

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

CASRN 117-81-7



August 2020

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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				
шеее	Zones				
ILO	International Labour Organization				
IMAP	Inventory Multi-Tiered Assessment and Prioritisation (Australia)				
ISHA	Industrial Safety and Health Act				
IECEA	Joint Expert Committee on Food Additives				
KOECT	Kirk-Othmer Encyclopedia of Chemical Technology				
Koc	Organic Carbon: Water Partition Coefficient				
Kow	Octanol: Water Partition Coefficient				
	Lethal Concentration				
	Lowest Observed Adverse Effect Level				
LOALL	Lowest Observed Effect Concentration				
LUEC	Maximum Ashiayahla Control Technology				
MACI	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 Inventory				
NESHAP	National Emission Standards for Hazardous Air Pollutants				
NICNAS	National Industrial Chemicals Notification and Assessment Scheme (Australia)				
NIOSH	National Institute for Occupational Safety and Health				
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				
PESO	Pathways and Processes Exposure Setting or Scenario and Outcomes				
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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
RESO	Receptors, Exposure, Setting or Scenario, and Outcomes
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 part 702) (Docket ID: EPA-HQ-OPPT-2019-0131). The first step of the risk evaluation process is the development of the draft scope document. EPA published the *Draft Scope of the Risk Evaluation for Di-ethylhexyl Phthalate CASRN 117-81-7* (EPA Document No. EPA-740-D-20-017) (U.S. EPA, 2020c) and provided a 45-day comment period on the draft scope per 40 CFR 702.41(c)(7). EPA has considered comments received (Docket ID: EPA-HQ-OPPT-2018-0433) during the public comment period to inform the development of the risk evaluation for di-ethylhexyl phthalate. This document fulfills the TSCA requirement to issue a final scope document per TSCA Section 6(b)(4)(D) and as described in 40 CFR 702.41(c)(8). The scope for di-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 the risk evaluation, along with a description of the reasonably available information, conceptual model, analysis plan and science approaches, and plan for peer review for this chemical substance.

General Information. Di-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 *Proposed Designation of Di-ethylhexyl phthalate (CASRN 117-81-7) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019e) to inform the development of this scope document. Furthermore, EPA conducted a comprehensive search to identify and screen multiple evidence streams (*i.e.*, chemistry, fate, release and engineering, exposure, hazard), and the search and screening results are provided in Section 2.1. EPA used the systematic review process described in Appendix A to search for and screen reasonably available information, including information already in EPA's possession, for inclusion in the risk evaluation. This information includes the hazards, exposures, PESS, and conditions of use that may help inform the risk evaluation di-ethylhexyl phthalate. EPA has focused on the data collection phase (consisting of data search, data screening, and data extraction) during the preparation of the scope document, whereas the data evaluation and integration stages will occur during the development of the risk evaluation and thus are not part of the scoping activities described in this document. EPA will consider additional information identified following publication of this scope document, as appropriate, in developing the risk evaluation, including the Chemical Data Reporting (CDR) information that the Agency will receive by the end of November 2020.

Conditions of Use. EPA plans to evaluate manufacturing (including importing); processing; distribution in commerce; industrial, commercial and consumer uses; and disposal of di-ethylhexyl phthalate in the risk evaluation. Di-ethylhexyl phthalate is manufactured (including imported) within the United States as well as imported into the United States. The chemical is processed as a reactant, incorporated into formulation, mixture, or reaction products, and incorporated into articles. The identified processing activities also include the repackaging and recycling of di-ethylhexyl phthalate. EPA revised the conditions of use in the final scope of the risk evaluation based on additional information and public comments (Docket ID: EPA-HQ-OPPT-2018-0433) on the draft scope document for 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. EPA considered reasonably available information as well as public comments received on the draft scope document for di-ethylhexyl phthalate in finalizing the exposure pathways, exposure routes, and hazards EPA plans to evaluate in the risk evaluation. As a result, EPA plans to focus the risk evaluation for di-ethylhexyl phthalate on the following exposures, hazards and receptors:

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

EPA's plan for evaluating environmental exposure pathways in the scope of the risk evaluation considers whether and how other EPA administered statutes and regulatory cover di-ethylhexyl phthalate in media pathways falling under the jurisdiction of those authorities. Section 2.6.3.1 discusses those pathways under the jurisdiction of other EPA-administered laws. In Section 2.6.3.2, EPA presents the conceptual model describing the identified exposures (pathways and routes), receptors and hazards associated with the conditions of use of di-ethylhexyl phthalate within the scope of the risk evaluation. Based on pathways under the jurisdiction of other EPA-administered laws, EPA does not plan to evaluate the general population as a receptor in the scope of the risk evaluation (see Figure 2-16).

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

- Occupational exposure: EPA plans to evaluate exposures to workers and occupational non-users (ONUs) via the inhalation route and exposures to workers via the dermal route associated with manufacturing, processing, use, and disposal of di-ethylhexyl phthalate. EPA plans to analyze dermal exposure for workers and ONUs to mists and dust that deposit on surfaces.
- Consumer and bystander exposure: EPA plans to evaluate oral, inhalation and dermal exposure routes to di-ethylhexyl phthalate for consumers and bystanders from 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; and mouthing of products/articles containing ethylhexyl phthalate for consumers.
- *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 exposure:* EPA plans to evaluate exposure to di-ethylhexyl phthalate for aquatic receptors.

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

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

Analysis Plan. The analysis plan for di-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, review of identified information as described in Section 2.1. Should additional data or approaches become reasonably available, EPA may consider them for the risk evaluation.

Peer Review. The draft risk evaluation for di-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 (U.S. EPA, 2015b) and other methods consistent with Section 26 of TSCA (see 40 CFR 702.45).

1 INTRODUCTION

This document presents the scope of the risk evaluation to be conducted for di-ethylhexyl phthalate under the Frank R. Lautenberg Chemical Safety for the 21st Century Act. The Frank R. Lautenberg Chemical Safety for the 21st Century Act amended TSCA on June 22, 2016. The new law includes statutory requirements and deadlines for actions related to conducting risk evaluations of existing chemicals.

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

TSCA § 6(b)(4)(D) and implementing regulations require that EPA publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use and PESS that the Administrator expects to consider, within 6 months after the initiation of a risk evaluation. In addition, a draft scope is to be published pursuant to 40 CFR 702.41. In December 2019, EPA published a list of 20 chemical substances that have been designated high priority substances for risk evaluations (Docket ID: <u>EPA-HQ-OPPT-2019-0131</u>) (84 FR 71924, December 30, 2019), as required by TSCA § 6(b)(2)(B), which initiated the risk evaluation process for those chemical substances. Di-ethylhexyl phthalate is one of the chemicals designated as a high priority substance for risk evaluation. On April 9, 2020, EPA published the *Draft Scope of the Risk Evaluation for Di-ethylhexyl Phthalate* (EPA Document No. 740-D-20-017) (85 FR 22733, April 23, 2020) (U.S. EPA, 2020c) for a 45-day public comment period. After reviewing and considering the public comments (Docket ID: <u>EPA-HQ-OPPT-2018-0433</u>) received on the draft scope document, EPA is now publishing this final scope document pursuant to 40 CFR 702.41(c)(8).

2 SCOPE OF THE EVALUATION

2.1 Reasonably Available Information

EPA conducted a comprehensive search for reasonably available information¹ to support the development of this final 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;

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

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

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

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

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

2.1.1 Search of Gray Literature

EPA surveyed the gray literature² and identified 94 search results relevant to EPA's risk evaluation needs for di-ethylhexyl phthalate. Appendix A.3.4 lists the gray literature sources that yielded 94 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 and chemical properties, environmental fate, environmental hazard, human health hazard, exposure, engineering) and the breakdown is shown in Figure 2-1. EPA plans to consider additional reasonably available information from gray literature if it becomes available during the risk evaluation phase.

 $^{^2}$ Gray literature is defined as the broad category of data/information sources not found in standard, peer-reviewed literature databases (*e.g.*, PubMed and Web of Science). Gray literature includes data/information sources such as white papers, conference proceedings, technical reports, reference books, dissertations, information on various stakeholder websites and other databases.





Figure 2-1. Gray Literature 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 has begun the systematic review process and has conducted searching and screening of the reasonably available literature using the process outlined in Appendix A. This includes performing a comprehensive search of the reasonably available peer review literature on physical and chemical properties, environmental fate and transport, engineering (environmental release and occupational exposure), exposure (environmental, general population and consumer) and environmental and human health hazards of di-ethylhexyl phthalate. Eligibility criteria were applied in the form of PECO statements (see Appendix A). Included references met the PECO criteria, whereas excluded references did not meet the criteria (*i.e.*, not relevant), and supplemental material was considered as potentially relevant (see Appendix A.2). EPA plans to evaluate the reasonably available information identified for each discipline during the development of the risk evaluation.

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

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



Figure 2-2. Peer-reviewed Literature Inventory Tree - Physical and chemical Properties Search Results for Di-ethylhexyl Phthalate

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



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

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

	mound					
Endpoint	Air	Soil, Sediment	Wastewater, Biosolids	Water	Other	Grand Total
Bioconcentration	8	41	8	40		59
Biodegradation	2	45	38	27		71
Hydrolysis				1		1
Photolysis	2	1	2	5		7
Sorption	5	49	14	42		57
Volatilization	6	5	1	5		9
Wastewater Treatment		6	38	21		40
Other	2	5	5	5	1	10
Grand Total	16	110	80	113	1	193

Media

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

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



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

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

Data Type 💈	Evidence Tags	
	Description of release source	25
	Release frequency	6
Environmental	Release or emission factors	25
Releases	Release quantity	24
	Waste treatment methods and pollution control	28
	Total	51
	Chemical concentration	38
	Life cycle description	16
General	Number of sites	12
Engineering	Process description	30
Assessment	Production, import, or use volume	26
	Throughput	9
	Total	72
	Area sampling data	28
	Dermal exposure data	16
	Engineering control	7
	Exposure duration	15
	Exposure frequency	9
	Exposure route	44
Occupational	No evidence tag	2
Exposures	Number of workers	20
	Particle size characterization	1
	Personal protective equipment	11
	Personal sampling data	24
	Physical form	21
	Worker activity description	29
	Total	68
Grand Total		127

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

Click <u>here</u> to view the interactive version for additional study details. Data in this figure represents references obtained from the publicly available databases search (see Appendix A.1.2) that were included during full-text screening as of August 5, 2020. Additional data may be added to the interactive version as they become available.



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

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

	Data Type							
Media (group)	Monitoring Study	Modeling Study	Completed Assessment	Experimental Study	Epidemiological Study	Database	Survey	Grand Total
Ambient Air								
Biosolids/Sludge	10	2	4	2	2			10
Drinking Water								
Groundwater								
Land Disposal/Landfill								
Sediment	9	5	4	2	2			11
Soil	23	9	16	1	6		1	31
Surface Water	12	4	7		4	1		16
Wastewater								
Aquatic Species	6	3	4	1	3		1	6
Terrestrial Species	7	1	4	3	2			9
Consumer	69	35	38	45	17	1	16	107
Dietary	70	36	39	19	9	2	10	93
Dust	102	47	46	7	23		20	127
Exposure Factors	31	24	16	4	14	2	6	44
Exposure Pathway	28	16	15	8	9	1	5	41
Human Biomonitoring	385	68	50	6	175	24	51	398
Indoor Air	88	48	38	25	14	1	9	124
Isomers	8	1	1		3			8
Use Information	16	8	13	4	8	1	5	23
No Evidence Type	3		1		1		1	3
Grand Total	565	149	117	62	199	26	70	645

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

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



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

Click <u>here</u> for interactive literature inventory tree. Data in this figure represent references obtained from the publicly available databases search (see Appendix A.1.2) that were included during full-text screening as of June 16, 2020. Additional data may be added to the interactive version as they become available.

Health Outcomes	Human	Animal - Human Health Model	Animal - Environmental Model	Plant	Grand Total
ADME	273	129	35	9	436
Cancer	18	81	8		102
Cardiovascular	24	34	5		63
Developmental	204	249	60	6	504
Endocrine	116	252	57	4	416
Gastrointestinal	4	20	3		25
Hematological and Immune	145	170	24		328
Hepatic	10	177	26		205
Mortality	10	25	25	2	60
Musculoskeletal	16	25	16		55
Neurological	51	58	20		124
Nutritional and Metabolic	95	117	30	6	239
Ocular and Sensory	28	20	4		52
РВРК	7	3	1		10
Renal	160	52	4		215
Reproductive	178	265	58	2	489
Respiratory	36	30	5		71
Skin and Connective Tissue	24	18	5		46
No Tag	2	18	24	6	48
Grand Total	312	441	123	21	871

Evidence Type

Figure 2-10. Peer-reviewed Literature Inventory Map – Human Health and Environmental Hazards Search Results for Di-ethylhexyl phthalate

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

2.1.3 Search of TSCA Submissions

Table 2-1 presents the results of screening the titles of data sources and reports submitted to EPA under various sections of TSCA. EPA screened a total of 279 submissions using PECO or similar statements that identify inclusion/exclusion criteria specific to individual disciplines (see Table 2-1 for the list of disciplines). The details about the criteria are presented in Appendix A.2.1. EPA identified 182 submissions that met the inclusion criteria in these statements and identified 76 submissions with

supplemental data.³ 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

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

Discipline	Included	Supplemental ^b
Physical and Chemical Properties	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

^a Individual submissions may be relevant to multiple disciplines.

^b Included submissions may contain supplemental data for other disciplines, which will be identified at full-text review.

2.2 Conditions of Use

As described in the *Proposed Designation of Di-ethylhexyl Phthalate (CASRN 117-81-7) as a High-Priority Substance for Risk Evaluation)* (U.S. EPA, 2019e) EPA assembled information from the CDR and TRI programs to determine conditions of use⁴ or significant changes in conditions of use of the chemical substance. Once the 2020 CDR reporting period ends in November 2020, EPA plans to utilize the most recent CDR information. EPA also consulted a variety of other sources to identify uses of diethylhexyl 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) (U.S. EPA, 2019d) 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 EPA plans to consider in the risk evaluation (Section 2.2.1; Table 2-2). The conditions of use included in the scope of the risk evaluation are those reflected in the life cycle diagrams and conceptual models.

³ EPA may further consider some supplemental or excluded references depending on the reasons for tagging as supplemental or excluded.

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

After gathering reasonably available information related to the manufacture, processing, distribution in commerce, use and disposal of di-ethylhexyl phthalate, EPA identified those activities for di-ethylhexyl phthalate the Agency determined not to be conditions of use or are otherwise excluded from the scope of the risk evaluation. These excluded activities are described in Section 2.2.2.

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

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

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

 Evaluation

Life Cycle Stage ^a	Category ^b	Subcategory ^c	References
Manufacture	Domestic Manufacture	Domestic Manufacture	U.S. EPA (2019c); ACROS Organics (2002); Eastman Chemical Company (2020); Harwick Standard (2015); Spectrum (2008); Tenoit Co. Ltd (2020)
	Import	Import	<u>U.S. EPA (2019c); Comet</u> Chemical Company Ltd (2016)
Processing	As a reactant	Plasticizer in plastic material and resin manufacturing, rubber product manufacturing, and synthetic rubber manufacturing	<u>U.S. EPA (2019c); Natrochem</u> (2016)
		Adhesive and sealant chemical in adhesive manufacturing	U.S. EPA (2019c); Morgan Advanced Materials (2016a, 2016b)
	Incorporation into article	Plasticizer in all other basic organic chemical manufacturing, plastics product manufacturing	<u>U.S. EPA (2019c); Victor</u> <u>Technologies (2012)</u>
		Plastic material and resin manufacturing	<u>U.S. EPA (2019c); 3M Company</u> (2018)
		Plasticizer in custom compounding of purchased resin	<u>U.S. EPA (2019c)</u>

	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;	<u>U.S. EPA (2019c)</u>
		Plasticizer in adhesive manufacturing; all other basic inorganic chemical manufacturing; rubber product manufacturing; and services	<u>U.S. EPA (2019c)</u>
		Plasticizer in all other chemical product and preparation manufacturing	<u>U.S. EPA (2019c)</u>
		Solid rocket motor insulation	EPA-HQ-OPPT-2019-0501-0043
	Intermediate	Intermediate in plastics product manufacturing	<u>U.S. EPA (2019c)</u>
	Recycling	Recycling	
	Repackaging	Other functional use in wholesale and retail trade	<u>U.S. EPA (2019c)</u>
Distribution	Distribution		
Industrial Use	Processing aid, specific to petroleum production	Hydraulic fracturing	U.S. House of Representatives (2011); NYSDEC (2011)
	Paints and Coatings	Paints and Coatings (<i>e.g.</i> , Industrial Polish)	<u>3M Company (2019b)</u>

	Reference material and/or laboratory reagent	Laboratory chemicals	<u>ULTRA Scientific Inc (2014);</u> <u>Restek (2019); EPA-HQ-OPPT-</u> 2019-0501-0043
	Transportation Equipment Manufacturing	(<i>e.g.</i> , formulations for diffusion bonding and manufacture of aero engine fan blades)	Morgan Advanced Materials (2016a, 2016b)
Commercial Use	Adhesives and sealants	Adhesives and sealants	U.S. EPA (2019c); NLM (2019); Airserco Manufacturing Company LLC (2009); 3M Company (2011); Imperial Tools (2012); Valspar (2019); Valspar (2017); Tremco (2015); StatSpin Inc (2004)
	Arts, crafts, and hobby materials	Arts, crafts, and hobby materials	<u>U.S. EPA (2019c)</u>
	Automotive care products	Automotive and interior car care products	<u>U.S. EPA (2019c); ACC (2019);</u> Danish EPA (2010); <u>3M Company</u> (2017)
	Batteries	Batteries (<i>e.g.</i> , Digital camera)	<u>Amazon (2020)</u>
	Building/construction materials not covered elsewhere ^d	Building/construction materials not covered elsewhere,	<u>U.S. EPA (2019c)</u>
	Dyes and pigments	Dyes, pigments, and fixing agents	<u>U.S. EPA (2019b); U.S. EPA</u> (1999); Identity Group (2016); SPIN (2019)
	Electrical and electronic products	Electrical and electronic products	<u>U.S. EPA (2019c); 3M Company</u> (2019a); <u>3M Company (2011);</u> <u>Rakuten (2019)</u>
	Fabric, textile, and leather products not covered elsewhere	Fabric, textile, and leather products not covered elsewhere	<u>U.S. EPA (2019c); Office Stock</u> <u>USA (2019)</u>
	Furniture and furnishings not covered elsewhere	Furniture and furnishings not covered elsewhere	<u>U.S. EPA (2019c)</u>
	Lawn and garden care products	Lawn and garden care products	<u>U.S. EPA (2019c)</u>
	Paints and coatings	Paints and coatings (<i>e.g.</i> , sealer for decorative concrete as	U.S. EPA (2019c); CETCO (2014); Chemsol (2020); Dupli-Color Products Company (2017); Glidden

		waterproof polyurethane)	Co (1999); LORD Corporation (2019); LORD Corporation (2015) Pacific Coast Lacquer (2016); Ramuc Specialty Pools (2010); Republic Powdered Metals Inc. (2002); The Sherwin-Williams Company (2019)
	Plastic and rubber products not covered elsewhere	Plastic and rubber products not covered elsewhere	U.S. EPA (2019c); Lighthouse Office Supply (2018); Quad City Safety Inc (2019a, 2019b)
	Toys, playground, and sporting equipment	Toys, playground, and sporting equipment	<u>U.S. EPA (2019c)</u>
Consumer Use	Adhesives and sealants	Adhesives and sealants	U.S. EPA (2019c); NLM (2019); Airserco Manufacturing Company LLC (2009); <u>3M Company (2011);</u> Valspar (2017); <u>Valspar (2019);</u> Tremco (2015); <u>StatSpin Inc (2004)</u>
	Arts, crafts, and hobby materials	Arts, crafts, and hobby materials	<u>U.S. EPA (2014)</u>
	Automotive care products	Automotive and interior car care products	<u>U.S. EPA (2019b); ACC (2019);</u> <u>Danish EPA (2010);</u> <u>3M Company (2017)</u>
	Batteries	Batteries (<i>e.g.</i> , digital camera)	<u>Amazon (2020)</u>
	Building/ construction materials not covered elsewhere	Building/construction materials not covered elsewhere	<u>U.S. EPA (2019c)</u>
	Dyes and pigments	Dyes, pigments, and fixing agents	<u>U.S. EPA (2019b); U.S. EPA</u> (1999); <u>Identity Group (2016);</u> <u>SPIN (2019)</u>
	Electrical and electronic products	Electrical and electronic products	<u>U.S. EPA (2019c); 3M Company</u> (2019a); <u>3M Company (2011);</u> <u>Rakuten (2019)</u>
	Fabric, textile, and leather products not covered elsewhere	Fabric, textile, and leather products not covered elsewhere	<u>U.S. EPA (2019c); Office Stock</u> <u>USA (2019)</u>
	Furniture and furnishings not covered elsewhere	Furniture and furnishings not covered elsewhere	<u>U.S. EPA (2019c);</u>
	Reference material and/or laboratory reagent	Laboratory chemicals	EPA-HQ-OPPT-2019-0501-0043

	Lawn and garden care products	Lawn and garden care products	<u>U.S. EPA (2019c)</u>
	Paints and coatings	Paints and coatings (<i>e.g.</i> , sealer for decorative concrete as waterproof polyurethane)	U.S. EPA (2019c); CETCO (2014); Chemsol (2020); Dupli-Color Products Company (2017); Glidden Co (1999); LORD Corporation (2019); LORD Corporation (2015); Pacific Coast Lacquer (2016);(Ramuc Specialty Pools, 2010); Republic Powdered Metals Inc. (2002); The Sherwin-Williams Company (2019)
	Plastic and rubber products not covered elsewhere	Plastic and rubber products not covered elsewhere	U.S. EPA (2019c); Lighthouse Office Supply (2018); Quad City Safety Inc (2019a, 2019b)
	Toys, playground, and sporting equipment	Toys, playground, and sporting equipment	<u>U.S. EPA (2019c)</u>
Disposal	Disposal	Disposal	

a) Life Cycle Stage Use Definitions (40 CFR § 711.3)

 "Industrial use" means use at a site at which one or more chemicals or mixtures are manufactured (including imported) or processed.

- "Commercial use" means the use of a chemical or a mixture containing a chemical (including as part of an article) in a commercial enterprise providing saleable goods or services.
- "Consumer use" means the use of a chemical or a mixture containing a chemical (including as part of an article, such as furniture or clothing) when sold to or made available to consumers for their use.
- Although EPA has identified both industrial and commercial uses here for purposes of distinguishing scenarios in this document, the Agency interprets the authority over "any manner or method of commercial use" under TSCA Section 6(a)(5) to reach both.

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

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

d) In the final scope, EPA added the condition of use for di-ethylhexyl phthalate for processing, incorporation into formulation, mixture, or reaction product solid rocket motor insulation based on consultation with industry (EPA-HQ-OPPT-2018-0433-0038).

2.2.2 Activities Excluded from the Scope of the Risk Evaluation

As explained in the final rule for *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act* (82 FR 33726, July 20, 2017), TSCA Section 6(b)(4)(D) requires EPA to identify the hazards, exposures, conditions of use, and the PESS the Administrator expects to consider in a risk evaluation, suggesting that EPA may exclude certain activities that it determines to be conditions

of use on a case-by-case basis (82 FR 33736, 33729; July 20, 2017). TSCA Section 3(4) also grants EPA discretion to determine the circumstances that are appropriately considered to be conditions of use for a particular chemical substance.⁵ As a result, EPA does not plan to include in this scope or in the risk evaluation activities described below that the Agency does not consider to be conditions of use or for which EPA is exercising discretionary authority provided by TSCA Section 6(b)(4)(D).

TSCA Section 3(2) also excludes from the definition of "chemical substance" "any food, food additive, drug, cosmetic, or device (as such terms are defined in Section 201 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 321]) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device" as well as "any pesticide (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 et seq.]) when manufactured, processed, or distributed in commerce for use as a pesticide." EPA has determined that the following uses of diethylhexyl 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, M, 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.
- EPA recognizes that the Food and Drug Administration lists di-ethylhexyl phthalate as an optional substance to be used in food packaging materials. Food packaging materials meet the definition for a "food additive" described in Section 201 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. § 321. Therefore, these uses are excluded from the definition of "chemical substance" in TSCA § 3(2)(B)(vi) and are not included in Table 2-2. Activities and releases associated with the use of such food packaging materials are therefore not "conditions of use" (defined as circumstances associated with "a chemical substance," TSCA § 3(4)) and will not be evaluated during risk evaluation.
- Medical Devices. Di-ethylhexyl phthalate has been listed as being used in medical devices and the flexible tubing and containers in the medical industry. These uses meet the definition of a "medical device" in Section 201 of the FFDCA, 21 U.S.C. § 321. Therefore, the uses are excluded from the definition of "chemical substance" in TSCA § 3(2)(B)(vi) and are not included in Table 2-2. Activities and releases associated with the use of medical devices are not "conditions of use" (defined as circumstances associated with "a chemical substance," TSCA § 3(4)) and will not be evaluated during risk evaluation.

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

- 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.
- EPA determined that di-ethylhexyl phthalate is used as a propellant in cartridge munitions and rocket motors. TSCA section 3(2)(B)(v) excludes from the definition of "chemical substance," any "article the sale of which is subject to the tax imposed by section 4181 of the Internal Revenue Code of 1986 [26 U.S.C. 4181] (determined without regard to any exemptions from such tax provided by section 4182 or 4221 or any other provision of such Code) and any component of such an article (limited to shot shells, cartridges, and components of shot shells and cartridges)". Section 4181 of the Internal Revenue Code imposes a tax on the following articles: "pistols", "revolvers", "firearms (other than pistols and revolvers)" and "Shells, and cartridges." Propellants used in cartridge munitions and rocket motors, when present as a component of a cartridge, meet this definition and, therefore, are excluded from the definition of "chemical substance" in TSCA § 3(2)(B)(vi) and are not included in Table 2-2. Activities and releases associated with these uses are not "conditions of use" (defined as circumstances associated with "a chemical substance," TSCA § 3(4)) and will not be evaluated during risk evaluation.

2.2.3 Production Volume

As reported to EPA during the 2016 CDR reporting period and described here as a range to protect production volumes that were claimed as confidential business information (CBI), total production volume of di-ethylhexyl phthalate in 2015 was between 100 million and 250 million pounds (U.S. EPA, 2020a). 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, 2019e) and will include more recent production volume information from the 2020 CDR reporting period in the risk evaluation to support the exposure assessment.

2.2.4 Overview of Conditions of Use and Lifecyle Diagram

Figure 2-11 provides the life cycle diagram for di-ethylhexyl phthalate. The life cycle diagram is a graphical representation of the various life stages of the industrial, commercial and consumer use categories included within the scope of the risk evaluation. The information in the life cycle diagram is grouped according to the CDR processing codes and use categories (including functional use codes for industrial uses and product categories for industrial, commercial and consumer uses). Appendix E contains additional descriptions (*e.g.*, process descriptions, worker activities, process flow diagrams) for each manufacturing, processing, distribution in commerce, use, and disposal category.



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

2.3 Exposures

For TSCA exposure assessments, EPA plans to analyze human and environmental exposures and releases to the environment resulting from the conditions of use within the scope of the risk evaluation for di-ethylhexyl phthalate. In this section, the physical and chemical properties, environmental fate and transport properties and releases to the environment are described in addition to potential human and environmental exposures from TSCA conditions of use and from other possible or known sources. Release pathways and routes will be described in Section 2.6 to characterize the relationship or connection between the conditions of use of the chemical and the exposure to human receptors, including PESS, and environmental receptors. EPA plans to consider, where relevant, the duration, intensity (concentration), frequency and number of exposures in characterizing exposures to di-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. It can also inform the hazard assessment. Table 2-3 summarizes the physical and chemical property values preliminarily selected for use in the risk evaluation from among the range of reported values collected as of June 2020. This table differs from that presented in the *Proposed Designation of Di*-*Ethylhexyl Phthalate (CASRN 117-81-7) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019e) and may be updated as EPA continues to evaluate and integrate additional information through systematic review methods. Figure 2-12. summarizes the distribution of reported values for eight physical and chemical properties routinely used in existing chemical risk evaluations. Appendix B presents summary statistics for reported physical and chemistry property values. All physical and chemistry property values that were extracted and evaluated as of June 2020 are presented in the supplemental file *Data Extraction and Data Evaluation Tables for Physical and Chemical Property Studies* (EPA-HQ-OPPT-2018-0433).

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	<u>Rumble (2018)</u>	High
Physical properties	Colorless, oily liquid; slight odor	<u>NLM (2015a)</u>	High
Melting point	-55°C	<u>NLM (2015a)</u>	High
Boiling point	384°C	<u>NLM (2015a)</u>	High
Density	0.981 g/cm ³ at 25°C	<u>NLM (2015a)</u>	High
Vapor pressure	1.42×10 ⁻⁷ mm Hg at 25°C	<u>NLM (2015a)</u>	High
Vapor density	16.0 (air = 1)	<u>NLM (2015a)</u>	High
Water solubility	0.27 mg/L at 25°C	<u>NLM (2015a)</u>	High

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

Octanol/water partition coefficient (log Kow)	7.6	<u>NLM (2015a)</u>	High
Henry's Law constant	$1.71 \times 10^{-5} \text{ atm} \cdot \text{m}^3/\text{mol}$	<u>Elsevier (2019)</u>	High
Flash point	206°C	<u>O'Neil (2013)</u>	High
Auto flammability	Not available		
Viscosity	57.94 cP at 25°C	<u>Mylona et al.</u> (2013)	High
Refractive index	1.4853	<u>Rumble (2018)</u>	High
Dielectric constant	5.06 at 25°C	<u>Elsevier (2019)</u>	High

^a Measured unless otherwise noted.

NA = Not applicable

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


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

2.3.2 Environmental Fate and Transport

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

2.3.3 Releases to the Environment

Releases to the environment from conditions of use are a component of potential exposure and may be derived from reported data that are obtained through direct measurement, calculations based on empirical data 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), diethylhexyl phthalate is a TRI-reportable substance effective January 1, 1987 (40 CFR 372.65). For TRI reporting⁶, 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.

Table 2-4 provides production-related waste management data for di-ethylhexyl phthalate reported by facilities to the TRI program for reporting year 2018.⁷ 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 ³/₄ of the total quantity was treated off-site. A relatively small portion (~710,000 pounds, 9%) of the stotal quantity of production-related waste was released to the environment, and most (90%) of this amount was disposed of or otherwise released off-site.

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 ^a Terminolog ^b Does not inc	e: U.S. EPA (2019f y used in these columns clude releases due to one	may not match th	e more detailed data e ssociated with produc	lement names ution such as re	used in the TRI public medial actions or ear	c data and analysis access points.

Table 2-4. Summary of Di-ethylhexyl Phthalate Production-Related Waste Managed in 2

^c Counts all releases including release quantities transferred and release quantities disposed of by a receiving facility reporting to TRI.

Table 2-5 provides a summary of the di-ethylhexyl phthalate disposed of or otherwise released to the environment during 2018.⁷ Less than 31 pounds of di-ethylhexyl phthalate were 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 offsite 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 (Resource Conservation and Recovery Act) 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

⁶ For TRI reporting criteria see <u>https://www.epa.gov/toxics-release-inventory-tri-program/basics-tri-reporting</u>

⁷ Reporting year 2018 is the most recent TRI data available. Data presented in Table 2-4 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.

to the environment during 2018. Nearly ³/₄ of these air releases were in the form of stack emissions, with fugitive air releases accounting for the remaining ¹/₄. The majority of "other releases" occurred off-site.

		Air Ro	eleases		Land Disposal				
Year	Number of Facilities	Stack Air Releases (lbs)	Fugitive Air Releases (lbs)	Water Releases (lbs)	Class I Under- ground Injection (lbs)	RCRA Subtitle C Landfills (lbs)	All other Land Disposal ^a	Other Releases ^a (lbs)	Total Releases ^{b,} c (lbs)
2018	118	33,879	12,795	30.57	5	22,909	619,423	21,651.8	710,694
		46,674			642,337			o	

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

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

^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 manufacture, processing, distribution in commerce, disposal or use such as remedial actions or earthquakes.

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

The total production-related waste managed quantity shown in Table 2-4 does not include any quantities reported as catastrophic or one-time releases or otherwise not associated with production. Release quantities shown in Table 2-5 include both production-related and non-production-related quantities. Total release quantities differ by 180 pounds between Table 2-4 and Table 2-5 due to differences in TRI calculation methods for reported release range estimates (U.S. EPA, 2019a). Table 2-4 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 offsite 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 2-5. 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 2-4 and Table 2-5 indicates that diethylhexyl 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 receptors (biota). Environmental exposures to biota are informed by releases into the environment, overall persistence, degradation, and bioaccumulation within the environment, and partitioning across different media. Concentrations of chemical substances

in biota provide evidence of exposure. EPA plans to review reasonably available environmental monitoring data for di-ethylhexyl phthalate.

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. 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, 2013a; 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, 2013a; ECB, 2008; ATSDR, 2002). EPA plans to review reasonably available environmental monitoring data for di-ethylhexyl phthalate.

2.3.5 Occupational Exposures

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

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

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

Di-ethylhexyl phthalate is a liquid at room temperature and has a vapor pressure of 1.42×10^{-7} mm Hg at 25 °C (NLM, 2015b) and inhalation exposure to vapor is expected to be low when working with the material at room temperature. However, EPA plans to analyze inhalation exposure for workers and ONUs in occupational scenarios where di-ethylhexyl phthalate is applied via spray or roll application methods or is handled as a dry powder or at elevated temperatures. In addition, for certain COUs, di-ethylhexyl phthalate may be present as a component of solid products. For these COUs, EPA plans to consider inhalation exposure to dust/particulates (*e.g.*, particulate generated during handling of plastic resins, finishing operations associated with the manufacture and finishing of plastics and plastic articles and incorporation of plastics and other article components into finished products) for workers and ONUs.

Di-ethylhexyl phthalate has an Occupational Safety and Health Administration (OSHA) permissible exposure limit (PEL) (<u>OSHA, 2009</u>). The PEL is 5 mg/m³ over an 8-hour workday, time weighted average (TWA). The American Conference of Governmental Industrial Hygienists (ACGIH) set the threshold limit value (TLV) at 5 mg/m³ TWA. The National Institute for Occupational Safety and Health

(NIOSH) has set the Recommended Exposure Limit (REL) of 5 mg/m³ TWA and set the short-term exposure limit (STEL) of 10 mg/m³ (NIOSH, 2019). NIOSH considers di-ethylhexyl phthalate to be a potential occupational carcinogen with an Immediately Dangerous to Life or Health (IDLH) value of 5000 mg/m³ (NIOSH, 2020, 2016).

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

EPA generally does not evaluate occupational exposures through the oral route. Workers and ONUs may inadvertently ingest inhaled particles that deposit in the upper respiratory tract. In addition, workers may transfer chemicals from their hands to their mouths. The frequency and significance of this exposure route are dependent on several factors including the physical and chemical properties of the substance during worker activities, the visibility of the chemicals on the hands while working, workplace training and practices, and personal hygiene that is difficult to predict (Cherrie et al., 2006). EPA plans to consider the relevance of this exposure route on a case-by-case basis, taking into consideration the aforementioned factors and any reasonably available information, and may assess oral exposure for workers for certain COUs and worker activities where warranted. For certain conditions of use of di-ethylhexyl phthalate, EPA plans to consider inhalation exposure to dust/particulates for workers and ONUs. As inhalation exposure to dust/particulates may occur, EPA plans to consider potential exposure for particulates that deposit in the upper respiratory tract from inhalation exposure and may be ingested via the oral route.

2.3.6 Consumer Exposures

CDR reporting and conversations with industry indicate the presence of 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 2-14.). These uses can result in exposures to consumers and bystanders (non-product users that are incidentally exposed to the product).

Based on reasonably available information on consumer conditions of use, inhalation of di-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, through mouthing of articles containing di-ethylhexyl phthalate, or via dust. Dermal exposure may occur via contact with vapor, mist, or dust deposition onto the skin; via direct liquid contact during use; or direct dermal contact of articles containing di-ethylhexyl phthalate. The consumer exposure pathways in the scope of this evaluation are described in Sections 2.6.2 and 2.7.2.4.

2.3.7 General Population Exposures

Releases of di-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 (<u>CPSC, 2015; ATSDR</u>,

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, 2013b; ECB, 2008; NTP-CERHR, 2006; ATSDR, 2002; OEHHA, 1997).

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

The presence in environmental media and biomonitoring data suggest that general population exposures are occurring. The general population pathways in the scope of this evaluation are described in Sections 2.6.3 and 2.7.2.5.

2.4 Hazards (Effects)

2.4.1 Environmental Hazards

EPA considered reasonably available information (*e.g.*, federal and international government chemical assignments) on di-ethylhexyl phthalate as well as public comments received on the *Proposed Designation of Di-Ethylhexyl Phthalate (CASRN 117-81-7) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019e) and draft scope for di-ethylhexyl phthalate (U.S. EPA, 2020c) to identify potential environmental hazards. During prioritization, EPA identified environmental hazard effects for aquatic and terrestrial organisms.

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

2.4.2 Human Health Hazards

EPA considered reasonably available information (*e.g.*, federal and international government chemical assessments) on di-ethylhexyl phthalate as well as public comments received on the *Proposed Designation of Di-ethylhexyl Phthalate (CASRN 117-81-7) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019e) and draft scope for di-ethylhexyl phthalate (U.S. EPA, 2020c) to identify potential human health hazards. During prioritization, EPA identified the following potential human health hazards and related information: reproductive, developmental and systemic effects.

Since prioritization, EPA applied automated techniques during the data screening phase of systematic review to identify the following additional potential human health hazards and related information that may be considered for the risk evaluation (as explained in Appendix A): ADME, PBPK, cancer, cardiovascular, endocrine, gastrointestinal, hematological and immune, hepatic, mortality, musculo-skeletal, neurological, nutritional and metabolic, ocular and sensory, renal, respiratory, and skin and

connective tissue (Figure 2-10). A summary of references identified during the screening step of systematic review is included in the interactive literature inventory trees (Figure 2-9). As EPA continues to evaluate reasonably available and relevant hazard information identified through systematic review, EPA may update the potential human health hazards considered in the risk evaluation.

2.5 Potentially Exposed or Susceptible Subpopulations

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

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

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

2.6 Conceptual Models

In this section, EPA presents the conceptual models describing the identified exposures (pathways and routes), receptors and hazards associated with the conditions of use of di-ethylhexyl phthalate. Pathways and routes of exposure associated with workers and ONU's are described in Section 2.6.1, and pathways and routes of exposure associated with consumers are described in Section 2.6.2. Pathways and routes of exposure associated with environmental releases and wastes, including those pathways that are under the jurisdiction of other EPA-administered laws, are discussed and depicted in the conceptual model shown in Section 2.6.3.1. Pathways and routes of exposure associated with environmental releases and wastes, excluding those pathways that are under the jurisdiction of other EPA-administered laws, are discussed and depicted in the conceptual model shown in Section 2.6.3.1. Pathways that are under the jurisdiction of other EPA-administered laws, are presented in the conceptual model shown in Section 2.6.3.2.

2.6.1 Conceptual Model for Industrial and Commercial Activities and Uses: Potential Exposures and Hazards

Figure 2-13 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 occupational non-users via inhalation routes and exposures to workers via dermal routes. The conceptual model also includes potential worker and ONU via dermal exposure to di-ethylhexyl phthalate in mists and dusts. EPA plans to evaluate activities resulting in exposures associated with distribution in commerce (*e.g.*, loading, unloading) throughout the various lifecycle stages and conditions of use (*e.g.*, manufacturing, processing, industrial use, commercial use, and disposal) rather than a single distribution scenario.

For each condition of use identified in Table 2-2, a determination was made as to whether or not EPA plans to evaluate each combination of exposure pathways, routes, and receptors in the risk evaluation. The results of that analysis along with the supporting rationale are presented in Appendix F.



Figure 2-13. 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 2-14 presents the exposure pathways, exposure routes and hazards to human receptors from consumer activities and uses of di-ethylhexyl phthalate. EPA expects that consumers and bystanders may be exposed through use of products or articles or via dust 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. EPA plans to analyze pathways and routes of exposure that may occur during the varied identified consumer activities and uses. The supporting rationale for consumer pathways considered for di-ethylhexyl phthalate are included in Appendix G.



Figure 2-14. 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 from environmental releases and wastes) and hazards to general population and environmental receptors associated with the conditions of use of di-ethylhexyl phthalate within the scope of the risk evaluation. This section also discusses those pathways that may be addressed pursuant to other EPA-administered laws.

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



Figure 2-15. 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.

- a) Industrial wastewater or liquid wastes may be treated on-site and then released to surface water (direct discharge), or pre-treated and released to Publicly Owned Treatment Works (POTW) (indirect discharge). For consumer uses, such wastes may be released directly to POTW. Drinking water will undergo further treatment in drinking water treatment plant. Ground water may also be a source of drinking water. Inhalation from drinking water may occur via showering
- b) Receptors include PESS (see Section 2.5).

2.6.3.1 Exposure Pathways and Risks Addressed by Other EPA Administered Statutes

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

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

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

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

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

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

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

TSCA Section 9(b)(1)

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

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

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

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

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

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

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

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

TSCA Sections 2(c) and 18(d)

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

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

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

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

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

Emission pathways to ambient air from commercial and industrial stationary sources and associated inhalation exposure of the general population or terrestrial species in this TSCA evaluation from stationary source releases of 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. As such, EPA does not plan to evaluate exposures to the general population from ambient air in the risk evaluation under TSCA. This regulatory coverage is represented by the red shading in Figure 2-15

Drinking Water Pathway

EPA has regular analytical processes to identify and evaluate unregulated drinking water contaminants of potential regulatory concern for public water systems under the SDWA. In addition, the SDWA requires EPA to review and revise "as appropriate" existing drinking water regulations every 6 years.

EPA has promulgated National Primary Drinking Water Regulations (NPDWRs) under the SDWA for di-ethylhexyl phthalate. See 40 CFR part 151. EPA has set an enforceable Maximum Contaminant Level (MCL) as close as feasible to a health based, non-enforceable Maximum Contaminant Level Goal (MCLG). 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 and the MCLG is 0 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 evaluate exposures to the general population from the drinking water exposure pathway in the risk evaluation for di-ethylhexyl phthalate under TSCA. This regulatory coverage is represented by the dark blue shading in Figure 2-15. 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.

Ambient Water Pathway

EPA has developed Clean Water Act (CWA) Section 304(a) recommended human health criteria for 122 chemicals and aquatic life criteria for 47 chemicals. A subset of these chemicals is identified as "priority pollutants" (103 human health and 27 aquatic life), including di-ethylhexyl phthalate. The CWA requires that states adopt numeric criteria for priority pollutants for which EPA has published recommended criteria under Section 304(a), the discharge or presence of which in the affected waters could reasonably be expected to interfere with designated uses adopted the state. For pollutants with recommended human health criteria, EPA regulations require that state criteria contain sufficient parameters and constituents to protect designated uses. Once states adopt criteria as water quality standards, the CWA requires that National Pollutant Discharge Elimination System (NPDES) discharge permits include effluent limits as stringent as necessary to meet standards CWA Section 301(b)(1)(C). This permit issuance process accounts for risk in accordance with the applicable ambient water exposure pathway (human health or aquatic life as applicable) for the designated water use.

EPA develops recommended water quality criteria under Section 304(a) of the Clean Water Act (CWA) for pollutants in surface water that are protective of aquatic life or human health designated uses. EPA has developed recommended water quality criteria for protection of human health for 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 and/or numeric criteria. See, *e.g.*, 40 CFR part 423, Appendix A; 40 CFR 131.11(b)(1); 40 CFR 122.44(d)(1)(vi). As such, EPA does not plan to evaluate exposures to the general population from surface water in the risk evaluation under TSCA. This regulatory coverage is represented by the light blue shading in Figure 2-15. EPA's OW and OPPT will continue to work together providing understanding and analysis of the CWA water quality criteria development process and to exchange information related to toxicity of chemicals undergoing risk evaluation under TSCA. EPA may update its CWA Section 304(a) water quality criteria for di-ethylhexyl phthalate in the future under the CWA.

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. As such, EPA is not evaluating exposures to the general population from surface water in the risk evaluation under TSCA. This regulatory coverage is represented by the light blue shading in Figure 2-15.

EPA has not developed CWA Section 304(a) recommended water quality criteria for the protection of aquatic life for 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 such, EPA is evaluating exposures to aquatic species from surface water in the risk evaluation under TSCA. The Office of Water may issue CWA Section 304(a) aquatic life criteria for *di*-ethylhexyl phthalate in the future.

Onsite Releases to Land Pathway

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

CERCLA Section 101(14) defines "hazardous substance" by referencing other environmental statutes, including toxic pollutants listed under CWA Section 307(a); hazardous substances designated pursuant to CWA Section 311(b)(2)(A); hazardous air pollutants listed under CAA Section 112; imminently hazardous substances with respect to which EPA has taken action pursuant to TSCA Section 7; and hazardous wastes having characteristics identified under or listed pursuant to RCRA Section 3001. See 40 CFR 302.4. CERCLA Section 102(a) also authorizes EPA to promulgate regulations designating as hazardous substances those substances which, when released into the environment, may present substantial danger to the public health or welfare or the environment. EPA must also promulgate

regulations establishing the quantity of any hazardous substance the release of which must be reported under Section 103. Section 103 requires persons in charge of vessels or facilities to report to the National Response Center if they have knowledge of a release of a hazardous substance above the reportable quantity threshold.

di-Ethylhexyl phthalate is a hazardous substance under CERCLA. Releases of *di*-ethylhexyl phthalate in excess of 100 pounds within a 24-hour period must be reported (40 CFR 302.4, 302.6). The scope of this EPA TSCA risk evaluation does not include on-site releases of di-ethylhexyl phthalate to the environment at Superfund sites and subsequent exposure of the general population or non-human species.

Disposal and Soil Pathways

di-Ethylhexyl phthalate is included on the list of hazardous wastes pursuant to the Resource Conservation and Recovery Act (RCRA) Section 3001 (40 CFR § 261.33) as a listed waste on the U list (U070). 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* wastes that are incinerated (subject to joint control under RCRA Subtitle C and the CAA hazardous waste combustion Maximum Achievable Control Technology (MACT)) or injected into Underground Injection Control (UIC) Class I hazardous waste wells (subject to joint control under Subtitle C and the SDWA).⁸

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

EPA does not plan to evaluate emissions to ambient air from municipal and industrial waste incineration and energy recovery units that form combustion by-products from incineration treatment of diethylhexyl phthalate wastes or associated exposures to the general population in the risk evaluation, as those emissions are subject to CAA regulations, as would di-ethylhexyl phthalate burned for energy recovery. See 40 CFR part 60.

EPA does not plan to evaluate on-site releases to land that go to underground injection or associated exposures to the general population or terrestrial species in its risk evaluation. TRI reporting in 2018 indicated 5 pounds released to underground injection to a Class I well (Table 2-5). 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

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

hazardous waste wells is not likely to result in environmental and general population exposures. See 40 CFR parts 144.

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 "all other land disposal" both on-site and off-site (Table 2-5). Diethylhexyl 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. See 40 CFR part 264. As a result, EPA does not plan to evaluate on-site releases to land from RCRA Subtitle C hazardous waste landfills or exposures of the general population or terrestrial species from such releases in the TSCA evaluation. This regulatory coverage is represented by the pink shading in Figure 2-15.

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

EPA does not plan to evaluate on-site releases to land from RCRA Subtitle D municipal solid waste (MSW) landfills or exposures of the general population or terrestrial species from such releases in the TSCA evaluation. 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. See 40 CFR part 258. As a result, EPA does not plan to evaluate on-site releases to land from RCRA Subtitle D municipal solid waste (MSW) landfills or exposures of the general population or terrestrial species from such releases in the TSCA evaluation. This regulatory coverage is represented by the pink shading in Figure 2-15.

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

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

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

The diagram shown in Figure 2-16 includes releases from industrial, commercial and/or consumer uses to water/sediment, biosolids and soil, via direct and indirect discharges to water, that may lead to exposure to aquatic receptors. The supporting basis for environmental pathways considered for diethylhexyl phthalate are included in Appendix H.



Figure 2-16. 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 and environmental receptors from releases and wastes from industrial, commercial, and consumer uses of di-ethylhexyl phthalate that EPA plans to consider in risk evaluation.

- a) Industrial wastewater or liquid wastes may be treated on-site and then released to surface water (direct discharge), or pre-treated and released to POTW (indirect discharge). For consumer uses, such wastes may be released directly to POTW.
- b) Receptors include PESS (see Section 2.5).

2.7 Analysis Plan

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

2.7.1 Physical and Chemical Properties and Environmental Fate

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

- Review reasonably available measured or estimated physical and chemical properties and environmental fate endpoint data collected using systematic review procedures and, where reasonably available, environmental assessments conducted by other regulatory agencies. EPA plans to evaluate data and information collected through the systematic review methods and public comments about the physical and chemical 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, 2019e). All sources cited in EPA's analysis will be evaluated according to the procedures and metrics described in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018). Where the systematic review process does not identify experimentally measured chemical property values of sufficiently high quality, testing will be requested under the TSCA Section 4 authority, or values will be estimated using chemical parameter estimation models as appropriate. Model-estimated fate properties will be reviewed for applicability and quality.
- 2) Using measured data and/or modeling, determine the influence of physical and chemical properties and environmental fate endpoints (*e.g.*, persistence, bioaccumulation, partitioning, transport) on exposure pathways and routes of exposure to human and environmental receptors.

Measured data and, where necessary, model predictions of physical and chemical properties and environmental fate endpoints will be used to characterize the persistence and movement of diethylhexyl phthalate within and across environmental media. The fate endpoints of interest include volatilization, sorption to organic matter in soil and sediments, water solubility, aqueous and atmospheric photolysis rates, aerobic and anaerobic biodegradation rates, and potential bioconcentration and bioaccumulation. These endpoints will be used in exposure calculations. **3)** Conduct a weight of the scientific evidence evaluation of physical and chemical properties and environmental fate data, including qualitative and quantitative sources of information. During risk evaluation, EPA plans to evaluate and integrate the physical and chemical properties and environmental fate evidence identified in the literature inventory using the methods described in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018).

2.7.2 Exposure

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

2.7.2.1 Environmental Releases

EPA plans to analyze releases to environmental media as follows:

1) Review reasonably available published literature and other reasonably available information on processes and activities associated with the conditions of use to analyze the types of releases and wastes generated.

EPA has reviewed some 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 additional data sources identified. Potential sources of environmental release data are summarized in Table 2-6 below:

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

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
National Emissions Inventory (NEI) data

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

Additionally, for conditions of use where no measured data on releases are reasonably available, EPA may use a variety of methods including release estimation approaches and assumptions in

the Chemical Screening Tool for Exposures and Environmental Releases (ChemSTEER) (U.S. EPA, 2015a).

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

EPA plans to review literature sources identified and if surrogate data are found, these data will be matched to applicable conditions of use for potentially filling data gaps. Measured or estimated release data for other phthalate esters may be considered as surrogates for diethylhexyl phthalate.

4) Review reasonably available data that may be used in developing, adapting or applying release models to the particular risk evaluation.

This item will be performed after completion of #2 and #3 above. EPA plans to evaluate relevant data to determine whether the data can be used to develop, adapt or apply models for specific conditions of use (and corresponding release scenarios). EPA has identified information from various EPA statutes and sources (including, for example, regulatory limits, reporting thresholds or disposal requirements) that may be relevant to consider for release estimation and environmental exposures. 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 <u>2009 ESD</u> on Adhesive Formulation (OECD, 2009a), the <u>2011 ESD</u> on Coating Application via Spray-Painting in the Automotive Refinishing Industry (OECD, 2011a), the <u>2011 ESD</u> on Chemical Industry (OECD, 2011c), the <u>2011 ESD</u> on Radiation Curable Coating, Inks and Adhesives (OECD, 2011b), the <u>2015 ESD</u> on the Use of Adhesives (OECD, 2015), and the <u>2009 ESD</u> on <u>Plastic Additives</u> (OECD, 2009b) 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: <u>https://www.epa.gov/tsca-screening-tools/using-predictive-methods-assess-exposure-and-fate-under-tsca#fate.</u>

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

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

6) Map or group each condition of use to a release assessment scenario(s).

EPA has identified release scenarios and mapped (*i.e.* grouped) them to relevant conditions of use as shown in Appendix F. EPA plans to refine the mapping/grouping of release scenarios

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

7) Evaluate the weight of the scientific evidence of environmental release data.

During risk evaluation, EPA plans to evaluate and integrate the environmental release evidence identified in the literature inventory using the methods described in the *Application of Systematic Review in TSCA Risk Evaluation* (U.S. EPA, 2018). EPA plans to integrate the data using systematic review methods to assemble the relevant data, evaluate the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence.

2.7.2.2 Environmental Exposures

EPA plans to analyze the following in developing its environmental exposure assessment of diethylhexyl phthalate:

1) Review reasonably available environmental and biological monitoring data for all media relevant to environmental exposure.

For di-ethylhexyl phthalate, environmental media which EPA plans to analyze are sediment, air, groundwater and surface water.

2) Review reasonably available information on releases to determine how modeled estimates of concentrations near industrial point sources compare with reasonably available monitoring data.

EPA plans to analyze and consider reasonably available environmental exposure models that meet the scientific standards under TSCA Section 26(h) that estimate surface water, and sediment concentrations will be analyzed and considered alongside reasonably available surface water, sediment, and monitoring data to characterize environmental exposures. Modeling approaches to estimate surface water concentrations, sediment concentrations may generally include the following inputs: direct release into surface water, or sediment, and indirect release into surface water, sediment, fate and transport (partitioning within media) and characteristics of the environment (*e.g.*, river flow, volume of lake, meteorological data).

3) Determine applicability of existing additional contextualizing information for any monitored data or modeled estimates during risk evaluation.

Any studies which relate levels of di-ethylhexyl phthalate in the environment or biota with specific sources or groups of sources will be evaluated. Review and characterize monitoring data or modeled estimates to determine how representative they are of applicable use patterns.

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, and sediment concentrations near industrial point sources based on reasonably available monitoring data.

- Consider the following modeling inputs: release into the media of interest, fate and transport and characteristics of the environment.
- Reasonably available biomonitoring data. Monitoring data could be used to compare with species or taxa-specific toxicological benchmarks.
- Applicability of existing additional contextualizing information for any monitored data or modeled estimates during risk evaluation. Review and characterize the spatial and temporal variability, to the extent that data are reasonably available, and characterize exposed aquatic populations.
- Weight of the scientific evidence of environmental occurrence data and modeled estimates.
- 5) Evaluate the weight of the scientific evidence of environmental occurrence data and modeled estimates.

During risk evaluation, EPA plans to evaluate and integrate the exposure evidence identified in the literature inventory using the methods described in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018).

2.7.2.3 Occupational Exposures

EPA plans to analyze both worker and 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 the OSHA and the 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 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 2-7) 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 2-7. 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 physical and chemical 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 (OECD, 2015) and the 2009 ESD on Plastic Additives (OECD, 2009b) are some of the ESDs and GS's that EPA may use to estimate occupational exposures. EPA plans to critically review these generic scenarios and ESDs to determine their applicability to the conditions of use assessed. EPA may conduct industry outreach or perform additional supplemental targeted searches of peer-reviewed or gray literature 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 such targeted supplemental searches to identify applicable models that EPA may use to estimate exposures for certain conditions of use.

4) Review reasonably available data that may be used in developing, adapting or applying exposure models to a particular risk evaluation scenario.

This step will be performed after #2 and #3 are completed, and based on information developed from #2 and #3, EPA plans to evaluate relevant data to determine whether the data can be used to develop, adapt, or apply models for specific conditions of use (and corresponding exposure scenarios). EPA may utilize existing, peer-reviewed exposure models developed by EPA, other government agencies, or reasonably available in the scientific literature, or EPA may elect to develop additional models to assess specific condition(s) of use. Inhalation exposure models may be simple box models or two-zone (near-field/far-field) models. In two-zone models, the near-field exposure represents potential inhalation exposures to workers, and the far-field exposure represents potential inhalation exposures to 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. OSHA recommends employers utilize the hierarchy of controls to address hazardous exposures in the workplace. The hierarchy of controls strategy outlines, in descending order of priority, the use of elimination, substitution, engineering controls, administrative controls, and lastly personal protective equipment (PPE). EPA plans to assess worker exposure pre- and post-implementation of EC, using reasonably available information on 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 completed an initial mapping of exposure scenarios to conditions of use. EPA plans to refine mapping or grouping of occupational exposure scenarios based on factors (*e.g.*, process equipment and handling, magnitude of production volume used, and exposure/release sources) corresponding to conditions of use as additional information is identified. EPA may perform supplemental targeted searches of peer-reviewed or gray literature to better understand certain conditions of use to further develop exposure scenarios.

7) Evaluate the weight of the scientific evidence of occupational exposure data, which may include qualitative and quantitative sources of information.

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

evidence when evaluating and integrating occupational data. EPA plans to integrate the data using systematic review methods to assemble the relevant data, evaluate the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence.

2.7.2.4 Consumer Exposures

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

1) Group each condition of use to consumer exposure assessment scenario(s).

Refine and finalize exposure scenarios for consumers by considering combinations of sources (ongoing consumer uses), exposure pathways including routes, and exposed populations.

For di-ethylhexyl phthalate, the following are noteworthy considerations in constructing consumer exposure scenarios:

- Conditions of use
- Duration, frequency and magnitude of exposure
- Weight fraction of chemical in products
- Amount of chemical used

2) Evaluate the relative potential of indoor exposure pathways based on reasonably available data.

Based on physical and chemical properties of di-ethylhexyl phthalate and the consumer uses identified, inhalation of particles is expected to be an important indoor exposure pathway for consumers. Other pathways include dust ingestion, mouthing of articles and dermal contact to liquids or articles as a result of indoor use of di-ethylhexyl phthalate consumer products. Inhalation of vapor and mist and oral ingestion of liquid and mist are also possible. The data sources associated with the inhalation, oral, and dermal pathways have not been comprehensively evaluated, so quantitative comparisons across exposure pathways have not yet been made. EPA plans to review all reasonably available information in developing the consumer exposure scenarios and evaluating the exposure pathways in indoor environments.

3) Review existing indoor exposure models that may be applicable in estimating indoor air exposures.

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

There are models that also estimate emission and migration of semi-volatile organic compounds (SVOCs) into the indoor environment models. These models generally consider indoor fate and transport properties such as mass transfer as informed by the gas-phase mass transfer coefficient, the solid-phase diffusion coefficient and the material-air partition coefficient. These properties vary based on physical and chemical properties and properties of the material. The OPPT's Indoor Environmental Concentrations in Buildings with Conditioned and Unconditioned Zones

(IECCU) model and other similar models can be used to estimate indoor air and dust exposures from indoor sources.

4) Review reasonably available empirical data that may be used in developing, adapting or applying exposure models to a particular risk evaluation scenario. For example, existing models developed for a chemical assessment may be applicable to another chemical assessment if model parameter data are reasonably available. To the extent other organizations have already modeled a di ethylbeavel phthalate consumer

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 diethylhexyl phthalate in specific media (*e.g.*, dust or indoor air).

The availability of di-ethylhexyl phthalate concentration for various conditions of use will be evaluated. This data provides the source term for any subsequent indoor modeling. EPA plans to analyze source attribution between overall indoor air and dust levels and various indoor sources will be analyzed.

6) Review reasonably available population- or subpopulation-specific exposure factors and activity patterns to determine if PESS need to be refined.

For di-ethylhexyl phthalate, EPA plans to evaluate exposure scenarios that involve PESS and plans to consider age-specific behaviors, activity patterns and exposure factors unique to those subpopulations. For some exposure scenarios related to consumer uses, EPA plans to consider whether exposures for adults may different from those of children due to different activities (*e.g.*, children may mouth certain products) or exposure factors (*e.g.*, inhalation rates).

7) Evaluate the weight of the scientific evidence of consumer exposure estimates based on different approaches.

EPA plans to rely on the weight of the scientific evidence when evaluating and integrating data related to consumer exposure. The weight of the scientific evidence may include qualitative and quantitative sources of information. EPA plans to integrate the data using systematic review methods to assemble the relevant data, evaluate the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence.

2.7.2.5 General Population

EPA does not plan to analyze general population exposures, based on a review of exposure pathways as described in Section 2.6.3.1. EPA does not plan to include in the risk evaluation pathways under programs of other environmental statutes administered by EPA.

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 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 organisms.

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

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

2) Derive hazard thresholds for aquatic 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 species. Identified environmental hazard thresholds may be used to derive concentrations of concern (COC), based on endpoints that may affect populations of organisms or taxa analyzed.

3) Evaluate the weight of the scientific evidence of environmental hazard data.

During risk evaluation, EPA plans to evaluate and integrate the environmental hazard evidence identified in the literature inventory using the methods described in the *Application of Systematic Review in TSCA Risk Evaluation* (U.S. EPA, 2018).

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

EPA plans to consider the persistence, bioaccumulation, and toxic (PBT) potential of diethylhexyl phthalate after reviewing relevant physical and chemical properties and exposure pathways. EPA plans to assess the reasonably available studies collected from the systematic review process relating to bioaccumulation and bioconcentration (*e.g.*, BAF, BCF) of diethylhexyl phthalate. In addition, EPA plans to integrate traditional environmental hazard endpoint values (*e.g.*, LC50, 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).

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

2.7.3.2 Human Health Hazards

EPA plans to analyze human health hazards as follows:

Review reasonably available human health hazard data, including data from alternative test methods (*e.g.*, computational toxicology and bioinformatics; high-throughput screening methods; data on categories and read-across; *in vitro* studies; systems biology).
 EPA plans to evaluate human health studies using the evaluation strategies laid out in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018) and updates to the epidemiological data quality criteria released with the first ten risk evaluations. The study evaluation results will be documented in the risk evaluation phase and data from acceptable studies will be extracted and integrated in the risk evaluation process.

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

2) In evaluating reasonably available data, determine whether particular human receptor groups may have greater susceptibility to the chemical's hazard(s) than the general population.

Reasonably available human health hazard data will be evaluated to ascertain whether some human receptor groups may have greater susceptibility than the general population to diethylhexyl phthalate hazard(s). Susceptibility of particular human receptor groups to diethylhexyl phthalate will be determined by evaluating information on factors that influence susceptibility.

EPA has reviewed some sources containing hazard information associated with susceptible populations and lifestages such as pregnant women and infants. Pregnancy (*i.e.*, gestation) and childhood are potential susceptible lifestages for di-ethylhexyl phthalate exposure. EPA may quantify these differences in the risk evaluation following further evaluation of the reasonably available data and information.

3) Conduct hazard identification (the qualitative process of identifying non-cancer and cancer endpoints) and dose-response assessment (the quantitative relationship between hazard and exposure) for identified human health hazard endpoints.

Human health hazards from acute and chronic exposures will be identified by evaluating the human and animal data that meet the systematic review data quality criteria described in the *Application of Systematic Review in TSCA Risk Evaluation* (U.S. EPA, 2018). Hazards identified by studies meeting data quality criteria will be grouped by routes of exposure relevant to humans (*e.g.*, oral, dermal, inhalation) and by the cancer and noncancer endpoints identified in Section 2.4.2.

Dose-response assessment will be performed in accordance with EPA guidance (U.S. EPA, 2012a, 2011b, 1994) developing points of departure (POD) for either margins of exposure (MOEs), cancer slope factors (CSFs), oral slope factors (OSFs), and/or inhalation unit risks (IURs). Dose-response analyses may be used if the data meet data quality criteria and if additional information on the identified hazard endpoints are not reasonably available or would not alter the analysis.

The cancer mode of action (MOA) analyses determine the relevancy of animal data to human risk and how data can be quantitatively evaluated. If cancer hazard is determined to be applicable to di-ethylhexyl phthalate, EPA plans to evaluate information on genotoxicity and the MOA for all cancer endpoints to determine the appropriate approach for quantitative cancer assessment in accordance with the *U.S. EPA Guidelines for Carcinogen Risk Assessment* (U.S. EPA, 2005a). In accordance with EPA's *Supplemental Guidance for Assessing Susceptibility from Early-life Exposures to Carcinogens* (U.S. EPA, 2005b), EPA plans to determine whether age-dependent adjustment factors (ADAFs) are appropriate for di-ethylhexyl phthalate for specific conditions of use based upon potential exposures to children.

4) Derive points of departure (PODs) where appropriate; conduct benchmark dose modeling depending on the reasonably available data. Adjust the PODs as appropriate to conform (*e.g.*, adjust for duration of exposure) to the specific exposure scenarios evaluated. Hazard data will be evaluated to determine the type of dose-response modeling that is applicable. Where modeling is feasible, a set of dose-response models that are consistent with a variety of potentially underlying biological processes will be applied to empirically model the dose-response relationships in the range of the observed data consistent with the EPA's *Benchmark Dose Technical Guidance Document* (U.S. EPA, 2012a). Where dose-response modeling is not feasible, NOAELs or LOAELs will be identified. Non-quantitative data will also be evaluated for contribution to weight of the scientific evidence or for evaluation of qualitative endpoints that are not appropriate for dose-response assessment.

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

5) Evaluate the weight of the scientific evidence of human health hazard data.

During risk evaluation, EPA plans to evaluate and integrate the human health hazard evidence identified in the literature inventory under acute and chronic exposure conditions using the methods described in the *Application of Systematic Review in TSCA Risk Evaluation* (U.S. EPA, 2018).

6) Consider the route(s) of exposure (*e.g.*, oral, inhalation, dermal), reasonably available route-to-route extrapolation approaches; biomonitoring data; and approaches to correlate internal and external exposures to integrate exposure and hazard assessment. At this stage of review, EPA believes there will be sufficient reasonably available data to conduct a dose-response analysis and/or benchmark dose modeling for the oral route of exposure. EPA plans to also evaluate any potential human health hazards following dermal and inhalation exposure to di-ethylhexyl phthalate, which could be important for worker, consumer and general population risk analysis. Reasonably available data will be assessed to determine whether or not a point of departure can be identified for the dermal and inhalation routes.

If sufficient reasonably available toxicity studies are not identified through the systematic review process to assess risks from inhalation or dermal exposure, then a route-to-route extrapolation may be needed. The preferred approach is to use a PBPK model (U.S. EPA, 2006a). Without an adequate PBPK model, considerations regarding the adequacy of data for route-to-route extrapolation are described in *Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry* (U.S. EPA, 1994). EPA may use these considerations when determining whether to extrapolate from the oral to the inhalation route of exposure. Similar approaches for oral-to-dermal route extrapolation are described in EPA guidance document *Risk Assessment Guidance for Superfund Volume I: Human Health Evaluation Manual (Part E, Supplemental Guidance for Dermal Risk Assessment)* (U.S. EPA, 2004).

If there are acceptable inhalation data after completion of systematic review, EPA may also consider extrapolating from the inhalation to the dermal route if first-pass metabolism through the liver via the oral route is expected because in that case, use of data from the oral route is not recommended (U.S. EPA, 1994). EPA may also consider inhalation-to-dermal route extrapolation if an inhalation toxicity study with a sensitive hazard endpoint is used to evaluate risks. Based on these considerations, EPA extrapolated from the inhalation to the dermal route for several of the first ten risk evaluations under amended TSCA, including methylene chloride (U.S. EPA, 2020d) and carbon tetrachloride (U.S. EPA, 2020b).

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

2.7.4 Summary of Risk Approaches for Characterization

Risk characterization is an integral component of the risk assessment process for both environmental and human health risks. EPA plans to derive the risk characterization in accordance with 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." (U.S. EPA, 2000). Risk characterization is considered to be a conscious and deliberate process to bring all important considerations about risk, not only the likelihood of the risk but also the strengths and limitations of the assessment, and a description of how others have assessed the risk into an integrated picture.

The level of information contained in each risk characterization varies according to the type of assessment for which the characterization is written. Regardless of the level of complexity or information, the risk characterization for TSCA risk evaluations will be prepared in a manner that is transparent, clear, consistent, and reasonable (U.S. EPA, 2000), and consistent with the requirements of the *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act* (82 FR 33726, July 20, 2017). As discussed in 40 CFR 702.43, risk characterization has a number of considerations. This is the step where EPA integrates the hazard and exposure assessments into risk estimates for the identified populations (including any PESS) and ecological characteristics and weighs the scientific evidence for the identified hazards and exposures. The risk characterization does not consider costs or other nonrisk factors, and takes into account, "where relevant, the likely duration, intensity, frequency, and number of exposures under the condition(s) of use...." The risk characterization also summarizes the following considerations: (1) uncertainty and variability in each step of the risk evaluation; (2) data quality, and any applicable assumptions used; (3) alternative interpretations of data and analyses, where appropriate; and (4) any considerations for environmental risk evaluations, if necessary (*e.g.*, related to nature and magnitude of effects).

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

2.8 Peer Review

Peer review will be conducted in accordance with EPA's regulatory procedures for chemical risk evaluations, including using EPA's Peer Review Handbook (U.S. EPA, 2015b) and other methods consistent with Section 26 of TSCA (see 40 CFR 702.45). As explained in the Risk Evaluation Rule, the purpose of peer review is for the independent review of the science underlying the risk assessment. Peer review will therefore address aspects of the underlying science as outlined in the charge to the peer review panel such as hazard assessment, assessment of dose-response, exposure assessment, and risk characterization. The draft risk evaluation for di-ethylhexyl phthalate will be peer reviewed.
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APPENDICES

Appendix A ABBREVIATED METHODS FOR SEARCHING AND SCREENING

A.1 Literature Search of Publicly Available Databases

A.1.1 Search Term Genesis and Chemical Verification

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

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

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

CHEMICAL SOURCE	CONTENTS	DOCUMENT LOCATION
Chemistry Dashboard	CAS Numbers, Synonyms, Structures,	Online
(https://comptox.epa.gov/dashboard)	Properties, Environmental Fate and Transport.	
Dictionary of Chemical Names and Synonyms	Wide assortment of chemical compounds by	ECOTOX
	and some structure data	
Farm Chemicals Handbook-1992	Pesticide information, CAS numbers and	ECOTOX
	synonyms, some structure data	
	***Sometimes CAS number presented for a	
	compound is for the main constituent only	
OPPT SMILES Verification Source	Structure Data	Electronic verification
RTECS (Registry of Toxic Effects of	Chemical names, synonyms and CAS numbers	ECOTOX
chemical substance, 1983-84 ed., 2 vols)		
Sigma – Aldrich website58784	Organic and inorganic Compounds by chemical	Online
http://www.sigma-aldrich.com	name, has CAS index and some structure and	
	Physical Property data	

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

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

A.1.2 Publicly Available Database Searches

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

After initial deduplication in HERO¹⁰, these studies were imported into <u>SWIFT Review</u> software (<u>Howard et al., 2016</u>) to identify those references most likely to be applicable to each discipline area (*i.e.* consumer, environmental, and general population exposure, occupational exposure and environmental releases, environmental hazards, human health hazards, and fate and physical chemistry).

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

Table_Apx A-2 presents a list of the data sources, the search dates and number of peer-reviewed references resulting from the searches for di-ethylhexyl phthalate. The sources are found as online databases and the resulting references were gathered and uploaded into the EPA Health and

⁹EPA's HERO database provides access to the scientific literature behind EPA science assessments. The database includes more than 600,000 scientific references and data from the peer-reviewed literature used by EPA to develop its regulations.

¹⁰ Deduplication in HERO involves first determining whether a matching unique ID exists (*e.g.*, PMID, WOSid, or DOI). If one matches one that already exists in HERO, HERO will tag the existing reference instead of adding the reference again. Second, HERO checks if the same journal, volume, issue and page number are already in HERO. Third, HERO matches on the title, year, and first author. Title comparisons ignore punctuation and case.

Environmental Research Online (HERO) database for literature screening.

Enterature Search Results for Difethymexyl I nenatate (DEATH)				
Source	Date of Search	Number of References		
Current Contents	07/05/2019	9488		
WOS Core Collection	09/11/2019	14,279		
ProQuest CSA	07/05/2019	13,506		
Dissertation Abstracts	07/11/2019	85		
Science Direct	07/05/2019	3332		
Agricola	07/10/2019	3391		
TOXNET	07/08/2019	3376		
PubMed	07/08/2019	8331		
UNIFY	07/23/2019	523		
Totals:		56,311		

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

<u>GENERAL</u>:

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

"1,2-Benzenedicarboxylic acid, 1,2-diisooctyl ester" OR "1,2-Benzedicarboxylic acid, bis(2-ethyl-hexyl) ester" OR "1,2-Benzenedicarboxylic acid bis(2-ethylhexyl) ester" OR "1,2-Benzenedicarboxylic acid, 1,2-bis(2-ethylhexyl) ester" OR "1,2-Benzenedicarboxylic acid, 1,2-diisooctyl ester" OR "1,2-Benzenedicarboxylic acid, bis(2-ethylhexyl) ester" OR "1,2-Benzenedicarboxylic acid, bis(2ethylhexyl)ester" OR "1,2-Benzenedicarboxylic acid, Butyl phenylmethyl ester" OR "1,2-Benzenedicarboxylic acid, diisooctyl ester" OR "1,2-Benzenedicarboxylic acid,bis(2-ethylhexylester)" OR "2-Ethylhexyl phthalate" OR "AI3-27697-X" OR "Bis(2-ethylhexyl) 1,2-benzenedicarboxylate" OR "Bis(2-ethylhexyl) benzene-1,2-dicarboxylate" OR "Bis(2-ethylhexyl) o-phthalate" OR "Bis(2ethylhexyl) phthalate" OR "Bis(2-ethylhexyl)ester, Phthalic acid" OR "Bis(2-ethylhexyl)phthalat" OR "Bis(2-ethylhexyl)phthalate" OR "Bis-(2-ethylhexyl)-phthalate" OR "Bis(ethylhexyl) phthalate" OR "Bisoflex 81" OR "Bisoflex DOP" OR "BRN 1890696" OR "Butylbenzyl Phthalate" OR "Butylbenzylphthalate" OR "Caswell No. 392K" OR "Codan Set L 86P" OR "Compound 889" OR "Corflex 400" OR "Corflex 880" OR "DEHP" OR "Di(2-ethylhexyl) o-phthalate" OR "Di(2-ethylhexyl) orthophthalate" OR "Di(2-ethylhexyl) phthalate" OR "Di-(2-ethylhexyl) phthalate" OR "Di(2ethylhexyl)orthophthalate" OR "Di(2-ethylhexyl)phthalate" OR "di(alpha-Ethylhexyl) phthalate" OR "Di(ethylhexyl) phthalate" OR "Di-(Ethylhexyl)phthalate" OR "Di(isooctyl) phthalate" OR "Di-2ethylhexlphthalate" OR "Di-2-ethylhexyl phthalate" OR "DI-2-ETHYLHEXYL-PHTHALATE" OR "Diacizer DOP" OR "Diethylhexyl phthalate" OR "Di-ethylhexyl phthalate" OR "Diethylhexylphthalate" OR "Diisooctyl 1,2-benzenedicarboxylate"

"Diisooctyl ester 1,2-Benzenedicarboxylic acid" OR "Diisooctyl o-phthalate" OR "Diisooctyl phthalate" OR "di-iso-Octyl phthalate" OR "Diisooctylphthalat" OR "Diisooctylphthalate" OR "Dioctyl phthalate" OR "Dioctyl phthalate" OR "Diplast O" OR "Di-sec-octyl phthalate" OR "Ergoplast FDO" OR "Ergoplast FDO-S" OR "ESBO-D 82" OR "Etalon" OR "Ethylhexyl phthalate" OR "Ethylhexyl phthlate" OR "Eviplast 80" OR "Eviplast 81" OR "Fleximel" OR "Flexol DOD" OR "Flexol DOP" OR "Flexol Plasticizer DIOP" OR "Flexol Plasticizer DOP" OR "Garbeflex DOP-D 40" OR "Good-rite GP 264" OR "Hatco DOP" OR "Hatcol DOP" OR "Hercoflex 260" OR "Hexaplas DIOP" OR "Hexaplas M/O" OR "Isooctyl phthalate" OR "Isooctyl phthalate" OR "Jayflex DIOP" OR "Jayflex DOP" OR "JSSD-DOP" OR "Kodaflex DEHP" OR "Kodaflex DOP" OR "Mollan O" OR "Monocizer DOP" OR "NCI-C52733" OR "NSC 17069" OR "NSC 6381" OR "Nuoplaz DOP" OR "Octoil" OR "Octyl phthalate" OR "Palatinol AH" OR "Palatinol AH-L" OR "Palatinol DOP" OR "PHTHALATE, BIS(2-ETHYLHEXYL)" OR "Phthalic acid bis(2ethylhexyl) ester" OR "Phthalic acid di(2-ethylhexyl) ester"

"Phthalic acid dioctyl ester" OR "Phthalic acid, bis(2-ethylhexyl) ester" OR "PHTHALIC ACID, BIS(2-ETHYLHEXYL)ESTER" OR "Phthalic acid, bis(6-methylheptyl)ester" OR "Phthalic acid, diisooctyl ester" OR "Pittsburgh PX 138" OR "Pittsburgh PX-138" OR "Plasthall DOP" OR "Platinol AH" OR "Platinol DOP" OR "RC Plasticizer DOP" OR "RCRA waste number U028" OR "Reomol D 79P" OR "Reomol DOP" OR "Sansocizer DOP" OR "Sansocizer R 8000" OR "Scandinol SC 1000" OR "Sconamoll DOP" OR "Sicol 150" OR "Staflex DOP" OR "Truflex DOP" OR "Unem 5005" OR "UNII-6A121LGB40" OR "UNII-C42K0PH13C" OR "Vestinol AH" OR "Vinicizer 80" OR "Vinycizer 80" OR "Vinycizer 312"

CURRENT CONTENTS CONNECT: (access.webofknowledge.com)

General search terms applied to the search strategy for Current Contents. Date Searched: 07/05/2019Date Range of Search: 1998 to Present N = 9488

Current Contents 01:

TS=("1,2-Benzenedicarboxylic acid, 1,2-diisooctyl ester" OR "1,2-Benzedicarboxylic acid, bis(2-ethylhexyl) ester" OR "1,2-Benzenedicarboxylic acid bis(2-ethylhexyl) ester" OR "1,2-Benzenedicarboxylic acid, 1,2-bis(2-ethylhexyl) ester" OR "1,2-Benzenedicarboxylic acid, 1,2-diisooctyl ester" OR "1,2-Benzenedicarboxylic acid, bis(2-ethylhexyl) ester" OR "1,2-Benzenedicarboxylic acid, bis(2ethylhexyl)ester" OR "1,2-Benzenedicarboxylic acid, Butyl phenylmethyl ester" OR "1,2-Benzenedicarboxylic acid, diisooctyl ester" OR "1,2-Benzenedicarboxylic acid,bis(2-ethylhexylester)" OR "2-Ethylhexyl phthalate" OR "AI3-27697-X" OR "Bis(2-ethylhexyl) 1,2-benzenedicarboxylate" OR "Bis(2-ethylhexyl) benzene-1,2-dicarboxylate" OR "Bis(2-ethylhexyl) o-phthalate" OR "Bis(2ethylhexyl) phthalate" OR "Bis(2-ethylhexyl)ester, Phthalic acid" OR "Bis(2-ethylhexyl)phthalat" OR "Bis(2-ethylhexyl)phthalate" OR "Bis-(2-ethylhexyl)-phthalate" OR "Bis(ethylhexyl) phthalate" OR "Bisoflex 81" OR "Bisoflex DOP" OR "BRN 1890696" OR "Butylbenzyl Phthalate" OR "Butylbenzylphthalate" OR "Caswell No. 392K" OR "Codan Set L 86P" OR "Compound 889" OR "Corflex 400" OR "Corflex 880" OR "DEHP" OR "Di(2-ethylhexyl) o-phthalate" OR "Di(2-ethylhexyl) orthophthalate" OR "Di(2-ethylhexyl) phthalate" OR "Di-(2-ethylhexyl) phthalate" OR "Di(2ethylhexyl)orthophthalate" OR "Di(2-ethylhexyl)phthalate" OR "di(alpha-Ethylhexyl) phthalate" OR "Di(ethylhexyl) phthalate" OR "Di-(Ethylhexyl)phthalate" OR "Di(isooctyl) phthalate" OR "Di-2ethylhexlphthalate" OR "Di-2-ethylhexyl phthalate" OR "DI-2-ETHYLHEXYL-PHTHALATE" OR "Diacizer DOP" OR "Diethylhexyl phthalate" OR "Di-ethylhexyl phthalate" OR "Diethylhexylphthalate" OR "Diisooctyl 1,2-benzenedicarboxylate") N = 4128

Current Contents 02:

TS=("Diisooctyl ester 1,2-Benzenedicarboxylic acid" OR "Diisooctyl o-phthalate" OR "Diisooctyl phthalate" OR "di-iso-Octyl phthalate" OR "Diisooctylphthalat" OR "Diisooctylphthalate" OR "Dioctyl

phthalate" OR "Diplast O" OR "Di-sec-octyl phthalate" OR "Ergoplast FDO" OR "Ergoplast FDO-S" OR "ESBO-D 82" OR "Etalon" OR "Ethylhexyl phthalate" OR "Ethylhexyl phthlate" OR "Eviplast 80" OR "Eviplast 81" OR "Fleximel" OR "Flexol DOD" OR "Flexol DOP" OR "Flexol Plasticizer DIOP" OR "Flexol Plasticizer DOP" OR "Garbeflex DOP-D 40" OR "Good-rite GP 264" OR "Hatco DOP" OR "Hatcol DOP" OR "Hercoflex 260" OR "Hexaplas DIOP" OR "Hexaplas M/O" OR "Isooctyl phthalate" OR "Isooctylphthalate" OR "Jayflex DIOP" OR "Jayflex DOP" OR "JSSD-DOP" OR "Kodaflex DEHP" OR "Kodaflex DOP" OR "Mollan O" OR "Monocizer DOP" OR "NCI-C52733" OR "NSC 17069" OR "NSC 6381" OR "Nuoplaz DOP" OR "Octoil" OR "Octyl phthalate" OR "Palatinol AH" OR "Palatinol AH-L" OR "Palatinol DOP" OR "PHTHALATE, BIS(2-ETHYLHEXYL)" OR "Phthalic acid bis(2ethylhexyl) ester" OR "Phthalic acid di(2-ethylhexyl) ester") N = 5359

Current Contents 03:

TS=("Phthalic acid dioctyl ester" OR "Phthalic acid, bis(2-ethylhexyl) ester" OR "PHTHALIC ACID, BIS(2-ETHYLHEXYL)ESTER" OR "Phthalic acid, bis(6-methylheptyl)ester" OR "Phthalic acid, diisooctyl ester" OR "Pittsburgh PX 138" OR "Pittsburgh PX-138" OR "Plasthall DOP" OR "Platinol AH" OR "Platinol DOP" OR "RC Plasticizer DOP" OR "RCRA waste number U028" OR "Reomol D 79P" OR "Reomol DOP" OR "Sansocizer DOP" OR "Sansocizer R 8000" OR "Scandinol SC 1000" OR "Sconamoll DOP" OR "Sicol 150" OR "Staflex DOP" OR "Truflex DOP" OR "Unem 5005" OR "UNII-6A121LGB40" OR "UNII-C42K0PH13C" OR "Vestinol AH" OR "Vinicizer 80" OR "Vinycizer 80" N = 1

WOS Core Collection: (https://intranet.epa.gov/desktop/databases.htm

General Search Terms applied to the search strategy for WOS Core Collection Date Searched: 09/11/2019Date Range of Search: 1998 to Present N = 14,279

WOS Core Collection 01:

TS=("1,2-Benzenedicarboxylic acid, 1,2-diisooctyl ester" OR "1,2-Benzedicarboxylic acid, bis(2-ethylhexyl) ester" OR "1,2-Benzenedicarboxylic acid bis(2-ethylhexyl) ester" OR "1,2-Benzenedicarboxylic acid, 1,2-bis(2-ethylhexyl) ester" OR "1,2-Benzenedicarboxylic acid, 1,2-diisooctyl ester" OR "1,2-Benzenedicarboxylic acid, bis(2-ethylhexyl) ester" OR "1,2-Benzenedicarboxylic acid, bis(2ethylhexyl)ester" OR "1,2-Benzenedicarboxylic acid, Butyl phenylmethyl ester" OR "1,2-Benzenedicarboxylic acid, diisooctyl ester" OR "1,2-Benzenedicarboxylic acid,bis(2-ethylhexylester)" OR "2-Ethylhexyl phthalate" OR "AI3-27697-X" OR "Bis(2-ethylhexyl) 1,2-benzenedicarboxylate" OR "Bis(2-ethylhexyl) benzene-1,2-dicarboxylate" OR "Bis(2-ethylhexyl) o-phthalate" OR "Bis(2ethylhexyl) phthalate" OR "Bis(2-ethylhexyl)ester, Phthalic acid" OR "Bis(2-ethylhexyl)phthalat" OR "Bis(2-ethylhexyl)phthalate" OR "Bis-(2-ethylhexyl)-phthalate" OR "Bis(ethylhexyl) phthalate" OR "Bisoflex 81" OR "Bisoflex DOP" OR "BRN 1890696" OR "Butylbenzyl Phthalate" OR "Butylbenzylphthalate" OR "Caswell No. 392K" OR "Codan Set L 86P" OR "Compound 889" OR "Corflex 400" OR "Corflex 880" OR "DEHP" OR "Di(2-ethylhexyl) o-phthalate" OR "Di(2-ethylhexyl) orthophthalate" OR "Di(2-ethylhexyl) phthalate" OR "Di-(2-ethylhexyl) phthalate" OR "Di(2ethylhexyl)orthophthalate" OR "Di(2-ethylhexyl)phthalate" OR "di(alpha-Ethylhexyl) phthalate" OR "Di(ethylhexyl) phthalate" OR "Di-(Ethylhexyl)phthalate" OR "Di(isooctyl) phthalate" OR "Di-2ethylhexlphthalate" OR "Di-2-ethylhexyl phthalate" OR "DI-2-ETHYLHEXYL-PHTHALATE" OR "Diacizer DOP" OR "Diethylhexyl phthalate" OR "Di-ethylhexyl phthalate" OR

"Diethylhexylphthalate" OR "Diisooctyl 1,2-benzenedicarboxylate") N = 5864

WOS Core Collection 02:

TS=("Diisooctyl ester 1,2-Benzenedicarboxylic acid" OR "Diisooctyl o-phthalate" OR "Diisooctyl phthalate" OR "Ergoplast FDO" OR "Ergoplast FDO-S" OR "ESBO-D 82" OR "Etalon" OR "Ethylhexyl phthalate" OR "Ethylhexyl phthalate" OR "Eviplast 81" OR "Fleximel" OR "Flexol DOD" OR "Flexol DOP" OR "Flexol Plasticizer DIOP" OR "Flexol Plasticizer DOP" OR "Garbeflex DOP-D 40" OR "Good-rite GP 264" OR "Hatco DOP" OR "Hatco DOP" OR "Hercoflex 260" OR "Hexaplas DIOP" OR "Hexaplas M/O" OR "Isooctyl phthalate" OR "Isooctyl phthalate" OR "Jayflex DIOP" OR "Jayflex DOP" OR "Stodaflex DEHP" OR "Kodaflex DOP" OR "Monocizer DOP" OR "NCI-C52733" OR "NSC 17069" OR "NSC 6381" OR "Nuoplaz DOP" OR "Octoil" OR "Octyl phthalate" OR "Palatinol AH" OR "Palatinol AH-L" OR "Palatinol DOP" OR "PHTHALATE, BIS(2-ETHYLHEXYL)" OR "Phthalic acid bis(2-ethylhexyl) ester") N = 8413

WOS Core Collection 03:

TS=("Phthalic acid dioctyl ester" OR "Phthalic acid, bis(2-ethylhexyl) ester" OR "PHTHALIC ACID, BIS(2-ETHYLHEXYL)ESTER" OR "Phthalic acid, bis(6-methylheptyl)ester" OR "Phthalic acid, diisooctyl ester" OR "Pittsburgh PX 138" OR "Pittsburgh PX-138" OR "Plasthall DOP" OR "Platinol AH" OR "Platinol DOP" OR "RC Plasticizer DOP" OR "RCRA waste number U028" OR "Reomol D 79P" OR "Reomol DOP" OR "Sansocizer DOP" OR "Sansocizer R 8000" OR "Scandinol SC 1000" OR "Sconamoll DOP" OR "Sicol 150" OR "Staflex DOP" OR "Truflex DOP" OR "Unem 5005" OR "UNII-6A121LGB40" OR "UNII-C42K0PH13C" OR "Vestinol AH" OR "Vinicizer 80" OR "Vinycizer 80" N = 2

PROQUEST Agricultural and Scientific Database: (www.csa.com)

General Search Terms applied to the search strategy for ProQuest Agricultural and Scientific Database. Date Searched: 07/05/2019Date Range of Search: 1900 to Present N = 13,506

PROQUEST 01:

ALL("1,2-Benzenedicarboxylic acid, 1,2-diisooctyl ester" OR "1,2-Benzedicarboxylic acid, bis(2-ethylhexyl) ester" OR "1,2-Benzenedicarboxylic acid bis(2-ethylhexyl) ester" OR "1,2-Benzenedicarboxylic acid, 1,2-bis(2-ethylhexyl) ester" OR "1,2-Benzenedicarboxylic acid, 1,2-diisooctyl ester" OR "1,2-Benzenedicarboxylic acid, bis(2-ethylhexyl) benzene-1,2-dicarboxylate" OR "Bis(2-ethylhexyl) 1,2-benzenedicarboxylate" OR "Bis(2-ethylhexyl) benzene-1,2-dicarboxylate" OR "Bis(2-ethylhexyl) o-phthalate" OR "Bis(2-ethylhexyl) phthalate" OR "Bisoflex 81" OR "Bisoflex DOP" OR "BRN 1890696" OR "Butylbenzyl Phthalate" OR "Compound 889" OR "Butylbenzylphthalate" OR "Compound 889" OR

"Corflex 400" OR "Corflex 880" OR "DEHP" OR "Di(2-ethylhexyl) o-phthalate" OR "Di(2-ethylhexyl) orthophthalate" OR "Di(2-ethylhexyl) phthalate" OR "Di(2-ethylhexyl) phthalate" OR "Di(2-ethylhexyl) phthalate" OR "Di(2-ethylhexyl) phthalate" OR "di(alpha-Ethylhexyl) phthalate" OR "Di(ethylhexyl) phthalate" OR "Di-(Ethylhexyl)phthalate" OR "Di(isooctyl) phthalate" OR "Di-2-ethylhexyl phthalate" OR "Di-2-ETHYLHEXYL-PHTHALATE" OR "Diacizer DOP" OR "Diethylhexyl phthalate" OR "Di-ethylhexyl phthalate" OR "Diethylhexyl phthalate" OR "Di-ethylhexyl phthalate" OR "Di-2-ethylhexyl phthalate" OR "Di-2-ETHYLHEXYL-PHTHALATE" OR "Diacizer DOP" OR "Diethylhexyl phthalate" OR "Di-ethylhexyl phthalate" OR "Di-2-ethylhexyl phthalate" OR "Di-2-Ethylhexy

PROQUEST 02:

ALL("Diisooctyl ester 1,2-Benzenedicarboxylic acid" OR "Diisooctyl o-phthalate" OR "Diisooctyl phthalate" OR "Ergoplast FDO-S" OR "ESBO-D 82" OR "Etalon" OR "Ethylhexyl phthalate" OR "Ethylhexyl phthalate" OR "Eviplast 80" OR "Eviplast 81" OR "Fleximel" OR "Flexol DOD" OR "Flexol DOP" OR "Flexol Plasticizer DIOP" OR "Flexol Plasticizer DOP" OR "Garbeflex DOP-D 40" OR "Good-rite GP 264" OR "Hatco DOP" OR "Hatco DOP" OR "Hercoflex 260" OR "Hexaplas DIOP" OR "Hexaplas M/O" OR "Isooctyl phthalate" OR "Isooctyl phthalate" OR "Isooctyl phthalate" OR "Isooctyl phthalate" OR "NCI-C52733" OR "NSC 17069" OR "NSC 6381" OR "Nuoplaz DOP" OR "OR "Octoil" OR "Octyl phthalate" OR "Palatinol AH" OR "Palatinol AH-L" OR "Palatinol DOP" OR "PHTHALATE, BIS(2-ETHYLHEXYL)" OR "Phthalic acid bis(2-ethylhexyl) ester" OR "Phthalic acid di(2-ethylhexyl) ester") AND STYPE("Scholarly Journals" OR Reports OR Thesis OR "Government Documents") AND LA(ENG) N = 6216

PROQUEST 03:

ALL("Phthalic acid dioctyl ester" OR "Phthalic acid, bis(2-ethylhexyl) ester" OR "PHTHALIC ACID, BIS(2-ETHYLHEXYL)ESTER" OR "Phthalic acid, bis(6-methylheptyl)ester" OR "Phthalic acid, diisooctyl ester" OR "Pittsburgh PX 138" OR "Pittsburgh PX-138" OR "Plasthall DOP" OR "Platinol AH" OR "Platinol DOP" OR "RC Plasticizer DOP" OR "RCRA waste number U028" OR "Reomol D 79P" OR "Reomol DOP" OR "Sansocizer DOP" OR "Sansocizer R 8000" OR "Scandinol SC 1000" OR "Sconamoll DOP" OR "Sicol 150" OR "Staflex DOP" OR "Truflex DOP" OR "Unem 5005" OR "UNII-6A121LGB40" OR "UNII-C42K0PH13C" OR "Vestinol AH" OR "Vinicizer 80" OR "Vinycizer 80" OR "Vinycizer 80K" OR "Witcizer 312") AND STYPE("Scholarly Journals" OR Reports OR Thesis OR "Government Documents") AND LA(ENG)

N = 1

PROQUEST Dissertations and Theses: (search.proquest.com)

General Search Terms applied to the search strategy for ProQuest Dissertations and Theses.Date Searched: 07/11/2019Date Range of Search: 1900 to Present N = 85

Dissertations and Theses 01:

ALL("1,2-Benzenedicarboxylic acid, 1,2-diisooctyl ester" OR "1,2-Benzedicarboxylic acid, bis(2-ethylhexyl) ester" OR "1,2-Benzenedicarboxylic acid bis(2-ethylhexyl) ester" OR "1,2-Benzenedicarboxylic acid, 1,2-bis(2-ethylhexyl) ester" OR "1,2-Benzenedicarboxylic acid, 1,2-diisooctyl ester" OR "1,2Benzenedicarboxylic acid, bis(2-ethylhexyl) ester" OR "1,2-Benzenedicarboxylic acid, bis(2ethylhexyl)ester" OR "1,2-Benzenedicarboxylic acid, Butyl phenylmethyl ester" OR "1,2-Benzenedicarboxylic acid, diisooctyl ester" OR "1,2-Benzenedicarboxylic acid,bis(2-ethylhexylester)" OR "2-Ethylhexyl phthalate" OR "AI3-27697-X" OR "Bis(2-ethylhexyl) 1,2-benzenedicarboxylate" OR "Bis(2-ethylhexyl) benzene-1,2-dicarboxylate" OR "Bis(2-ethylhexyl) o-phthalate" OR "Bis(2ethylhexyl) phthalate" OR "Bis(2-ethylhexyl)ester, Phthalic acid" OR "Bis(2-ethylhexyl)phthalat" OR "Bis(2-ethylhexyl)phthalate" OR "Bis-(2-ethylhexyl)-phthalate" OR "Bis(ethylhexyl) phthalate" OR "Bisoflex 81" OR "Bisoflex DOP" OR "BRN 1890696" OR "Butylbenzyl Phthalate" OR "Butylbenzylphthalate" OR "Caswell No. 392K" OR "Codan Set L 86P" OR "Compound 889" OR "Corflex 400" OR "Corflex 880" OR "DEHP" OR "Di(2-ethylhexyl) o-phthalate" OR "Di(2-ethylhexyl) orthophthalate" OR "Di(2-ethylhexyl) phthalate" OR "Di-(2-ethylhexyl) phthalate" OR "Di(2ethylhexyl)orthophthalate" OR "Di(2-ethylhexyl)phthalate" OR "di(alpha-Ethylhexyl) phthalate" OR "Di(ethylhexyl) phthalate" OR "Di-(Ethylhexyl)phthalate" OR "Di(isooctyl) phthalate" OR "Di-2ethylhexlphthalate" OR "Di-2-ethylhexyl phthalate" OR "DI-2-ETHYLHEXYL-PHTHALATE" OR "Diacizer DOP" OR "Diethylhexyl phthalate" OR "Di-ethylhexyl phthalate" OR "Diethylhexylphthalate" OR "Diisooctyl 1.2-benzenedicarboxylate") AND LA(ENG) N = 22

Dissertations and Theses 02:

ALL("Diisooctyl ester 1,2-Benzenedicarboxylic acid" OR "Diisooctyl o-phthalate" OR "Diisooctyl phthalate" OR "Ergoplast FDO-S" OR "ESBO-D 82" OR "Etalon" OR "Ethylhexyl phthalate" OR "Ethylhexyl phthalate" OR "Eviplast 81" OR "Fleximel" OR "Flexol DOD" OR "Flexol DOP" OR "Flexol Plasticizer DIOP" OR "Flexol Plasticizer DOP" OR "Garbeflex DOP-D 40" OR "Good-rite GP 264" OR "Hatco DOP" OR "Hatco DOP" OR "Hexaplas DIOP" OR "Hexaplas M/O" OR "Isooctyl phthalate" OR "Isooctyl phthalate" OR "Jayflex DIOP" OR "Jayflex DOP" OR "Jayflex DOP" OR "NCI-C52733" OR "NSC 17069" OR "NSC 6381" OR "Nuoplaz DOP" OR "Octoil" OR "Octyl phthalate" OR "Palatinol AH" OR "Palatinol AH-L" OR "Palatinol DOP" OR "PHTHALATE, BIS(2-ETHYLHEXYL)" OR "Phthalic acid bis(2-ethylhexyl) ester" OR "Phthalic acid di(2-ethylhexyl) ester") AND LA(ENG) N = 63

Dissertations and Theses 03:

ALL("Phthalic acid dioctyl ester" OR "Phthalic acid, bis(2-ethylhexyl) ester" OR "PHTHALIC ACID, BIS(2-ETHYLHEXYL)ESTER" OR "Phthalic acid, bis(6-methylheptyl)ester" OR "Phthalic acid, diisooctyl ester" OR "Pittsburgh PX 138" OR "Pittsburgh PX-138" OR "Plasthall DOP" OR "Platinol AH" OR "Platinol DOP" OR "RC Plasticizer DOP" OR "RCRA waste number U028" OR "Reomol D 79P" OR "Reomol DOP" OR "Sansocizer DOP" OR "Sansocizer R 8000" OR "Scandinol SC 1000" OR "Sconamoll DOP" OR "Sicol 150" OR "Staflex DOP" OR "Truflex DOP" OR "Unem 5005" OR "UNII-6A121LGB40" OR "UNII-C42K0PH13C" OR "Vestinol AH" OR "Vinicizer 80" OR "Vinycizer 80" OR "Vinyc

SCIENCE DIRECT: (www.sciencedirect.com)

General Search Terms applied to the search strategy for Science Direct Date Searched: 07/05/2019

Date Range of Search: 1823 to Present N = 3332

Science Direct 01:

"1,2-Benzenedicarboxylic acid, 1,2-diisooctyl ester" OR "1,2-Benzedicarboxylic acid, bis(2-ethyl-hexyl) ester" OR "1,2-Benzenedicarboxylic acid bis(2-ethylhexyl) ester" OR "1,2-Benzenedicarboxylic acid, 1,2-bis(2-ethylhexyl) ester" OR "1,2-Benzenedicarboxylic acid, 1,2-diisooctyl ester" OR "1,2-Benzenedicarboxylic acid, 1,2-diisooctyl ester" OR "1,2-Benzenedicarboxylic acid, bis(2-ethylhexyl) ester" OR "1,2-Benzenedicarboxylic acid, bis(2-ethylhexy

Science Direct 02:

"1,2-Benzenedicarboxylic acid,bis(2-ethylhexylester)" OR "2-Ethylhexyl phthalate" OR "AI3-27697-X" OR "Bis(2-ethylhexyl) 1,2-benzenedicarboxylate" OR "Bis(2-ethylhexyl) benzene-1,2-dicarboxylate" OR "Bis(2-ethylhexyl) o-phthalate" OR "Bis(2-ethylhexyl) phthalate" OR "Bis(2-ethylhexyl) phthalate" OR "Bis(2-ethylhexyl) phthalate" OR "Bis(2-ethylhexyl) phthalate" N = 0

Science Direct 03:

"Bis(2-ethylhexyl)phthalate" OR "Bis-(2-ethylhexyl)-phthalate" OR "Bis(ethylhexyl) phthalate" OR "Bisoflex 81" OR "Bisoflex DOP" OR "BRN 1890696" OR "Butylbenzyl Phthalate" OR "Butylbenzylphthalate" OR "Caswell No. 392K" N = 0

Science Direct 04:

"Codan Set L 86P" OR "Compound 889" OR "Corflex 400" OR "Corflex 880" OR "DEHP" OR "Di(2ethylhexyl) o-phthalate" OR "Di(2-ethylhexyl) orthophthalate" OR "Di(2-ethylhexyl) phthalate" OR "Di-(2-ethylhexyl) phthalate"

N = 0

Science Direct 05:

"Di(2-ethylhexyl)orthophthalate" OR "Di(2-ethylhexyl)phthalate" OR "di(alpha-Ethylhexyl) phthalate" OR "Di(ethylhexyl) phthalate" OR "Di-(Ethylhexyl)phthalate" OR "Di(isooctyl) phthalate" OR "Di-2-ethylhexyl phthalate" OR "DI-2-ETHYLHEXYL-PHTHALATE" N = 0

Science Direct 06: "Diacizer DOP" OR "Diethylhexyl phthalate" OR "Di-ethylhexyl phthalate" OR "Diethylhexylphthalate" OR "Diisooctyl 1,2-benzenedicarboxylate" N = 197

Science Direct 07:

"Diisooctyl ester 1,2-Benzenedicarboxylic acid" OR "Diisooctyl o-phthalate" OR "Diisooctyl phthalate" OR "di-iso-Octyl phthalate" OR "Diisooctylphthalat" OR "Diisooctylphthalate" OR "Dioctyl phthalate" OR "Diplast O" OR "Di-sec-octyl phthalate" N = 283

Science Direct 08: "Ergoplast FDO" OR "Ergoplast FDO-S" OR "ESBO-D 82" OR "Etalon" OR "Ethylhexyl phthalate" OR "Ethylhexyl phthlate" OR "Eviplast 80" OR "Eviplast 81" OR "Fleximel" N = 2684Science Direct 09: "Flexol DOD" OR "Flexol DOP" OR "Flexol Plasticizer DIOP" OR "Flexol Plasticizer DOP" OR "Garbeflex DOP-D 40" OR "Good-rite GP 264" OR "Hatco DOP" OR "Hatcol DOP" OR "Hercoflex 260" N = 0Science Direct 10: "Hexaplas DIOP" OR "Hexaplas M/O" OR "Isooctyl phthalate" OR "Isooctylphthalate" OR "Jayflex DIOP" OR "Jayflex DOP" OR "JSSD-DOP" OR "Kodaflex DEHP" OR "Kodaflex DOP" N = 7Science Direct 11: "Mollan O" OR "Monocizer DOP" OR "NCI-C52733" OR "NSC 17069" OR "NSC 6381" OR "Nuoplaz DOP" OR "Octoil" OR "Octyl phthalate" OR "Palatinol AH" N = 161 Science Direct 12: "Palatinol AH-L" OR "Palatinol DOP" OR "PHTHALATE, BIS(2-ETHYLHEXYL)" OR "Phthalic acid bis(2-ethylhexyl) ester" OR "Phthalic acid di(2-ethylhexyl) ester" $\mathbf{N} = \mathbf{0}$ Science Direct 13: "Phthalic acid dioctyl ester" OR "Phthalic acid, bis(2-ethylhexyl) ester" OR "PHTHALIC ACID, BIS(2-ETHYLHEXYL)ESTER" OR "Phthalic acid, bis(6-methylheptyl)ester" OR "Phthalic acid, diisooctyl ester" OR "Pittsburgh PX 138" OR "Pittsburgh PX-138" OR "Plasthall DOP" OR "Platinol AH" N = 0Science Direct 14: "Platinol DOP" OR "RC Plasticizer DOP" OR "RCRA waste number U028" OR "Reomol D 79P" OR "Reomol DOP" OR "Sansocizer DOP" OR "Sansocizer R 8000" OR "Scandinol SC 1000" OR "Sconamoll DOP" N = 0Science Direct 15: "Sicol 150" OR "Staflex DOP" OR "Truflex DOP" OR "Unem 5005" OR "UNII-6A121LGB40" OR "UNII-C42K0PH13C" OR "Vestinol AH" OR "Vinicizer 80" OR "Vinycizer 80" N = 0Science Direct 16: "Vinycizer 80K" OR "Witcizer 312" $\mathbf{N} = \mathbf{0}$

AGRICOLA: (www.nal.usda.gov)

General Search Terms applied to the search strategy for Agricola. The Agricola database contains a significant amount of gray literature including proceedings, symposia, and progress reports from government and educational institutions. Agricola is not used when conducting a search for the Office of Water.

Date Searched: 07/10/2019Date Range of Search: 15^{th} century to the Present N = 3391

Agricola 01:

1,2-Benzenedicarboxylic acid, 1,2-diisooctyl ester 1,2-Benzedicarboxylic acid, bis(2-ethyl-hexyl) ester 1,2-Benzenedicarboxylic acid bis(2-ethylhexyl) ester 1,2-Benzenedicarboxylic acid, 1,2-bis(2-ethylhexyl) ester 1,2-Benzenedicarboxylic acid, 1,2-diisooctyl ester 1,2-Benzenedicarboxylic acid, bis(2-ethylhexyl) ester 1,2-Benzenedicarboxylic acid, diisooctyl ester 1,2-Benzenedicarboxylic acid, diisooctyl ester 1,2-Benzenedicarboxylic acid, bis(2-ethylhexylester) N = 0

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Agricola 02:
2-Ethylhexyl phthalate
AI3-27697-X
Bis(2-ethylhexyl) 1,2-benzenedicarboxylate
Bis(2-ethylhexyl) benzene-1,2-dicarboxylate
Bis(2-ethylhexyl) o-phthalate
Bis(2-ethylhexyl) o-phthalate
Bis(2-ethylhexyl) phthalate
Bis(2-ethylhexyl)phthalat
Bis(2-ethylhexyl)phthalate
Bis(2-ethylhexyl)phthalate
Bis(2-ethylhexyl)phthalate
Bis-(2-ethylhexyl)-phthalate
N = 787
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Agricola 03: Bis(ethylhexyl) phthalate Bisoflex 81 Bisoflex DOP BRN 1890696 Butylbenzyl Phthalate Butylbenzylphthalate Caswell No. 392K Codan Set L 86P Compound 889 Corflex 400 N = 37

Agricola 04: Corflex 880 DEHP Di(2-ethylhexyl) o-phthalate Di(2-ethylhexyl) orthophthalate Di(2-ethylhexyl) phthalate Di-(2-ethylhexyl) phthalate Di(2-ethylhexyl)orthophthalate Di(2-ethylhexyl)phthalate di(alpha-Ethylhexyl) phthalate Di(ethylhexyl) phthalate N = 885

Agricola 05: Di-(Ethylhexyl)phthalate Di(isooctyl) phthalate Di-2-ethylhexlphthalate Di-2-ethylhexyl phthalate DI-2-ETHYLHEXYL-PHTHALATE **Diacizer DOP** Diethylhexyl phthalate Di-ethylhexyl phthalate Diethylhexylphthalate Diisooctyl 1,2-benzenedicarboxylate N = 681

Agricola 06: Diisooctyl ester 1,2-Benzenedicarboxylic acid Diisooctyl o-phthalate Diisooctyl phthalate di-iso-Octyl phthalate Diisooctylphthalat Diisooctylphthalate Dioctyl phthalate Diplast O Di-sec-octyl phthalate Ergoplast FDO N = 73

Agricola 07: **Ergoplast FDO-S** ESBO-D 82 Etalon Ethylhexyl phthalate Ethylhexyl phthlate Eviplast 80 Eviplast 81 Fleximel

Flexol DOD Flexol DOP N = 822Agricola 08: Flexol Plasticizer DIOP Flexol Plasticizer DOP Garbeflex DOP-D 40 Good-rite GP 264 Hatco DOP Hatcol DOP Hercoflex 260 Hexaplas DIOP Hexaplas M/O Isooctyl phthalate N = 2Agricola 09: Isooctylphthalate Jayflex DIOP Jayflex DOP JSSD-DOP Kodaflex DEHP Kodaflex DOP Mollan O Monocizer DOP NCI-C52733 NSC 17069 N = 0Agricola 10: NSC 6381 Nuoplaz DOP Octoil Octyl phthalate Palatinol AH Palatinol AH-L Palatinol DOP PHTHALATE, BIS(2-ETHYLHEXYL) Phthalic acid bis(2-ethylhexyl) ester Phthalic acid di(2-ethylhexyl) ester N = 104 Agricola 11: Phthalic acid dioctyl ester Phthalic acid, bis(2-ethylhexyl) ester PHTHALIC ACID, BIS(2-ETHYLHEXYL)ESTER

Phthalic acid, bis(6-methylheptyl)ester

Phthalic acid, diisooctyl ester Pittsburgh PX 138 Pittsburgh PX-138 Plasthall DOP Platinol AH Platinol DOP N = 0Agricola 12: **RC** Plasticizer DOP RCRA waste number U028 Reomol D 79P Reomol DOP Sansocizer DOP Sansocizer R 8000 Scandinol SC 1000 Sconamoll DOP Sicol 150 Staflex DOP N = 0Agricola 13: Truflex DOP Unem 5005 UNII-6A121LGB40 UNII-C42K0PH13C Vestinol AH Vinicizer 80 Vinycizer 80 Vinycizer 80K Witcizer 312 N = 0**TOXNET:** (toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?TOXLINE) General Search Terms applied to the search strategy for TOXNET. Date Searched: 07/08/2019 Date Range of Search: 1900 to Present N = 3376 TOXNET 01: 117-81-7 OR 27554-26-3 OR 8033-53-2 OR 40120-69-2 OR 50885-87-5 N = 3374 TOXNET 02: 109630-52-6 OR 126639-29-0 OR 137718-37-7 OR 205180-59-2 OR 275818-89-8 N = 1**TOXNET 03:**

607374-50-5 OR 1330-91-2 OR 25103-50-8 OR 41375-90-0 N = 1

PubMed:

PubMed may be accessed through the EPA Desktop Library (*https://www.ncbi.nlm.nih.gov/pubmed/*)Date Searched: 07/08/2019 Date Range of Search: 1900 to present N = 8331

PubMed 01:

"1,2-Benzenedicarboxylic acid, 1,2-diisooctyl ester" OR "1,2-Benzedicarboxylic acid, bis(2-ethyl-hexyl) ester" OR "1,2-Benzenedicarboxylic acid bis(2-ethylhexyl) ester" OR "1,2-Benzenedicarboxylic acid, 1,2-bis(2-ethylhexyl) ester" OR "1,2-Benzenedicarboxylic acid, 1,2-diisooctyl ester" OR "1,2-Benzenedicarboxylic acid, bis(2-ethylhexyl) ester" OR "1,2-Benzenedicarboxylic acid, bis(2ethylhexyl)ester" OR "1,2-Benzenedicarboxylic acid, Butyl phenylmethyl ester" OR "1,2-Benzenedicarboxylic acid, diisooctyl ester" OR "1,2-Benzenedicarboxylic acid,bis(2-ethylhexylester)" OR "2-Ethylhexyl phthalate" OR "AI3-27697-X" OR "Bis(2-ethylhexyl) 1,2-benzenedicarboxylate" OR "Bis(2-ethylhexyl) benzene-1,2-dicarboxylate" OR "Bis(2-ethylhexyl) o-phthalate" OR "Bis(2ethylhexyl) phthalate" OR "Bis(2-ethylhexyl)ester, Phthalic acid" OR "Bis(2-ethylhexyl)phthalat" OR "Bis(2-ethylhexyl)phthalate" OR "Bis-(2-ethylhexyl)-phthalate" OR "Bis(ethylhexyl) phthalate" OR "Bisoflex 81" OR "Bisoflex DOP" OR "BRN 1890696" OR "Butylbenzyl Phthalate" OR "Butylbenzylphthalate" OR "Caswell No. 392K" OR "Codan Set L 86P" OR "Compound 889" OR "Corflex 400" OR "Corflex 880" OR "DEHP" OR "Di(2-ethylhexyl) o-phthalate" OR "Di(2-ethylhexyl) orthophthalate" OR "Di(2-ethylhexyl) phthalate" OR "Di-(2-ethylhexyl) phthalate" OR "Di(2ethylhexyl)orthophthalate" OR "Di(2-ethylhexyl)phthalate" OR "di(alpha-Ethylhexyl) phthalate" OR "Di(ethvlhexyl) phthalate" OR "Di-(Ethylhexyl)phthalate" OR "Di(isooctyl) phthalate" OR "Di-2ethylhexlphthalate" OR "Di-2-ethylhexyl phthalate" OR "DI-2-ETHYLHEXYL-PHTHALATE" OR "Diacizer DOP" OR "Diethylhexyl phthalate" OR "Di-ethylhexyl phthalate" OR "Diethylhexylphthalate" OR "Diisooctyl 1,2-benzenedicarboxylate" N = 4229

PubMed 02:

"Diisooctyl ester 1,2-Benzenedicarboxylic acid" OR "Diisooctyl o-phthalate" OR "Diisooctyl phthalate" OR "di-iso-Octyl phthalate" OR "Diisooctylphthalat" OR "Diisooctylphthalate" OR "Dioctyl phthalate" OR "Diplast O" OR "Di-sec-octyl phthalate" OR "Ergoplast FDO" OR "Ergoplast FDO-S" OR "ESBO-D 82" OR "Etalon" OR "Ethylhexyl phthalate" OR "Ethylhexyl phthlate" OR "Eviplast 80" OR "Eviplast 81" OR "Fleximel" OR "Flexol DOD" OR "Flexol DOP" OR "Flexol Plasticizer DIOP" OR "Flexol Plasticizer DOP" OR "Garbeflex DOP-D 40" OR "Good-rite GP 264" OR "Hatco DOP" OR "Hatco DOP" OR "Hexaplas DIOP" OR "Hexaplas M/O" OR "Isooctyl phthalate" OR "Isooctylphthalate" OR "Jayflex DIOP" OR "Jayflex DOP" OR "JSSD-DOP" OR "Kodaflex DEHP" OR "Kodaflex DOP" OR "Monocizer DOP" OR "NCI-C52733" OR "NSC 17069" OR "NSC 6381" OR "Nuoplaz DOP" OR "Octoil" OR "Octyl phthalate" OR "Palatinol AH" OR "Palatinol AH-L" OR "Palatinol DOP" OR "PHTHALATE, BIS(2-ETHYLHEXYL)" OR "Phthalic acid bis(2-ethylhexyl) ester" OR "Phthalic acid di(2-ethylhexyl) ester" N = 4102

PubMed 03:

"Phthalic acid dioctyl ester" OR "Phthalic acid, bis(2-ethylhexyl) ester" OR "PHTHALIC ACID, BIS(2-ETHYLHEXYL)ESTER" OR "Phthalic acid, bis(6-methylheptyl)ester" OR "Phthalic acid, diisooctyl ester" OR "Pittsburgh PX 138" OR "Pittsburgh PX-138" OR "Plasthall DOP" OR "Platinol AH" OR "Platinol DOP" OR "RC Plasticizer DOP" OR "RCRA waste number U028" OR "Reomol D 79P" OR "Reomol DOP" OR "Sansocizer DOP" OR "Sansocizer R 8000" OR "Scandinol SC 1000" OR "Sconamoll DOP" OR "Sicol 150" OR "Staflex DOP" OR "Truflex DOP" OR "Unem 5005" OR "UNII-6A121LGB40" OR "UNII-C42K0PH13C" OR "Vestinol AH" OR "Vinicizer 80" OR "Vinycizer 80" N = 0

ECOTOX UNIFY:

This is an internal EPA database that is not accessible to the public. Results from the ECOTOX Unify search strategy. Date Searched: 07/23/2019Date Range of Search: all years N = 523

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

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

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

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

A.2 Peer-Reviewed Screening Process

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

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

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

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

A.2.1 Inclusion/Exclusion Criteria

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

A.2.1.1 PECO for Environmental and Human Health Hazards

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

I Intilatate	
PECO Element	Evidence
P	 Human: Any population and life stage (<i>e.g.</i>, occupational or general population, including children and other sensitive populations). Animal: Aquatic and terrestrial species (live, whole organism) from any life stage (<i>e.g.</i>, preconception, in utero, lactation, peripubertal, and adult stages). Animal models will be inventoried according to the categorization below: <u>Human health models</u>: rat, mouse, rabbit, dog, hamster, guinea pig, cat, non-human primate, pig, hen (neurotoxicity only) <u>Environmental models</u>: invertebrates (<i>e.g.</i>, insects, spiders, crustaceans, mollusks, and worms) and vertebrates (<i>e.g.</i>, mammals and all amphibians, birds, fish, and reptiles). All hen studies (including neurotoxicity studies) will be included for ecotoxicological models. Plants: All aquatic and terrestrial species (live), including algal, moss, lichen and fungi species. <u>Screener note:</u>
P	 To identify human health and environmental hazards, other organisms not listed above in their respective categories can also be used. Non-mammalian model systems are increasingly used to identify potential human health hazards (<i>e.g.</i>, <i>Xenopus</i>, zebrafish), and traditional human health models (<i>e.g.</i>, rodents) can be used to identify potential environmental hazard. Neurotoxicity studies performed in hens (<i>e.g.</i>, OECD 418 and 419) are considered relevant to both human and eco hazard PECO considerations should be directed toward effects on target species only and not on the indirect effects expressed in taxa as a result of chemical treatment (<i>e.g.</i>, substance is lethal to a targeted pest species). Tests of the single toxicants in <i>in vitro</i> and <i>ex vivo</i> systems or on gametes, embryos, or plant or fungal sections capable of forming whole, new organisms will be tagged as potentially supplemental (mechanistic studies). Bacteria and yeast studies specific for assessing genotoxicity or mutagenicity (<i>e.g.</i>, Ames assay) will also be tagged as potentially supplemental (mechanistic studies) but are otherwise excluded. Studies on viruses are excluded.
Е	 <u>Relevant forms:</u> Diethylhexyl phthalate (DEHP) (CASRN 117-81-7) <u>Isomer:</u> Isooctyl phthalate - CASRN 27554-26-3 Synonyms for Diethylhexyl phthalate (CASRN 27554-26-3) can be found on the <u>EPA Chemistry</u> <u>Dashboard</u>. Human: Any exposure to DEHP singularly or in mixture, including exposure as measured by internal concentrations of these chemicals or metabolites of these chemicals in a biological matrix (<i>i.e.</i>, urine, blood, semen, etc.). See list of common metabolites for each phthalate below. Animal: Any exposure to DEHP including via water (including environmental aquatic exposures), soil or sediment, diet, gavage, injection, dermal, and inhalation. Plants: Any exposure to DEHP including via water or soil, or sediment. <u>Screener note:</u> Field studies with media concentrations (surface water, interstitial water, soil, sediment) and/or body/tissue concentrations of animals or plants are to be identified as <u>Supplemental</u> if any biological effects are reported. Studies involving exposures to mixtures will be <u>Included only</u> if they also include exposure to DEHP alone. Otherwise, mixture studies will be tagged as supplemental. Controlled outdoor experimental studies (<i>e.g.</i>, controlled crop/greenhouse studies, mesocosm studies, artificial stream studies) are considered to be laboratory studies (not field studies) because

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

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

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

Category	Evidence			
Mechanistic studies	All studies that report results at the cellular level and lower in both mammalian and non- mammalian model systems, including <i>in vitro</i> , <i>in vivo</i> , <i>ex vivo</i> , and <i>in silico</i> studies. These studies include assays for genotoxicity or mutagenicity using bacteria or yeast.			
ADME, PBPK, and toxicokinetic	Studies designed to capture information regarding absorption, distribution, metabolism, and excretion (ADME), toxicokinetic studies, or physiologically based pharmacokinetic (PBPK) models.			
Case reports or case series	Case reports ($n \le 3$ cases) and case series (non-occupational) will be tracked as potentially relevant supplemental information.			
Susceptible populations	Studies that identify potentially susceptible subgroups; for example, studies that focus on a specific demographic, life stage, or genotype. This tag applies primarily during full-text screening.			
(no health outcome)	Screener note: If biological susceptibility issues are clearly present or <i>strongly</i> implied in the title/abstract, this supplemental tag may be applied at the title abstract level. If uncertain at title/abstract, do not apply this tag to the reference during title/abstract screening.			
Mixture studies	Experimental mixture studies that are not considered PECO-relevant because they do not contain an exposure or treatment group assessing only the chemical of interest. Human health			

Category	Evidence			
	animal model and environmental animal model/plant will be tagged separately for mixture studies.			
Records with no original	Records that do not contain original data, such as other agency assessments, informative			
data	scientific literature reviews, editorials or commentaries.			
Conference abstracts	Records that do not contain sufficient documentation to support study evaluation and data extraction.			
Field Studies	Field studies with media concentrations (<i>e.g.</i> , surface water, interstitial water, soil, sediment) and/or body/tissue concentrations of animals or plants if biological effects reported.			
Isomer	PECO-relevant studies with an exposure to one of the identified isomers, if any.			

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

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

PECO Element	Evidence
P opulation	Human: General population; consumers; bystanders in the home; near-facility populations (includes industrial and commercial facilities manufacturing, processing, or using the chemical substance); children; susceptible populations (life stages, preexisting conditions, genetic factors), pregnant women; lactating women, women of childbearing age. Many human population groups may be exposed. No chemical-specific exclusions are suggested at this time.
	Environmental: Aquatic species, terrestrial species, terrestrial plants, aquatic plants (field studies only).
	Expected Primary Exposure Sources, Pathways, Routes:
<u>E</u> xposure	<u>Pathways:</u> indoor air/vapor/mist; indoor dust; particles; outdoor/ambient air; surface water; biosolids; sediment; breastmilk; food items containing di-ethylhexyl phthalate including fish; consumer product uses in the home (including consumer product containing chemical);
	Routes of Exposure: Inhalation, Oral, Dermal
Comparator (Scenario)	Human: Consider media-specific background exposure scenarios and use/source specific exposure scenarios as well as which receptors are and are not reasonably exposed across the projected exposure scenarios.
	Environmental Consider media-specific background exposure scenarios and use/source specific exposure scenarios as well as which receptors are and are not reasonably exposed across the projected exposure scenarios.
<u>O</u> utcomes for Exposure Concentration or	Human: Acute, subchronic, and/or indoor air and water concentration estimates (mg/m ³ or mg/L). Both external potential dose and internal dose based on biomonitoring and reverse dosimetry mg/kg/day will be considered. Characteristics of consumer products or articles (weight fraction, emission rates, etc) containing di-ethylhexyl phthalate.
Dose	Environmental: A wide range of ecological receptors will be considered (range depending on available ecotoxicity data) using surface water concentrations, sediment concentrations.

Chemical	Drinking Water	Ambient Air	Air Disposal	Land Disposal	Underground Disposal	Ground Water
Di-ethylhexyl phthalate (DEHP)	X	Х	Х	Х	Х	Х

Table_Apx A-6. Pathways Identified as Supplemental for Di-ethylhexyl Phthalate^a

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

A.2.1.3 **RESO** for Occupational Exposure and Environmental Releases

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

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

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

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

* Metrics (*e.g.*, mg/kg/day or mg/m³ for worker exposures, kg/site/day for releases) are determined by toxicologists for worker exposures and by exposure assessors for releases; also, the Engineering, Release and Occupational Exposure Data Needs (Table_Apx A-8) provides a list of related and relevant general information. TSCA=Toxic Substances Control Act

Ohissting	
Determined	Type of Data ^a
during Sconing	Type of Data
during Scoping General Engineering Assessment (may apply to Occupational Exposures and / or Environmental Releases)	 Description of the life cycle of the chemical(s) of interest, from manufacture to end-of-life (<i>e.g.</i>, each manufacturing, processing, or use step), and material flow between the industrial and commercial life cycle stages. The total annual U.S. volume (lb/yr or kg/yr) of the chemical(s) of interest manufactured, imported, processed, and used; and the share of total annual manufacturing and import volume that is processed or used in each life cycle step. Description of processes, equipment, and unit operations during each industrial/ commercial life cycle step. Material flows, use rates, and frequencies (lb/site-day or kg/site-day and days/yr; lb/site-batch and batches/yr) of the chemical(s) of interest during each industrial/ commercial life cycle step. Note: if available, include weight fractions of the chemicals (s) of interest and material flows of all associated primary chemicals (especially water). Number of sites that manufacture, process, or use the chemical(s) of interest for each industrial/
	commercial life cycle step and site locations.
Occupational Exposures	 Concentration of the chemical of interest Description of worker activities with exposure potential during the manufacture, processing, or use of the chemical(s) of interest in each industrial/commercial life cycle stage. Potential routes of exposure (<i>e.g.</i>, inhalation, dermal). Physical form of the chemical(s) of interest for each exposure route (<i>e.g.</i>, liquid, vapor, mist) and activity. Breathing zone (personal sample) measurements of occupational exposures to the chemical(s) of interest, measured as time-weighted averages (TWAs), short-term exposures, or peak exposures in each occupational life cycle stage (or in a workplace scenario similar to an occupational life cycle stage). Area or stationary measurements of airborne concentrations of the chemical(s) of interest in each occupational setting and life cycle stage (or in a workplace scenario similar to the life cycle stage of interest). For solids, bulk and dust particle size characterization data. Dermal exposure data. Exposure duration (hr/day). Exposure frequency (days/yr). Number of workers who potentially handle or have exposure to the chemical(s) of interest in each occupational life cycle stage. PPE types employed by the industries within scope. EC employed to reduce occupational exposures in each occupational life cycle stage (or in a workplace scenario similar to the life cycle stage (or in a workplace scenario similar to the life cycle stage (or in a workplace scenario similar to the life cycle stage.
Environmental Releases (to relevant environmental media)	reductions. Description of sources of potential environmental releases, including cleaning of residues from process equipment and transport containers, involved during the manufacture, processing, or use of the chemical(s) of interest in each life cycle stage. Estimated mass (lb or kg) of the chemical(s) of interest released from industrial and commercial sites to each environmental medium (water) and treatment and disposal methods (POTW), including releases per site and aggregated over all sites (annual release rates, daily release rates) Release or emission factors. Number of release days per year. Waste treatment methods and pollution control devices employed by the industries within scope and associated data on release/emission reductions.
describe more spec	s included in the fun-text selection form. The selection makes a selection from these specific tags, which is included in the selection formation.

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

Objective	
Determined	Type of Data ^a
during Scoping	
In addition to the d	ata types listed above, EPA may identify additional data needs for mathematical modeling. These data
needs will be deter	mined on a case-by-case basis.
Abbreviations:	
hr=Hour	
kg=Kilogram(s)	
lb=Pound(s)	
yr=Year	
PV=Particle volum	e
POTW=Publicly or	wned treatment works
PPE=Personal prot	ection equipment
PSD=Particle size	distribution
TWA=Time-weigh	ited average

A.2.1.4 PESO for Fate and Transport

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

Assessors seek information on various chemical-specific fate endpoints and associated fate processes, environmental media and exposure pathways as part of the process of developing the environmental fate assessment for each risk evaluation. EPA uses the PESO statement (

Table_Apx A-9) along with the information in Table_Apx A-10 when screening the fate data or information sources to ensure complete coverage of the processes, pathways and data or information relevant to the environmental fate and transport of the chemical substance undergoing risk evaluation.

PESO Element	Evidence
<u>P</u> athways and <u>P</u> rocesses	 Environmental fate, transport, partitioning and degradation behavior across environmental media to inform exposure pathways of the chemical substance of interest Exposure pathways included in the conceptual models: air, surface water, groundwater, wastewater, soil, sediment and biosolids. Processes associated with the target exposure pathways Bioconcentration and bioaccumulation Destruction and removal by incineration Please refer to the conceptual models for more information about the exposure pathways included in each TSCA risk evaluation.

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

PESO Element	Evidence	
<u>E</u> xposure	 Environmental exposure of environmental receptors (<i>i.e.</i>, aquatic and terrestrial organisms) to the chemical substance of interest, mixtures including the chemical substance, and/or its degradation products and metabolites Environmental exposure of human receptors, including any PESS, to the chemical substance of interest, mixtures including the chemical substance, and/or its degradation products and metabolites Please refer to the conceptual models for more information about the environmental and human receptors included in each TSCA risk evaluation. 	
<u>S</u> etting or <u>S</u> cenario	Any setting or scenario resulting in releases of the chemical substance of interest into the natural or built environment (<i>e.g.</i> , buildings including homes or workplaces, or wastewater treatment facilities) that would expose environmental (<i>i.e.</i> , aquatic and terrestrial organisms) or human receptors (<i>i.e.</i> , general population, and PESS)	
<u>O</u> utcomes	Fate properties which allow assessments of exposure pathways: Abiotic and biotic degradation rates, mechanisms, pathways, and products Bioaccumulation magnitude and metabolism rates Partitioning within and between environmental media (see Pathways and Processes)	

Table_Apx A-10. Fate En	dpoints and Associated Processes,	Media and Exposure Pathways
Considered in the Develo	pment of the Environmental Fate	Assessment

_		Associat	ed Media/Ex	posure Pathways			
Fate Data Endpoint	Associated Process(es)	Surface Water, Wastewater, Sediment	Soil, Biosolids	Groundwater	Air		
Required Environmental Fate	Required Environmental Fate Data						
Abiotic reduction rates or half- lives	Abiotic reduction, Abiotic dehalogenation	X					
Aerobic biodegradation rates or half-lives	Aerobic biodegradation	Х	X				
Anaerobic biodegradation rates or half-lives	Anaerobic biodegradation	Х	Х	Х			
Aqueous photolysis (direct and indirect) rates or half-lives	Aqueous photolysis (direct and indirect)	Х					
Atmospheric photolysis (direct and indirect) rates or half-lives	Atmospheric photolysis (direct and indirect)				Х		
Bioconcentration factor (BCF), Bioaccumulation factor (BAF)	Bioconcentration, Bioaccumulation	Х	Х		Х		
Biomagnification and related information	Trophic magnification	Х					
Desorption information	Sorption, Mobility	Х	Х	Х			
Destruction and removal by incineration	Incineration				X		
Hydrolysis rates or half-lives	Hydrolysis	X	Х	Х			
K_{OC} and other sorption information	Sorption, Mobility	Х	Х	Х			
Wastewater treatment removal information	Wastewater treatment	Х	Х				
Supplemental (or Optional) En	vironmental Fate Data	1	T				
Abiotic transformation products	Hydrolysis, Photolysis, Incineration	X			X		
Aerobic biotransformation products	Aerobic biodegradation	Х	Х				
Anaerobic biotransformation products	Anaerobic biodegradation	X	X	Х			
Atmospheric deposition information	Atmospheric deposition				X		
Coagulation information	Coagulation, Mobility	X		X			
Incineration removal	Incineration				Х		

A.2.1.5 Generation of Hazard Heat Maps

As stated in Appendix A.1.2.2, SWIFT Review has pre-set literature search strategies ("filters") developed by information specialists that can be applied to identify studies that are more likely to be useful for identifying human health and ecotoxicity content. The filters function like a typical search

strategy where studies are tagged as belonging to a certain filter if the terms in the filter literature search strategy appear in title, abstract, keyword or MeSH fields content.

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

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

A.3 Gray Literature Search and Screening Strategies

EPA conducted a gray literature search for available information to support the TSCA risk evaluations for the next twenty TSCA risk evaluations. Gray literature is defined as the broad category of data/information sources not found in standard, peer-reviewed literature databases (*e.g.*, PubMed and Web of Science). Gray literature includes data/information sources such as white papers, conference proceedings, technical reports, reference books, dissertations, information on various stakeholder websites, and other databases. Given the nature of how gray literature is searched and collected, results may not come with a bibliographic citation or abstract and were therefore processed using a decision tree logic described in Appendix A.3.1 for potential relevance prior to entering full text screening where a discipline-specific PECO is applied.

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

A.3.1 Screening of Gray Literature

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



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

A.3.2 Initial Screening of Sources using Decision Logic Tree

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

Step	Metric	Questions to consider
1	Potential Relevance	Does the result have information (qualitative or quantitative) related to TSCA risk evaluations? *Apply Discipline relevancy metric
2.1.1	Complete / Available	Is it a secondary data source (assessment, robust summary, TSCA submission databases, etc.)?
2.1.2		Is the document from a peer reviewed/published journal?

Table_Apx A-11. Decision Logic Tree Overview
Step	Metric	Questions to consider
2.2		Is there an established procedure for data collection, communication, peer review, and/or reporting?
2.2.1		Has the data been provided by a US governmental/state source?
2.2.2		Has the data been provided by an international governmental source?
2.3		Are these data publicly available/accessible?
2.3.1		Is the source TSCA CBI, proprietary, TSCA or NGO stakeholder submission?
3	Duplicate	Does the result contain any duplicative information found in other sources?

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

A.3.3 TSCA Submission Searching and Title Screening

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

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

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

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

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

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

A.3.4 Gray Literature Search Results for Di-ethylhexyl phthalate

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

Source Agency	Source Name	Source Type	Source Category	Source Website
ATSDR	ATSDR Tox Profile Updates and Addendums	Other US Agency Resources	Assessment or Related Document	https://www.atsdr.cdc.gov/tox profiles/profilesaddenda.asp
ATSDR	ATSDR Toxicological Profiles (original publication)	Other US Agency Resources	Assessment or Related Document	https://www.atsdr.cdc.gov/tox profiles/index.asp
Australian Government, Department of Health	NICNAS Assessments (human health, Tier I, II or III)	International Resources	Assessment or Related Document	https://www.industrialchemica ls.gov.au/chemical- information/search- assessments
Australian Government, Department of Health	NICNAS Assessments (eco)	International Resources	Assessment or Related Document	https://www.industrialchemica ls.gov.au/chemical- information/search- assessments
CAL EPA	Technical Support Documents for regulations: Cancer Potency Information	Other US Agency Resources	Assessment or Related Document	https://oehha.ca.gov/chemicals
CAL EPA	Technical Support Documents for regulations: Proposition 65, Reproductive Toxicity	Other US Agency Resources	Assessment or Related Document	https://oehha.ca.gov/chemicals
CAL EPA	Technical Support Documents for regulations: Drinking Water Public Health Goals	Other US Agency Resources	Assessment or Related Document	https://oehha.ca.gov/chemicals
CAL EPA	Technical Support Documents for regulations: Proposition 65, Cancer	Other US Agency Resources	Assessment or Related Document	https://oehha.ca.gov/chemicals
CPSC	Chronic Hazard Advisory Panel Reports	Other US Agency Resources	Assessment or Related Document	https://www.cpsc.gov/chap
CPSC	Technical Reports: Exposure/Risk Assessment	Other US Agency Resources	Assessment or Related Document	https://www.cpsc.gov/Researc hStatistics/Chemicals
CPSC	Technical Reports: Toxicity Review	Other US Agency Resources	Assessment or Related Document	https://www.cpsc.gov/Researc hStatistics/Chemicals

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

Source Agency	Source Name	Source Type	Source Category	Source Website
ECHA	Annex XVII Restriction Reports	International Resources	Assessment or Related Document	https://echa.europa.eu/substanc es-restricted-under-reach
ECHA	European Union Risk Assessment Report	International Resources	Assessment or Related Document	https://echa.europa.eu/informat ion-on-chemicals/information- from-existing-substances- regulation
ECHA	ECHA Documents	International Resources	Assessment or Related Document	https://echa.europa.eu/informat ion-on-chemicals
ECHA	Annex XVII To REACH - Conditions of Use	International Resources	Assessment or Related Document	https://echa.europa.eu/substanc es-restricted-under-reach
Env Canada	Guidelines, Risk Management, Regulations	International Resources	Assessment or Related Document	https://www.canada.ca/en.html
Env Canada	Chemicals at a Glance (fact sheets)	International Resources	Assessment or Related Document	https://www.canada.ca/en/heal th-canada/services/chemical- substances/fact- sheets/chemicals-glance.html
EPA	OPPT: TSCATS database maintained at SRC (TSCA submissions)	US EPA Resources	Database	
EPA	Office of Water: STORET and WQX	US EPA Resources	Database	https://www.waterqualitydata. us/portal/
EPA	EPA Office of Water: Ambient Water Quality Criteria documents	US EPA Resources	Assessment or Related Document	www.epa.gov/wqc/
EPA	IRIS Summary	US EPA Resources	Assessment or Related Document	https://cfpub.epa.gov/ncea/iris _drafts/atoz.cfm?list_type=alp ha
EPA	EPA: AP-42	US EPA Resources	Regulatory Document or List	https://www.epa.gov/air- emissions-factors-and- quantification/ap-42- compilation-air-emissions- factors
EPA	Office of Water: Drinking Water Standards Health Effects Support Documents	US EPA Resources	Regulatory Document or List	https://www.epa.gov/eg
EPA	Office of Air: CFRs and Dockets	US EPA Resources	Regulatory Document or List	https://www.epa.gov/stationar y-sources-air-pollution

Source Agency	Source Name	Source Type	Source Category	Source Website
EPA	EPA: Generic Scenario	US EPA Resources	Assessment or Related Document	https://www.epa.gov/tsca- screening-tools/chemsteer- chemical-screening-tool- exposures-and-environmental- releases#genericscenarios
FDA	FDA technical support documents for regulations	Other US Agency Resources	Assessment or Related Document	https://www.fda.gov/
IARC	IARC Monograph	International Resources	Assessment or Related Document	http://monographs.iarc.fr/ENG /Monographs/PDFs/index.php
ILO	International Chemical Safety Cards (ICSCs)	International Resources	Database	https://www.ilo.org/safework/i nfo/publications/WCMS_1131 34/langen/index.htm
Japan	Japanese Ministry of the Environment Assessments - Environmental Risk Assessments (Class I Designated Chemical Substances Summary Table)	International Resources	Regulatory Document or List	https://www.env.go.jp/en/che mi/prtr/substances/
KOECT	Kirk-Othmer Encyclopedia of Chemical Technology Journal Article	Other Resource	Encyclopedi a	https://onlinelibrary.wiley.com /doi/book/10.1002/047123896 1
NIOSH	CDC NIOSH - Occupational Health Guideline Documents	Other US Agency Resources	Assessment or Related Document	www.cdc.gov/niosh/topics/che mical.html/
NIOSH	CDC NIOSH - Pocket Guide	Other US Agency Resources	Database	https://www.cdc.gov/niosh/np g/default.html
NIOSH	CDC NIOSH - Health Hazard Evaluations (HHEs)	Other US Agency Resources	Assessment or Related Document	https://www2a.cdc.gov/hhe/se arch.asp
NIOSH	CDC NIOSH - Publications and Products	Other US Agency Resources	Assessment or Related Document	https://www2a.cdc.gov/nioshti c-2/
NLM	National Library of Medicine's PubChem	Other US Agency Resources	Database	https://pubchem.ncbi.nlm.nih.g
NTP	Additional NTP Reports	Other US Agency Resources	Assessment or Related Document	https://ntp.niehs.nih.gov/public ations/index.html
NTP	Technical Reports	Other US Agency Resources	Assessment or Related Document	https://ntp.niehs.nih.gov/public ations/reports/index.html?type =Technical+Report

Source Agency	Source Name	Source Type	Source Category	Source Website
NTP	OHAT Monographs	Other US Agency Resources	Assessment or Related Document	https://ntp.niehs.nih.gov/pubhe alth/hat/noms/evals.html
OECD	OECD: General Site	International Resources	General Search	https://www.oecd.org/
OECD	OECD Emission Scenario Documents	International Resources	Assessment or Related Document	http://www.oecd.org/document /46/0,2340,en_2649_201185_2 412462_1_1_1_1,00.html
OSHA	OSHA Chemical Exposure Health Data	Other US Agency Resources	Database	www.osha.gov/opengov/health samples.html/
RIVM	RIVM Reports: Risk Assessments	International Resources	Assessment or Related Document	https://www.rivm.nl/en
TERA	Toxicology Excellence for Risk Assessment	Other Resources	Assessment or Related Document	http://www.tera.org/
UNEP	Risk Profile / Stockholm Convention	International Resources	Assessment or Related Document	http://chm.pops.int/TheConven tion/ThePOPs/AllPOPs/tabid/2 509/Default.aspx

Appendix B PHYSICAL AND CHEMICAL INFORMATION OF DI-ETHYLHEXYL PHTHALATE

Table_Apx B-1summarizes statistics for the physical and chemical property values identified through systematic review as of June 2020. The "N" column indicates the number of unique primary sources of data for that endpoint. That is, if multiple sources presented equivalent values and cited the same primary source, only one of those was included in these statistics and included in the statistical calculations. All physical and chemical property values that were extracted and evaluated as of June 2020 are presented in the supplemental file *Data Extraction and Data Evaluation Tables for Physical and Chemical Property Studies* (EPA-HQ-OPPT-2018-0433).

Property or Endpoint	Ν	Unit	Mean	Standard Deviation	Min	Max
Molecular formula	-	-	NA	NA	NA	NA
Molecular weight	-	g/mol	NA	NA	NA	NA
Physical state	6	-	NA	NA	NA	NA
Physical properties	4	-	NA	NA	NA	NA
Melting point	13	°C	-51.8	3.2	-55	-47
Boiling point	11	°C	349	80	230	460
Density	7	g/cm ³	0.9827	0.0028	0.98	0.9861
Vapor pressure	9	mm Hg	10.8	32.0	4.05×10^{-8}	96
Vapor density	1	-	16	-	16	16
Water solubility	11	mg/L	0.22	0.15	6.0 × 10 ⁻⁴	0.4
Octanol/water partition coefficient (log Kow)	11	-	6.66	2.48	1.9	9.64
Henry's Law constant	1	atm·m³/mol	1.71×10^{-5}	-	1.71×10^{-5}	1.71 × 10 ⁻⁵
Flash point	4	°C	209.05	4.66	206	216
Auto flammability	0	°C	-	-	-	-
Viscosity	3	cP	23.89	29.51	5.6	57.94

Table_Apx B-1. Summary Statistics for Reviewed Physical Properties

Property or Endpoint	Ν	Unit	Mean	Standard Deviation	Min	Max
Refractive index	7	-	1.49	0.0190	1.48	1.535
Dielectric constant	2	-	4.68	0.54	4.3	5.06

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. This information was presented in the *Proposed Designation of Di-ethylhexyl Phthalate (CASRN 117-81-7) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019e) and may be updated as EPA collects additional information through systematic review methods.

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 (2015b) citing Kawaguchi (1994)
Direct Photodegradation	Direct photolysis and photooxidation are not likely to be important removal pathways	<u>ATSDR (2002)</u> citing <u>Wams (1987)</u>
Direct Photodegradation	$t1/2 = \langle 2 days$	<u>NLM (2015b)</u> citing <u>Cadogan et al. (1994)</u>
Indirect Photodegradation	$t1/2 = 5.85$ hours (based on ·OH reaction rate constant of 21.96 $\times 10^{-12}$ cm ³ /mol·second at 25 °C and 1.5×10^{6} ·OH radicals/cm ³) (estimated) ^b	<u>U.S. EPA (2012b)</u>
Hydrolysis	t1/2 = 2,000 years (pH 7; calculated)	NLM (2015b) citing Staples et al. (1997) (calculated from data in Wolfe et al. (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%.	<u>NLM (2015b)</u> citing <u>Tabak et al. (1981)</u>
Biodegradation (Aerobic)	t1/2 = 0.8 days (activated sludge)	<u>NLM (2015b)</u> citing <u>Saeger and Tucker</u> (1976)

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

Property or Endpoint	Value ^a	Reference
Biodegradation (Aerobic)	>64% removal in activated sludge reactor and a biological aerated filter	<u>NLM (2015b)</u> citing <u>Clapp et al. (1994)</u>
Biodegradation (Aerobic)	t1/2 = 4.5 weeks (river water) t1/2 = 14 days (hydrosoil)	<u>NLM (2015b)</u> citing <u>Wams (1987)</u>
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	<u>NLM (2015b)</u>
Biodegradation (Anaerobic)	83.3% (municipal sludge)	<u>NLM (2015b)</u> citing Parker et al. (1994)
Biodegradation (Anaerobic)	0%/278 days (municipal solid waste samples)	NLM (2015b) citing Ejlertsson et al. (1996)
Biodegradation (Anaerobic)	t1/2 = 198 days, 173 days (anaerobic sludge)	<u>NLM (2015b)</u> citing <u>Gavala et al. (2003)</u>
Wastewater Treatment	t1/2 = 23 days (wastewater treatment plants)	<u>NLM (2015b)</u> citing <u>Byrns (2001)</u>
Wastewater Treatment	94% total removal (0.78% by biodegradation, 93% by sludge adsorption, and 0% by volatilization to air; estimated) ^b	<u>U.S. EPA (2012b)</u>
Bioconcentration Factor	1,380 (Pimephales promelas)	<u>ECHA (2019)</u>
Bioconcentration Factor	582–614, 737–891 (Pimephales promelas)	<u>ECHA (2019)</u>
Bioconcentration Factor	850 (Pimephales promelas)	<u>NLM (2015b)</u> citing <u>Veith et al. (1979)</u>
Bioconcentration Factor	199 (Lepomis macrochirus)	NLM (2015b) citing Barrows et al. (1980)
Soil Organic Carbon:Water Partition Coefficient (Log KOC)	4.9–6	ATSDR (2002) citing Staples et al. (1997)
Soil Organic Carbon:Water Partition Coefficient (Log KOC)	4–5 in clays and sediments	NLM (2015b) citing Sullivan et al. (1982)

^aMeasured unless otherwise noted

^bEPI SuiteTM physical property inputs: Log Kow = 7.60, BP = 384 °C, MP = \Box 55 °C, VP = 1.42 × 10⁻⁷ mm Hg, WS = 0.27 mg/L

 $K_{OC} = organic carbon-water partition coefficient; \Box OH = hydroxyl radical$

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

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
EPA Statutes/Regulations	<u>.</u>	
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 and 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 (<u>84</u> <u>FR 71924</u> , 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 types,	Di-ethylhexyl phthalate manufacturing (including importing), processing and use information is reported under the

Table_Apx D-1. Federal Laws and Regulations

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	quantities and uses of chemical substances produced domestically and imported into the United States.	CDR rule (<u>76_FR_50816</u> , 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 (<u>60 FR</u> <u>16309</u> , 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)" (<u>40</u> <u>CFR 716.120</u>).
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 (<i>e.g.</i> , 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>i.e.</i> , air, land and water).	Di-ethylhexyl phthalate is a listed substance subject to reporting requirements under <u>40 CFR 372.65</u> effective as of January 1, 1987.

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
Clean Air Act (CAA) – Section 112(b)	Defines the original list of 189 hazardous air pollutants (HAPs). Under 112(c) of the CAA, EPA must identify and list source categories that emit HAP and then set emission standards for those listed source categories under CAA Section 112(d). CAA Section 112(b)(3)(A) specifies that any person may petition the Administrator to modify the list of HAP by adding or deleting a substance. Since 1990, EPA has removed two pollutants from the original list leaving 187 at present.	Di-ethylhexyl phthalate is listed as a HAP (<u>42 U.S.C. 7412</u>).
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(μ g/L) 0.32 Human Health for the consumption of Organism Only (μ g/L) 0.37 Human Health WQC is based on carcinogenicity of 10 ⁻⁶ risk.

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
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 statute specifies a list of families of toxic pollutants also listed in the Code of Federal Regulations at 40 CFR Part 401.15. The "priority pollutants" specified by those families are listed in 40 CFR Part 423 Appendix A. These are pollutants for which best available technology effluent limitations must be established on either a national basis through rules (Sections 301(b), 304(b), 307(b), 306) or on a case-by-case best professional judgement basis in NPDES permits, see Section 402(a)(1)(B). EPA identifies the best available technology that is economically achievable for that industry after considering statutorily prescribed factors and sets regulatory requirements based on the performance of that technology.	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 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 a non- enforceable maximum contaminant level goal (MCLG) for a contaminant for which EPA makes the determination that the contaminant: 1. may have an adverse	Di-ethylhexyl phthalate is subject to NPDWR under the SDWA with an MCLG of zero and an enforceable MCL of .006 mg/L (<u>40</u> <u>CFR 141.24</u>).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	effect on the health of persons; 2. is 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 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.	
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 (<u>40 CFR 261.33</u>). (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 (<u>40</u> <u>CFR 302.4</u>).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
Superfund Amendments and Reauthorization Act (SARA)	Requires the Agency to revise the hazardous ranking system and update the National Priorities List of hazardous waste sites, increases state and citizen involvement in the superfund program and provides new enforcement authorities and settlement tools.	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.
Other Federal Statutes/Regu	lations	
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 (<u>16 CFR part 1307</u>).
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 that 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 (<u>16 CFR part</u> <u>1307</u>)
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	OSHA established a PEL for di- ethylhexyl phthalate of 5 mg/m3 as an 8-hour, TWA (<u>29 CFR</u> <u>1910.1000</u>).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	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 Sampling and Analytical Method for DEHP.
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) (<u>49 CFR 172.1</u> , 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 (<u>Env-A 1400: Regulated Toxic Air Pollutants</u>) 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 (<u>Air Pollution Regulation No. 22</u>) Acceptable Ambient Levels (AALs) (mg/m3) 24 Hour 70, Annual 0.4
State Drinking Water	Arizona (<u>14 Ariz. Admin. Register 2978, August 1, 2008</u>) MCL .0006 mg/L MCLG 0 mg/L Discharge from rubber and chemical factories California (<u>Cal Code Regs. Title 26, § 22-64444</u>)

State Actions	Description of Action
Standards and Guidelines	Table 64444-A Maximum Contaminant Levels Organic Chemicals 0.004 mg/LConnecticut (Conn. Agencies Regs. § 19-13-B102)Maximum Contaminant Level (mg/l) 0.006Delaware (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 CCRunits 6, MCLG 0Florida (Fla. Admin. Code R. Chap. 62-550), 6 µg/L MCLMaine (10 144 Me. Code R. Chap. 231), 0.006 mg/LMassachusetts (310 Code Mass. Regs. § 22.00), 0.006 mg/LMichigan (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 ppbNew Jersey (7:10 N.J Admin. Code § 5.2), Standard 6 µg/LPennsylvania (25 Pa. Code § 109.202)Synthetic Organic Chemicals (SOCs): 0.006 mg/LRhode 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 (<u>Cal Code Regs. Title 8, § 5155</u>) Hawaii PEL TWA 5 mg/m ³ and PEL STEL 10 mg/m3 (<u>Hawaii Administrative Rules</u> <u>Section 12-60-50</u>)
State Right- to-Know Acts	Massachusetts (<u>105 Code Mass. Regs. § 670.000 Appendix A)</u> New Jersey (<u>8:59 N.J. Admin. Code § 9.1</u>) Carcinogen, Teratogen Pennsylvania (<u>P.L. 734, No. 159 and 34 Pa. Code § 323</u>)
Chemicals of High Concern to Children	Several states have adopted reporting laws for chemicals in children's products containing di-ethylhexyl phthalate including: Maine (<u>38 MRSA Chapter 16-D</u>) Minnesota (<u>Toxic Free Kids Act Minn. Stat. 116.9401 to 116.9407</u>) Oregon (<u>Toxic-Free Kids Act, Senate Bill 478, 2015</u>) Vermont (<u>18 V.S.A § 1776</u>) Washington State (<u>Wash. Admin. Code 173-334-130</u>)
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 (<u>Hazard Evaluation System and Information Service, 2016</u>). California lists di-ethylhexyl phthalate as a designated priority chemical for biomonitoring (<u>California SB 1379</u>).

State Actions	Description of Action
	Di-ethylhexyl phthlate is on the MA Toxic Use Reduction Act (TURA) list MGL, <u>Chapter 211, Section 1 to Section 23</u>
	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 (<u>Government of</u> <u>Canada. Managing substances in the environment. Substances search.</u> Database accessed April 30, 2020).
	Other Canadian regulations include:
	• Canada's National Pollutant Release Inventory (<u>NPRI</u>).
	• 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 <u>Phthalates Regulations under the Canada Consumer Product Safety Act.</u>
	• Compliance and enforcement of the existing requirements for medical devices containing di-ethylhexyl phthalate will continue as part of the regular enforcement of the <u>Medical Devices Regulations under the Food and Drugs Act</u> .
	• Di-ethylhexyl phthlate, which was previously concluded to be harmful to human health, was added to the <u>Cosmetic Ingredient Hotlist</u> 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 (<u>European Chemicals Agency</u> (<u>ECHA) database</u> . 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

Country/ Organization	Requirements and Restrictions
	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.
	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 <u>Restriction of Hazardous Substances</u> <u>Directive (RoHS), EU/2015/863</u> , 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 (<u>IMAP</u>).
	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) <u>Air Pollution Control Law</u> <u>Water Pollution Control Law</u>
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.

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, 2019c). 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, 2019c).

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, 2006). 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).

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 (U.S. EPA, 2019c). Of the 14 facilities in 2016 CDR (U.S. EPA, 2019c) 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, 2020a).

E.1.2 Processing and Distribution

E.1.2.1 Processing as a Reactant

Processing as a reactant 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, 2020a) (U.S. EPA, 2019c; Natrochem, 2016). Di-ethylhexyl phthalate is also processed as a reactant in the manufacture of the adhesives and sealants (U.S. EPA, 2019c; Morgan Advanced Materials, 2016b).

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. Di-ethylhexyl phthalate is also used in solid rocket motor insulation, which the commenter noted was a critical use (EPA-HQ-OPPT-2019-0501-0043). 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, 2019c; <u>3M Company, 2018</u>; <u>Victor Technologies, 2012</u>). 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 the 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, emulsion paints, lacquers, varnishes, paints for traffic markings, and wood coatings (<u>3M</u> <u>Company, 2019b; LORD Corporation, 2019; The Sherwin-Williams Company, 2019; Valspar, 2019; Dupli-Color Products Company, 2017; Valspar, 2017; Pacific Coast Lacquer, 2016; LORD Corporation, <u>4017</u>; Valspar, 2017; Pacific Coast Lacquer, 2016; LORD Corporation, <u>4017</u>; Valspar, 2017; Pacific Coast Lacquer, 2016; LORD Corporation, <u>4017</u>; Valspar, 2017; Pacific Coast Lacquer, 2016; LORD Corporation, <u>4017</u>; Valspar, 2017; Pacific Coast Lacquer, 2016; LORD Corporation, <u>4017</u>; Valspar, 2017; Pacific Coast Lacquer, 2016; LORD Corporation, <u>4017</u>; Valspar, 2017; Pacific Coast Lacquer, 2016; LORD Corporation, <u>4017</u>; Valspar, 2017; Pacific Coast Lacquer, 2016; LORD Corporation, <u>4017</u>; Valspar, 2017; Pacific Coast Lacquer, 2016; LORD Corporation, <u>4017</u>; Valspar, 2017; Pacific Coast Lacquer, 2016; LORD Corporation, <u>4017</u>; Valspar, 2017; Pacific Coast Lacquer, 2016; LORD Corporation, <u>4017</u>; Valspar, 2017; Pacific Coast Lacquer, 2016; LORD Corporation, <u>4017</u>; Valspar, 2017; Pacific Coast Lacquer, 2016; Pacific Coast Lacque</u>

2015; NLM, 2015b; Tremco, 2015; CETCO, 2014; 3M Company, 2011; Ramuc Specialty Pools, 2010; Airserco Manufacturing Company LLC, 2009; StatSpin Inc, 2004; Republic Powdered Metals Inc., 2002; Glidden Co, 1999). A commenter reported di-ethylhexyl phthalate is used as a component of common off the shelf paints and sealants and specifically in sealant for vacuum system connection points, which the commenter also noted was a critical use (EPA-HQ-OPPT-2019-0501-0043). 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 (<u>ACC, 2019</u>; <u>3M Company, 2017</u>; <u>Dionisio</u> et al., 2015; <u>Danish EPA, 2010</u>). 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, 2019c; <u>3M</u> Company, 2018; <u>Clemons Concrete Coatings, 2018</u>; <u>Valero Marketing & Supply Company, 2014</u>; <u>3M</u> 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. Di-ethylhexyl phthlate is a plasticizer found in plastic and rubber products, such as plastics used in the building and construction industry and in furniture and furnishings (U.S. EPA, 2019c; <u>3M Company, 2018</u>). 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 batteries (<u>Amazon, 2020</u>), dyes and pigments (<u>SPIN, 2019; U.S. EPA, 2019b, c; Identity Group, 2016</u>), lawn and garden care products (<u>U.S. EPA, 2019c</u>), and hydraulic fracturing chemicals (<u>U.S. House of Representatives, 2011</u>). Di-ethylhexyl phthlate was also identified as a laboratory chemical (<u>Restek, 2019; ULTRA Scientific Inc, 2014</u>). A commenter also reported laboratory use including such applications as analytical standards, research, equipment calibration, sample preparation (<u>EPA-HQ-OPPT-2019-0501-0043</u>). 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 or treatment. The presence of di-ethylhexyl phthalate in the reuse of produced waters is included in the disposal condition of use. Industrial sites that treat or dispose onsite wastes that they themselves generate are assessed in each condition of use assessment. Similarly, point source discharges of di-ethylhexyl phthalate to surface water are assessed in each condition of use assessment. 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 wastewater and solid waste. 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 are defined under RCRA as any material that is discarded by being: abandoned; inherently waste-like; a discarded military munition; or recycled in certain ways (certain instances of the generation and legitimate reclamation of secondary materials are exempted as solid wastes under RCRA).

According to 2018 TRI (U.S. EPA, 2019f), 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.

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

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^a Table includes HHEs identified to date. HHEs can be found at <u>https://www.cdc.gov/niosh/hhe/.</u>

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 SamplesAvailable from OSHA Inspections Conducted Between 2010 and 2019

NAICS	NAICS Description	Number of Data Points ^a
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	1

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

Appendix FSUPPORTING INFORMATION – CONCEPTUAL MODEL FOR INDUSTRIAL
AND COMMERCIAL ACTIVITIES AND USES

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. 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 = $1.4 \times 10-6$ 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	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
	Import	Import	Repackaging of import containers	Liquid Contact	Dermal	Workers	Yes	2016 CDR references import in liquid form. The potential for exposures to workers exists during import, but exposure will only occur in the event the imported material is repackaged.
				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

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
								occur in the event the imported material is repackaged.
				Vapor	Inhalation	Workers, ONU	No	Due to di-ethylhexyl phthalate's vapor pressure (VP) (VP = $1.4 \times$ 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	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
Processing	Processing as a Reactant	Plasticizer in plastic material and resin manufacturing, rubber product manufacturing, and synthetic rubber	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.
		manufacturing Adhesive and sealant chemical in adhesive manufacturing		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.
		Intermediate in plastics product manufacturing		Vapor	Inhalation	Workers, ONU	Yes	Due to di-ethylhexyl phthalate's vapor pressure (VP) (VP = $1.4 \times 10-6$ 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.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
				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	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
	Incorporation into formulation, mixture or reaction product	Plasticizer in all other basic organic chemical manufacturing; custom compounding of purchased resins; miscellaneous	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.
		manufacturing; paint and coating manufacturing; plastics material and resin manufacturing; plastics product manufacturing;		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.
		adhesive manufacturing; all other basic inorganic chemical manufacturing; rubber product manufacturing; services; all other chemical product and preparation		Vapor	Inhalation	Workers, ONU	Yes	Due to di-ethylhexyl phthalate's vapor pressure (VP) (VP = $1.4 \times 10-6$ 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.
		manufacturing; solid rocket motor insulation		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	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
	Incorporation into articles	Plasticizer in all other basic organic chemical manufacturing, plastics product manufacturing; plastic material and	Plastics and Rubber product manufacturing (Plastic Converting) Other article	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.
		resin manufacturing; custom compounding of purchased resin	manufacturing	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 = $1.4 \times 10-6$ 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 (incorporation into articles), as di- ethylhexyl phthalate may be in solid form, such as for resins.
				Liquid/Solid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
	Repackaging	Repackaging	Repackaging into large and small containers	Liquid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during repackaging, as di-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 = $1.4 \times$ 10-6 mm Hg) at room

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
								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	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
	Recycling	Recycling	Recycling of di- ethylhexyl phthalate and products containing di-	Liquid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during this use as liquid formulations may be recycled.
			ethylhexyl phthalate	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 = $1.4 \times 10-6$ 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	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
Industrial/ Commercial Use	Paints and coatings; adhesives and sealants; lawn	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.
	and garden care products; Transportation	Transportation equipment manufacturing (<i>e.g.</i> ,		Solid Contact	Dermal	Workers	No	The potential for exposures to solid di-ethylhexyl phthalate is not expected during the use of these

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
	equipment manufacturing	formulations for diffusion bonding and						products because they are in liquid form.
	(<i>e.g.</i> , formulations for diffusion bonding and manufacture of	manufacture of aero engine fan blades)		Vapor	Inhalation	Workers, ONU	No	Due to di-ethylhexyl phthalate's vapor pressure (VP) (VP = $1.4 \times$ 10-6 mm Hg) at room temperature, potential for vapor generation is low.
	aero engine fan blades)			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 expected during the use of these products because they are in liquid form.
				Liquid/Solid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
	Hydraulic fracturing; Laboratory chemicals; arts,	Hydraulic fracturing; Laboratory chemicals; arts, crafts, and hobby materials; automotive	Use in hydraulic fracturing Use in laboratories	Liquid Contact	Dermal	Workers	Yes	These products are in liquid form; therefore, exposures to workers exists for di-ethylhexyl phthalate used in these products.
	crafts, and hobby materials; automotive care products; dyes and pigments	care products; dyes and pigments	Use of arts, crafts, and hobby materials Use of automotive	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.
			care products Use of dyes and pigments	Vapor	Inhalation	Workers, ONU	No	Due to di-ethylhexyl phthalate's vapor pressure (VP) (VP = $1.4 \times$ 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	Dermal exposure by ONU is not expected for this condition of use

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
								as they are not expected to directly handle the chemical.
	Batteries; building and construction materials not covered	Batteries; building and construction materials not covered elsewhere; electrical and electronic products; fabric, textile,	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 these products because they are solid articles.
	elsewhere; electrical and electronic products; fabric, textile, and leather products not covered	and leather products not covered elsewhere; furniture and furnishings not covered elsewhere; plastic and rubber products not covered elsewhere;		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.
	elsewhere; furniture and furnishings not covered elsewhere;	toys, playground, and sporting equipment		Vapor	Inhalation	Workers, ONU	No	Due to di-ethylhexyl phthalate's vapor pressure (VP) (VP = $1.4 \times 10-6$ mm Hg) at room temperature, potential for vapor generation is low.
	plastic and rubber products			Mist	Inhalation/ Dermal	Workers, ONU	No	Mist generation is not expected during use of these products.
	not covered elsewhere; toys, playground, and sporting equipment			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	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
Disposal	Disposal	Disposal of di- 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 = $1.4 \times$

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	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.

Appendix G SUPPORTING INFORMATION – CONCEPTUAL MODEL FOR CONSUMER ACTIVITIES AND USES

Life Cycle Stage	Category	Subcategory	Release from source	Exposure Pathway	Route	Receptor	Plans to Evaluate	Rationale
		Duilding/	Direct contact through handling of articles containing chemical	Direct Contact	Dermal	Consumers	Yes	Dermal exposure may occur for this condition of use and will be analyzed.
Consumer Use	Construction, Paint, Electrical, and Metal Products	Construction Materials Not Covered Elsewhere (Article)	Direct contact through mouthing of articles containing chemical	Mouthing	Oral	Consumers	Yes	Oral exposure may occur for this condition of use and will be analyzed.
		(Aiticle)	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 handling of articles containing chemical	Direct Contact	Dermal	Consumers	Yes	Dermal exposure may occur for this condition of use, dermal exposure will be analyzed.
Consumer Use	Construction, Paint, Electrical, and Metal Products	Electrical and Electronic Products (Article)	Direct contact through mouthing of articles containing chemical	Mouthing	Oral	Consumers	Yes	Oral exposure may occur for this condition of use and will be analyzed.
			Long-term emission/mass- transfer, Abrasion, Transfer to Dust	Dust	Dermal, Inhalation, Oral	Consumers, Bystanders	Yes	Dermal, oral and inhalation exposure from this condition of use may occur and will be analyzed.
Consumer Use	Furnishing, Cleaning, Treatment/Care Products	Fabric, Textile and Leather Products no	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.

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
		Covered Elsewhere (Article)	Direct contact through mouthing of articles containing chemical	Mouthing	Oral	Consumers	Yes	Oral exposure may occur for this condition of use and will be analyzed.
			Long-term emission/mass- transfer, Abrasion, Transfer to Dust	Dust	Dermal, Inhalation, Oral	Consumers, Bystanders	Yes	Dermal, oral and inhalation exposure from this condition of use may occur and will be analyzed.
			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.
Consumer Use	Furnishing, Cleaning, Treatment/Care Products	Furniture and Furnishings not Covered Elsewhere (Article)	Direct contact through mouthing of articles containing chemical	Mouthing	Oral	Consumers	Yes	Oral exposure may occur for this condition of use and will be analyzed.
			Long-term emission/mass- transfer, Abrasion, Transfer to Dust	Dust	Dermal, Inhalation, Oral	Consumers, Bystanders	Yes	Dermal, oral and inhalation exposure from this condition of use may occur and will be analyzed.
			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.
Consumer Use	Packaging, Paper, Plastic,	Plastic and Rubber Products not Covered	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.
	Hobby Products	Elsewhere (Article)	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 handling of articles containing chemical	Direct Contact	Dermal	Consumers	Yes	Dermal exposure may occur for this condition of use, dermal exposure will be analyzed.
Consumer Use	Packaging, Paper, Plastic, Hobby Products	Toys, Playground, and Sporting Equipment (Article)	Direct contact through mouthing of articles containing chemical	Mouthing	Oral	Consumers	Yes	Oral exposure may occur for this condition of use and will be analyzed.
			Long-term emission/mass- transfer, Abrasion, Transfer to Dust	Dust	Dermal, Inhalation, Oral	Consumers, Bystanders	Yes	Dermal, oral and inhalation exposure from this condition of use may occur and will be analyzed.
			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	Construction,	Adhesives and	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.
Use	and Metal Products	Sealants (Product)	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.
	Destrocing	Arts, Crafts,	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 P Use H	Paper, Plastic, Hobby Products	and Hobby Materials (Product)	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.
	noody moducts	((Product)	Long-term emission/mass- transfer through	Vapor	Inhalation	Consumers and Bystanders	Yes

Life Cycle Stage	Category	Subcategory	Release from source	Exposure Pathway	Route	Receptor	Plans to Evaluate	Rationale
			application or use of products					
			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.
			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,	Lawn and Garden Care	Long-term emission/mass-	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
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	Outdoor Use Products	Products (Product)	transfer, Abrasion, Transfer to Dust					
			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.
			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.

Life Cycle Stage	Category	Subcategory	Release from source	Exposure Pathway	Route	Receptor	Plans to Evaluate	Rationale
			Long-term emission/mass- transfer through application or use of products	Vapor	Inhalation	Consumers and Bystanders	Yes	Inhalation is possible and will be analyzed.
			Direct contact through application or use of products	Mist	Inhalation and Dermal	Consumers and Bystanders	No	Mist generation is not expected during handling or disposal.

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

Life Cycle Stage	Category	Release	Exposure Pathway / Media	Exposure Routes	Receptor / Population	Plans to Evaluate	Rationale
All	Emissions to Air	Emissions to Air	Near facility ambient air concentrations	Inhalation	General Population	No	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 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 (<i>e.g.</i> , showering)	General Population	No	Drinking water exposure pathway for di- ethylhexyl phthalate is currently addressed in the NPDWR
			Biosolids: application to soil and/or migration to groundwater and/or surface water	Oral 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.
				TBD	Aquatic Receptors	Yes	
		Underground injection	Migration to groundwater, potential	Oral Dermal Inhalation	General Population	No	Di-ethylhexyl phthlate is released to Class I Underground Injection Wells which are covered by SDWA and RCRA.

Table_Apx H-1. General Population and Environmental Exposure Conceptual Model Supporting Table

Life Cycle Stage	Category	Release	Exposure Pathway / Media	Exposure Routes	Receptor / Population	Plans to Evaluate	Rationale
			surface/drinking water		Aquatic and Terrestrial Species		
				TBD			
	Solid and	Municipal landfill	Leachate to soil, ground	Oral Dermal	General Population	No	Di-ethylhexyl phthlate is included on the list of hazardous wastes pursuant to RCRA 3001 (40 CFR §§ 261.33).
Disposal	Liquid Wastes	and other land disposal	water and/or mitigation to surface water	TBD	Aquatic and Terrestrial Receptors		