for di-ethylhexyl phthalate identified during prioritization. The health effect categories identified during prioritization included acute toxicity, repeated dose toxicity, genetic toxicity, reproductive toxicity, developmental toxicity, irritation/corrosion, dermal sensitization, respiratory sensitization, carcinogenicity, immunotoxicity, neurotoxicity, epidemiological or biomonitoring studies and ADME.

The broad health effect categories included for further evaluation from designation are developmental and reproductive effects and cancer. 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-ethylhexyl 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 (PESS) identified as relevant to the risk evaluation." TSCA §3(12) states that "the term 'potentially exposed or susceptible subpopulation' means a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly." General population is "the total of individuals inhabiting an area or making up a whole group" and refers here to the U.S. general population (U.S. EPA, 2011a).

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

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

2.6 Conceptual Models

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

2.6.1 Conceptual Model for Industrial and Commercial Activities and Uses

Figure 2-8 illustrates the conceptual model for the pathways of exposure from industrial and commercial activities and uses of di-ethylhexyl phthalate that EPA plans to include in the risk evaluation. There is potential for exposures to workers and/or occupational non-users 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 EPA plans to assess each combination of exposure pathways, routes, and receptors will be in the risk evaluation. The results of that analysis along with the supporting rationale are presented in Appendix F.

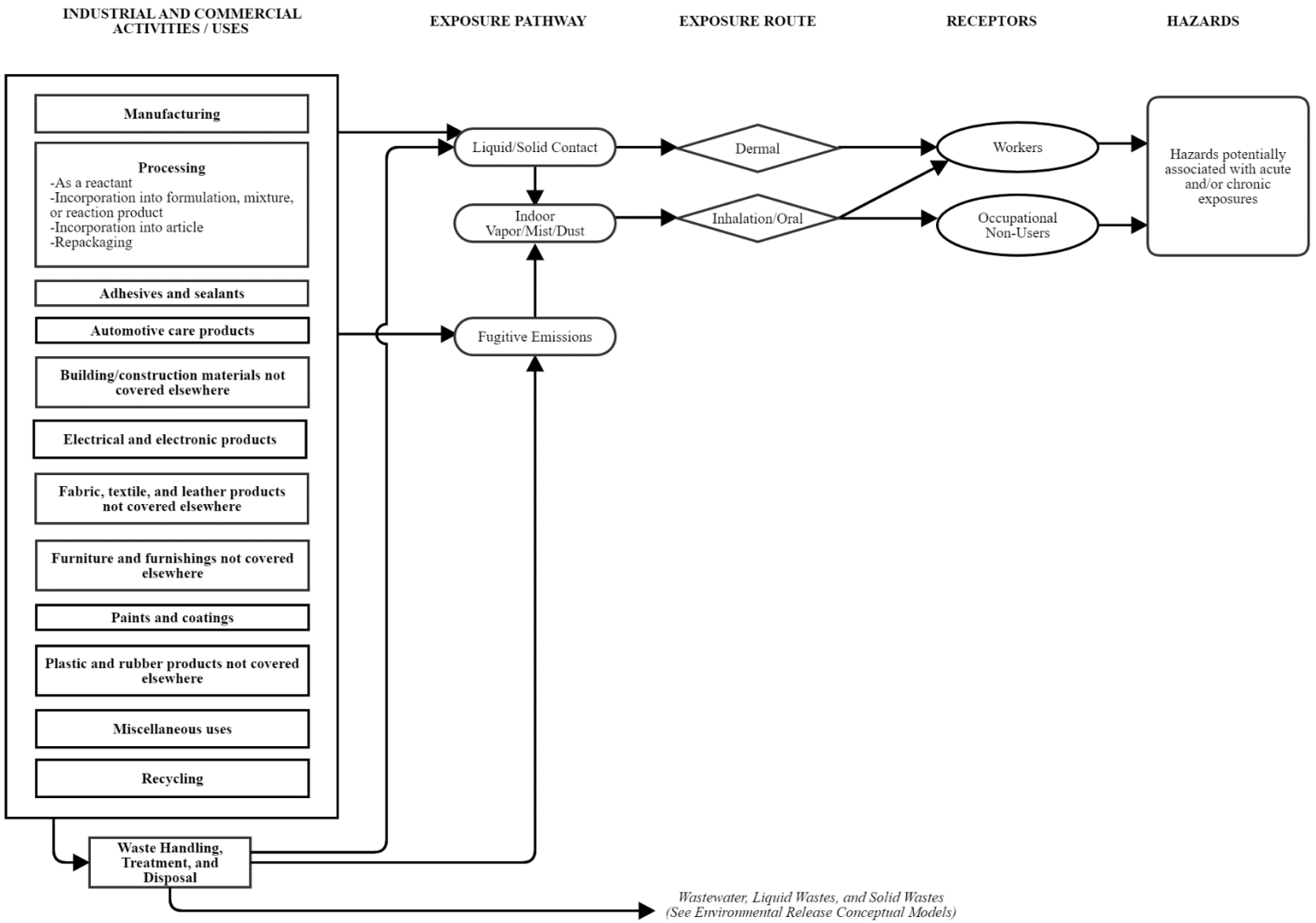

Figure 2-8. Di-Ethylhexyl Phthalate Conceptual Model for Industrial and Commercial Activities and Uses: Worker and Occupational Non-User Exposures and Hazards

The conceptual model presents the exposure pathways, exposure routes and hazards to human receptors from industrial and commercial activities and uses of di-ethylhexyl 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-ethylhexyl phthalate. EPA expects that consumers may be exposed through use of products or articles containing di-ethylhexyl 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. EPA expects 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-ethylhexyl phthalate are included in Appendix G.

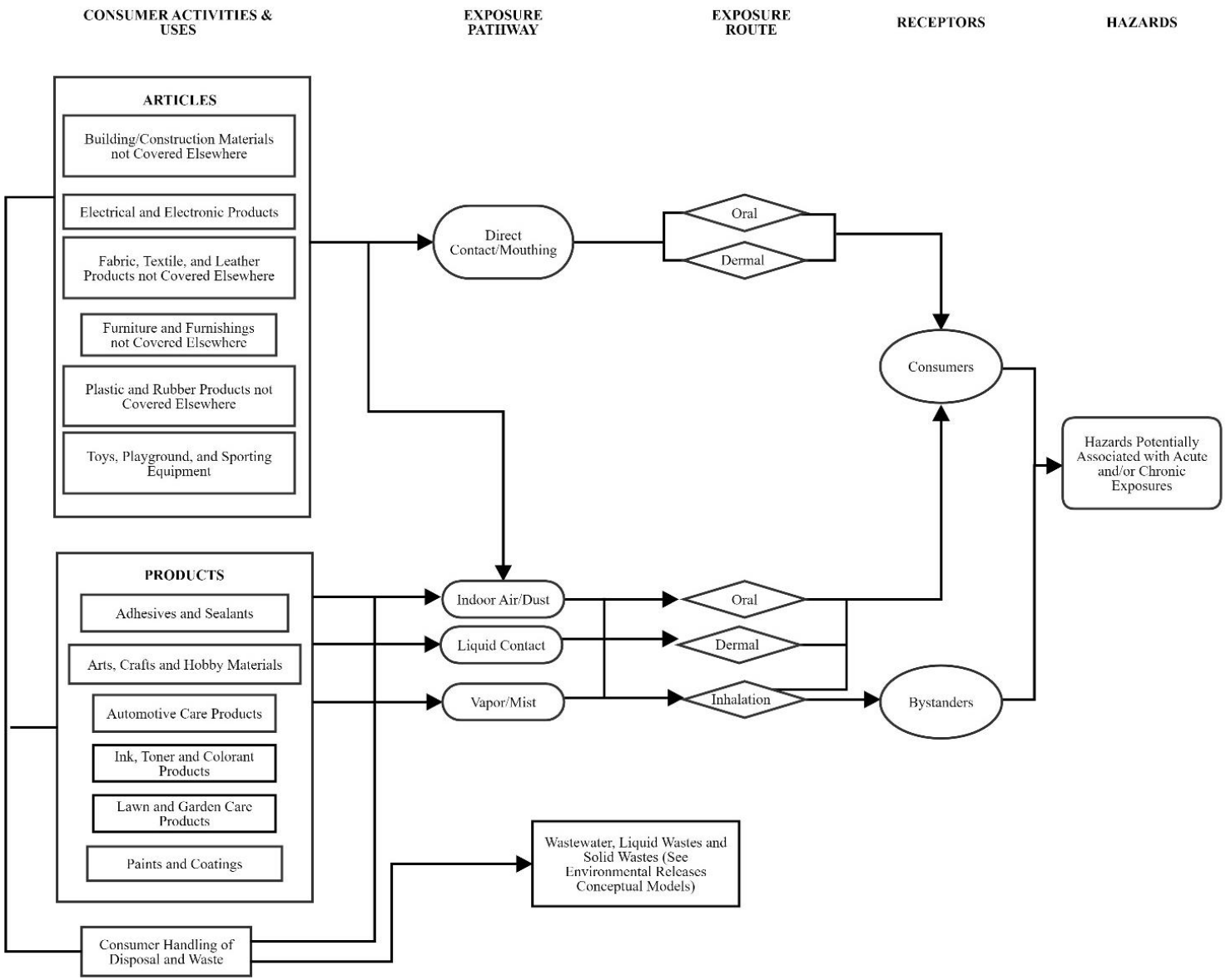

Figure 2-9. Di-ethylhexyl Phthalate Conceptual Model for Consumer Activities and Uses: Consumer Exposures and Hazards

The conceptual model presents the exposure pathways, exposure routes and hazards to human receptors from consumer activities and uses of di-ethylhexyl phthalate.

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

In this section, EPA presents the conceptual models describing the identified exposures (pathways and routes), receptors and hazards associated with the conditions of use of di-ethylhexyl phthalate within the scope of the risk evaluation. It also discusses those pathways that may be addressed pursuant to other Federal laws.

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

The conceptual model in Figure 2-10 presents the potential exposure pathways, exposure routes and hazards to human and environmental receptors from releases and waste streams associated with industrial and commercial uses of di-ethylhexyl phthalate. This figure includes overlays, labeled and shaded to depict the regulatory programs (e.g., CAA, SDWA, CWA, RCRA) and associated pathways that EPA considered in developing this conceptual model for the draft scope document. The pathways are further described in Section 2.6.3.1 through Section 2.6.3.4.

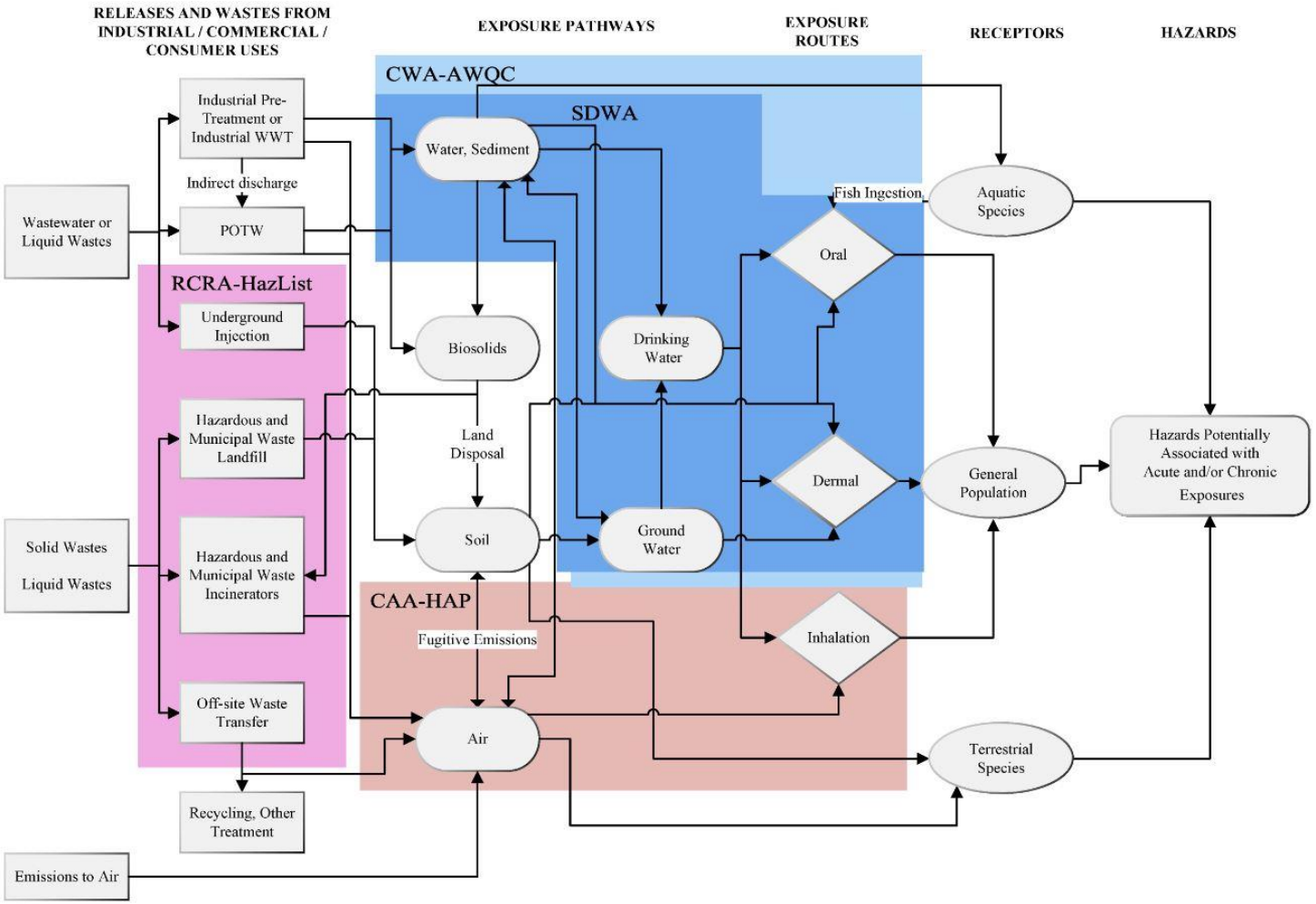

Figure 2-10. Di-ethylhexyl Phthalate Conceptual Model for Environmental Releases and Wastes: Environmental and General Population Exposures and Hazards (Regulatory Overlay)

The conceptual model presents the exposure pathways, exposure routes and hazards to human and environmental receptors from releases and wastes from industrial, commercial, and consumer uses of Di-ethylhexyl phthalate including the environmental statutes covering those pathways. Notes:

a) Industrial wastewater or liquid wastes may be treated on-site and then released to surface water (direct discharge), or pre-treated and released to 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).

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

2.6.3.1 Ambient Air Pathway

The Clean Air Act (CAA) contains a list of hazardous air pollutants (HAP) and provides EPA with the authority to add to that list pollutants that present, or may present, a threat of adverse human health effects or adverse environmental effects. For stationary source categories emitting HAP, the CAA requires issuance of technology-based standards and, if necessary, additions or revisions to address developments in practices, processes, and control technologies, and to ensure the standards adequately protect public health and the environment. The CAA thereby provides EPA with comprehensive authority to regulate emissions to ambient air of any hazardous air pollutant.

Di-ethylhexyl phthalate is a HAP (see Appendix D). EPA has issued a number of technology-based standards for source categories that emit di-ethylhexyl phthalate to ambient air and, as appropriate, has reviewed, or is in the process of reviewing remaining risks. Because stationary source releases of di-ethylhexyl phthalate to ambient air are covered under the jurisdiction of the CAA. EPA's Office of Air and Radiation and Office of Pollution Prevention and Toxics will continue to work together to provide an understanding and analysis of the CAA regulatory analytical processes and to exchange information related to toxicity and occurrence data on chemicals undergoing risk evaluation under TSCA.

2.6.3.2 Drinking Water Pathway

EPA has promulgated National Primary Drinking Water Regulations (NPDWRs) under the Safe Drinking Water Act for di-ethylhexyl phthalate. EPA has set an enforceable Maximum Contaminant Level (MCL) as close as feasible to a health based, non-enforceable Maximum Contaminant Level Goal (MCLG). Feasibility refers to both the ability to treat water to meet the MCL and the ability to monitor water quality at the MCL,(SDWA Section 1412(b)(4)(D), and public water systems are required to monitor for the regulated chemical based on a standardized monitoring schedule to ensure compliance with the MCL. The MCL for di-ethylhexyl phthalate in water is 0.006 mg/L.

Hence, because the drinking water exposure pathway for di-ethylhexyl phthalate is currently addressed in the SDWA regulatory analytical process for public water systems, EPA does not plan to include this pathway in the risk evaluation for di-ethylhexyl phthalate under TSCA. EPA's Office of Water and Office of Pollution Prevention and Toxics will continue to work together providing understanding and analysis of the SDWA regulatory analytical processes and to exchange information related to toxicity and occurrence data on chemicals undergoing risk evaluation under TSCA.

2.6.3.3 Ambient Water Pathway

EPA develops recommended water quality criteria under Section 304(a) of the CWA for pollutants in surface water that are protective of aquatic life or human health designated uses. EPA has developed recommended water quality criteria for protection of human health for di-ethylhexyl phthalate which are available for possible adoption into state water quality standards and are available for possible use by National Pollution Discharge Elimination System (NPDES) permitting authorities in deriving effluent limits to meet state narrative criteria. EPA's OW and OPPT will continue to work together providing understanding and analysis of the CWA water quality criteria development process and to exchange information related to toxicity of chemicals undergoing risk evaluation under TSCA.

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

aquatic life as applicable) for the designated water use and, therefore, can the risk from the pathway can be considered assessed and managed.

EPA has not developed CWA Section 304(a) recommended water quality criteria for the protection of aquatic life for di-ethylhexyl phthalate, so there are no national recommended criteria for this use available for adoption into state water quality standards and available for use in NPDES permits. As a result, this pathway will undergo aquatic life risk evaluation under TSCA. EPA may issue CWA Section 304(a) aquatic life criteria for di-ethylhexyl phthalate in the future if it is identified as a priority under the CWA.

2.6.3.4 Disposal and Soil Pathways

Di-ethylhexyl phthalate is included on the list of hazardous wastes pursuant to RCRA 3001 (40 CFR §§ 261.33) as a listed waste on the U028 list. The general standard in Section RCRA 3004(a) for the technical criteria that govern the management (treatment, storage, and disposal) of hazardous waste are those "necessary to protect human health and the environment," RCRA 3004(a). The regulatory criteria for identifying “characteristic” hazardous wastes and for “listing” a waste as hazardous also relate solely to the potential risks to human health or the environment (40 CFR §§ 261.11, 261.21-261.24). RCRA statutory criteria for identifying hazardous wastes require EPA to “*tak[e] into account toxicity, persistence, and degradability in nature, potential for accumulation in tissue, and other related factors such as flammability, corrosiveness, and other hazardous characteristics.*” Subtitle C controls cover not only hazardous wastes that are landfilled, but also hazardous wastes that are incinerated (subject to joint control under RCRA Subtitle C and the Clean Air Act (CAA) hazardous waste combustion Maximum Achievable Control Technology (MACT)) or injected into Underground Injection Control (UIC) Class I hazardous waste wells (subject to joint control under Subtitle C and the Safe Drinking Water Act (SDWA)).

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

TRI reporting in 2018 indicated 5 pounds released to underground injection to a Class I well. Environmental disposal of di-ethylhexyl phthalate injected into Class I hazardous well types fall under the jurisdiction of RCRA and SDWA; and the disposal of di-ethylhexyl phthalate via underground injection to Class I hazardous waste wells is not likely to result in environmental and general population exposures.

EPA has identified releases to land that go to RCRA Subtitle C hazardous waste landfills in the risk evaluation. Based on 2018 reporting, TRI land disposal includes Subtitle C landfills (22,909 lbs) with another 619,423 lbs transferred to “other landfills” both on-site and off-site. Di-ethylhexyl phthalate is present in commercial and consumer products that may be disposed of in landfills, such as Municipal Solid Waste landfills. Design standards for Subtitle C landfills require double liner, double leachate collection and removal systems, leak detection system, run on, runoff, and wind dispersal controls, and a construction quality assurance program. They are also subject to closure and post-closure care requirements including installing and maintaining a final cover, continuing operation of the leachate collection and removal system until leachate is no longer detected, maintaining and monitoring the leak detection and groundwater monitoring system. Bulk liquids may not be disposed in Subtitle C landfills. Subtitle C landfill operators are required to implement an analysis and testing program to ensure adequate knowledge of waste being managed, and to train personnel on routine and emergency operations at the facility. Hazardous waste being disposed in Subtitle C landfills must also meet RCRA

waste treatment standards before disposal. Given these controls, general population exposure in groundwater from Subtitle C landfill leachate is not expected to be a significant pathway.

Di-ethylhexyl phthalate is present in commercial and consumer products that may be disposed of in landfills, such as Municipal Solid Waste (MSW) landfills. On-site releases to land from RCRA Subtitle D municipal solid waste landfills leading to exposures of the general population (including susceptible populations) or terrestrial species from such releases in this TSCA evaluation may occur. While permitted and managed by the individual states, municipal solid waste (MSW) landfills are required by federal regulations to implement some of the same requirements as Subtitle C landfills. MSW landfills generally must have a liner system with leachate collection and conduct groundwater monitoring and corrective action when releases are detected. MSW landfills are also subject to closure and post-closure care requirements and must have financial assurance for funding of any needed corrective actions. MSW landfills have also been designed to allow for the small amounts of hazardous waste generated by households and very small quantity waste generators (less than 220 lbs per month). Bulk liquids, such as free solvent, may not be disposed of at MSW landfills.

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

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

As described in Section 2.6.3, some pathways in the conceptual models are covered under the jurisdiction of other environmental statutes administered by EPA. The conceptual model depicted in Figure 2-11 presents the exposure pathways, exposure routes and hazards to human and environmental receptors from releases and wastes from industrial, commercial, and consumer uses of di-ethylhexyl phthalate that EPA plans to consider in the risk evaluation. The exposure pathways, exposure routes and hazards presented in this conceptual model are subject to change in the final scope, in light of comments received on this draft scope and other reasonably available information. EPA continues to consider whether and how other EPA-administered statutes and any associated regulatory programs address the presence of di-ethylhexyl phthalate in exposure pathways falling under the jurisdiction of these EPA statutes.

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

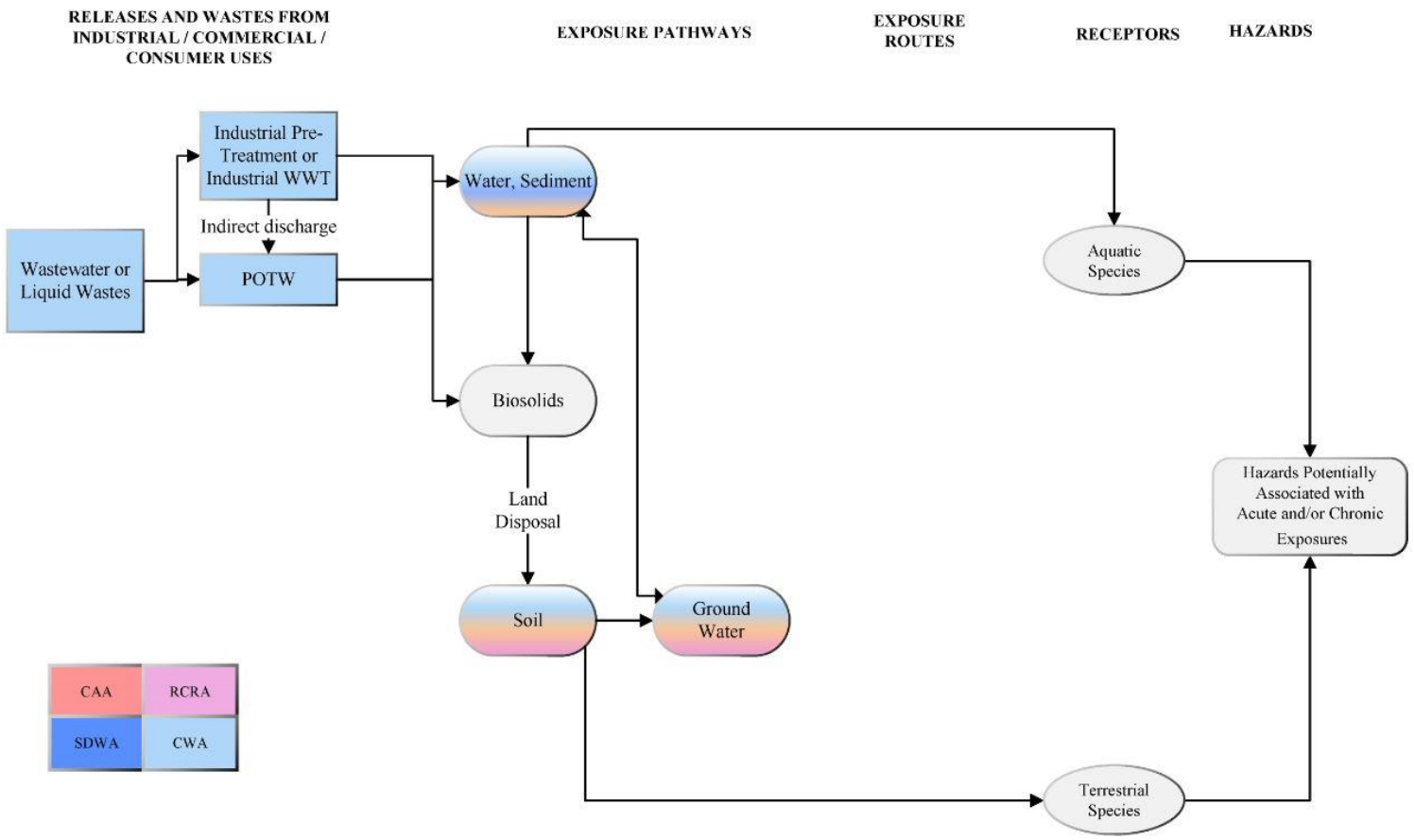

Figure 2-11. Di-ethylhexyl Phthalate Conceptual Model for Environmental Releases and Wastes: Environmental Exposures and Hazards

The conceptual model presents the exposure pathways, exposure routes and hazards to human receptors from releases and wastes from industrial and commercial uses of di-ethylhexyl phthalate.

a) Industrial wastewater or liquid wastes may be treated on-site and then released to surface water (direct discharge), or pre-treated and released to POTW (indirect discharge). For consumer uses, such wastes may be released directly to POTW.

b) Receptors include PESS (see Section 2.5).

2.7 Analysis Plan

The analysis plan is based on EPA's knowledge of di-ethylhexyl phthalate to date which includes a partial, but not complete review of reasonably available information as described in Section 2.1. EPA encourages submission of additional data, such as full study reports or workplace monitoring from industry sources, that may be relevant for EPA's evaluation of conditions of use, exposures, hazards and 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 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 fate and transport in environmental media as follows:

1) **Review reasonably available measured or estimated environmental fate endpoint data collected through the literature search.**
   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-Ethylhexyl Phthalate (CASRN 117-81-7) as a High-Priority Substance for Risk Evaluation* (U.S. EPA 2019a). All sources cited in EPA's analysis will be evaluated according to the procedures described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document. Where the systematic review process fails to identify experimentally measured chemical property values of sufficiently high quality, these values will be estimated using chemical parameter estimation models as appropriate. Model-estimated fate properties will be reviewed for applicability and quality.

2) **Using measured data and/or modeling, determine the influence of 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-ethylhexyl 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) **Evaluate the weight of scientific evidence of environmental fate data, which include 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, ambient air, surface water, groundwater, sediment, soil, aquatic biota, and terrestrial biota associated to exposure to di-ethylhexyl 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 combinations of sources (uses), exposure pathways, and exposed receptors. Draft release/exposure scenarios corresponding to various conditions of use for di-ethylhexyl phthalate are presented in Appendix G. 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 available monitoring data and modeling approaches.

2.7.2.1 Environmental Releases

EPA plans to analyze releases to environmental media as follows:

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

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

U.S. EPA TRI Data
U.S. EPA Generic Scenarios
OECD Emission Scenario Documents
Discharge Monitoring Report (DMR) surface water discharge data from NPDES-permitted facilities

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

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

3) **Review reasonably available measured or estimated release data for surrogate chemicals that have similar uses and physical properties.**
   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-ethylhexyl 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 assessed.

EPA Generic Scenarios are available at the following: https://www.epa.gov/tsca-screening-tools/using-predictive-methods-assess-exposure-and-fate-under-tsca#fate.

OECD Emission Scenario Documents are available at the following: http://www.oecd.org/chemicalsafety/risk-assessment/emissionscenariodocuments.htm

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

6) **Map or group each condition of use to a release assessment scenario(s).**
EPA has identified release scenarios and mapped (i.e., grouped) them to relevant conditions of use as shown in Appendix F. EPA may 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-ethylhexyl phthalate and articles and formulations containing di-ethylhexyl phthalate, or professional judgment) corresponding to conditions of use as additional information is identified during risk evaluation.

7) **Evaluate the weight of 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-ethylhexyl phthalate:

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

2) **Review reasonably available information on releases to determine how modeled estimates of concentrations near industrial point sources compare with available monitoring data.**
   Available environmental exposure models that meet the TSCA Section 26(h) and (i) Science Standards and that estimate surface water, sediment, and soil concentrations will be analyzed and considered alongside available surface 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 surface water, sediment, or soil, indirect release into 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-ethylhexyl 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-ethylhexyl 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 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 occupational non-user exposures as follows:

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

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

   EPA plans to consider the influence of regulatory limits and recommended exposure guidelines on occupational exposures set by OSHA, NIOSH, and ACGIH in the occupational exposure assessment.

Table 2-6. Potential Sources of Occupational Exposure Data

2019 Draft ATSDR Toxicological Profile for DEHP
U.S. OSHA Chemical Exposure Health Data (CEHD) program data
U.S. NIOSH Health Hazard Evaluation (HHE) Program reports

2) **Review reasonably available exposure data for surrogate chemicals that have uses, volatility and chemical and physical properties similar to di-ethylhexyl 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-ethylhexyl phthalate may serve as surrogates for di-ethylhexyl 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 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/OPPT, other government agencies, or 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 occupational non-users.

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/grouping of occupational exposure scenarios based on factors (e.g., process equipment and handling, magnitude of production volume used, and exposure/release sources) corresponding to conditions of use as additional information is identified during risk evaluation.

7) **Evaluate the weight of 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-ethylhexyl 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 available data.**
Indoor exposure pathways expected to be relatively higher include dust ingestion and mouthing of products. Indoor exposure pathways expected to be relatively lower include inhalation of indoor air, dermal contact with dust and articles. The data sources associated with these respective pathways have not 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 dust concentrations, or indoor dust surface loadings.**
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. In addition, direct transfer to surface dust or physical abrasion may influence emissions. 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 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 reasonably available.**
To the extent other organizations have already modeled a di-ethylhexyl 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-ethylhexyl 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-ethylhexyl phthalate in specific media (e.g., dust or indoor air).**
The availability of di-ethylhexyl 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 and dust 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 Systematic Review methods.

7) **Evaluate the weight of scientific evidence of consumer exposure estimates based on different approaches.**
EPA plans to rely on the weight of scientific evidence when evaluating and integrating data related to consumer exposure. The weight of 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 does not plan to analyze general population exposures, based on a review of exposure pathways as described in Section 2.6.3. EPA does not expect to include in the risk evaluation pathways under programs of other environmental statutes, administered by EPA, for which long-standing regulatory and analytical processes already exist.

2.7.3 Hazards (Effects)

2.7.3.1 Environmental Hazards

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

5) **Conduct an environmental risk characterization of di-ethylhexyl phthalate.**
EPA plans to conduct a risk characterization of di-ethylhexyl phthalate to identify if there are risks to the aquatic and/or terrestrial environments from the measured and/or predicted concentrations of di-ethylhexyl 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-ethylhexyl phthalate.**
EPA plans to consider the persistence, bioaccumulation, and toxic (PBT) potential of di-ethylhexyl 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-ethylhexyl 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-ethylhexyl 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-ethylhexyl phthalate. EPA plans to publish the systematic review documentation prior to finalizing the scope document.

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

2) **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-ethylhexyl phthalate hazard(s). Susceptibility of particular human receptor groups to di-ethylhexyl phthalate will be determined by evaluating information on factors that influence susceptibility.

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

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

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

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

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

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

   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 the EPA's *Risk Characterization Handbook* (U.S. EPA, 2000). As defined in the 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.

Risk characterization at EPA assumes different levels of complexity depending on the nature of the risk assessment being characterized. 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 (TCCR) (U.S. EPA, 2000). EPA plans to also present information in this section consistent with approaches described in 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 the EPA's Information Quality Guidelines (U.S, 2002) as it provides guidance for presenting risk information. Consistent with those guidelines, in the risk characterization, EPA plans to also identify: (1) Each population addressed by an estimate of applicable risk effects; (2) the expected risk or central estimate of risk for the PESS subpopulations affected; (3) each appropriate upper-bound or lower bound estimate of risk; (4) each significant uncertainty identified in the process of the assessment of risk effects and the studies that would assist in resolving the uncertainty; and (5) peer reviewed studies known to the Agency that support, are directly relevant to, or fail to support any estimate of risk effects and the methodology used to reconcile inconsistencies in the scientific information.

2.8 Peer Review

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

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APPENDICES

Appendix A LIST OF GRAY LITERATURE SOURCES

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

Source/Agency	Source Name	Source Type	Source Category
ATSDR	ATSDR Tox Profile Updates and Addendums	Other US Agency Resources	Assessment or Related Document
ATSDR	ATSDR Toxicological Profiles (original publication)	Other US Agency Resources	Assessment or Related Document
Australian Assessment, Department of Health	NICNAS Assessments (eco)	International Resources	Assessment or Related Document
Australian Assessment, Department of Health	NICNAS Assessments (human health, Tier I, II or III)	International Resources	Assessment or Related Document
CAL EPA	Technical Support Documents for regulations: Cancer Potency Information	Other US Agency Resources	Assessment or Related Document
CAL EPA	Technical Support Documents for regulations: Proposition 65, Cancer	Other US Agency Resources	Assessment or Related Document
CAL EPA	Technical Support Documents for regulations: Proposition 65, Reproductive Toxicity	Other US Agency Resources	Assessment or Related Document
CAL EPA	Technical Support Documents for regulations: Drinking Water Public Health Goals	Other US Agency Resources	Assessment or Related Document
CPSC	Chronic Hazard Advisory Panel Reports	Other US Agency Resources	Assessment or Related Document

Source/Agency	Source Name	Source Type	Source Category
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	European Union Risk Assessment Report	International Resources	Assessment or Related Document
ECHA	ECHA Documents	International Resources	Assessment or Related Document
ECHA	Annex XVII Restriction Reports	International Resources	Assessment or Related Document
ECHA	Annex XVII To REACH - Conditions of Use	International Resources	Assessment or Related Document
Env Canada	Chemicals at a Glance (fact sheets)	International Resources	Assessment or Related Document
Env Canada	Guidelines, Risk Management, Regulations	International Resources	Assessment or Related Document
EPA	Office of Water: STORET and WQX	US EPA Resources	Database
EPA	EPA Office of Water: Ambient Water Quality Criteria documents	US EPA Resources	Assessment or Related Document
EPA	TSCA Hazard Characterizations	US EPA 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

Source/Agency	Source Name	Source Type	Source Category
EPA	EPA: Generic Scenario	US EPA Resources	Assessment or Related Document
EPA	EPA Discharge Monitoring Report Data	US EPA Resources	Database
EPA	Office of Water: Drinking Water Standards Health Effects Support Documents	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
IARC	IARC Monograph	International Resources	Assessment or Related Document
Japan	Japanese Ministry of the Environment Assessments - Environmental Risk Assessments (Class I Designated Chemical Substances Summary Table)	International Resources	Regulatory Document or List
KOECT	Kirk-Othmer Encyclopedia of Chemical Technology Journal Article	Other Resource	Encyclopedia
NIOSH	CDC NIOSH - Occupational Health Guideline Documents	Other US Agency Resources	Assessment or Related Document
NIOSH	CDC NIOSH - Pocket Guides	Other US Agency Resources	Database

Source/Agency	Source Name	Source Type	Source Category
NIOSH	CDC NIOSH - Health Hazard Evaluations (HHEs)	Other US Agency Resources	Assessment or Related Document
NIOSH	CDC NIOSH - Publications and Products	Other US Agency Resources	Assessment or Related Document
NLM	National Library of Medicine's PubChem	Other US Agency Resources	Database
NTP	OHAT Monographs	Other US Agency Resources	Assessment or Related Document
NTP	Technical Reports	Other US Agency Resources	Assessment or Related Document
NTP	Additional NTP Reports	Other US Agency Resources	Assessment or Related Document
OECD	OECD Emission Scenario Documents	International Resources	Assessment or Related Document
OECD	OECD: General Site	International Resources	General Search
OSHA	OSHA Chemical Exposure Health Data	Other US Agency Resources	Database
OSHA	U.S. OSHA Chemical Exposure Health Data (CEHD) program data [ERG]	Other US Agency Resources	Database
RIVM	RIVM Reports: Risk Assessments	International Resources	Assessment or Related Document
TERA	Toxicology Excellence for Risk Assessment	Other Resources	Assessment or Related Document
UNEP	Risk Profile / Stockholm Convention	International Resources	Assessment or Related Document

Appendix B PHYSICAL AND CHEMICAL INFORMATION

This appendix provides p-chem information and data found in preliminary data gathering for di-ethylhexyl 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-Ethylhexyl Phthalate (CASRN 117-81-7) as a High-Priority Substance for Risk Evaluation* (U.S. EPA 2019a) and may be updated as EPA collects additional information through systematic review methods. All p-chem property values that were extracted and evaluated as of March 2020 are presented in the supplemental file *Data Extraction and Data Evaluation Tables for Physical Chemical Property Studies* (EPA-HQ-OPPT-2018-0433).

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

Property or Endpoint	Value[a]	Reference	Data Quality Rating
Molecular formula	$C_{24}H_{38}O_4$	NA	NA
Molecular weight	390.57 g/mol	NA	NA
Physical state	Liquid	Rumble, 2018	High
Physical properties	Colorless, oily liquid; slight odor	NLM, 2015	High
Melting point	-55°C	NLM, 2015	High
Boiling point	384°C	NLM, 2015	High
Density	0.981 g/cm^3 at 25°C	NLM, 2015	High
Vapor pressure	1.42×10^{-7} mm Hg at 25°C	NLM, 2015	High
Vapor density	16.0 (air = 1)	NLM, 2015	High
Water solubility	0.27 mg/L at 25°C	NLM, 2015	High
Log Octanol/water partition coefficient (Log Kow)	7.6	NLM, 2015	High
Henry's Law constant	1.71×10^{-5} atm·m^3/mol	Elsevier, 2019	High
Flash point	206°C	O'Neil, 2013	High

Property or Endpoint	Value[a]	Reference	Data Quality Rating
Auto flammability	Not available		
Viscosity	57.94 cP at 25°C	Mylona, 2013	High
Refractive index	1.4853	Rumble, 2018	High
Dielectric constant	5.06 at 25°C	Elsevier, 2019	High

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

Appendix C ENVIRONMENTAL FATE AND TRANSPORT PROPERTIES

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

Table_Apx C-1. Environmental Fate and Transport Properties of Di-ethylhexyl Phthalate

Property or Endpoint	Value[a]	Reference
Direct Photodegradation	di-ethylhexyl phthalate contains chromophores that absorb at wavelengths >290 nm and will undergo photolysis; irradiation with a 300 W xenon lamp resulted in the decomposition of this compound with gaseous carbon dioxide being one of the main products 2-ethyl-1-hexene, 2-ethylhexanol, and phthalic acid were major byproducts	NLM, 2015 citing Kawaguchi, 1994
Direct Photodegradation	Direct photolysis and photooxidation are not likely to be important removal pathways	ATSDR, 2002 citing Wams, 1987
Direct Photodegradation	$t_{1/2}$ = <2 days	NLM, 2015 citing Cadogan, 1994, 5349210
Indirect Photodegradation	$t_{1/2}$ = 5.85 hours (based on ·OH reaction rate constant of 21.96 × 10^{-12} cm^3/mol·second at 25 ºC and 1.5 × 10^6 ·OH radicals/cm^3) (estimated)[b]	U.S. EPA, 2012b
Hydrolysis	$t_{1/2}$ = 2,000 years (pH 7; calculated)	NLM, 2015 citing Staples, 1997 (calculated from data in Wolfe, 1980)
Biodegradation (Aerobic)	In a static flask test with domestic wastewater as the inoculum, degradation increased weekly as adaptation increased. Weekly degradation from week 0-3 were 0, 43, 80, and 95%.	NLM, 2015 citing Tabak, 1981, 9861
Biodegradation (Aerobic)	$t_{1/2}$ = 0.8 days (activated sludge)	NLM, 2015 citing Saeger and Tucker, 1976
Biodegradation (Aerobic)	>64% removal in activated sludge reactor and a biological aerated filter	NLM, 2015 citing Clapp, 1994, 3585789
Biodegradation (Aerobic)	$t_{1/2}$ = 4.5 weeks (river water) $t_{1/2}$ = 14 days (hydrosoil)	NLM, 2015 citing Wams, 1987

Property or Endpoint	Value[a]	Reference
Biodegradation (Aerobic)	Over 63 days 34–50% in Neuherburg soil at pH 7.2 28–41% in Ebersberger Forest soil at pH 3.4 24–36% in Baierbrunn soil at pH 4.5	NLM, 2015
Biodegradation (Anaerobic)	83.3% (municipal sludge)	NLM, 2015 citing Parker, 1994
Biodegradation (Anaerobic)	0%/278 days (municipal solid waste samples)	NLM, 2015 citing Ejlertsson, 1996
Biodegradation (Anaerobic)	$t_{1/2}$ = 198 days, 173 days (anaerobic sludge)	NLM, 2015 citing Gavala, 2003
Wastewater Treatment	$t_{1/2}$ = 23 days (wastewater treatment plants)	NLM, 2015 citing Byrns, 2001
Wastewater Treatment	94% total removal (0.78% by biodegradation, 93% by sludge adsorption, and 0% by volatilization to air; estimated)[b]	U.S. EPA, 2012b
Bioconcentration Factor	1,380 (*Pimephales promelas*)	ECHA, 2019
Bioconcentration Factor	582–614, 737–891 (*Pimephales promelas*)	ECHA, 2019
Bioconcentration Factor	850 (*Pimephales promelas*)	NLM, 2015 citing Veith, 1979
Bioconcentration Factor	199 (*Lepomis macrochirus*)	NLM, 2015 citing Barrows, 1980
Soil Organic Carbon:Water Partition Coefficient (Log K_{OC})	4.9–6	ATSDR, 2002 citing Staples, 1997
Soil Organic Carbon:Water Partition Coefficient (Log K_{OC})	4–5 in clays and sediments	NLM, 2015 citing Sullivan, 1982

[a]Measured unless otherwise noted

[b]EPI Suite™ physical property inputs: Log K_{OW} = 7.60, BP = 384 ºC, MP = □55 ºC, VP = 1.42 × 10^{-7} mm Hg, WS = 0.27 mg/L

K_{OC} = organic carbon-water partition coefficient; □OH = hydroxyl radical

Appendix D REGULATORY HISTORY

The chemical substance, di-ethylhexyl 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-ethylhexyl 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 4	Provides EPA with authority to issue rules, orders, or consent agreements requiring manufacturers (including importers) and processors to test chemical substances and mixtures.	25 chemical data submissions from test rules received for di-ethylhexyl phthalate: Ecotoxicity Acute aquatic plant toxicity (1) Acute aquatic toxicity (8) Chronic aquatic toxicity (1) Environmental fate Persistence (3) Biodegradation (3) Transport Between Environmental Compartments (Fugacity) (1) Sorption to Soil and Sediments (1) Human health Metabolism and Pharmacokinetics (3) Mutagenicity/Genetic toxicity (6) Physical-Chemical properties Vapor pressure (1) Water solubility (1) (1982-1985) (U.S. EPA, ChemView. Accessed April 9, 2019).
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-ethylhexyl 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-ethylhexyl 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	Di-ethylhexyl phthalate manufacturing (including importing), processing and use

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	types, quantities and uses of chemical substances produced domestically and imported into the United States.	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-ethylhexyl 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.	No health and safety studies were received for di-ethylhexyl phthalate (1982-1992). (U.S. EPA, ChemView. Accessed April 24, 2019). Di-ethylhexyl 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 conclusion that a chemical substance or mixture presents a substantial risk of injury to health or the environment.	14 risk reports received for di-ethylhexyl phthalate (1992-2009) (U.S. EPA, ChemView. Accessed (April 9, 2019)).
Emergency Planning and Community Right-To-Know Act (EPCRA) – Section 313	Requires annual reporting from facilities in specific industry sectors that employ 10 or more full-time equivalent employees and that manufacture, process or otherwise use a TRI-listed chemical in quantities above threshold levels. A facility that meets reporting requirements must submit a reporting form for each chemical for which it triggered reporting, providing data across a variety of categories, including activities and uses of the chemical, releases and other waste management (e.g., quantities recycled, treated, combusted) and pollution prevention activities (under Section 6607 of the Pollution Prevention Act). These data include on- and off-site data as well as multimedia data (i.e., air, land and water).	Di-ethylhexyl phthalate is a listed substance subject to reporting requirements under 40 CFR 372.65 effective as of January 1, 1987.
Clean Air Act (CAA) – Section 112(b)	Defines the original list of 189 hazardous air pollutants (HAPs). Under 112(c) of the CAA,	Di-ethylhexyl phthalate is listed as a HAP (42 U.S.C. 7412).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	EPA must identify and list source categories that emit HAP and then set emission standards for those listed source categories under CAA Section 112(d). CAA Section 112(b)(3)(A) specifies that any person may petition the Administrator to modify the list of HAP by adding or deleting a substance. Since 1990, EPA has removed two pollutants from the original list leaving 187 at present.	
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-ethylhexyl phthalate to air (See https://www.epa.gov/stationary-sources-air-pollution/national-emission-standards-hazardous-air-pollutants-neshap-9).
Clean Water Act (CWA) - Section 304(a)(1)	Requires EPA to develop and publish ambient water quality criteria (AWQC) reflecting the latest scientific knowledge on the effects on human health that may be expected from the presence of pollutants in any body of water.	In 2015, EPA published updated AWQC for di-ethylhexyl phthalate, including recommendations for "water + organism" and "organism only" human health criteria for states and authorized tribes to consider when adopting criteria into their water quality standards. Human Health for the consumption of Water + Organism(µg/L) 0.32 Human Health for the consumption of Organism Only (µg/L) 0.37
Clean Water Act (CWA) – Section 301, 304, 306, 307, and 402	Clean Water Act Section 307(a) established 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	Di-ethylhexyl phthalate is designated as a toxic pollutant under Section 307(a)(1) of the CWA and as such is subject to effluent limitations (40 CFR 401.15). Under CWA Section 304, di-ethylhexyl phthalate is included in

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	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.	the list of total toxic organics (TTO) (40 CFR 413.02(i)). Appendix A to 40 CFR, Part 423--126 Priority Pollutants Aluminum Forming Point Source Category 40 CFR 467 The Centralized Waste Treatment Point Source Category 40 CFR 437 Coil Coating Point Source Category 40 CFR 465 Electrical and Electronic Components Point Source Category 40 CFR 469 Electroplating Point Source Category 40 CFR 413 Metal Finishing Point Source Category 40 CFR 433 Metal Molding and Casting Point Source Category 40 CFR 464 Organic Chemicals, Plastics, And Synthetic Fibers 40 CFR 414 Plastics Molding And Forming Point Source Category 40 CFR 463 Steam Electric Power Generating Point Source Category 40 CFR 423
Safe Drinking Water Act (SDWA) – Section 1412	Requires EPA to publish non-enforceable maximum contaminant level goals (MCLGs) for contaminants which 1. may have an adverse effect on the health of persons; 2. are known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern; and 3. in the sole judgement of the	Di-ethylhexyl phthalate is subject to NPDWR under the SDWA with an MCLG of zero and an enforceable MCL of .006 mg/L (40 CFR 141.24). On January 11, 2017, EPA announced a review of the seventy-six existing NPDWRs and determined that eight are candidates for regulatory revision

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	Administrator, regulation of the contaminant presents a meaningful opportunity for health risk reductions for persons served by public water systems. When EPA publishes an MCLG, EPA must also promulgate a National Primary Drinking Water Regulation (NPDWR) which includes either an enforceable maximum contaminant level (MCL), or a required treatment technique. Public water systems are required to comply with NPDWRs.	(82 FR 3518). EPA requested comment on the eight NPDWRs identified as candidates for revision.
Resource Conservation and Recovery Act (RCRA) – Section 3001	Directs EPA to develop and promulgate criteria for identifying the characteristics of hazardous waste, and for listing hazardous waste, taking into account toxicity, persistence, and degradability in nature, potential for accumulation in tissue and other related factors such as flammability, corrosiveness, and other hazardous characteristics.	Di-ethylhexyl phthalate is included on the list of hazardous wastes pursuant to RCRA 3001. RCRA Hazardous Waste Code: U028 (40 CFR 261.33). (Appendix VIII to Part 261—Hazardous Constituents).
Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) – Sections 102(a) and 103	Authorizes EPA to promulgate regulations designating as hazardous substances those substances which, when released into the environment, may present substantial danger to the public health or welfare or the environment. EPA must also promulgate regulations establishing the quantity of any hazardous substance the release of which must be reported under Section 103. Section 103 requires persons in charge of vessels or facilities to report to the National Response Center if they have knowledge of a release of a hazardous substance above the reportable quantity threshold.	Di-ethylhexyl phthalate is a hazardous substance under CERCLA. Releases of di-ethylhexyl phthalate in excess of 100 pounds must be reported (40 CFR 302.4).
Superfund Amendments and Reauthorization Act (SARA)	Requires the Agency to revise the hazardous ranking system and update the National Priorities List of hazardous waste sites, increases state and citizen involvement in the superfund program and provides new enforcement authorities and settlement tools.	Di-ethylhexyl phthalate is listed on SARA, an amendment to CERCLA and the CERCLA Priority List of Hazardous Substances. This list includes substances most commonly found at facilities on the CERCLA National Priorities List (NPL) that have been deemed to pose the greatest threat to public health. ATSDR ranked #77.

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
Other Federal Regulations		
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: DEHP, DBP, BBP, DINP, DIBP, DPENP, DHEXP and DCHP.	The use of di-ethylhexyl phthalate at concentrations greater than 0.1 percent is banned in toys and child care articles (16 CFR part 1307).
Federal Hazardous Substance Act (FHSA)	Requires precautionary labeling on the immediate container of hazardous household products and allows the Consumer Product Safety Commission (CPSC) to ban certain products that are so dangerous or the nature of the hazard is such that labeling is not adequate to protect consumers.	Use of di-ethylhexyl phthalate was banned by the CPSC in 2008 in any children's toy or child care article that contains concentrations of more than 0.1 percent of di-ethylhexyl phthalate (16 CFR part 1307)
Federal Food, Drug, and Cosmetic Act (FFDCA)	Provides the FDA with authority to oversee the safety of food, drugs and cosmetics.	Di-ethylhexyl phthalate is an optional substance that can be used in: the base sheet and coating of cellophane, alone or in combination with other phthalates where total phthalates do not exceed 5 percent (21 CFR § 177.1200). **Non-regulatory Warning** FDA Public Health Notification: PVC Devices Containing the Plasticizer DEHP (medical).
Occupational Safety and Health Act (OSHA)	Requires employers to provide their workers with a place of employment free from recognized hazards to safety and health, such as exposure to toxic chemicals, excessive noise levels, mechanical dangers, heat or cold stress or unsanitary conditions (29 U.S.C Section 651 et seq.). Under the Act, OSHA can issue occupational safety and health standards including such provisions as Permissible Exposure Limits (PELs), exposure monitoring, engineering and administrative control measures, and respiratory protection.	OSHA established a PEL for di-ethylhexyl phthalate of 5 mg/m3 as an 8-hour, TWA (29 CFR 1910.1000). OSHA established a Sampling and Analytical Method for DEHP.

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
Federal Hazardous Materials Transportation Act (HMTA)	Section 5103 of the Act directs the Secretary of Transportation to: • Designate material (including an explosive, radioactive material, infectious substance, flammable or combustible liquid, solid or gas, toxic, oxidizing or corrosive material, and compressed gas) as hazardous when the Secretary determines that transporting the material in commerce may pose an unreasonable risk to health and safety or property. • Issue regulations for the safe transportation, including security, of hazardous material in intrastate, interstate and foreign commerce.	D-ethylhexyl phthalate is listed as a hazardous material with regard to transportation and is subject to regulations prescribing requirements applicable to the shipment and transportation of listed hazardous materials Reportable Quantity 100 lbs. (45.4 kg) (49 CFR 172.1, Appendix A, Table 1).

D.2 State Laws and Regulations

Table_Apx D-2. State Laws and Regulations

State Actions	Description of Action
State Air Regulations	New Hampshire (Env-A 1400: Regulated Toxic Air Pollutants) Toxicity Class I, 24-Hr AAL 18 (µg/m3), Annual AALB 12 (µg/m3), 24-Hr De Minimis 0.21 (lbs/day), Annual De Minimis 78 (lbs/yr) Rhode Island (Air Pollution Regulation No. 22) Acceptable Ambient Levels (AALs) (mg/m3) 24 Hour 70, Annual 0.4
State Drinking Water Standards and Guidelines	Arizona (14 Ariz. Admin. Register 2978, August 1, 2008) MCL .0006 mg/L MCLG 0 mg/L Discharge from rubber and chemical factories California (Cal Code Regs. Title 26, § 22-64444) Table 64444-A Maximum Contaminant Levels Organic Chemicals 0.004 mg/L Connecticut (Conn. Agencies Regs. § 19-13-B102) Maximum Contaminant Level (mg/l) 0.006 Delaware (Del. Admin. Code Title 16, § 4462) Synthetic organic contaminants including pesticides and herbicides: Traditional MCL 0.006 mg/L To convert for CCR, multiply by 1000 MCL in CCR units 6, MCLG 0 Florida (Fla. Admin. Code R. Chap. 62-550) 6 µg/L MCL Maine (10 144 Me. Code R. Chap. 231), 0.006 mg/L

State Actions	Description of Action
	Massachusetts (310 Code Mass. Regs. § 22.00), 0.006 mg/L Michigan (Mich. Admin. Code r.299.44 and r.299.49, 2017) Minnesota (Minn R. Chap. 4720) Maximum Contaminant Level (MCL) for di-ethylhexyl phthalate of 6 ppb New Jersey (7:10 N.J Admin. Code § 5.2), Standard 6 µg/L Pennsylvania (25 Pa. Code § 109.202) Synthetic Organic Chemicals (SOCs): 0.006 mg/L Rhode Island (Rules and Regulations Pertaining to Public Drinking Water R46-13-DWQ) MCLG 0 mg/L MCL 0.006 mg/L
State PELs	California (PEL of 5 mg/m^3 (Cal Code Regs. Title 8, § 5155) Hawaii PEL TWA 5 mg/m^3 and PEL STEL 10 mg/m3 (Hawaii Administrative Rules Section 12-60-50)
State Right-to-Know Acts	Massachusetts (105 Code Mass. Regs. § 670.000 Appendix A) New Jersey (8:59 N.J. Admin. Code § 9.1) Carcinogen, Teratogen Pennsylvania (P.L. 734, No. 159 and 34 Pa. Code § 323)
Chemicals of High Concern to Children	Several states have adopted reporting laws for chemicals in children's products containing di-ethylhexyl phthalate including: Maine (38 MRSA Chapter 16-D) Minnesota (Toxic Free Kids Act Minn. Stat. 116.9401 to 116.9407) Oregon (Toxic-Free Kids Act, Senate Bill 478, 2015) Vermont (18 V.S.A § 1776) Washington State (Wash. Admin. Code 173-334-130)
Other	California listed di-ethylhexyl phthalate on Proposition 65 in 1988 due cancer and in 2003 due to developmental male cancer. (Cal Code Regs. Title 27, § 27001). California issued a Health Hazard Alert for DEHP (Hazard Evaluation System and Information Service, 2016). California lists di-ethylhexyl phthalate as a designated priority chemical for biomonitoring (California SB 1379). Di-ethylhexyl phthlate is on the MA Toxic Use Reduction Act (TURA) list MGL, Chapter 21I, Section 1 to Section 23 Maine 2019 ME H 1043 Prohibition of sale of food package containing phthalates.

D.3 International Laws and Regulations

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

Country/ Organization	Requirements and Restrictions
Canada	Di-ethylhexyl phthlate is on the Canadian List of Toxic Substances (CEPA 1999 Schedule 1). Other Canadian regulations include: • Canada's National Pollutant Release Inventory (NPRI). • For soft vinyl children's toys and child-care articles, compliance and enforcement of the existing regulation of di-ethylhexyl phthalate (and 5 other phthalates) will continue as part of the regular enforcement of the Phthalates Regulations under the Canada Consumer Product Safety Act. • Compliance and enforcement of the existing requirements for medical devices containing di-ethylhexyl phthalate will continue as part of the regular enforcement of the Medical Devices Regulations under the Food and Drugs Act. • Di-ethylhexyl phthlate, which was previously concluded to be harmful to human health, was added to the Cosmetic Ingredient Hotlist in 2009. The listing indicates that the use of di-ethylhexyl phthalate is prohibited and must not be present in cosmetic products. • Risk Management Scope for 1,2-Benzenedicarboxylic acid, bis(2-ethylhexyl) ester [DEHP] Chemical Abstracts Service Registry Number (CAS RN): 117-81-7.
European Union	Di-ethylhexyl phthlate is registered for use in the EU (European Chemicals Agency (ECHA) database. Accessed February 3, 2020). **Restriction** Annex XVII TO REACH – Conditions of restriction Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles. **Candidate Substance** In 2008, di-ethylhexyl phthalate was listed on the Candidate list as a Substance of Very High Concern (SVHC) under Article 59 regulation (EC) No 1907/2006 - REACH (Registration, Evaluation, Authorization and Restriction of Chemicals due to its reproductive toxicity (category 1B). Reason for inclusion: Toxic for reproduction (Article 57c), Endocrine disrupting properties (Article 57(f) - environment), Endocrine disrupting properties (Article 57(f) - human health.

Country/ Organization	Requirements and Restrictions
	Authorisation In August 2013, di-ethylhexyl 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 (European Chemicals Agency (ECHA) database. Accessed April 24, 2019). Commission Delegated Directive ../…/EU of 31.3.2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances. **Restriction of Hazardous Substances Directive (RoHS), EU/2015/863** Di-ethylhexyl phthlate 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-ethylhexyl phthlate was assessed under Human Health Tier II of the Inventory Multi-Tiered Assessment and Prioritisation (IMAP). The chemical is listed on the 2006 High Volume Industrial Chemicals List (HVICL) with a total reported volume between 10,000 and 99,000 tonnes per annum. Di-ethylhexyl phthlate is used in the production of plastic products. Plastic products that contain more than 1 per cent of di-ethylhexyl phthalate are permanently banned from sale. (*1,2-Benzenedicarboxylic acid, bis(2-ethylhexyl) ester: Human health tier II assessment (2013)*. Accessed April 24, 2019*).*
Japan	Di-ethylhexyl phthlate is regulated in Japan under the following legislation: • Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Chemical Substances Control Law; CSCL) • Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof • Industrial Safety and Health Act (ISHA) • Air Pollution Control Law • Water Pollution Control Law
World Health Organization (WHO)	Evaluations of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) 1989

Country/ Organization	Requirements and Restrictions
	The Committee previously concluded that di-ethylhexyl phthalate is a peroxisome-proliferator and carcinogen in the livers of both rats and mice and induces age-dependent testicular atrophy in rats. The use of food-contact materials from which bis(2-ethylhexyl) phthalate may migrate is provisionally accepted on condition that the amount of the substance migrating into food is reduced to the lowest level technologically attainable. **Tolerable Intake: NONE ESTABLISHED** 1999 Monograph
Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Hungary, Ireland, Japan, New Zealand, Poland, South Korea, Spain, Sweden Switzerland, United Kingdom	Occupational exposure limits for DEHP (GESTIS International limit values for chemical agents (Occupational exposure limits, OELs) database. Accessed April 24, 2019).

Appendix E PROCESS, RELEASE AND OCCUPATIONAL EXPOSURE INFORMATION

This appendix provides information and data found in preliminary data gathering for di-ethylhexyl 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 22 facilities that submitted activity data for 2015. 14 of these facilities stated that they imported di-ethylhexyl phthalate in 2015, one stated that they manufactured di-ethylhexyl phthalate in 2015, and the remaining seven facilities' 2015 manufacture or import activity is withheld or claimed as CBI (U.S. EPA 2017). According to 2016 public CDR data, di-ethylhexyl phthalate is imported into the United States in liquid or pellet form and manufactured in liquid form (U.S. EPA 2017).

E.1.1.1 Domestic Manufacturing

Di-ethylhexyl phthlate is classified as part of the phthalate ester grouping of compounds predominantly used as plasticizers in the production of flexible plastic products (TURI 2019). Di-ethylhexyl phthlate is typically manufactured through catalytic esterification of phthalic anhydride with 2-ethylhexyl alcohol in the presence of an acid catalyst. Manufacturing operations take place in closed systems either via batch or more automated continuous operations and will typically involve the purification of di-ethylhexyl phthalate product streams via either vacuum distillation or by passing over activated charcoal as a means of recovering unreacted alcohols (CPSC 2010). In addition, dimerization of butyraldehyde can also be used as a means of di-ethylhexyl phthalate manufacture (Cadogan & Howick 2001).

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-ethylhexyl phthlate is shipped in liquid or solid pellet form according to 2016 CDR. Of the 14 facilities in 2016 CDR that imported di-ethylhexyl phthalate in 2015 (excluding the facilities for which the importation/manufacturing activity was withheld or claimed CBI), EPA has identified two sites that imported di-ethylhexyl phthalate directly to their sites for on-site processing or use and 12 sites that imported di-ethylhexyl phthalate directly to other sites for processing or use (the importing site does not directly handle or store the imported di-ethylhexyl phthalate) (U.S. EPA 2017).

E.1.2 Processing and Distribution

E.1.2.1 Reactant or Intermediate

Processing as a reactant or intermediate is the use of di-ethylhexyl phthalate as a feedstock in the production of another chemical via a chemical reaction in which di-ethylhexyl phthalate is consumed to form the product. One company that reported to 2016 CDR indicated that di-ethylhexyl phthalate was

processed as a reactant in the production of plastic material and resin, rubber products, and synthetic rubber (U.S. EPA 2017; Natrochem, 2016). Di-ethylhexyl phthlate is also processed as a reactant in the manufacture of the adhesives and sealants (U.S. EPA 2017; Morgan Advanced Materials, 2016a).

Exact operations for the use of di-ethylhexyl phthalate as a reactant to produce other chemicals are not known at this time. For using a chemical as a reactant, operations would typically involve unloading the chemical from transport containers and feeding the chemical into a reaction vessel(s), where the chemical would react either fully or to a lesser extent. Following completion of the reaction, the produced substance may be purified further, thus removing unreacted di-ethylhexyl phthalate (if any exists).

E.1.2.2 Incorporated into a Formulation, Mixture or Reaction Product

Incorporation into a formulation, mixture or reaction product refers to the process of mixing or blending of several raw materials to obtain a single product or preparation. Exact process operations involved in the incorporation of di-ethylhexyl phthalate into a chemical formulation, mixture, or reaction product are dependent on the specific manufacturing process or processes involved. Companies reported to 2016 CDR that di-ethylhexyl phthalate is used as a plasticizer in the formulation of adhesives, all other basic inorganic and organic chemicals, paints and coatings, printing inks, plastic products, rubber products, plastic material and resins, compounding of purchased resins, and in other miscellaneous products (U.S. EPA 2017). The exact processes used to formulate products containing di-ethylhexyl 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-ethylhexyl phthalate during risk evaluation.

E.1.2.3 Incorporated into an Article

Incorporation into an article typically refers to a process in which a chemical becomes an integral component of an article (as defined at 40 CFR 704.3) for distribution in commerce. Exact process operations involved in the incorporation of di-ethylhexyl phthalate-containing formulations or reaction products are dependent on the article. Di-ethylhexyl phthalate is primarily used as a plasticizer in compounded resin, rubber products, and plastic products (U.S. EPA 2017; 3M, 2018; Victor Technologies, 2012). EPA plans to evaluate processing uses of di-ethylhexyl phthalate during risk evaluation.

E.1.2.4 Repackaging

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

E.1.2.5 Recycling

According to 2018 TRI, approximately 82% of all di-ethylhexyl phthalate production-related waste, or more than 6.5 million pounds, was recycled. Approximately 67% of the recycled waste was recycled on site.

E.1.3 Uses

E.1.3.1 Adhesives, Sealants, Paints, and Coatings

Di-ethylhexyl phthlate is used in a variety of adhesive, sealant, paint, and coating products. Specifically, di-ethylhexyl phthalate is used in adhesives for electrical tape, industrial adhesives, curing and sealing

compounds, food packaging adhesives, emulsion paints, lacquers, varnishes, paints for traffic markings, and wood coatings (3M, 2019a; NLM 2015; The Sherwin Williams Company, 2019; Valspar, 2019; Dupli-Color Products Company, 2017; Valspar, 2017; Pacific Coast Lacquer, 2016; Lord Corporation, (2015, 2019); Tremco, 2015; CETCO, 2014; Imperial Tools, 2012; 3M, 2011; Ramuc, 2010; StatSpin, Inc., 2004; Republic Powdered Metals, Inc., 2002; Glidden Co, 1999; Airserco, 2009). 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 Automotive Products

Di-ethylhexyl phthlate is used as an additive in automotive interior and exterior care products, namely glazing putty and cleaning/washing/stain removing products (Dionisio 2015; American Chemistry Council, 2019; 3M, 2017; Danish EPA, 2010). EPA plans to evaluate these uses of di-ethylhexyl phthalate during risk evaluation.

E.1.3.3 Building/Construction Materials Not Covered Elsewhere

Di-ethylhexyl phthlate is a constituent of building and construction materials used for joinery installation, brick laying, and other, similar end uses. In addition, di-ethylhexyl phthalate is a constituent of asphalt, concrete coatings, and is an additive found in casting and vinyl tapes (U.S. EPA 2017; Valero, 2014; Clemens Concrete Coatings, 2018; 3M Company, 2018; 3M Company, 2011). EPA plans to evaluate investigate these uses of di-ethylhexyl phthalate during risk evaluation.

E.1.3.4 Plastic and Rubber Products

As described in Section E.1.2.3, di-ethylhexyl phthalate is used to increase the flexibility of plastic and rubber products, which may be used industrially, commercially, and by consumers. Of note, di-ethylhexyl phthalate is the most common plasticizer found in plastic and rubber products used in medical applications such casting tape, storage containers, fluid bags, and tubing for medical devices (3M, 2018). Di-ethylhexyl phthlate is also used in plastics used in the building and construction industry, in furniture and furnishings, and in food and beverage packaging (e.g., cellophane and other polymers) (U.S. EPA 2017; 3M, 2018). Di-ethylhexyl phthlate is likely entrained in the products; however, di-ethylhexyl phthalate may be available for exposure depending on the application of the end use products, such as if building and construction materials are cut prior to installation. EPA plans to evaluate these uses of di-ethylhexyl phthalate during risk evaluation.

E.1.3.5 Other Uses

Di-ethylhexyl phthlate is used as a constituent in hydraulic fracturing fluids (U.S. House of Representatives, 2011; NYSDEC, 2011), batteries (Amazon, n.d.), dyes and pigments (U.S. EPA 2017; EPA, 1999; Identity Group, 2016; SPIN, 2019), lawn and garden care products (U.S. EPA 2017). Di-ethylhexyl phthlate was also identified as a reference material and/or laboratory reagent in laboratory settings (Restek, 2019; UltraScientific, 2014). 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-ethylhexyl phthalate during risk evaluation.

E.1.4 Disposal

Each of the conditions of use of di-ethylhexyl 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-ethylhexyl 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-ethylhexyl 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-ethylhexyl phthalate may be contained in wastewater discharged to POTW or other, non-public treatment works for treatment. Industrial wastewater containing di-ethylhexyl 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-ethylhexyl 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-ethylhexyl phthlate is a U-listed hazardous waste under code U028 under RCRA; therefore, discarded, unused pure and commercial grades of di-ethylhexyl phthalate are regulated as a hazardous waste under RCRA (40 CFR § 261.33(f)).

- Wastes Exempted as Solid Wastes under RCRA: Certain conditions of use of di-ethylhexyl phthalate may generate wastes of di-ethylhexyl 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-ethylhexyl phthalate may be exempt as a solid waste.

According to 2018 TRI, 118 facilities managed, in total, nearly 8 million pounds of di-ethylhexyl phthalate as waste. Of this total: more than 6.5 million pounds (82% of all waste) were recycled; over 600,000 pounds were treated; nearly 80,000 pounds were burned for energy recovery, and just over 710,000 pounds were released to the environment. Approximately 60% of the production-related waste was managed on site. For recycling and energy recovery, the portions managed on site were higher at 67% and 82%, respectively. The inverse was true for treatment-related quantities; approximately three-quarters of the total quantity was treated off-site. A relatively small portion (710,000 pounds or 9%) of the total quantity of production-related waste was released to the environment, and most (90%) of this amount was disposed of or otherwise released off-site.

E.2 Preliminary Occupational Exposure Data

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

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

Table_Apx E-1. Summary of NIOSH HHEs with Monitoring for Di-ethylhexyl Phthalate[a]

Year of Publication	Report Number	Facility Description
1984	HETA 79-034-1440	Plastic/Resin Products Manufacturing – Coating, Laminating, Printing, and Solvent Use
1983	HETA 82-032-1384	Phthalate Anhydride and DEHP Production

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

Table_Apx E-2. Summary of Industry Sectors with Di-ethylhexyl Phthalate Monitoring Samples Available from OSHA Inspections Conducted Between 2010 and 2019

NAICS	NAICS Description	Number of Data Points
312113	Ice Manufacturing	2
323111	Commercial Printing (except Screen and Books)	2
326299	All Other Rubber Product Manufacturing	2
333411	Air Purification Equipment Manufacturing	1
334416	Capacitor, Resistor, Coil, Transformer, and Other Inductor Manufacturing	1

Appendix F SUPPORTING INFORMATION FOR OCCUPATIONAL EXPOSURE CONCEPTUAL MODEL

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

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
Manufacture	Domestic Manufacture	Domestic Manufacture	Manufacture and Packaging	Liquid Contact	Dermal	Workers	Yes	2016 CDR references manufacture in liquid form. Thus, the potential for exposures to workers exists during manufacturing.
				Solid Contact	Dermal	Workers	Yes	2016 CDR references manufacture in pellet form form. Thus, the potential for exposures to workers exists during manufacturing.
				Vapor	Inhalation	Workers, Occupational Non-Users (ONU)	No	Due to di-ethylhexyl phthalate's vapor pressure (VP) (VP = 1.4 × 10-6 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	Yes	2016 CDR references manufacture in pellet form, which may form dust. Thus, the potential for exposures to workers exists during manufacturing.
				Liquid/Solid Contact	Dermal	ONU	No	Exposure is expected to be primarily restricted to workers who are directly involved in working with the chemical. ONUs are not expected to come in direct contact with the chemicals.
	Import	Import	Repackaging of import containers	Liquid Contact	Dermal	Workers	Yes	2016 CDR references import in liquid form. 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
				Solid Contact	Dermal	Workers	Yes	2016 CDR references import in pellet form. The potential for exposures to workers exists during import, but exposure will only occur in the event the imported material is repackaged.
				Vapor	Inhalation	Workers, ONU	No	Due to di-ethylhexyl phthalate's vapor pressure (VP) (VP = 1.4 × 10-6 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 pellet 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	Exposure is expected to be primarily restricted to workers who are directly involved in working with the chemical. ONUs are not expected to come in direct contact with the chemicals.
Processing	Processing as a Reactant	Plasticizer in plastic material and resin manufacturing, rubber product manufacturing, and synthetic rubber manufacturing Adhesive and sealant chemical in adhesive manufacturing	Processing as a reactant	Liquid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during manufacturing of other chemicals, as di-ethylhexyl phthalate may be in liquid form.
				Solid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during manufacturing of other chemicals, as di-ethylhexyl phthalate may be in solid form.
				Vapor	Inhalation	Workers, ONU	Yes	Due to di-ethylhexyl phthalate's vapor pressure (VP) (VP = 1.4 ×

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
		Intermediate in plastics product manufacturing						10-6 mm Hg) at room temperature, potential for vapor generation is low. However, some of these operations may occur at elevated temperatures, which increase the potential for vapor generation.
				Mist	Inhalation/ Dermal	Workers, ONU	No	Mist generation is not expected during processing as a reactant.
				Dust	Inhalation/ Dermal	Workers, ONU	Yes	The potential for dust exposures to workers and ONUs exists during manufacturing of other chemicals, as di-ethylhexyl phthalate may be in solid form.
				Liquid/Solid Contact	Dermal	ONU	No	Exposure is expected to be primarily restricted to workers who are directly involved in working with the chemical. ONUs are not expected to come in direct contact with the chemicals.
	Incorporation into formulation, mixture or reaction product	Plasticizer in all other basic organic chemical manufacturing; custom compounding of purchased resins; miscellaneous manufacturing; paint and coating manufacturing; plastics material and resin manufacturing; plastics product manufacturing; adhesive manufacturing; all other basic inorganic chemical manufacturing; rubber product manufacturing; and services	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-ethylhexyl 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-ethylhexyl phthalate may be in solid form.
				Vapor	Inhalation	Workers, ONU	Yes	Due to di-ethylhexyl phthalate's vapor pressure (VP) (VP = 1.4 × 10-6 mm Hg) at room temperature, potential for vapor generation is low. However, some of these operations may occur at elevated temperatures, which

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
								increase the potential for vapor generation.
				Mist	Inhalation/ Dermal	Workers, ONU	No	Mist generation is not expected during processing (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-ethylhexyl phthalate may be in solid form.
				Liquid/Solid Contact	Dermal	ONU	No	Exposure is expected to be primarily restricted to workers who are directly involved in working with the chemical. ONUs are not expected to come in direct contact with the chemicals.
	Incorporation into articles	Plasticizer in all other basic organic chemical manufacturing, plastics product manufacturing; food, beverage, and tobacco product manufacturing; medical devices; plastic material and resin manufacturing; custom compounding of purchased resin	Plastics and Rubber product manufacturing (Plastic Converting) Other article manufacturing	Liquid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during incorporation into articles, as di-ethylhexyl phthalate may be in liquid form.
				Solid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during processing (incorporation into articles), as di-ethylhexyl phthalate may be in solid form, such as for resins.
				Vapor	Inhalation	Workers, ONU	Yes	Due to di-ethylhexyl phthalate's vapor pressure (VP) (VP = 1.4 × 10-6 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

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
								(incorporation into articles), as di-ethylhexyl phthalate may be in solid form, such as for resins.
				Liquid/Solid Contact	Dermal	ONU	No	Exposure is expected to be primarily restricted to workers who are directly involved in working with the chemical. ONUs are not expected to come in direct contact with the chemicals.
	Repackaging	Repackaging	Repackaging into large and small containers	Liquid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during repackaging, as di-ethylhexyl phthalate may be in liquid form.
				Solid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during repackaging, as di-ethylhexyl phthalate may be incorporated into products in solid form.
				Vapor	Inhalation	Workers, ONU	No	Due to di-ethylhexyl phthalate's vapor pressure (VP) (VP = 1.4 × 10-6 mm Hg) at room temperature, potential for vapor generation is low.
				Mist	Inhalation/ Dermal	Workers, ONU	No	Mist generation is not expected during repackaging.
				Dust	Inhalation/ Dermal	Workers, ONU	Yes	The potential for dust exposures to workers and ONUs exists during processing (repackaging), as di-ethylhexyl phthalate may be incorporated into products in solid form.
				Liquid/Solid Contact	Dermal	ONU	No	Exposure is expected to be primarily restricted to workers who are directly involved in working with the chemical. ONUs are not expected to come in direct contact with the chemicals.
	Recycling	Recycling	Recycling of di-ethylhexyl phthalate	Liquid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during this use as

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
			and products containing di-ethylhexyl phthalate					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-ethylhexyl phthalate's vapor pressure (VP) (VP = 1.4 × 10-6 mm Hg) at room temperature, potential for vapor generation is low.
				Mist	Inhalation/ Dermal	Workers, ONU	No	Mist generation is not expected during recycling of liquid wastes.
				Dust	Inhalation/ Dermal	Workers, ONU	Yes	Dust generation is possible during recycling of solid wastes.
				Liquid/Solid Contact	Dermal	ONU	No	Exposure is expected to be primarily restricted to workers who are directly involved in working with the chemical. ONUs are not expected to come in direct contact with the chemicals.
Industrial/ Commercial Use	Paints and coatings; adhesives and sealants; lawn and garden care products	Paints and coatings; adhesives and sealants; lawn and garden care products	Spray, brush, roll, dip, and other forms of application	Liquid Contact	Dermal	Workers	Yes	These products are in liquid form; therefore, exposures to workers exists for di-ethylhexyl phthalate used in these products.
				Solid Contact	Dermal	Workers	No	The potential for exposures to solid di-ethylhexyl phthalate is not expected during the use of these products because they are in liquid form.
				Vapor	Inhalation	Workers, ONU	No	Due to di-ethylhexyl phthalate's vapor pressure (VP) (VP = 1.4 × 10-6 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-ethylhexyl phthalate is not

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
								expected during the use of these products because they are in liquid form.
				Liquid/Solid Contact	Dermal	ONU	No	Exposure is expected to be primarily restricted to workers who are directly involved in working with the chemical. ONUs are not expected to come in direct contact with the chemicals.
	Hydraulic fracturing; Laboratory chemicals; arts, crafts, and hobby materials; automotive care products; dyes and pigments	Hydraulic fracturing; Laboratory chemicals; arts, crafts, and hobby materials; automotive care products; dyes and pigments	Use in hydraulic fracturing Use in laboratories Use of arts, crafts, and hobby materials Use of automotive care products Use of dyes and pigments	Liquid Contact	Dermal	Workers	Yes	These products are in liquid form; therefore, exposures to workers exists for di-ethylhexyl phthalate used in these products.
				Solid Contact	Dermal	Workers	No	The potential for exposures to solid di-ethylhexyl phthalate is not expected during the use of these products because they are in liquid form.
				Vapor	Inhalation	Workers, ONU	No	Due to di-ethylhexyl phthalate's vapor pressure (VP) (VP = 1.4 × 10-6 mm Hg) at room temperature, potential for vapor generation is low.
				Mist	Inhalation/ Dermal	Workers, ONU	No	Mist generation is not expected during use of these products.
				Dust	Inhalation/ Dermal	Workers, ONU	No	The potential for exposures to solid di-ethylhexyl phthalate does not exist during the use of these products because they are in liquid form.
				Liquid/Solid Contact	Dermal	ONU	No	Exposure is expected to be primarily restricted to workers who are directly involved in working with the chemical. ONUs are not expected to come in direct contact with the chemicals.
	Transportation equipment manufacturing	Transportation equipment manufacturing (engine	Use of articles made using di-ethylhexyl phthalate	Liquid Contact	Dermal	Workers	No	The potential for exposures to liquid di-ethylhexyl phthalate is not expected during the use of

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
	(engine fan blades); batteries; building and construction materials not covered elsewhere; electrical and electronic products; fabric, textile, and leather products not covered elsewhere; furniture and furnishings not covered elsewhere; plastic and rubber products not covered elsewhere; toys, playground, and sporting equipment	fan blades); batteries; building and construction materials not covered elsewhere; electrical and electronic products; fabric, textile, and leather products not covered elsewhere; furniture and furnishings not covered elsewhere; plastic and rubber products not covered elsewhere; toys, playground, and sporting equipment						these products because they are solid articles.
				Solid Contact	Dermal	Workers	Yes	These products may include solid articles in which di-ethylhexyl phthalate is entrained; therefore, di-ethylhexyl phthalate exposures to workers is unlikely but may occur if cutting /sawing / other machining operations occur.
				Vapor	Inhalation	Workers, ONU	No	Due to di-ethylhexyl phthalate's vapor pressure (VP) (VP = 1.4 × 10-6 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-ethylhexyl phthalate is entrained; therefore, di-ethylhexyl phthalate exposures to workers and ONUs is unlikely but may occur if cutting /sawing / other machining operations occur.
				Liquid/Solid Contact	Dermal	ONU	No	Exposure is expected to be primarily restricted to workers who are directly involved in working with the chemical. ONUs are not expected to come in direct contact with the chemicals.
Disposal	Disposal	Disposal of di-ethylhexyl 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-ethylhexyl phthalate's vapor pressure (VP) (VP = 1.4 ×

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
								10-6 mm Hg) at room temperature, potential for vapor generation is low.
				Mist	Inhalation/ Dermal	Workers, ONU	No	Mist generation is not expected during disposal of liquid wastes.
				Dust	Inhalation/ Dermal	Workers, ONU	Yes	Dust generation is possible during disposal of solid wastes.
				Liquid/Solid Contact	Dermal	ONU	No	Exposure is expected to be primarily restricted to workers who are directly involved in working with the chemical. ONUs are not expected to come in direct contact with the chemicals.

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

Table_Apx G-1. Consumer Exposure Conceptual Model Supporting Table

Life Cycle Stage	Category	Subcategory	Release from source	Exposure Pathway	Route	Receptor	Plans to Evaluate	Rationale
Consumer Use	Construction, Paint, Electrical, and Metal Products	Building/ Construction Materials Not Covered Elsewhere (Article)	Direct contact through handling of articles containing chemical	Direct Contact	Dermal	Consumers	Yes	Dermal exposure may occur for this condition of use, dermal exposure will be analyzed.
			Direct contact through mouthing of articles containing chemical	Mouthing	Oral	Consumers	Yes	Oral exposure may occur for this condition of use and will be analyzed.
			Long-term emission/mass-transfer, Abrasion, Transfer to Dust	Dust	Dermal, Inhalation, Oral	Consumers, Bystanders	Yes	Dermal, oral and inhalation exposure from this condition of use may occur and will be analyzed
Consumer Use	Construction, Paint, Electrical, and Metal Products	Electrical and Electronic Products (Article)	Direct contact through handling of articles containing chemical	Direct Contact	Dermal	Consumers	Yes	Dermal exposure may occur for this condition of use, 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,	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
			Abrasion, Transfer to Dust					
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 Productss	Furniture and Furnishings not Covered Elsewhere (Article)	Direct contact through handling of articles containing chemical	Direct Contact	Dermal	Consumers	Yes	Dermal exposure may occur for this condition of use, 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	Direct contact through handling of articles	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
		not Covered Elsewhere (Article)	containing chemical					
			Direct contact through mouthing of articles containing chemical	Mouthing	Oral	Consumers	Yes	Oral exposure may occur for this condition of use 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
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

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

Life Cycle Stage	Category	Subcategory	Release from source	Exposure Pathway	Route	Receptor	Plans to Evaluate	Rationale
			Direct contact through application or use of products	Liquid Contact	Dermal	Consumers	Yes	Exposure is expected to be primarily restricted to consumers who are directly involved in using the chemical.
			Long-term emission/mass-transfer through application or use of products	Vapor	Inhalation	Consumers and Bystanders	Yes	Inhalation is possible and will be analyzed
			Direct contact through application or use of products	Mist	Inhalation and Dermal	Consumers and Bystanders	Yes	If product is applied as a mist, inhalation and dermal exposures would be expected and evaluated
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	Automotive, Fuel, Agriculture, Outdoor Use Products	Lawn and Garden 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

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

Life Cycle Stage	Category	Subcategory	Release from source	Exposure Pathway	Route	Receptor	Plans to Evaluate	Rationale
			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[6]	Rationale
All	Emissions to Air	Emissions to Air	Near facility ambient air concentrations	Inhalation	General Population	No	di-ethylhexyl phthalate is a HAP. Because stationary source releases of di-ethylhexyl phthalate to ambient air are under the jurisdiction of the CAA.
			Indirect deposition to nearby bodies of water and soil catchments	Oral Dermal	General Population	No	
				TBD	Aquatic and Terrestrial Receptors	No	
	Wastewater or Liquid Wastes	Industrial pre-treatment and wastewater treatment, or POTW	Direct release into surface water and indirect partitioning to sediment	TBD	Aquatic and Terrestrial Receptors	Yes	EPA has developed Ambient Water Quality Criteria for protection of human health for di-ethylhexyl phthalate.
				Oral Dermal	General Population	No	
			Drinking Water via Surface or Ground Water	Oral Dermal and Inhalation (e.g. showering)	General Population	No	Drinking water exposure pathway for di-ethylhexyl phthalate is currently addressed in the SDWA
			Biosolids: application to soil and/or migration to groundwater	Oral (e.g. ingestion of soil) Inhalation	General Population	No	Unlikely to be a route to general population since di-ethylhexyl phthalate is not expected to migrate to groundwater from biosolids.

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

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