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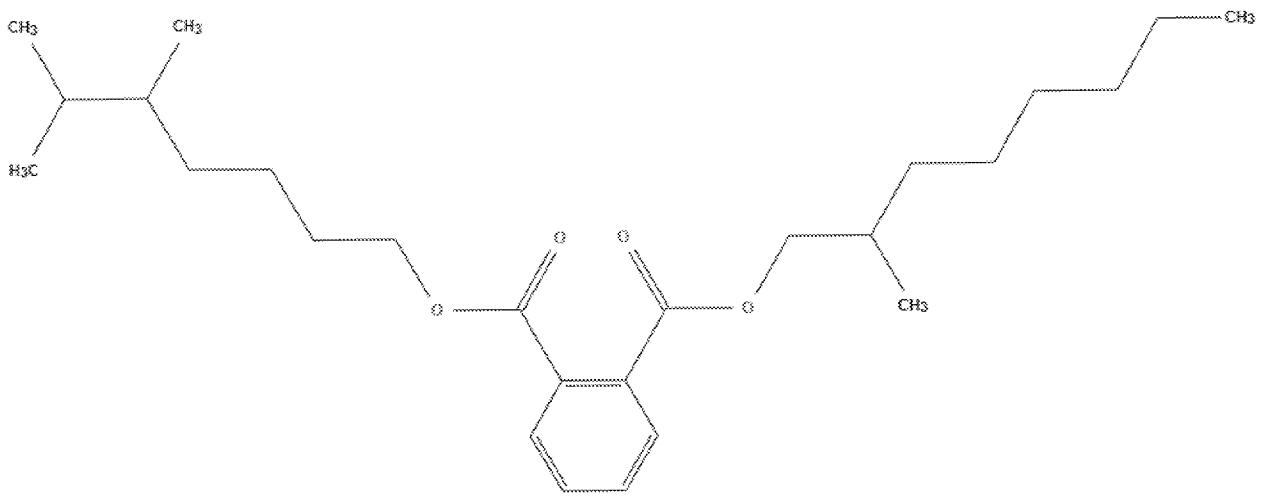
Final Scope of the Risk Evaluation for Di-isononyl Phthalate (DINP)

(1,2-Benzene-dicarboxylic acid, 1,2-diisononyl ester, and 1,2-Benzenedicarboxylic acid, di-C8-10-branched alkyl esters, C9-rich)

CASRNs 28553-12-0 and 68515-48-0



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Docket
Supporting information can be found in public docket, Docket ID: EPA-HQ-OPPT-2018-0436.

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.

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ABBREVIATIONS AND ACRONYMS

ACC HPP	American Chemistry Council High Phthalates Panel
ACGIH	American Conference of Governmental Industrial Hygienists
ADAF	Age-dependent adjustment factor
ADME	Absorption, distribution, metabolism, and excretion
BAF	Bioaccumulation factor
BBP	Butylbenzyl phthalate
BCF	Bioconcentration factor
BMF	Biomagnification factor
$BW^{3/4}$	Body weight scaling to the 3/4 power
CASRN	Chemical Abstracts Service Registry Number
CBI	Confidential business information
CDR	Chemical Data Reporting
CEM	Consumer Exposure Model
CFR	Code of Federal Regulations
ChemSTEER	Chemical Screening Tool for Exposure and Environmental Releases
COC	Concentration(s) of concern
COU	Condition of use
CPCat	Chemical and Product Categories
CPSC	Consumer Product Safety Commission
CPSIA	Consumer Product Safety Improvement Act
CSCL	Chemical Substances Control Law
CSF	Cancer slope factor
CWA	Clean Water Act
DBP	Dibutyl phthalate
DCHP	Dicyclohexyl phthalate
DEHP	Di-ethylhexyl phthalate
DIBP	Di-isobutyl phthalate
DIDP	Di-isodecyl phthalate
DINP	Di-isononyl phthalate
ECHA	European Chemicals Agency
EC_x	Effective concentration that causes a response that is x% of the maximum
EPA	Environmental Protection Agency
ERG	Eastern Research Group
ESD	Emission Scenario Document
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug and Cosmetic Act
FR	Federal Register
GDIT	General Dynamics Information Technology
GESTIS	International Occupational Exposure Limit Database
GS	Generic Scenario
HAWC	Health Assessment Workplace Collaborative
HERO	Health and Environmental Research Online (Database)
Hg	Mercury
HHE	Health Hazard Evaluation
HSDB	Hazardous Substances Data Bank
ICF	ICF (a global consulting company)

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IECCU	Indoor Environmental Concentrations in Buildings with Conditioned and Unconditioned Zones
IMIS	Integrated Management Information System
IUR	Inhalation unit risk
K_{OC}	Organic carbon: water partition coefficient
K_{OW}	Octanol: water partition coefficient
LC_{50}	Lethal concentration of 50% test organisms
LOAEL	Lowest-observed-adverse-effect-level
LOEC	Lowest-observed-effect-concentration
MITI	Ministry of International Trade and Industry
MOA	Mode of action
MOE	Margin of exposure
MP	Melting point
MRSA	Maine Revised Statutes Annotated
NHANES	National Health and Nutrition Examination Survey
NICNAS	National Industrial Chemicals Notification and Assessment Scheme (Australia)
NIOSH	National Institute for Occupational Safety and Health
NITE	National Institute of Technology and Evaluation
NLM	National Library of Medicine
NOAEL	No-observed-adverse-effect-level
NOEC	No-observed-effect-concentration
NPDES	National Pollutant Discharge Elimination System
OCSPP	Office of Chemical Safety and Pollution Prevention
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational exposure limit
ONU	Occupational non-user
OPPT	Office of Pollution Prevention and Toxics
OSF	Oral slope factor
OSHA	Occupational Safety and Health Administration
PBPK	Physiologically based pharmacokinetic
PBT	Persistent, bioaccumulative, toxic
PECO	Population, exposure, comparator, and outcome
PESO	Pathways and processes, exposure, setting or scenario, and outcomes
PESS	Potentially exposed or susceptible subpopulations
POD	Point of departure
POTW	Publicly owned treatment works
PPE	Personal protective equipment
PVC	Polyvinyl chloride
RCRA	Resource Conservation and Recovery Act
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals (European Union)
RESO	Receptors, exposure, setting or scenario, and outcomes
RQ	Risk quotient
SACC	Science Advisory Committee on Chemicals
SDS	Safety data sheet
SDWA	Safe Drinking Water Act
SMILES	Simplified molecular-input line-entry system
SRC	SRC, Inc., formerly Syracuse Research Corporation
SVHC	Substance of very high concern (European Union)
$T_{1/2}$	Half-life

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TCCR	Transparent, clear, consistent, and reasonable
TIAB	Title and abstract
TMF	Trophic magnification factors
TRI	Toxics Release Inventory
TSCA	Toxic Substances Control Act
U.S.C.	United States Code
VP	Vapor pressure
WS	Water solubility
WWTP	Wastewater treatment plant

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EXECUTIVE SUMMARY

On May 24, 2019, EPA received a request, pursuant to 40 CFR 702.37, from ExxonMobil Chemical Company, Evonik Corporation, and Teknor Apex, through the American Chemistry Council's High Phthalates Panel (ACC HPP), to conduct a risk evaluation for di-isononyl phthalate (DINP) (CASRNs 28553-12-0 and 68515-48-0) (Docket ID: EPA-HQ-OPPT-2018-0436). EPA determined that these two CASRNs should be treated as a category of chemical substances as defined in 15 U.S.C. § 2625(c). On August 19, 2019, EPA opened a 45-day public comment period to gather information relevant to the requested risk evaluation. EPA reviewed the request (along with additional information received during the public comment period) and assessed whether the circumstances identified in the request constitute conditions of use under 40 CFR 702.33, and whether those conditions of use warrant inclusion within the scope of a risk evaluation for DINP. EPA determined that the request meets the applicable regulatory criteria and requirements, as prescribed under 40 CFR 702.37. The Agency granted the request on December 2, 2019.

The first step of the risk evaluation process is the development of the scope document. EPA published the *Draft Scope of the Risk Evaluation for Di-isononyl Phthalate* (CASRNs 28553-12-0 and 68515-48-0) (EPA Document No. EPA-740-D-20-033) (U.S. EPA, 2020d) 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-2018-0436) during the public comment period to inform the development of this final scope document, and public comments received will continue to inform the development of the risk evaluation for DINP. This document fulfills the statutory and regulatory requirements under the Toxic Substances Control Act (TSCA) to issue a final scope document per TSCA section 6(b)(4)(D) and 40 CFR 702.41(c)(8). The scope for DINP includes the following information: the conditions of use; potentially exposed or susceptible subpopulations (PESS), hazards, and exposures that EPA plans to consider in this risk evaluation, along with a description of the reasonably available information and science approaches EPA plans to use in the risk evaluation; a conceptual model; an analysis plan; and the plan for peer review of the draft risk evaluation for this category of chemical substances.

General Information: DINP is a common chemical name for the category of chemical substances that includes the following substances: 1,2-benzenedicarboxylic acid, 1,2-isononyl ester (CASRN 28553-12-0) and 1,2-benzenedicarboxylic acid, di-C9-11-branched alkyl esters, C9-rich (CASRN 68515-48-0). Both CASRNs contain mainly C9 dialkyl phthalate esters. DINP has a total production volume in the United States between 200 and 500 million pounds (U.S. EPA, 2020a).

Reasonably Available Information: To inform the development of this scope document, EPA leveraged the data and information sources identified within the ACC HPP submission requesting EPA conduct the risk evaluation for DINP (Docket ID: EPA-HQ-OPPT-2018-0436), as well as any other data or information sources identified throughout the course of the submission and review process for this manufacturer requested risk evaluation. To further develop this scope document, EPA conducted a comprehensive search to identify and screen multiple evidence streams (*i.e.,* chemistry, fate, release and engineering, exposure, hazard), and the search and screening results to date are provided in Section 2.1.

Conditions of Use: EPA plans to evaluate manufacturing (including importing); processing; distribution in commerce; industrial, commercial, and consumer uses; and disposal of DINP in the risk evaluation. DINP is manufactured (including imported) in the United States. The chemical is processed as a reactant, incorporated into a formulation, mixture, or reaction product, and incorporated into articles. The identified processing activities also include the repackaging and recycling of DINP. DINP is primarily used as a plasticizer in polyvinyl chloride (PVC) in consumer, commercial, and industrial

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applications. Industrial and commercial uses were identified, including use of automotive, fuel, agriculture, and outdoor use products and construction, paint, electrical, and metal products. Consumer uses, such as use of furnishing, cleaning, and treatment/care products, were also identified.

Some of these conditions of use were identified in the manufacturer request as circumstances on which EPA was requested to conduct a risk evaluation. EPA identified other conditions of use from information reported to EPA through Chemical Data Reporting (CDR), published literature, and consultation with stakeholders for both uses currently in production and uses whose production may have ceased. EPA presented the proposed additions of these EPA-identified conditions of use and the basis for these proposed additions, along with the manufacturer request, for a 45-day comment period in August 2019. EPA revised the conditions of use in the final scope of the risk evaluation based on additional information received from public comments (Docket ID: EPA-HQ-OPPT-2018-0436) on the draft scope document for DINP. Section 2.2 provides additional details about the conditions of use within the scope of the risk evaluation.

Conceptual Model: The conceptual models for DINP 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 a chemical substance or category of chemical substances—from manufacturing (including import), processing, distribution in commerce, use, or disposal. EPA considered reasonably available information, including information received in the ACC HPP submission, as well as public comments received on the draft scope document for DINP, in finalizing the exposure pathways, exposure routes, and hazards EPA plans to evaluate in the risk evaluations. As a result, EPA plans to focus the risk evaluation for DINP on the following exposures, hazards, and receptors:

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

  In Section 2.6, EPA presents the conceptual models describing the identified exposures (pathways and routes), receptors and hazards associated with the conditions of use of DINP within the scope of the risk evaluation.

  EPA considered reasonably available information and comments received on the draft scope for DINP 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, including incidental ingestion of inhaled dust, and exposures to workers via the dermal route associated with the manufacturing, processing, use and disposal of DINP. 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 inhalation, dermal, and oral exposure to DINP for consumers and bystanders from the use of adhesives and sealants; air care products; arts, crafts, and hobby materials; automotive care products; building/construction materials not covered elsewhere; cleaning and furniture care products; electrical and electronic products; fabric, textile, and leather products not

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covered elsewhere; floor coverings; foam seating and bedding products; furniture and furnishings not covered elsewhere; ink, toner, and colorant products; paints and coatings; paper products; plastic and rubber products not covered elsewhere; and toys, playground, and sporting equipment; and direct contact and/or mouthing of products or articles containing DINP for consumers.

  - *General population exposure:* EPA plans to evaluate general population exposure to DINP via the oral route from drinking water, surface water, groundwater, ambient air, soil, fish ingestion, and human breast milk; via the inhalation route from air and drinking water; and via the dermal route from contact with drinking water, surface water, groundwater and soil.
  - *PESS:* EPA plans to include children; women of reproductive age (*e.g.,* women who may be pregnant or breastfeeding); workers; ONUs; consumers; and bystanders as receptors and PESS in the risk evaluation (Section 2.5).
  - *Environmental exposure:* EPA plans to evaluate exposure to DINP for aquatic and terrestrial receptors.

- *Hazards:* Hazards for DINP are discussed in Section 2.4. EPA preliminarily reviewed information from the ACC HPP submission requesting EPA conduct the risk evaluation for DINP (Docket ID: EPA-HQ-OPPT-2018-0436) in order to identify potential environmental and human health hazards for DINP. EPA also considered reasonably available information identified through systematic review methods as outlined in Appendix A and public comments received on the draft scope for DINP to determine the broad categories of environmental and human health hazard effects to be evaluated in the risk evaluation. EPA plans to evaluate the epidemiological and toxicological literature for DINP using revised evaluation strategies. These revised evaluation strategies are described in a draft systematic review protocol that EPA plans to release later this year.

  EPA plans to evaluate all potential environmental and human health hazard effects identified for DINP in Sections 2.4.1 and 2.4.2, respectively. Identified through preliminary review of information contained in the ACC HPP submission as well as through the data screening phase of systematic review, the potential environmental hazard effects and related information that EPA plans to consider for the risk evaluation for DINP include: absorption, distribution, metabolism, and excretion (ADME); cardiovascular; developmental; endocrine; hematological and immune; hepatic; mortality; musculoskeletal; neurological; nutritional and metabolic; renal; reproductive; and respiratory effects. Similarly, the potential human health hazard effects and related information identified through the data screening phase of systematic review for DINP that EPA plans to consider for the risk evaluation include: ADME, physiologically based pharmacokinetic (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 DINP 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 DINP to date, which includes a review of identified information as described in Section 2.1. EPA plans to consider new information submitted by the public. Should additional data or approaches become reasonably available, EPA may consider them for the risk evaluation.

Peer Review: The draft risk evaluation for DINP will be peer reviewed. Peer review will be conducted in accordance with relevant and applicable methods for chemical risk evaluations, including using

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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

On May 24, 2019, EPA received a request from ExxonMobil Chemical Company, Evonik Corporation, and Teknor Apex, through the ACC HPP, to conduct a risk evaluation for DINP (CASRNs 28553-12-0 and 68515-48-0) (Docket ID: EPA-HQ-OPPT-2018-0436) under the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the legislation that amended TSCA on June 22, 2016. In December 2019, EPA notified the requesters that the Agency had granted their manufacturer requested risk evaluation for DINP. Pursuant to 40 CFR 702.37(e)(6)(iv), the requesters had 30 days subsequent to receipt of this notification to withdraw their request. In January of 2020, upon the expiration of this 30-day period, the risk evaluation for DINP was initiated.

Amended TSCA includes requirements and deadlines for actions related to conducting risk evaluations of existing chemicals, including requirements for manufacturer requested risk evaluations. TSCA section 6(b)(4) and 40 CFR 702.37 direct EPA to review manufacturer requests for risk evaluations on a chemical substance or for a category of chemical substances, and upon granting the request pursuant to 40 CFR 702.37, TSCA section 6(b)(4) directs EPA to initiate a risk evaluation on the chemical substance or category of chemical substances. TSCA section 6(b)(4)(A) directs EPA, in conducting risk evaluations for existing chemicals, to "determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other 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 section 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 document is to be published pursuant to 40 CFR 702.41. On November 27, 2020, EPA published the *Draft Scope of the Risk Evaluation for Di-isononyl Phthalate* (CASRNs 28553-12-0 and 68515-48-0) (EPA Document No. EPA-740-D-20-033) (85 FR 76072, November 27, 2020) (U.S. EPA, 2020d) for a 45-day public comment period. After reviewing and considering the public comments received (Docket ID: EPA-HQ-OPPT-2018-0436) on the draft scope document, EPA is now publishing this final scope document pursuant to 40 CFR 702.41(c)(8).

2 SCOPE OF THE EVALUATION

2.1 Reasonably Available Information

EPA conducted a comprehensive search for reasonably available information[1] to support the development of this scope document for DINP. EPA leveraged the data and information sources already identified in the ACC HPP submission requesting that EPA conduct the risk evaluation for DINP (see Appendix A.4), as well as any other data or information identified throughout the public comment period for the submission and EPA's review process for this manufacturer requested risk evaluation, as laid out in 40 CFR 702.37. In addition, EPA conducted an independent search for additional data and information on physical and chemical properties, environmental fate, engineering, exposure,

[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).

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environmental and human health hazards that could be obtained from the following general categories of sources:

1. Databases containing publicly available, peer-reviewed literature;
2. Gray literature, which is defined as the broad category of data/information sources not found in standard, peer-reviewed literature databases, including data/information sources such as white papers, conference proceedings, technical reports, reference books, dissertations, information on various stakeholder websites, and other databases; and
3. Data and information submitted under TSCA sections 4, 5, 8(e), and 8(d), as well as "for your information" (FYI) submissions.

Search terms were used to search each of the literature streams and gather 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 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, and outcome (PECO), population, exposure, setting or scenario, and outcome (PESO), and receptor, exposure, setting or scenario, and outcome (RESO) statements listed in Appendix A. The screening process results are presented in the form of literature inventory trees and heat maps in Section 2.1.2. The screening process was conducted based on EPA's planning, execution, and assessment activities outlined in Appendix A.

In addition, 166 data and information sources identified by ACC HPP in Appendix C of the manufacturer request submission (Docket ID: EPA-HQ-OPPT-2018-0436) (see Appendix A.4) were not included in EPA's search results, and these additional references will undergo the same systematic review methods as applied to those sources identified by EPA.

The subsequent sections summarize the data collection activities completed to date for the general categories of sources and topic areas (or disciplines) using literature acquisition and screening methods as outlined in Appendix A and described in the draft systematic review protocol that EPA plans to release later this year.

2.1.1 Search of Gray Literature

EPA surveyed the gray literature and identified 152 search results relevant to EPA's risk assessment needs for DINP. Appendix A.3.4 lists the gray literature sources that yielded 152 discrete data or information sources relevant to DINP. EPA further categorized the data and information into the various topic areas (or disciplines) supporting the risk evaluation (*e.g.,* physical and chemical properties, environmental fate, environmental hazard, human health hazard, exposure, engineering) and the breakdown is shown in Figure 2-1. EPA will consider additional reasonably available information from gray literature if it becomes available during the risk evaluation phase.

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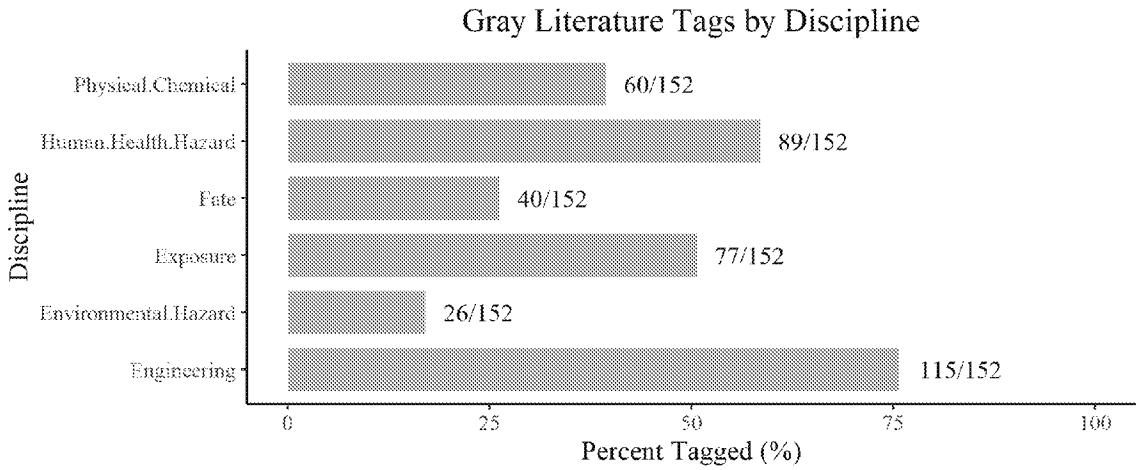

Figure 2-1. Gray Literature Tags by Discipline for DINP
The percentages across disciplines do not add up to 100%, as each source may provide data or information for various topic areas (or disciplines). The gray literature sources depicted in this figure were identified by EPA using systematic review methods.

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

EPA 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 reviewed 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 DINP. Eligibility criteria were applied in the form of PECO, RESO, and PESO statements (see Appendix A). Included references met the PECO, RESO, and PESO 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.. For all disciplines, static screen captures are provided in addition to links within each figure's caption to the interactive literature inventory trees. The links show individual studies that were tagged as included, excluded, or supplemental. Supplemental studies did not meet all inclusion criteria, but may be considered during the risk evaluation as supporting information (see Appendix A). These studies can be accessed through the hyperlink provided in the associated caption below each figure. In some figures, the sum of the numbers for the various sub-categories may be larger than the broader category because some studies may be included under multiple sub-categories. In other cases, the sum of the various sub-categories may be smaller than the

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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.

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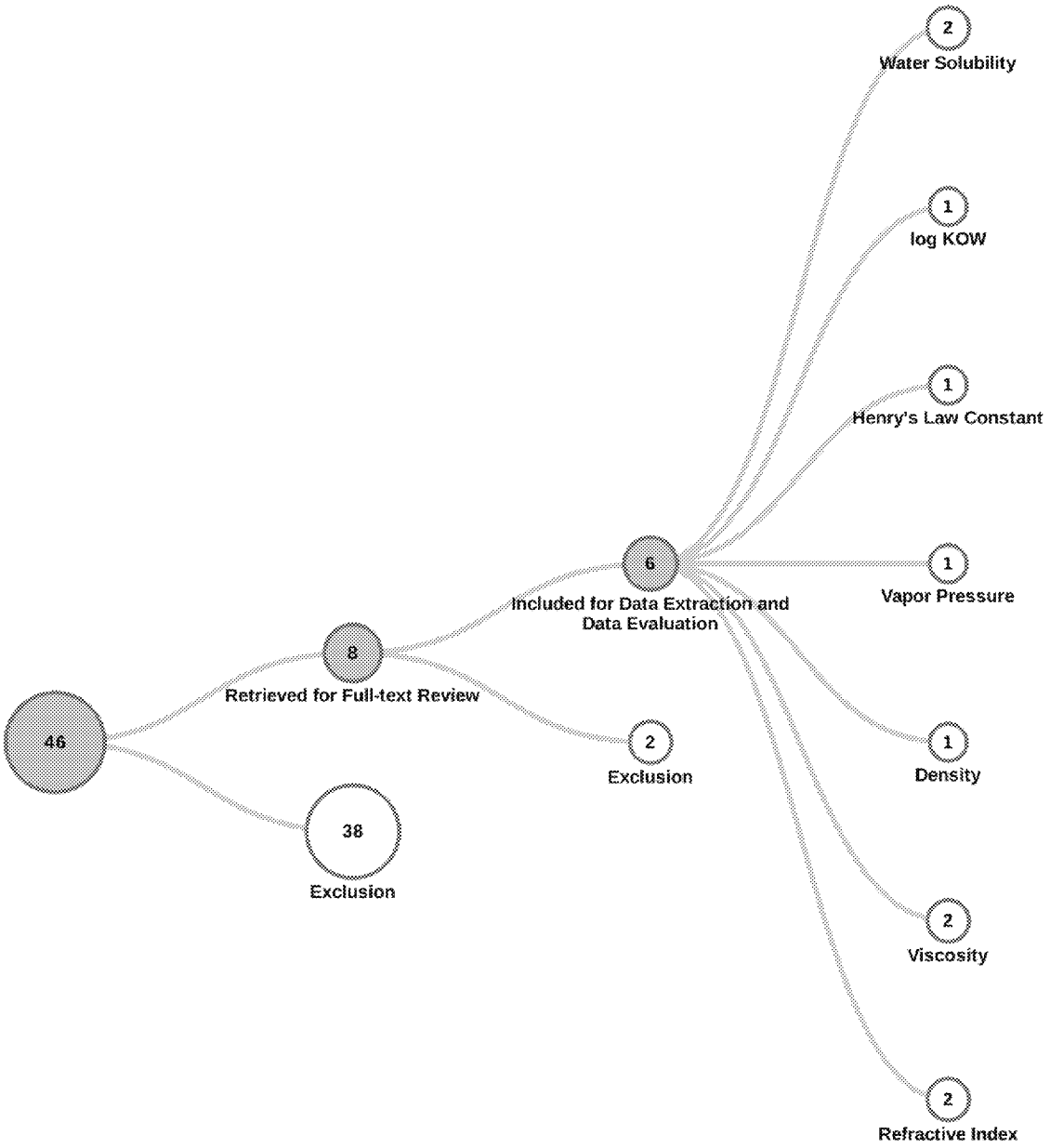

Figure 2-2. Peer-Reviewed Literature – Physical and Chemical Properties Search Results for DINP

See the interactive literature inventory tree in HAWC. 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 April 12, 2021. Additional data may be added to the interactive version as they become available.

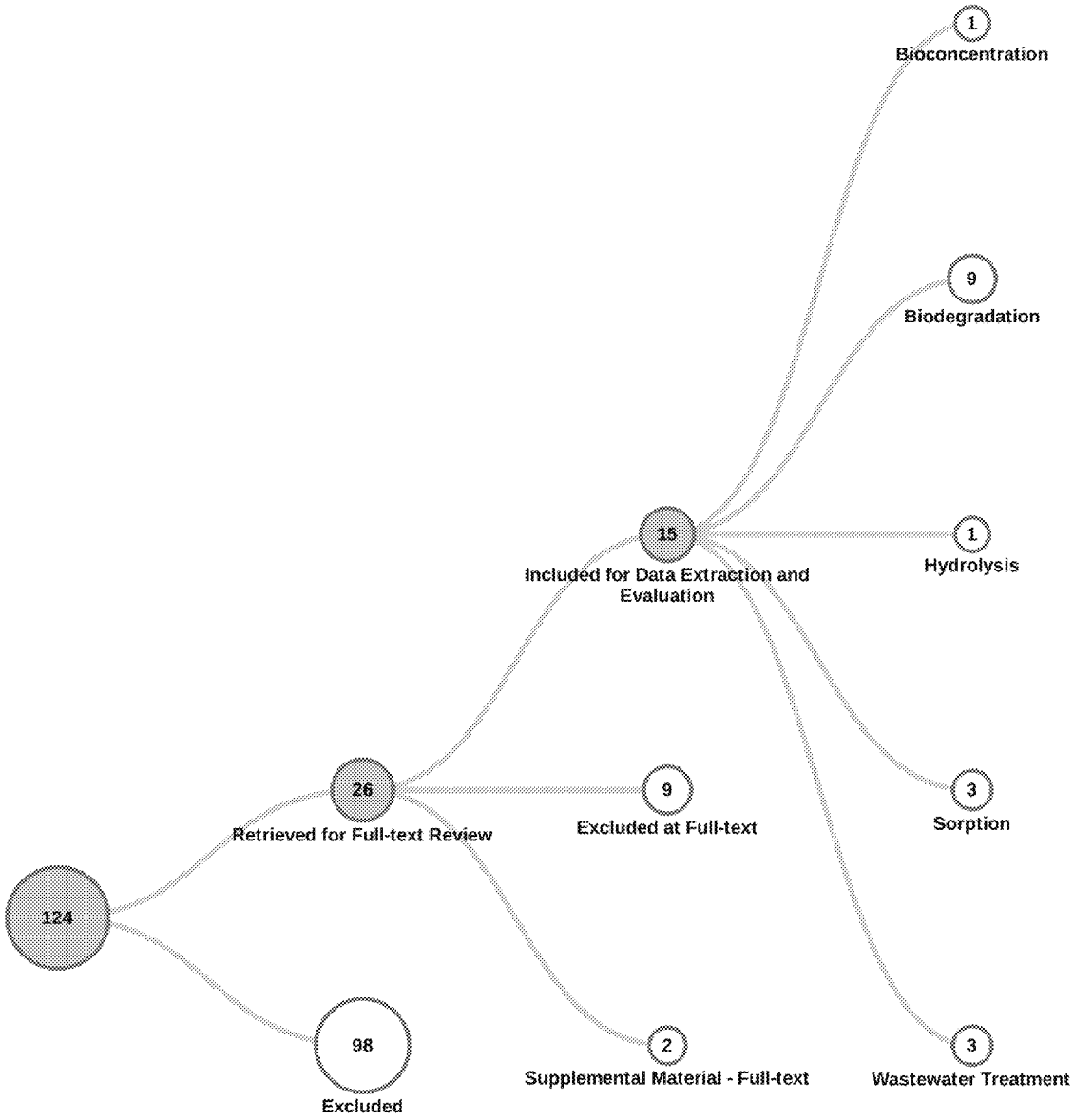

Figure 2-3. Peer-Reviewed Literature – Fate and Transport Search Results for DINP
See the interactive literature inventory tree in HAWC. Data in this figure represents references obtained from the publicly available databases search (see Appendix A.1.2) that were included during full-text screening as of April 26, 2021. Additional data may be added to the interactive version as they become available.

	Media					
Endpoint	Air	Soil, Sediment	Wastewater, Biosolids	Water	Other	Grand Total
Bioconcentration		1		1		1
Biodegradation		5	2	2	1	9
Hydrolysis				1		1
Photolysis						
Sorption		2		3		3
Volatilization						
Wastewater Treatment			3	1		3
Other						
Grand Total		7	4	7	1	15

Figure 2-4. Peer-Reviewed Literature Inventory Heat Map – Fate and Transport Search Results for DINP

See the interactive version in HAWC 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 represents references obtained from the publicly available databases search (see Appendix A.1.2) that were included during full-text screening as of April 26, 2021. Additional data may be added to the interactive version as they become available.

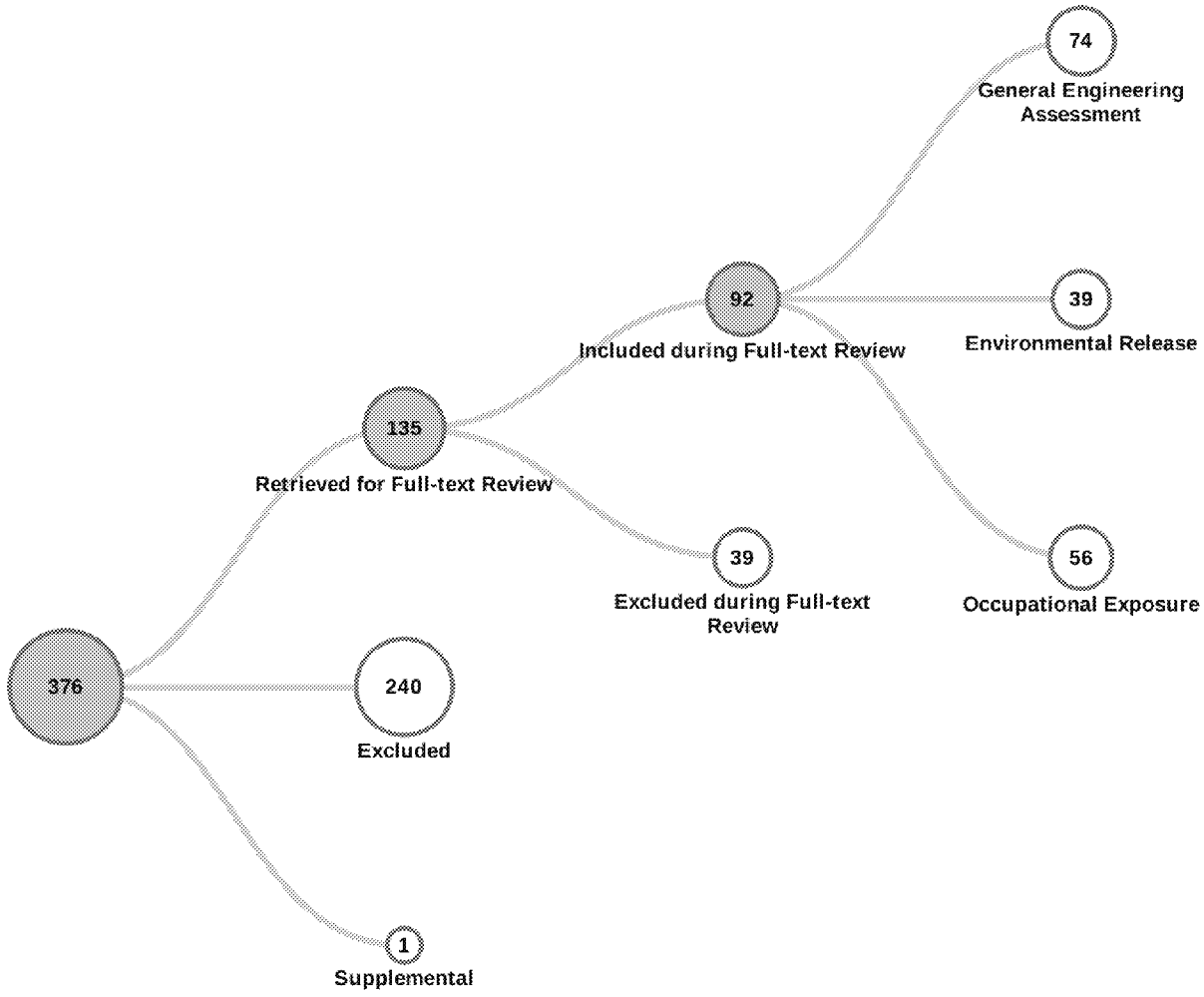

Figure 2-5. Peer-Reviewed Literature Inventory Tree – Engineering Search Results for DINP
See the interactive literature inventory tree in HAWC. Data in this figure represent references obtained from the publicly available databases search (see Appendix A.1.2) that were included during full-text screening as of April 21, 2021. Additional data may be added to the interactive version as they become available.

Data Type	Evidence Tags	
Environmental Releases	Description of release source	32
	No evidence tag	2
	Release frequency	4
	Release or emission factors	22
	Release quantity	16
	Waste treatment methods and pollution control	14
	Total	39
General Engineering Assessment	Chemical concentration	47
	Exposure route	
	Life cycle description	24
	No evidence tag	3
	Number of sites	12
	Physical form	
	Process description	30
	Production, import, or use volume	42
	Throughput	7
	Total	74
Occupational Exposures	Area sampling data	17
	Dermal exposure data	22
	Engineering control	8
	Exposure duration	10
	Exposure frequency	3
	Exposure route	41
	No evidence tag	5
	Number of workers	14
	Particle size characterization	1
	Personal protective equipment	9
	Personal sampling data	15
	Physical form	24
	Worker activity description	22
	Total	56
Grand Total		92

Figure 2-6. Peer-Reviewed Literature Inventory Heat Map – Engineering Search Results for DINP

See the interactive version in HAWC for additional study details. 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 April 21, 2021. Additional data may be added to the interactive version as they become available.

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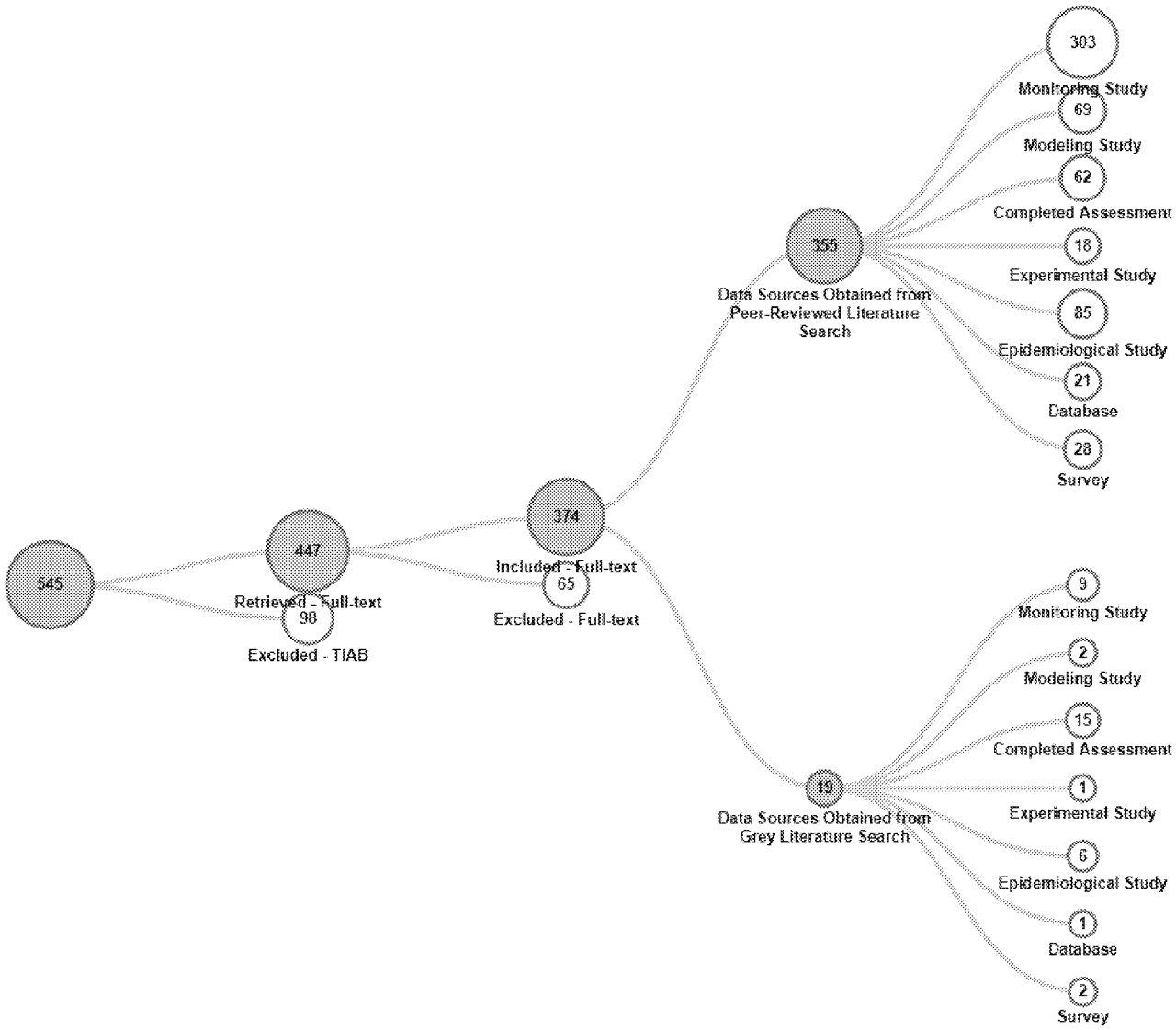

Figure 2-7. Peer-Reviewed and Gray Literature – Exposure Search Results for DINP
See the interactive literature inventory tree in HAWC. Data in this figure represents references obtained from the publicly available databases search (see Appendix A.1.2), and gray literature references search (see Appendix A.3) that were included during full-text screening as of April, 28, 2021. Additional data may be added to the interactive version as they become available.

Media (group)	Data Type: Monitoring Study	Modeling Study	Completed Assessment	Experimental Study	Epidemiological Study	Database	Survey	Grand Total
Ambient Air	16	7	10	1	2		2	22
Biosolids/Sludge	8		3	1				10
Drinking Water	5	1	3	1	1		1	6
Groundwater	3	1	4					6
Sediment	26	2	10					31
Soil	13	4	8	1	2		1	18
Surface Water	24	3	8					29
Wastewater	6		5					9
Aquatic Species	5	2	8	1	1		1	10
Terrestrial Species	6	1	3					8
Consumer	28	16	35	16	8		6	64
Dietary	29	16	22	4	6	1	2	43
Dust	42	23	20	3	11		10	56
Exposure Factors	16	9	22	2	10	1	2	32
Exposure Pathway	12	4	12	2	6		3	20
Human Biomonitoring	137	32	32	2	78	21	21	202
Indoor Air	27	16	12	5	5		4	40
Isomers	1		2					3
Use Information	7	4	22	2	2		1	26
Land Disposal/Landfill	1		1					2
Grand Total	312	71	77	19	91	22	30	374

Figure 2-8. Peer-Reviewed and Gray Literature Inventory Heat Map – Exposure Search Results for DINP

See the interactive version in HAWC for additional study details. The column totals, row totals, and grand totals indicate total numbers of unique references only, 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 April 28, 2021. Additional data may be added to the interactive version as they become available.

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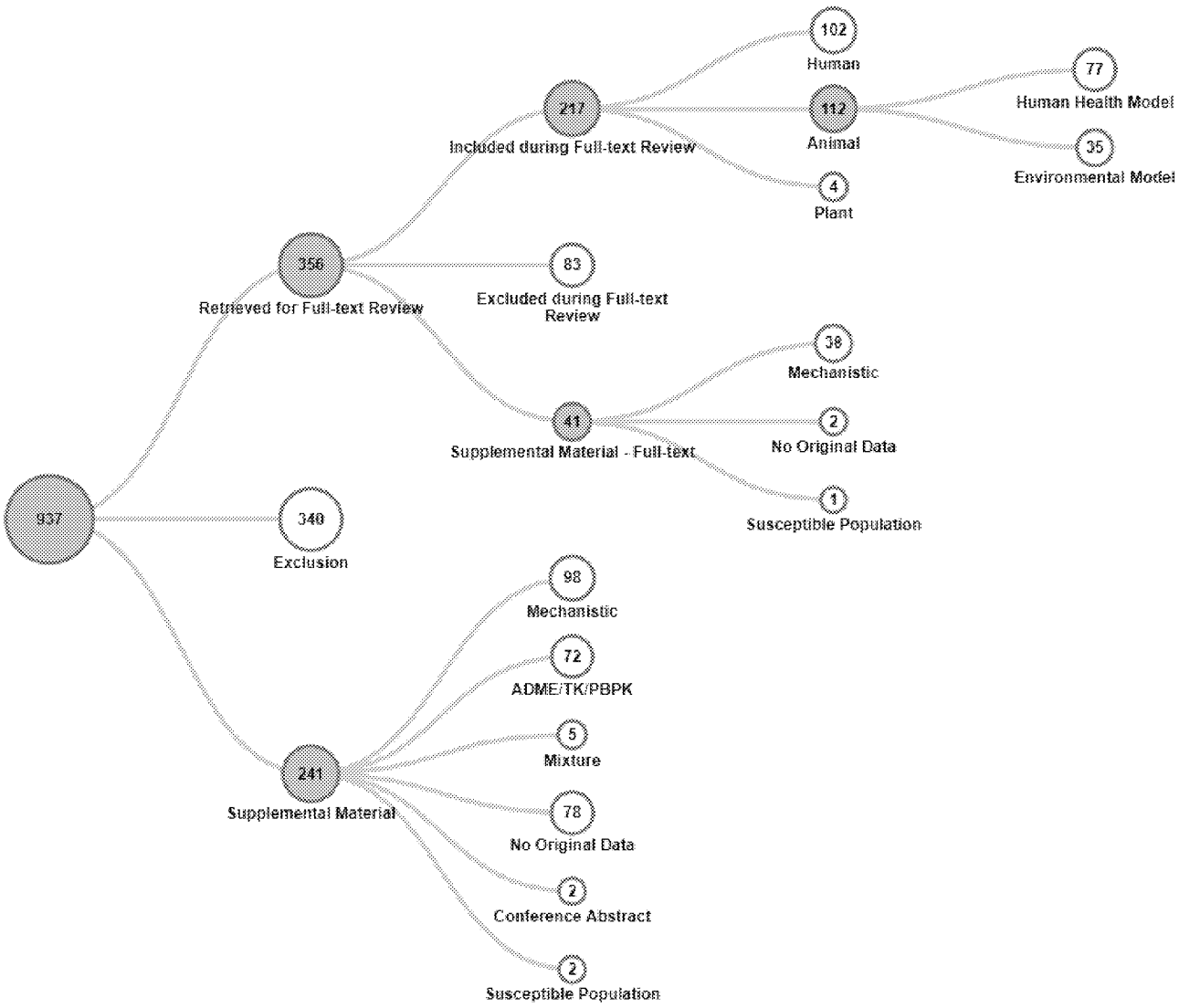

Figure 2-9. Peer-Reviewed Literature Inventory Tree – Human Health and Environmental Hazards Search Results for DINP

See the interactive literature inventory tree in HAWC. 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 May 3, 2021. Additional data may be added to the interactive version as they become available.

Health Outcomes	Evidence Type: Human	Animal - Human Health Model	Animal - Environmental Model	Plant	Grand Total
ADME	91	13	6	1	111
Cancer	5	8			13
Cardiovascular	8	1	1		10
Developmental	65	23	10		98
Endocrine	36	21	9		66
Gastrointestinal	1	1			2
Hematological and Immune	40	22	3		65
Hepatic		20	3		23
Mortality	2	2	9	1	13
Musculoskeletal	3	5	1		9
Neurological	12	6	1		19
Nutritional and Metabolic	34	10	6	1	51
Ocular and Sensory	11	6			17
PBPK	2	1			3
Renal	47	8	1		56
Reproductive	60	26	8		94
Respiratory	14	3	1		18
Skin and Connective Tissue	8	8			16
No Tag	1	23	22	2	48
Grand Total	102	77	35	4	217

Figure 2-10. Peer-Reviewed Literature Inventory Heat Map – Human Health and Environmental Hazards Search Results for DINP

See the interactive version in HAWC 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 DINP. Evidence types were manually extracted, and Health Outcomes 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 May 3, 2021. 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 108 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 72 submissions that met the inclusion criteria in these statements and identified 26 submissions with supplemental data.[2] EPA excluded 10 submissions because the reports were identified as one of the following:

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

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- Interim report of a final available submitted report;
- Submission on a different chemical;
- Letter of notification with no data;
- Letter declassifying a previous submission; and
- Letter with correction to a previous submission.

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

Discipline	Included	Supplemental[b]
Physical and Chemical	4	0
Environmental Fate and Transport	17	2
Environmental and General Population Exposure	1	0
Occupational Exposure/Release Information	0	0
Environmental Hazard	27	1
Human Health Hazard	28	24

[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

The ACC HPP submission requesting that EPA conduct a risk evaluation of DINP included a list of circumstances that EPA has since determined to be conditions of use[3] that warrant inclusion in the risk evaluation for this category of chemical substances, pursuant to TSCA section 3(4). EPA further assembled reasonably available information from CDR to identify additional conditions of use for inclusion in this scope of the risk evaluation. EPA consulted a variety of other sources (including published literature, company websites, and government and commercial trade databases and publications) to identify conditions of use of DINP. To identify formulated products containing DINP, EPA searched for safety data sheets (SDS) using internet searches, EPA Chemical and Product Categories (CPCat) (U.S. EPA, 2014) 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 on the draft scope to supplement the information on conditions of use. EPA presented the proposed additions of these EPA-identified conditions of use and the basis for these proposed additions, along with the manufacturer request, for a 45-day comment period in August 2019. The December 2, 2019, notification in which EPA granted the request for a risk evaluation for DINP identified additional conditions of use that are included in the scope of the risk evaluation.

The categories and subcategories of conditions of use that EPA plans to consider in the risk evaluation are presented in 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] *Conditions of use* means the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of (15 U.S.C. § 2602(4)).

The circumstances on which ACC HPP is requesting that EPA conduct a risk evaluation were determined to be conditions of use. After gathering reasonably available information related to the manufacture, processing, distribution in commerce, use, and disposal of DINP, EPA also identified those activities for DINP the Agency determined not to be conditions of use. 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.

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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 of Use[c e]	Reference (CASRN 28553-12-0)	Reference (CASRN 68515-48-0)
Manufacturing	Domestic manufacturing	Domestic manufacturing[d]	U.S. EPA (2020a)	U.S. EPA (2020a)
	Importing	Importing[d]	U.S. EPA (2020a)	U.S. EPA (2020a)
Processing	Processing as a reactant	Plasticizers	U.S. EPA (2020a)	
		Plastic material and resin manufacturing		U.S. EPA (2020a)
		Processing aids not otherwise listed (*e.g.,* mixed metal stabilizer)	U.S. EPA (2020a)	
		Rubber product manufacturing		U.S. EPA (2020a)
		Synthetic rubber manufacturing		U.S. EPA (2020a)
	Incorporation into articles	Finishing agents (*e.g.,* all other chemical products and preparation manufacturing)		U.S. EPA (2020a)
		Plasticizers (*e.g.,* toys, playground, and sporting equipment manufacturing)	U.S. EPA (2020a)	U.S. EPA (2020a)
		Textiles, apparel, and leather manufacturing		U.S. EPA (2020a)
		Electrical equipment, appliance, and component manufacturing		U.S. EPA (2020a)
	Incorporation in formulation, mixture, or reaction product	Adhesives and sealants chemicals (*e.g.,* adhesive and sealant manufacturing;	U.S. EPA (2020a)	U.S. EPA (2020a)

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Life Cycle Stage[a]	Category[b]	Subcategory of Use[c e]	Reference (CASRN 28553-12-0)	Reference (CASRN 68515-48-0)
		construction; wholesale and retail trade)		
		Intermediates (*e.g.,* adhesive manufacturing; all other chemical products and preparation manufacturing; plastic material and resin manufacturing)	U.S. EPA (2020a)	U.S. EPA (2020a)
		Laboratory chemicals	Spex Certiprep (2019); TCI America (2019)	
		Plasticizers (*e.g.,* adhesive manufacturing; custom compounding of purchased resin; paint and coating manufacturing; plastic product manufacturing; plastic material and resin manufacturing; synthetic rubber manufacturing; transportation equipment manufacturing; wholesale and retail trade)	U.S. EPA (2020a)	U.S. EPA (2020a)
		Processing aids, not otherwise listed (*e.g.,* all, other basic organic chemical manufacturing; furniture and related product manufacturing)	U.S. EPA (2020a)	

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Life Cycle Stage[a]	Category[b]	Subcategory of Use[c e]	Reference (CASRN 28553-12-0)	Reference (CASRN 68515-48-0)
		Process regulators (*e.g.*, paint and coating manufacturing)	U.S. EPA (2020a)	
		Not known or reasonably ascertainable (*e.g.*, petroleum refineries)		U.S. EPA (2020a)
		Viscosity adjustors (*e.g.*, wholesale and retail trade)	U.S. EPA (2020a)	
	Repackaging	Repackaging	U.S. EPA (2020a)	U.S. EPA (2020a)
	Recycling	Recycling		
Distribution in commerce	Distribution in commerce	Distribution in commerce		
Industrial uses	Adhesive and sealant chemicals	Adhesive and sealant chemicals[d]		
	Plasticizer	Plasticizer[d]	Silver Fern Chemical Inc (2015); O'Sullivan Films Inc (2016) EPA-HQ-OPPT-2018-0436-0018	Polyone (2018)
	Automotive, fuel, agriculture, outdoor use products	Automotive care products[d]	U.S. EPA (2020a)	
	Construction, paint, electrical, and metal products	Adhesives and sealants[d]	EPA-HQ-OPPT-2018-0436-0004	EPA-HQ-OPPT-2018-0436-0004
		Building/construction materials not covered elsewhere (*e.g.*, roofing)[d]	U.S. EPA (2020a)	U.S. EPA (2020a)

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Life Cycle Stage[a]	Category[b]	Subcategory of Use[c e]	Reference (CASRN 28553-12-0)	Reference (CASRN 68515-48-0)
Commercial uses	Automotive, fuel, agriculture, outdoor use products	Automotive care products[d]	EPA-HQ-OPPT-2018-0436-0004	EPA-HQ-OPPT-2018-0436-0004
	Construction, paint, electrical, and metal products	Adhesives and sealants[d]	EPA-HQ-OPPT-2018-0436-0004	EPA-HQ-OPPT-2018-0436-0004
		Building/construction materials not covered elsewhere (*e.g.*, roofing)[d]	U.S. EPA (2020a); EPA-HQ-OPPT-2018-0436-0004	U.S. EPA (2020a); EPA-HQ-OPPT-2018-0436-0004
		Electrical and electronic products[d]	U.S. EPA (2020a)	U.S. EPA (2020a)
		Paint and coatings[d]	EPA-HQ-OPPT-2018-0436-0004	EPA-HQ-OPPT-2018-0436-0004
	Furnishing, cleaning, treatment/care products	Foam seating and bedding products	CPSC (2015)	CPSC (2015)
		Cleaning and furniture care products	U.S. EPA (2020a)	U.S. EPA (2020a)
		Air care products		Rustic Escentuals (2015)
		Floor coverings[d]	EPA-HQ-OPPT-2018-0436-0004	U.S. EPA (2020a)
		Fabric, textile, and leather products not covered elsewhere	U.S. EPA (2020a)	U.S. EPA (2020a)
		Furniture and furnishings not covered elsewhere	U.S. EPA (2020a)	U.S. EPA (2020a)
	Packaging, paper, plastic, hobby products	Arts, crafts, and hobby materials	U.S. EPA (2020a)	U.S. EPA (2020a)

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Life Cycle Stage[a]	Category[b]	Subcategory of Use[c e]	Reference (CASRN 28553-12-0)	Reference (CASRN 68515-48-0)
		Plastic and rubber products[d]	U.S. EPA (2020a)	U.S. EPA (2020a)
		Plastic and rubber products not covered elsewhere (*e.g.,* tool handles, flexible tubes, profiles, and hoses)[d]	EPA-HQ-OPPT-2018-0436-0004	EPA-HQ-OPPT-2018-0436-0004
		Toys, playground, and sporting equipment[d]	U.S. EPA (2020a)	U.S. EPA (2020a)
	Construction, paint, electrical, and metal products	Adhesives and sealants[d]	3M (2017)	EPA-HQ-OPPT-2018-0436-0004
		Building/construction materials not covered elsewhere[d]	U.S. EPA (2020a)	U.S. EPA (2020a)
		Paints and coatings[d]	EPA-HQ-OPPT-2018-0436-0004	EPA-HQ-OPPT-2018-0436-0004
	Solvents (for cleaning or degreasing)	Solvents (for cleaning or degreasing)	Green Mountain International (2008)	
	Other uses	Laboratory chemicals	EPA-HQ-OPPT-2018-0504-0019	EPA-HQ-OPPT-2018-0504-0019
		Hydraulic fluids	EPA-HQ-OPPT-2018-0436-0019	EPA-HQ-OPPT-2018-0436-0019
		Pigment	EPA-HQ-OPPT-2018-0436-0019	EPA-HQ-OPPT-2018-0436-0019
Consumer uses	Automotive, fuel, agriculture, outdoor use products	Automotive care products[d]	U.S. EPA (2020a)	U.S. EPA (2020a)
		Electrical and electronic products[d]	U.S. EPA (2020a)	U.S. EPA (2020a)
		Adhesives and sealants[d]	U.S. EPA (2020a)	U.S. EPA (2020a)

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Life Cycle Stage[a]	Category[b]	Subcategory of Use[c e]	Reference (CASRN 28553-12-0)	Reference (CASRN 68515-48-0)
	Construction, paint, electrical, and metal products	Building construction materials not covered elsewhere (*e.g.,* wire and cable jacketing, vinyl tiles, resilient flooring, PVC-backed carpeting, wall coverings, roofing, pool applications, etc.)[d]	U.S. EPA (2020a)	U.S. EPA (2020a)
		Electrical and electronic products[d]	U.S. EPA (2020a)	U.S. EPA (2020a)
		Paint and coatings[d]	U.S. EPA (2020a)	U.S. EPA (2020a)
	Furnishing, cleaning, treatment/care products	Foam seating and bedding products	CPSC (2015)	CPSC (2015)
		Floor coverings[d]	U.S. EPA (2020a)	U.S. EPA (2020a)
		Cleaning and furniture care products	U.S. EPA (2020a)	U.S. EPA (2020a)
		Air care products		Rustic Escentuals (2015)
		Fabric, textile, and leather products not covered elsewhere[d]	U.S. EPA (2020a)	U.S. EPA (2020a)
		Furniture and furnishings not covered elsewhere	U.S. EPA (2020a)	U.S. EPA (2020a)
	Packaging, paper, plastic, hobby products	Arts, crafts, and hobby materials	U.S. EPA (2020a)	U.S. EPA (2020a)
		Ink, toner, and colorant products[d]	Evonik Industries (2019)	U.S. EPA (2020a)
		Plastic and rubber products	U.S. EPA (2020a)	U.S. EPA (2020a)

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Life Cycle Stage[a]	Category[b]	Subcategory of Use[c e]	Reference (CASRN 28553-12-0)	Reference (CASRN 68515-48-0)
		Plastic and rubber products not covered elsewhere (*e.g.,* textiles, apparel, and leather; vinyl tape; flexible tubes; profiles; hoses)[d]	U.S. EPA (2020a)	U.S. EPA (2020a)
		Toys, playground, and sporting equipment[d]	U.S. EPA (2020a)	U.S. EPA (2020a)
		Paper products	Nazdar Company (2015)	
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 DINP in industrial and/or commercial settings.

[c] These subcategories reflect more specific conditions of use of DINP.

[d] Circumstances on which ACC HPP is requesting that EPA conduct a risk evaluation.

[e] In the final scope, EPA has added the following conditions of use: processing aids not otherwise listed (*e.g.,* mixed metal stabilizer); and foam seating and bedding products, air care products, furniture and furnishings not covered elsewhere (EPA-HQ-OPPT-2018-0436-0028). Due to additional information from stakeholder outreach, public comments, and further research, the following condition of use was removed after the publication of the draft scope document: personal care products.

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2.2.2 Activities Excluded from the Scope of the Risk Evaluation

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. 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.[4] As a result, EPA does not plan to include in this scope document or in the risk evaluation activities that the Agency does not consider to be conditions of use.

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."

The Food and Drug Administration lists DINP 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, use of DINP in food packaging materials is excluded from the definition of "chemical substance" in TSCA section 3(2)(B)(vi) and is 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 section 3(4)) and will not be evaluated during risk evaluation.

As described in the preamble to the Risk Evaluation Rule (*See Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act*, 33726 Fed. Reg. 33735 (July 20, 2017), EPA may consider potential risk from non-TSCA uses in evaluating whether a chemical substance presents an unreasonable risk. Although EPA would not regulate non-TSCA uses, the potential exposures of non-TSCA uses may help inform the Agency's risk determination for the exposures from uses that are covered under TSCA (*e.g.,* as background exposures that would be accounted for, should EPA decide to evaluate aggregate exposures).

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 CASRN 28553-12-0 in 2015 was between 100 million and 250 million pounds, and total production volume of CASRN 68515-48-0 in 2015 was between 100 million and 250 million pounds (U.S. EPA, 2020a). EPA plans to include more recent production volume information from the 2020 CDR reporting period in the risk evaluation to support the exposure assessment.

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

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2.2.4 Overview of Conditions of Use and Life Cycle Diagram

Figure 2-11 provides the life cycle diagram for DINP. 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 commercial and consumer uses). Appendix E contains additional descriptions (*e.g.,* process descriptions, worker activities, process flow diagrams) for each manufacture, processing, distribution in commerce, use and disposal category.

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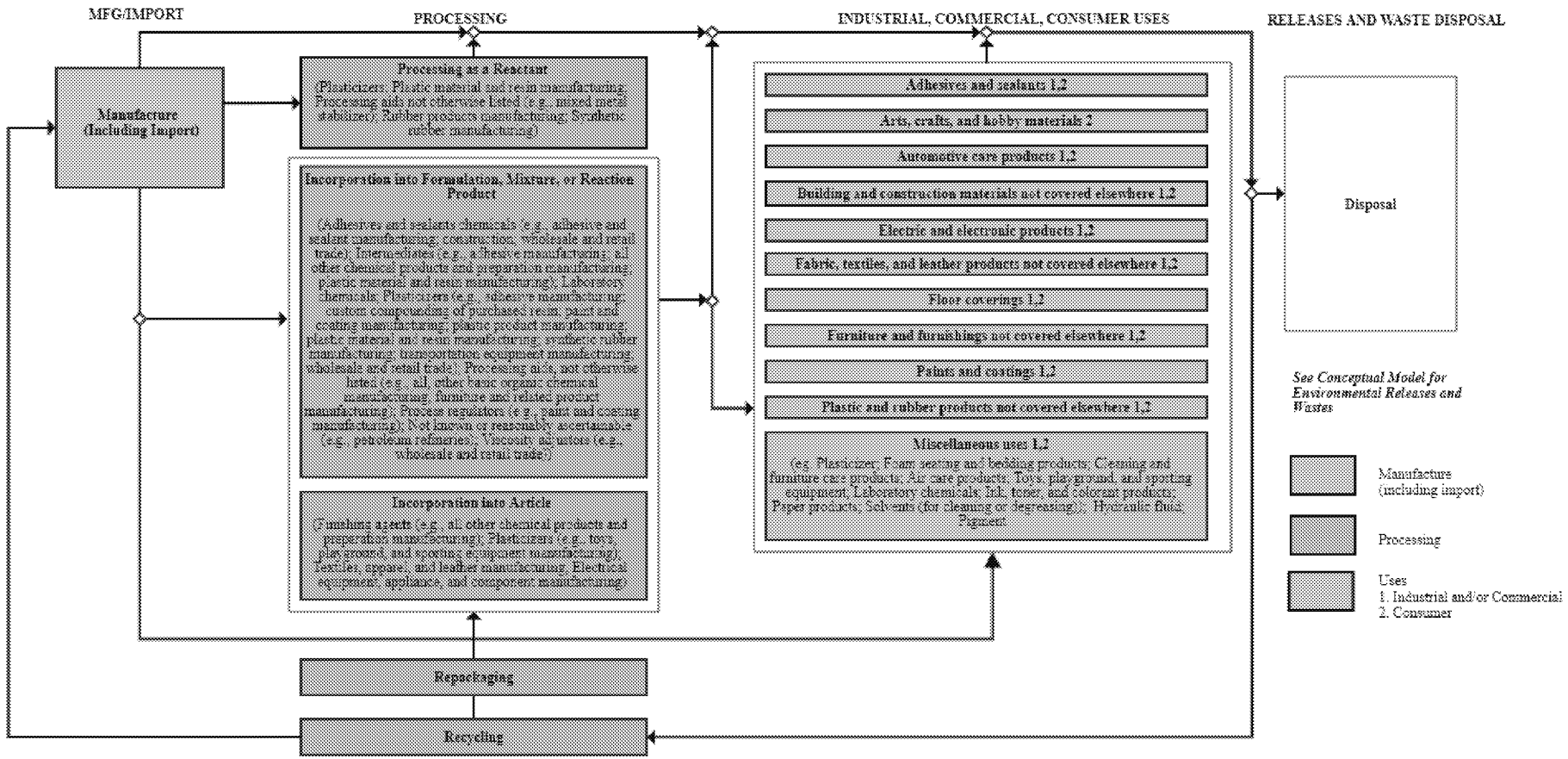

Figure 2-11. DINP Life Cycle Diagram

Distribution in commerce not included in life cycle diagram: For the purposes of the risk evaluation, distribution in commerce is the transportation associated with moving chemical substances in commerce. Unloading and loading activities are associated with other conditions of use. EPA assumes transportation of DINP is in compliance with existing regulations for the transportation of hazardous materials, and emissions are therefore minimal (with the exception of spills and leaks, which are outside the scope of the risk evaluation).

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2.3 Exposures

For TSCA exposure assessments, EPA plans to analyze human and environmental exposures and releases to the environment resulting from the conditions of use within the scope of the risk evaluation of DINP. 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 DINP.

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 may be updated as EPA continues to evaluate and integrate additional information through systematic review and provided in the ACC HPP submission (Docket ID: EPA-HQ-OPPT-2018-0436). Figure 2-12 summarizes the distribution of reported values for eight physical and chemical properties routinely used in existing chemical risk evaluations. Appendix B presents summary statistics for reported physical and chemical property values. All physical and chemical property values that were extracted and evaluated as of June 2020 are presented in the supplemental file *Data Extraction and Data Evaluation Tables for Physical and Chemical Property Studies* (Docket ID: EPA-HQ-OPPT-2018-0436).

Table 2-3. Physical and Chemical Properties of DINP

Property or Endpoint	Value[a]	Reference	Data Quality Rating
Molecular formula	$C_{26}H_{42}O_4$	NA	NA
Molecular weight	418.62 g/mol	NA	NA
Physical state	Liquid	(NLM, 2020)	High
Physical properties	Colorless liquid	(NLM, 2020)	High
Melting point	−48 °C	(NLM, 2020)	High
Boiling point	252 °C at 5 torr	(O'Neil, 2013)	High
Density	0.97578 g/cm^3 at 20°C	(De Lorenzi et al., 1998)	High
Vapor pressure	5.4×10^{-7} mm Hg at 25 °C	(Howard et al., 1985)	High

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Property or Endpoint	Value[a]	Reference	Data Quality Rating
Vapor density	Not available		
Water solubility	0.2 mg/L at 25 °C	(Howard et al., 1985)	High
Log Octanol/water partition coefficient (Log Kow)	9.37	(NLM, 2020)	High
Henry's Law constant	2.08×10^{-5} atm-m^3/mole at 25°C (Bond method)	(U.S. EPA, 2012b)	
Flash point	213 °C	(O'Neil, 2013)	High
Auto flammability	Not available		
Viscosity	55.334 cP at 25 °C	(De Lorenzi et al., 1998)	High
Refractive index	1.48610 at 20 °C	(De Lorenzi et al., 1998)	High
Dielectric constant	Not available		

[a] Measured unless otherwise noted.

Figure 2-12 displays a summary of the data collected by EPA during its independent systematic review process 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. Where no data could be identified through systematic review, text appears to clearly demonstrate the gap for the endpoint.

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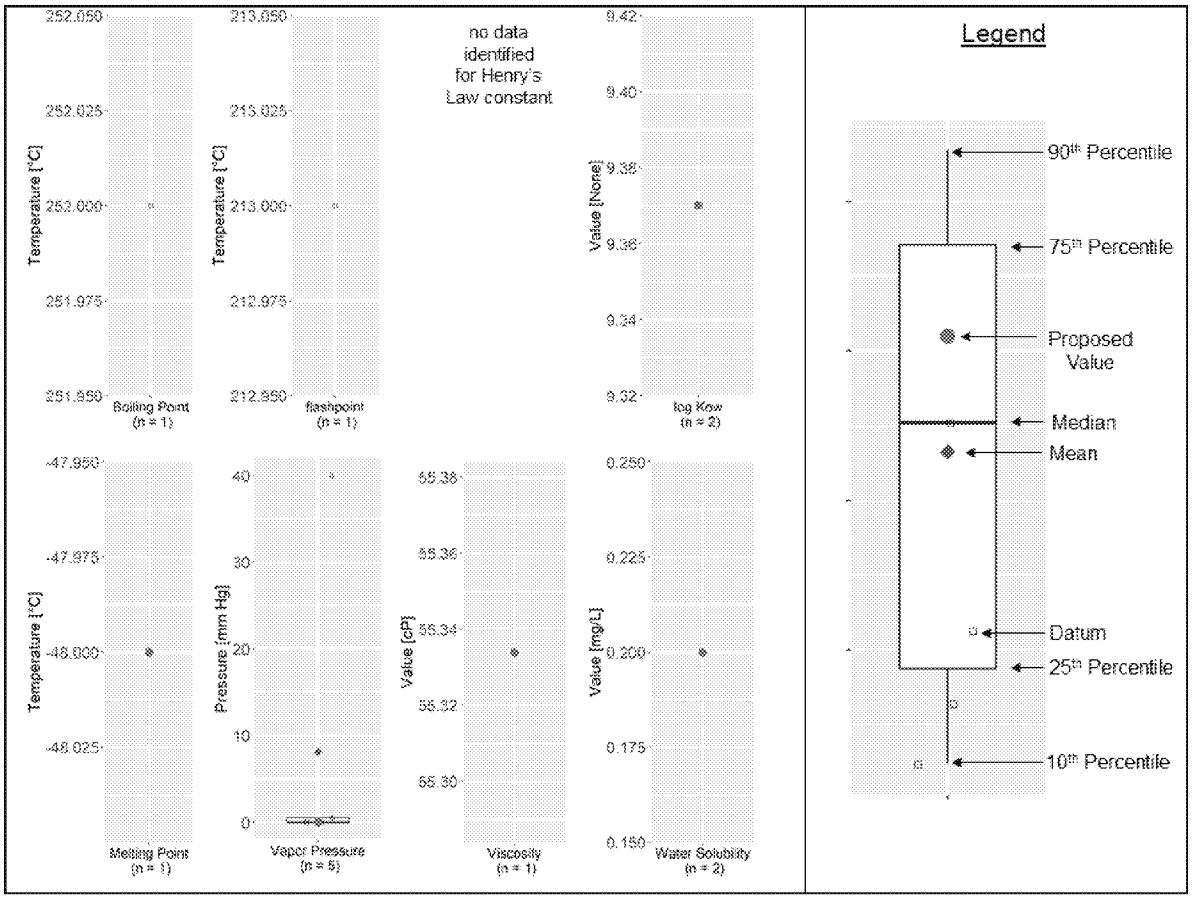

Figure 2-12. Box and Whisker Plots of Reported Physical and Chemical Property Values[5]

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 DINP. EPA plans to use the environmental fate characteristics described in Appendix C to support the development of the risk evaluation for DINP. 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 and information provided in the ACC HPP submission (Docket ID: EPA-HQ-OPPT-2018-0436).

2.3.3 Releases to the Environment

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

DINP is not reported to the Toxics Release Inventory (TRI). There may be releases of DINP from industrial sites to wastewater treatment plants (WWTP), surface water, air and landfills. Articles that contain DINP may release DINP to the environment during use or through recycling and disposal. EPA plans to review these data in conducting the exposure assessment component of the risk evaluation for DINP.

[5] These values may be updated as EPA continues to evaluate and integrate additional information through systematic review and provided in the ACC HPP submission (Docket ID: EPA-HQ-OPPT-2018-0436).

2.3.4 Environmental Exposures

The manufacturing, processing, distribution, use, and disposal of DINP can result in releases to the environment and exposure to aquatic and terrestrial receptors (biota). Environmental exposures 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 DINP.

2.3.5 Occupational Exposures

EPA plans to evaluate worker activities where there is a potential for exposure under the various conditions of use (distribution in commerce, 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 will not make risk determinations based on assumptions about the use of personal protective equipment (PPE) or other control technologies. However, EPA plans to develop exposure scenarios with and without the use of PPE or other control technologies to inform any potential risk management required subsequent to an unreasonable risk determination for workers or ONUs.

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

- Unloading and transferring DINP to and from storage containers to process vessels;
- Handling, transporting, and disposing of waste containing DINP;
- Cleaning and maintaining equipment;
- Sampling chemicals, formulations, or products containing DINP for quality control;
- Repackaging chemicals, formulations, or products containing DINP; and
- Application of formulations containing DINP (*e.g.,* spray, roll).

DINP is a liquid at room temperature and has a vapor pressure of 5.4×10^{-7} mm Hg at 25 °C (Howard et al., 1985) 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 DINP is applied via spray or roll application methods or is handled as a dry powder or at elevated temperatures. DINP does not have occupational exposure limits established by the Occupational Health and Safety Administration (OSHA), the National Institute for Occupational Safety and Health (NIOSH), or the American Conference of Governmental Industrial Hygienists (ACGIH).

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

Workers and ONUs may inadvertently ingest inhaled particles that deposit in the upper respiratory tract. In addition, workers may transfer chemicals from their hands to their mouths. The frequency and significance of this exposure route are dependent on several factors, including the physical and chemical properties of the substance during worker activities, the visibility of the chemicals on the hands while working, workplace training and practices, and personal hygiene that is difficult to predict (Cherrie et al., 2006). EPA will consider the relevance of this exposure route on a case-by-case basis, taking into consideration the aforementioned factors and any reasonably available information, and may assess oral exposure for workers for certain COUs and worker activities where warranted. For certain conditions of use of DINP, 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

Information contained in the submission requesting the risk evaluation for DINP along with CDR reporting and other sources indicate the presence of DINP in a number of consumer products and articles, including: Air Care Products, Adhesives and Sealants; Arts, Crafts, and Hobby Materials; Automotive Care Products; Building/Construction Materials not Covered Elsewhere; Cleaning and Furniture Care Products; Electrical and Electronic Products; Fabric, Textile, and Leather Products not Covered Elsewhere; Foam Seating and Bedding Products; Floor Coverings; Furniture and Furnishings not Covered Elsewhere; Ink, Toner, and Colorant Products; Paints and Coatings; Paper Products; Plastic and Rubber Products not Covered Elsewhere; and Toys, Playground, and Sporting Equipment (see Section 2.6.2 and Figure 2-14) (CPSC, 2010), (CPSC, 2014), (CPSC, 2015b). 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 DINP is possible through either inhalation of vapor/mist during product usage or indoor air/dust. Oral exposure of DINP is possible through either ingestion through product use via transfer from hand to mouth or through mouthing of articles containing DINP. 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 DINP. Based on these potential sources and pathways of exposure, EPA plans to analyze oral, dermal, and inhalation exposures to consumers and inhalation exposures to bystanders that may result from the conditions of use of DINP as described in Section 2.6.2 and the analysis plan.

2.3.7 General Population Exposures

Releases of DINP from certain conditions of use, such as, but not limited to, manufacturing, processing, or disposal activities, may result in general population exposures. A prior report stated that the primary source of exposure to DINP for the general population is expected to be via oral ingestion of food and household dust (EC/HC, 2015). A previous risk assessment, which focused specifically on subpopulations, indicated that the main routes of exposure to DINP for pregnant women/women of reproductive age and children are from dietary intake (CPSC, 2014). Food and food packaging are excluded under the TSCA definition of chemical substance (TSCA section 3(2)) and will not be considered COUs in EPA's risk evaluation as these activities are covered under FFDCA (as described in Section 2.2.2). EPA plans to review the information contained in the ACC HPP submission requesting the risk evaluation for DINP (Docket ID: EPA-HQ-OPPT-2018-0436) as well as other reasonably available information for the presence of DINP in environmental media relevant to general population exposure.

Human biomonitoring data exist, including a Consumer Product Safety Commission (CPSC) study which analyzed exposure to DINP and seven other phthalates in the United States and calculated estimated daily intake concentrations, using National Health and Nutrition Examination Survey (NHANES) 2005/2006, 2007/2008, 2009/2010, and 2011/2012 data sets for measured metabolites in urine (CPSC, 2015a). In addition, the 2019 ACC HPP submission (Docket ID: EPA-HQ-OPPT-2018-0436) references the biomonitoring data from Study for Future Families to estimate exposures prenatal, postnatal, and to children aged 2 to 36 months (Swan et al., 2009).

The presence in environmental media and biomonitoring data suggest that general population exposures are occurring. EPA plans to review reasonably available information related to general population

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exposures in the risk evaluation. The general population pathways in the scope of this evaluation are described in Section 2.6.3.

2.4 Hazards (Effects)

2.4.1 Environmental Hazards

EPA considered information in the ACC HPP submission requesting the risk evaluation for DINP (Docket ID: EPA-HQ-OPPT-2018-0436) and other reasonably available information (*e.g.,* federal and international government chemical assessments). Using automated techniques during the data screening phase of systematic review, EPA identified the following potential hazard effects for aquatic and terrestrial organisms, along with related information that may be considered for the risk evaluation (as explained in Appendix A): ADME, cardiovascular, developmental, endocrine, hematological and immune, hepatic, mortality, musculoskeletal, neurological, nutritional and metabolic, renal, reproductive, and respiratory (Figure 2-10). A summary of references identified during the screening step of systematic review is included in the interactive literature inventory tree (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 information in the ACC HPP submission requesting the risk evaluation for DINP (Docket ID: EPA-HQ-OPPT-2018-0436) and other reasonably available information (*e.g.,* federal and international government chemical assessments). Using automated techniques during the data screening phase of systematic review, EPA identified the following potential human health hazards, along with 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, musculoskeletal, 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 tree (Figure 2-9). As EPA continues to evaluate reasonably available and relevant hazard information identified through systematic review, EPA may update the list of potential hazard effects to be analyzed in the risk evaluation.

2.5 Potentially Exposed or Susceptible Subpopulations

TSCA section 6(b)(4) requires EPA to determine whether a chemical substance or category of chemical substances presents an unreasonable risk to "a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation." TSCA section 3(12) states that "the term 'potentially exposed or susceptible subpopulation' means a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population for adverse health effects from exposure to a chemical substance or mixture, such as infants, children, women who are or may become pregnant, 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 expects to consider the following groups as PESS based on reasonably available information, including studies reporting developmental and reproductive effects, in the risk evaluation: infants, children, women of reproductive age (*e.g.,* women who are or may become pregnant), workers, ONUs, consumers, and bystanders (U.S. EPA, 2012c). Other PESS may be identified based on reasonably available information.

EPA plans to increase consideration of environmental justice[6] issues by evaluating available evidence on factors that may make population groups of concern more vulnerable to adverse effects (*e.g.,* unique pathways; cumulative exposure from multiple stressors; and behavioral, biological, or environmental factors that increase susceptibility), identifying unique considerations for subsistence populations when relevant, and following best practices from (U.S. EPA, 2016). EPA plans to include fenceline analyses where appropriate to screen for potential effects with emphasis on PESS and environmental justice communities, followed by more in-depth analysis where warranted. EPA will continue to develop the science of how to better consider different dimensions of susceptibility when selecting critical endpoints, PODs, determination of uncertainty factors, and margins of exposure.

In developing exposure scenarios, EPA plans to analyze reasonably available data in order to determine whether some human receptor groups may be exposed via exposure pathways that may be distinct to a particular subpopulation or life stage (*e.g.,* reproductive age females who may be or become pregnant; lactating women; infants, toddlers, and children at various developmental stages in life, and elderly) 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 in order to determine 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 expand the PESS considered 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 DINP. Pathways and routes of exposure associated with workers and ONUs are described in Section 2.6.1, and pathways and routes of exposure associated with consumers are described in Section 2.6.2. Pathways and routes of exposure associated with environmental releases and wastes are depicted in the conceptual model shown in Section 2.6.3.

2.6.1 Conceptual Model for Industrial and Commercial Activities and Uses

Figure 2-13 illustrates the conceptual model for the pathways of exposure from industrial and commercial activities and uses of DINP that EPA plans to include in the risk evaluation. There is potential for exposures to workers and/or ONUs via inhalation routes and exposures to workers via dermal routes. The conceptual model also includes potential worker and ONU dermal exposure to DINP in mists and dusts. Dermal exposure to DINP in both liquid and solid form is expected as DINP can be used/transported in liquid or solid form. EPA plans to evaluate activities resulting in exposures associated with distribution in commerce (*e.g.,* loading, unloading) throughout the various life cycle stages and conditions of use (*i.e.,* manufacturing, processing, industrial use, commercial use, and disposal) rather than a single distribution scenario.

Appendix F presents the combinations of exposure pathways, routes, and receptors for each condition of use identified in Table 2-2 along with supporting rationale for whether EPA plans to evaluate those combinations.

[6] Additional information is available regarding EPA's Office of Environmental Justice.

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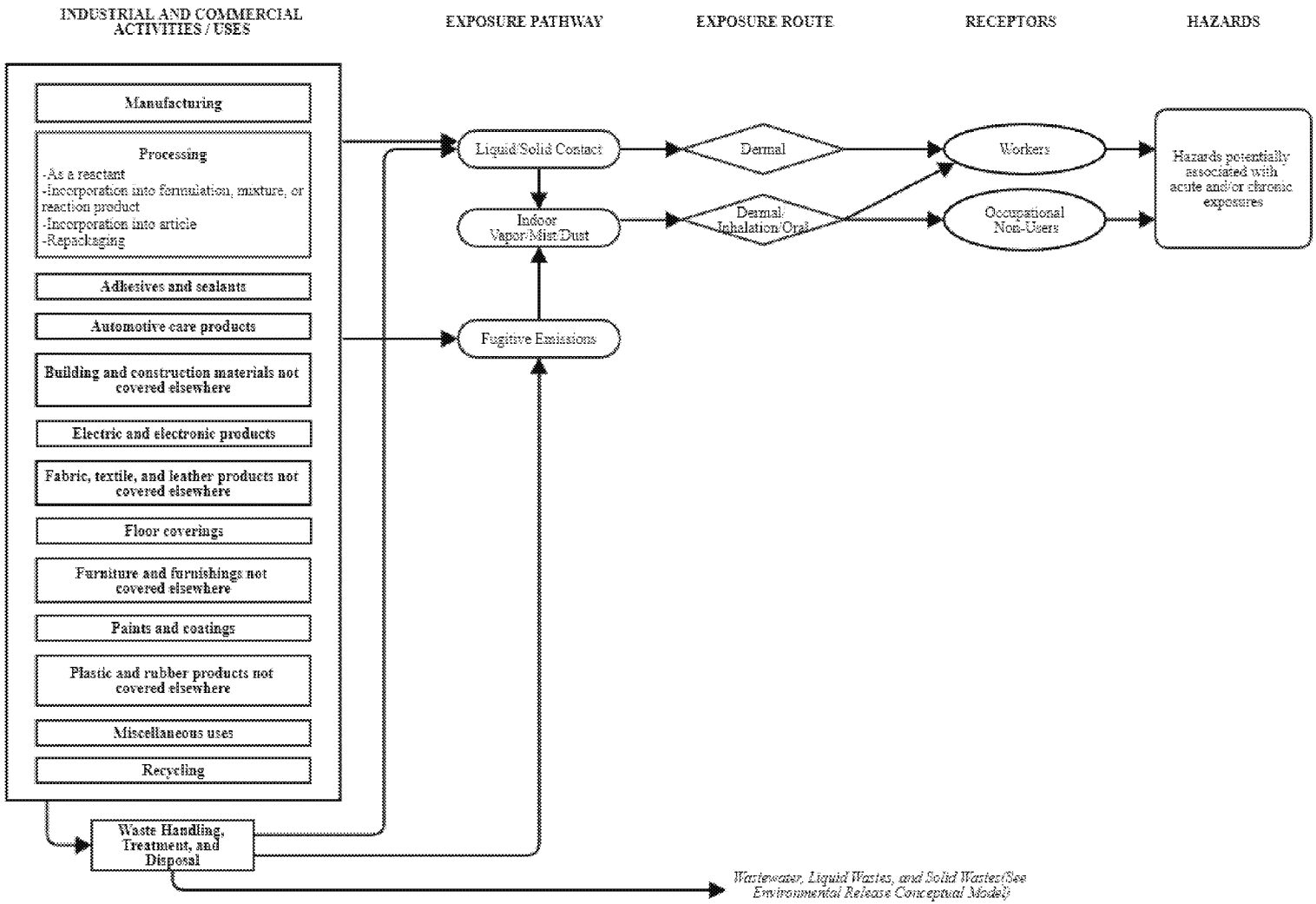

Figure 2-13. DINP Conceptual Model for Industrial and Commercial Activities and Uses: Worker and ONU Exposures and Hazards
The conceptual model presents the exposure pathways, exposure routes, and hazards to human receptors from industrial and commercial activities and uses of DINP.

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 DINP through products and articles.

An "article," as defined at 40 CFR 704.3, is distinct from a "product" in that an article is, "a manufactured item":

1. which is formed to a specific shape or design during manufacture;
2. which has end use function(s) dependent in whole or in part upon its shape or design during end use; and
3. which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article, and that result from a chemical reaction that occurs upon end use of other chemical substances, mixtures, or articles; except that fluids and particles are not considered articles regardless of shape or design."

EPA expects that consumers and bystanders may be exposed through use of products containing DINP through oral, dermal, and inhalation routes via indoor air or dust, liquid contact, and vapor or mist. Additionally, during use of articles, EPA expects that consumers may be exposed through dermal and oral routes via direct dermal contact or mouthing. EPA plans to analyze pathways and routes of exposure that may occur during the identified consumer activities and uses. The supporting rationale for consumer pathways considered for DINP are included in Appendix G.

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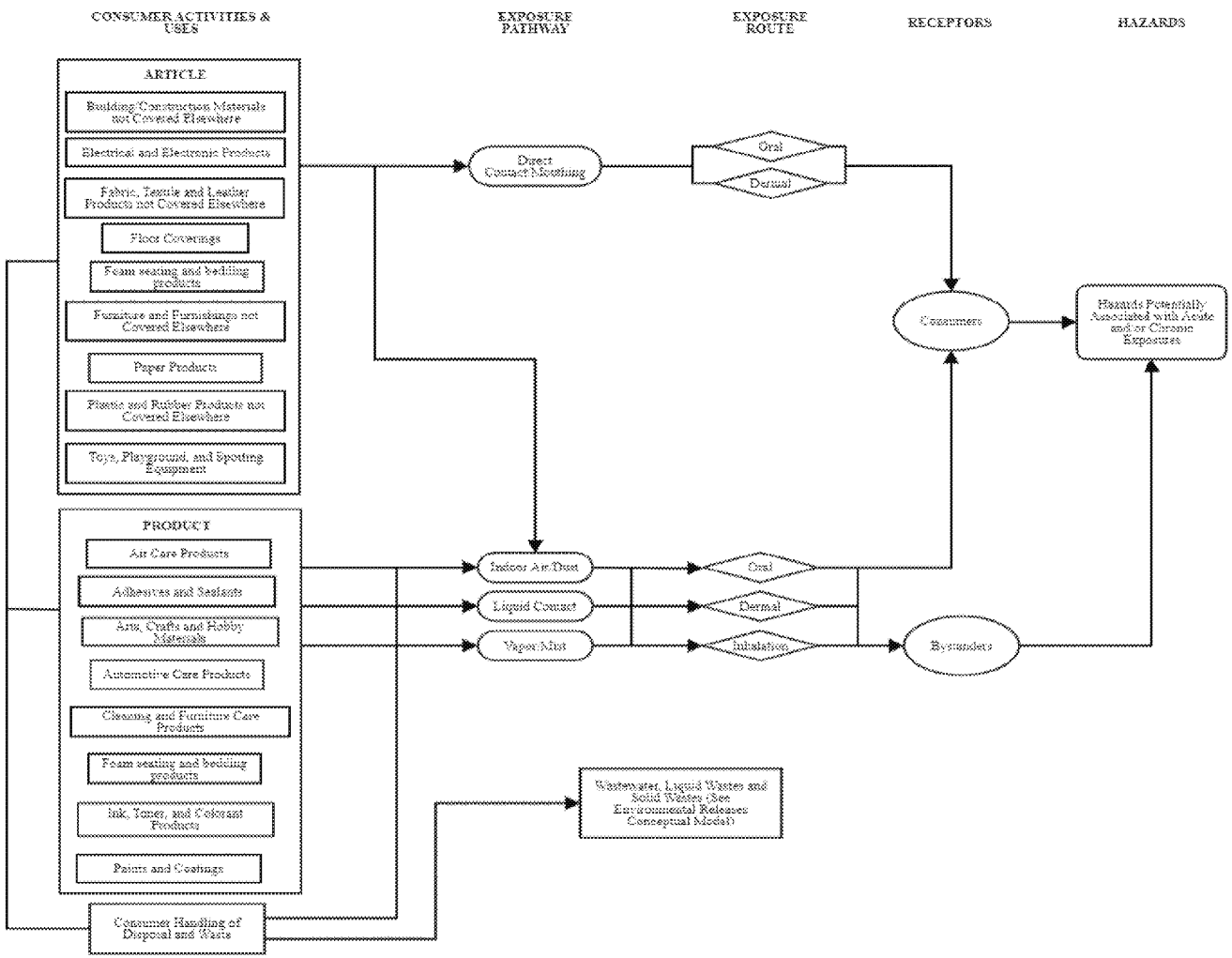

Figure 2-14. DINP Conceptual Model for Consumer Activities and Uses: Consumer Exposures and Hazards[a]

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

[a] Receptors include PESS (see Section 2.5).

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

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 DINP within the scope of the risk evaluation.

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 DINP within the scope of the risk evaluation. EPA plans to evaluate exposures to receptors (*e.g.,* general population, aquatic, terrestrial species) that may occur from releases to air, drinking water, surface water, groundwater, and land, including biosolids and soil. EPA expects the general population to be exposed to DINP through inhalation from direct air emissions and emissions to air from surface water, drinking water, and liquid and solid waste releases; orally via drinking water, and fish and soil ingestion; and dermally from contact with surface water, liquid and solid waste release, groundwater, and soil. The supporting rationale for general population and environmental pathways considered for DINP are included in Appendix H.

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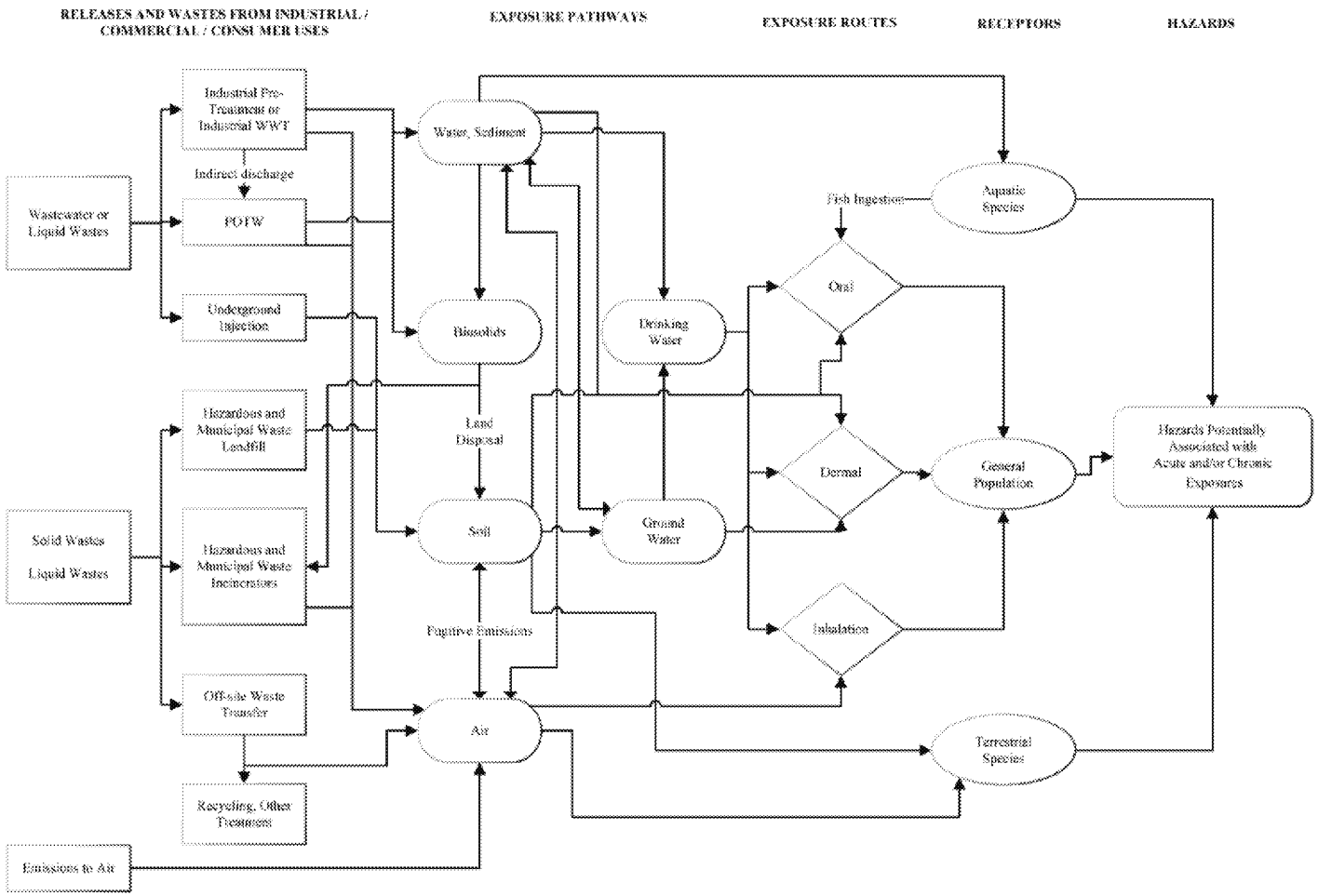

Figure 2-15. DINP Conceptual Model for Environmental Releases and Wastes: Environmental and General Population Exposures and Hazards[a] [b]

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 DINP that EPA plans to consider in the risk evaluation.

[a] Industrial wastewater or liquid wastes may be treated on-site and then released to surface water (direct discharge), or pre-treated and released to publicly owned treatment works (POTW) (indirect discharge). For consumer uses, such wastes may be released directly to POTWs. Drinking water will undergo further treatment in drinking water treatment plants. Groundwater may also be a source of drinking water. Inhalation from drinking water may occur via showering.

[b] Receptors include PESS (see Section 2.5).

2.7 Analysis Plan

The analysis plan is based on EPA's knowledge of DINP resulting from the full-text screening of reasonably available information identified through EPA's literature searches as well as the information included in the ACC HPP submission (see Section 2.1). EPA encourages submission of additional existing information, 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 the risk evaluation. Targeted supplemental searches during the analysis phase may be necessary to identify additional reasonably available information (*e.g.,* commercial mixtures) for the risk evaluation of DINP. For any 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 DINP as follows:

1) **Review reasonably available measured or estimated physical and chemical properties and environmental fate endpoint data.**
   EPA plans to review data and information submitted with the request for risk evaluation and collected through the systematic review process and public comments about the physical and chemical properties (A.4) and fate endpoints (Appendix C). EPA plans to evaluate all sources cited in EPA's analysis plan according to the procedures and metrics described in a draft systematic review protocol that EPA plans to release later this year. Where experimentally measured chemical property values are not reasonably available or of sufficiently high quality, 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 DINP 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 and in the ACC HPP submission using revised systematic review methods described in a draft systematic review protocol that EPA plans to release later this year.

2.7.2 Exposure

EPA plans to analyze exposure levels for indoor dust, indoor air, ambient air, surface water, drinking water, groundwater, sediment, soil, biosolids, fish ingestion, aquatic biota, and terrestrial biota associated with exposure to DINP. Based on their physical and chemical properties, expected sources,

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and transport and transformation within the outdoor and indoor environment, DINP is more likely to be present in some media and less likely to be present in others. Exposure level(s) can be characterized using a combination of reasonably available monitoring data and estimated exposure levels from modeling approaches. EPA has not yet determined the exposure levels in these media. Exposure scenarios are combinations of sources (uses), exposure pathways, and exposed receptors. Draft exposure scenarios corresponding to various conditions of use for DINP are presented in Appendix F, Appendix G, and Appendix H. EPA plans to analyze scenario-specific exposures.

2.7.2.1 Environmental Releases

EPA plans to analyze releases to environmental media as follows:

1) **Review reasonably available published literature and other reasonably available information on processes and activities associated with the conditions of use to analyze the types of releases and wastes generated.**
   EPA has reviewed some sources containing information on processes and activities resulting in releases, and the information found is described in Appendix E. EPA plans to review additional data sources identified. Potential sources of environmental release data are summarized in Table 2-4 below:

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

EPA Generic Scenarios
OECD Emission Scenario Documents
European Union 2003, 2013, and 2018 DINP Risk Evaluations
Australian National Industrial Chemicals Notification and Assessment Scheme 2012 DINP Hazard and Risk Assessment
Environment Canada and Health Canada 2015 and 2017 DINP Risk Evaluations

2) **Review reasonably available chemical-specific release data, including measured or estimated release data (*e.g.*, data from risk assessments by other environmental agencies).**
   EPA plans to consider additional reasonably available information and will evaluate it during development of the risk evaluation. EPA plans to match identified data to applicable conditions of use and identify conditions of use for which data are limited. EPA plans to augment and/or supplement data through the use of models and potential surrogate data, where appropriate.

   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 measured or estimated 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 to potentially augment and/or supplement existing data.

4) **Review reasonably available data that may be used in developing, adapting, or applying exposure models to the particular risk evaluation.**
   This item will be performed after completion of #2 and #3 above. EPA plans to evaluate relevant data to determine whether the data can be used to develop, adapt, or apply models for specific

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conditions of use (and corresponding release scenarios). EPA has identified information from various EPA statutes and sources (including, for example, regulatory limits, reporting thresholds, or disposal requirements) that may be relevant to release estimation and environmental exposures. EPA plans to further consider relevant regulatory requirements in estimating releases during risk evaluation.

5) **Review and determine applicability of OECD Emission Scenario Documents (ESDs) and EPA Generic Scenarios (GSs) to estimation of environmental releases.**
EPA has identified potentially relevant OECD ESDs and EPA GSs that correspond to some conditions of use; for example, the 2009 ESD on Adhesive Formulation (OECD, 2009a), the 2011 ESD on Coating Application via Spray-Painting in the Automotive Refinishing Industry (OECD, 2011a), the 2011 ESD on Radiation Curable Coating, Inks and Adhesives (OECD, 2011b), the 2015 ESD on the Use of Adhesives (OECD, 2015), and the 2009 ESD on Plastic Additives (OECD, 2009b) may be useful to assess potential releases. EPA plans to critically review these ESDs and GSs to determine their applicability to the conditions of use assessed.

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 reasonably available, EPA may use a variety of methods including the application of default assumptions such as standard loss fractions associated with drum cleaning (3%) or single process vessel cleanout (1%).

6) **Map or group each condition of use to a release assessment scenario(s).**
EPA has completed initial mapping of release scenarios to relevant conditions of use as shown in Appendix F. EPA plans to refine the mapping/grouping of release scenarios based on factors (*e.g.,* process equipment and handling, magnitude of production volume used, 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 these 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 revised systematic review methods described in a draft systematic review protocol that EPA plans to release later this year. 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 DINP:

1) **Review reasonably available environmental and biological monitoring data for all media relevant to environmental exposure.**
For DINP, environmental media which EPA plans to analyze are sediment, soil, biosolids, air, drinking water, groundwater, and surface water.

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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) and that estimate air, surface water, groundwater, sediment, biosolids, and soil concentrations alongside reasonably available air, surface water, groundwater, sediment, and soil monitoring data to characterize environmental exposures. Modeling approaches to estimate air concentrations, surface water concentrations, sediment concentrations. biosolids concentrations, and soil concentrations consider the following inputs: direct release into air, groundwater, surface water, sediment, or soil, indirect release into air, groundwater, surface water, sediment or soil (*i.e.,* air deposition), fate and transport (partitioning within media) and characteristics of the environment (*e.g.,* river flow, volume of lake, meteorological data).

3) **Determine applicability of existing additional contextualizing information for any monitored data or modeled estimates during risk evaluation.**
Any studies which relate levels of DINP in the environment or biota with specific sources or groups of sources will be evaluated.

4) **Group each condition(s) of use to environmental assessment scenario(s).**
Refine and finalize exposure scenarios for environmental receptors by considering combinations of sources (use descriptors), exposure pathways including routes, and populations exposed. For DINP, the following are noteworthy considerations in constructing exposure scenarios for environmental receptors:
   - Estimates of air concentrations, groundwater concentrations, surface water concentrations, sediment concentrations, and soil concentrations near industrial point sources based on reasonably available monitoring data;
   - Consider the following modeling inputs: release into the media of interest, fate and transport, and characteristics of the environment;
   - Reasonably available biomonitoring data. Monitoring data could be used to compare with species or taxa-specific toxicological benchmarks;
   - Applicability of existing additional contextualizing information for any monitored data or modeled estimates during risk evaluation. Review and characterize the spatial and temporal variability, to the extent that data are reasonably available, and characterize exposed aquatic and terrestrial populations; and
   - 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 revised systematic review methods described in a draft systematic review protocol that EPA plans to release later this year.

2.7.2.3 Occupational Exposures

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

1) **Review reasonably available exposure monitoring data for specific condition(s) of use.**

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EPA plans to review exposure monitoring data including workplace monitoring data collected by government agencies such as OSHA and NIOSH, as well as monitoring data found in published literature and any relevant information provided in the ACC HPP submission. These workplace monitoring data include personal exposure monitoring data (direct exposures) and area monitoring data (indirect exposures).

EPA has preliminarily reviewed reasonably available monitoring data collected by NIOSH (identified in Table 2-5) and will match these data to applicable conditions of use. EPA has also identified additional data sources that may contain relevant monitoring data for the various conditions of use. EPA plans to review these sources (identified in Table 2-5) and extract relevant data for consideration and analysis during risk evaluation.

Table 2-5. Potential Sources of Occupational Exposure Data

U.S. NIOSH Health Hazard Evaluation (HHE) Program Reports
European Union 2003, 2013, and 2018 DINP Risk Evaluations
Australian National Industrial Chemicals Notification and Assessment Scheme 2012 DINP Hazard and Risk Assessment
Environment Canada and Health Canada 2015 and 2017 DINP Risk Evaluations

2) **Review reasonably available exposure data for surrogate chemicals that have uses, volatility, and physical and chemical properties similar to DINP.**
EPA plans to review literature sources submitted in the ACC HPP submission and identified through systematic review, and if surrogate data are found, these data will be matched to applicable conditions of use to potentially augment and/or supplement existing data. For example, EPA believes other phthalate esters utilized in similar ways to DINP may serve as surrogates for DINP.

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 GSs 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 GSs that EPA may use to estimate occupational exposures. EPA plans to critically review these ESDs and GSs to determine their applicability to the conditions of use assessed. EPA may conduct or perform supplemental targeted searches of peer-reviewed or gray literature to understand those conditions of use, which may inform identification of exposure scenarios. EPA may also need to perform targeted supplemental searches to identify applicable models that EPA may use to estimate exposures for certain conditions of use.

4) **Review reasonably available data that may be used in developing, adapting, or applying exposure models to a particular risk evaluation scenario.**
This step will be performed after #2 and #3 are completed. 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, provided in the ACC HPP submission, 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

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inhalation exposures to workers, and the far-field exposure represents potential inhalation exposures to ONUs.

5) **Consider and incorporate applicable engineering controls and PPE into occupational exposure scenarios.**
In the risk evaluation, EPA plans to examine the effects of engineering controls and PPE on occupational exposures to support any potential risk management in the event of an unreasonable risk determination. 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 PPE. EPA plans to identify the engineering controls and PPE relevant to occupational exposure scenarios based on reasonably available information on control technology and effectiveness. Furthermore, to better inform any potential risk management, EPA plans to assess in the risk evaluation worker exposure pre- and post-implementation of engineering controls (*e.g.,* local exhaust ventilation) and with and without the use of PPE (*e.g.,* respirator).

6) **Map or group each condition of use to occupational exposure assessment scenario(s).**
EPA has identified occupational exposure scenarios and mapped them to relevant conditions of use (see Appendix F). As presented in the fourth column in Table_Apx F-1, EPA has completed an initial mapping of exposure scenarios to conditions of use. EPA plans to refine mapping 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 revised systematic review methods described in a draft systematic review protocol that EPA plans to release later this year. 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 DINP, the following are noteworthy considerations in constructing consumer exposure scenarios:

- Conditions of use and type of consumer product;
- Duration, frequency and magnitude of exposure;

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- Weight fraction of chemical in products; and
- Amount of chemical used.

2) **Evaluate the relative potential of indoor exposure pathways based on reasonably available data.**
Indoor exposures may include dust ingestion, mouthing of products, inhalation of indoor air and dust, and dermal contact with dust, articles, and product use. EPA plans to evaluate the reasonably available data sources associated with these respective pathways in order to make any quantitative comparisons across exposure pathways or in relation to toxicity thresholds.

3) **Review existing indoor exposure models that may be applicable in estimating indoor air concentrations.**
Indoor exposure models that estimate emissions from 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.

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

4) **Review reasonably available empirical data that may be used in developing, adapting or applying exposure models to a particular risk evaluation scenario. For example, existing models developed for a chemical assessment may be applicable to another chemical assessment if model parameter data are reasonably available.**
To the extent other organizations have already modeled a DINP consumer exposure scenario that is relevant to the OPPT's assessment (*e.g.,* (CPSC, 2010), (CPSC, 2014), (CPSC, 2015b)). EPA plans to evaluate those modeled estimates. In addition, if other chemicals similar to DINP 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 DINP in specific media (*e.g.,* indoor dust).**
EPA plans to evaluate the availability of DINP concentration for various ongoing uses. These data provide the source term for any subsequent indoor modeling. EPA plans to analyze source attribution between overall indoor air levels and various indoor sources.

6) **Review reasonably available population- or subpopulation-specific exposure factors and activity patterns to determine if PESS need to be further refined.**
For DINP, EPA plans to evaluate exposure scenarios that involve PESS and plans to consider age-specific behaviors, activity patterns, and exposure factors for those subpopulations. For some exposure scenarios related to consumer uses, EPA plans to consider whether exposures for adults

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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 plans to analyze general population exposures as follows:

1) **Refine and finalize exposure scenarios for general population by considering combinations of sources and uses, exposure pathways including routes, and exposed populations.**
For DINP, the following are noteworthy considerations in constructing exposure scenarios for the general population:
   - Review reasonably available environmental and biological monitoring data for media to which general population exposures are expected;
   - For exposure pathways where data are not reasonably available, review existing exposure models that may be applicable in estimating exposure levels;
   - Consider and incorporate applicable media-specific regulations into exposure scenarios or modeling;
   - Review reasonably available data that may be used in developing, adapting, or applying exposure models to the particular risk evaluation. For example, existing models developed for a chemical assessment may be applicable to another chemical assessment if model parameter data are reasonably available;
   - Review reasonably available information on releases to determine how modeled estimates of concentrations near industrial point sources compare with reasonably available monitoring data;
   - Review reasonably available population- or subpopulation-specific exposure factors and activity patterns to determine if PESS need to be further defined;
   - Develop approaches and methodologies that use reasonably available information, modeling, and geospatial analysis to evaluate impacts to population groups of concern (*e.g.,* fenceline and environmental justice communities);
   - Evaluate the weight of the scientific evidence of general population exposure data; and
   - Map or group each condition of use to general population exposure assessment scenario(s).

EPA plans to evaluate a variety of data types to determine which types are most appropriate when quantifying exposure scenarios. Environmental monitoring data, biomonitoring data, modeled estimates, experimental data, epidemiological data, and survey-based data can all be used to quantify exposure scenarios. EPA anticipates that there will be a range in the potential exposures associated with the exposure scenarios identified in Section 2.6.

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

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upon the reasonably available data and approaches to quantify scenarios. When quantifying exposure scenarios, EPA plans to use a tiered approach. First-tier analysis is based on data that is reasonably available without a significant number of additional inputs or assumptions, and may be qualitative, semi-quantitative, or quantitative. The results of first tier analyses inform whether scenarios require more refined analysis. Refined analyses will be iterative and require careful consideration of variability and uncertainty.

2) **For exposure pathways where empirical data are not reasonably available, review existing exposure models that may be applicable in estimating exposure levels.**
For DINP, media where exposure models may be considered for general population exposure include models that estimate ambient air concentrations, drinking water concentrations, surface water concentrations, groundwater concentrations, sediment concentrations, soil concentrations, and uptake from aquatic and terrestrial environments into edible aquatic and terrestrial organisms.

3) **Review reasonably available exposure modeled estimates. For example, existing models developed for a previous DINP chemical assessment may be applicable to EPA's assessment. In addition, another chemical's assessment may also be applicable if model parameter data are reasonably available.**
To the extent other organizations have already modeled DINP general population exposure scenario that is relevant to this assessment, EPA plans to evaluate those modeled estimates. In addition, if modeled estimates for other chemicals with similar physical and chemical properties and similar uses are reasonably available, those modeled estimates, along with their underlying parameters and assumptions, will also be evaluated.

4) **Review reasonably available information on releases to determine how modeled estimates of concentrations near industrial point sources compare with reasonably available monitoring data.**
The expected releases from industrial facilities are changing over time. EPA plans to carefully compare any modeled concentrations based on recent release estimates with reasonably available monitoring data to determine representativeness.

5) **Review reasonably available information about population- or subpopulation-specific exposure factors and activity patterns to determine if PESS need to be further defined (*e.g.*, early life and/or puberty as a potential critical window of exposure).**
For DINP, EPA plans to consider age-specific behaviors, activity patterns, and exposure factors unique to PESS for exposure scenarios that involve those subpopulations (*e.g.*, children may have different intake rates for soil than adults; infants may be exposed via ingestion of breastmilk).

6) **Evaluate the weight of the scientific evidence of general population exposure estimates based on different approaches.**
During risk evaluation, EPA plans to evaluate and integrate the exposure evidence submitted in the request for risk evaluation as well as evidence identified in the literature inventory using revised systematic review methods described in a draft systematic review protocol that EPA plans to release later this year.

2.7.3 Hazards (Effects)

2.7.3.1 Environmental Hazards

EPA plans to conduct an environmental hazard assessment of DINP 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 DINP to aquatic and/or terrestrial organisms, including plants, invertebrates (*e.g.,* insects, arachnids, mollusks, crustaceans), and vertebrates (*e.g.,* mammals, birds, amphibians, fish, reptiles) across exposure durations and conditions if potential environmental hazards are identified through systematic review results, the ACC HPP submission 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 DINP to aquatic and/or terrestrial organisms.

   EPA plans to evaluate environmental hazard data using revised evaluation strategies described in a draft systematic review protocol that EPA plans to release later this year. The study evaluation results will be documented in the risk evaluation phase and data from acceptable studies will be extracted and integrated in the risk evaluation process.

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

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

3) **Evaluate the weight of the scientific evidence of environmental hazard data.**
   During risk evaluation, EPA plans to evaluate and integrate the environmental hazard evidence identified in the literature inventory using revised systematic review methods described in a draft systematic review protocol that EPA plans to release later this year.

4) **Consider the route(s) of exposure, based on reasonably available monitoring and modeling data and other reasonably available approaches to integrate exposure and hazard assessments.**
   EPA plans to consider aquatic (*e.g.,* water and sediment exposures) and terrestrial pathways in the DINP conceptual model (Figure 2-15). Aquatic and terrestrial organisms may be exposed to DINP via a number of environmental pathways (*e.g.,* air, surface water, sediment, soil, diet).

5) **Consider a persistent, bioaccumulative, and toxic (PBT) assessment of DINP.**
   EPA plans to consider the persistence, bioaccumulation, and toxic (PBT) potential of DINP after reviewing relevant physical and chemical properties and exposure pathways. EPA plans to assess the studies submitted in the request for risk evaluation as well as reasonably available studies

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collected from the systematic review process relating to bioaccumulation and bioconcentration (*e.g.,* BAF, BCF) of DINP. In addition, EPA plans to integrate traditional environmental hazard endpoint values (*e.g.,* LC_{50}, LOEC) and exposure concentrations (*e.g.,* surface water concentrations, tissue concentrations) for DINP with the fate parameters (*e.g.,* BAF, BCF, BMF, TMF).

2.7.3.2 Human Health Hazards

EPA plans to analyze human health hazards as follows:

1) **Review reasonably available human health hazard data, including data from human and animal studies (human health animal models defined in Table_Apx A-3) and 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 revised evaluation strategies described in a draft systematic review protocol that EPA plans to release later this year. These evaluation strategies also apply to human health studies described in Appendix C of the Manufacturer Request for Risk Evaluation for DINP (ACC, 2019). 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, identify any PESS that 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 DINP hazard(s). Susceptibility of particular human receptor groups to DINP will be determined by evaluating information on factors that influence susceptibility.

   EPA has reviewed some sources containing hazard information associated with PESS, such as pregnant women and infants. Pregnancy (*i.e.,* gestation) and childhood are potential susceptible lifestages for DINP 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 revised systematic review data quality criteria described in a draft systematic review protocol that EPA plans to release later this year. Hazards identified by studies meeting data quality criteria will be grouped by routes of exposure relevant to humans (*e.g.,* oral, dermal, inhalation) and by cancer and noncancer endpoints 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 DINP, 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 DINP for specific conditions of use based upon potential exposures to children.

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

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

5) **Evaluate the weight of the scientific evidence of human health hazard data.**
During risk evaluation, EPA plans to evaluate and integrate the human health hazard evidence identified in the literature inventory under acute and chronic exposure conditions using revised systematic review methods described in a draft systematic review protocol that EPA plans to release later this year.

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.**
Based on previous assessments of DINP (*e.g.*, see NTP CERHR (NTP CERHR, 2003)), EPA believes there will be sufficient reasonably available data to conduct dose-response analysis and/or benchmark dose modeling for the oral route of exposure. EPA plans to also evaluate any potential human health hazards following dermal and inhalation exposure to DINP, 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.

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If sufficient reasonably available toxicity studies are not identified through the systematic review process to assess risks from dermal and inhalation exposures, then a route-to-route extrapolation from oral toxicity studies 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 the methylene chloride (U.S. EPA, 2020c), carbon tetrachloride (U.S. EPA, 2020b), and perchloroethylene (U.S. EPA, 2020c) risk evaluations under amended TSCA.

2.7.4 Summary of Risk Approaches for Characterization

EPA plans to conduct a risk estimation and characterization of DINP to identify if there are risks to the environment or human health. For environmental risk characterization, EPA plans to identify if there are risks to aquatic and/or terrestrial environments from the measured and/or predicted concentrations of DINP in environmental media (*e.g.,* air, water, sediment, soil). Risk quotients (RQs) may be derived by the application of hazard and exposure benchmarks to characterize environmental risk (U.S. EPA, 1998; Barnthouse et al., 1982). Similarly, for human health risk characterization, EPA plans to integrate exposure estimates from measured and/or modeled data with hazard data to characterize risk to human health. Analysis of environmental or human health 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.

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

The level of information contained in each risk characterization varies according to the type of assessment for which the characterization is written. Regardless of the level of complexity or information, the risk characterization for TSCA risk evaluations will be prepared in a manner that is

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

2.8 Peer Review

The draft risk evaluation for DINP will be peer-reviewed. 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 final rule *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act* (82 FR 33726, 33744; July 20, 2017), the purpose of peer review is for the independent review of the science underlying the risk assessment. Peer review will therefore address aspects of the underlying science as outlined in the charge to the peer review panel such as hazard assessment, assessment of dose-response, exposure assessment, and risk characterization.

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APPENDICES

Appendix A 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 DINP, several online sources were queried.

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

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

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

Chemical Source	Contents	Document Location
USEPA Chemistry Dashboard (https://comptox.epa.gov/dashboard)	CAS numbers, synonyms, structures, properties, environmental fate and transport.	Online
Dictionary of Chemical Names and Synonyms	Wide assortment of chemical compounds by chemical name and synonym, has CAS index and some structure data	ECOTOX
Farm Chemicals Handbook-1992	Pesticide information, CAS numbers and synonyms, some structure data ***Sometimes CAS number presented for a compound is for the main constituent only	ECOTOX
OPPT SMILES Verification Source	Structure data	Electronic verification
RTECS (Registry of Toxic Effects of chemical substance, 1983-84 ed., 2 vols)	Chemical names, synonyms, and CAS numbers	ECOTOX
Sigma – Aldrich website58784 http://www.sigma-aldrich.com	Organic and inorganic compounds by chemical name, has CAS index and some structure and physical property data	Online

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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_Chemicals.jsp)	Pesticides searchable by name or CAS #. Includes CAS #, name, synonyms, targets, toxicity data, related chemicals, and regulatory information.	Online
US EPA Office of Pesticide Programs Pesticide Fate Database – No web access available. An electronic copy of the data file is located at the Contractor site: PFATE_37_Tables.mdb.	Multiple databases containing chemicals, pesticides, companies, products, etc.	Online

A.1.2 Publicly Available Database Searches

The databases listed below were searched for literature containing the chemical search terms. Database searching occurred during April and May of 2019 by an information specialist, and the results were stored in the HERO database and assigned a HERO reference identification number.[7] The present literature search focused only on the chemical name (including synonyms and trade names) with no additional limits. Full details of the search strategy for each database are presented in Appendix A.1.2.1.

After initial deduplication in HERO,[8] these studies were imported into SWIFT Review software (Howard et al., 2016) to identify those references most likely to be applicable to each discipline area (*i.e.,* consumer, environmental, and general population exposure, occupational exposure and environmental releases, environmental hazards, human health hazards, and fate and physical chemistry).

A.1.2.1 Query Strings for the Publicly Available Database Searches on DINP

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 DINP. The sources are found as online databases and the resulting references were gathered and uploaded into the EPA Health and Environmental Research Online (HERO) database for literature screening.

[7] EPA's HERO database provides access to the scientific literature behind EPA science assessments. The database includes more than 600,000 scientific references and data from the peer-reviewed literature used by EPA to develop its regulations.
[8] 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.

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Table_Apx A-2. Summary of Data Sources, Search Dates and Number of Peer-Reviewed Literature Search Results for DINP

Source	Date of Search	Number of References
Current Contents	08/28/2019	416
WOS Core Collection	08/28/2019	474
ProQuest CSA	08/28/2019	686
Dissertation Abstracts	08/29/2019	2
Science Direct	08/28/2019	334
Agricola	08/29/2019	149
TOXNET	08/28/2019	401
PubMed	08/28/2019	363
UNIFY	08/29/2019	41
Totals:	–	**2866**

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

"1,2-Benzenedicarboxylic acid diisononyl ester" OR "1,2-Benzenedicarboxylic acid, 1,2-diisononyl ester" OR "1,2-Benzenedicarboxylic acid, diisononyl ester" OR "1,2-Benzenedicarboxylic acid, di-isononyl ester" OR "Baylectrol 4200" OR "BIS-ISONONYL PHTHALATE" OR "Di(C8-10, C9 rich) branched alkyl phthalates" OR "Di(isononyl) phthalate branched" OR "Diacizer DINP" OR "Diisononyl phthalate" OR "Di-isononyl phthalate" OR "Diisononyl phthalate (mixed isomers)" OR "Diisononylphthalate" OR "DINP" OR "DINP branched" OR "Isononyl alcohol, phthalate (2:1)" OR "JAY-DINP" OR "Jayflex DINP" OR "Monocizer DINP" OR "Palatinol DINP" OR "Palatinol DN" OR "Palatinol N" OR "PHTHALATE, DIISONONYL" OR "Phthalic acid diisononyl ester" OR "Phthalic acid, diisononyl ester" OR "Phthalisocizer DINP" OR "Sansocizer DINP" OR "Vestinol 9" OR "Vestinol NN" OR "Vinycizer 90" OR "Vinylcizer 90" OR "Witamol 150"

CURRENT CONTENTS CONNECT: (access.webofknowledge.com)
General search terms applied to the search strategy for Current Contents.
Date Searched: 08/28/2019
Date Range of Search: 1998 to Present
N = 416

TS = ("1,2-Benzenedicarboxylic acid diisononyl ester" OR "1,2-Benzenedicarboxylic acid, 1,2-diisononyl ester" OR "1,2-Benzenedicarboxylic acid, diisononyl ester" OR "1,2-Benzenedicarboxylic acid, di-isononyl ester" OR "Baylectrol 4200" OR "BIS-ISONONYL PHTHALATE" OR "Di(C8-10, C9 rich) branched alkyl phthalates" OR "Di(isononyl) phthalate branched" OR "Diacizer DINP" OR "Diisononyl phthalate" OR "Di-isononyl phthalate" OR "Diisononyl phthalate (mixed isomers)" OR

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"Diisononylphthalate" OR "DINP" OR "DINP branched" OR "Isononyl alcohol, phthalate (2:1)" OR "JAY-DINP" OR "Jayflex DINP" OR "Monocizer DINP" OR "Palatinol DINP" OR "Palatinol DN" OR "Palatinol N" OR "PHTHALATE, DIISONONYL" OR "Phthalic acid diisononyl ester" OR "Phthalic acid, diisononyl ester" OR "Phthalisocizer DINP" OR "Sansocizer DINP" OR "Vestinol 9" OR "Vestinol NN" OR "Vinycizer 90" OR "Vinylcizer 90" OR "Witamol 150")
N = 416

WOS Core Collection: (https://apps.webofknowledge.com).
General search terms applied to the search strategy for WOS Core Collection.
Date Searched: 09/11/19
Date Range of Search: 1998 to Present
N = 474

TS = ("1,2-Benzenedicarboxylic acid diisononyl ester" OR "1,2-Benzenedicarboxylic acid, 1,2-diisononyl ester" OR "1,2-Benzenedicarboxylic acid, diisononyl ester" OR "1,2-Benzenedicarboxylic acid, di-isononyl ester" OR "Baylectrol 4200" OR "BIS-ISONONYL PHTHALATE" OR "Di(C8-10, C9 rich) branched alkyl phthalates" OR "Di(isononyl) phthalate branched" OR "Diacizer DINP" OR "Diisononyl phthalate" OR "Di-isononyl phthalate" OR "Diisononyl phthalate (mixed isomers)" OR "Diisononylphthalate" OR "DINP" OR "DINP branched" OR "Isononyl alcohol, phthalate (2:1)" OR "JAY-DINP" OR "Jayflex DINP" OR "Monocizer DINP" OR "Palatinol DINP" OR "Palatinol DN" OR "Palatinol N" OR "PHTHALATE, DIISONONYL" OR "Phthalic acid diisononyl ester" OR "Phthalic acid, diisononyl ester" OR "Phthalisocizer DINP" OR "Sansocizer DINP" OR "Vestinol 9" OR "Vestinol NN" OR "Vinycizer 90" OR "Vinylcizer 90" OR "Witamol 150")
N = 474

PROQUEST Agricultural and Environmental Science Database: (www.csa.com)
General search terms applied to the search strategy for ProQuest Agricultural and Scientific Database.
Date Searched: 08/28/19
Date Range of Search: 1900 to Present
N = 686

ALL("1,2-Benzenedicarboxylic acid diisononyl ester" OR "1,2-Benzenedicarboxylic acid, 1,2-diisononyl ester" OR "1,2-Benzenedicarboxylic acid, diisononyl ester" OR "1,2-Benzenedicarboxylic acid, di-isononyl ester" OR "Baylectrol 4200" OR "BIS-ISONONYL PHTHALATE" OR "Di(C8-10, C9 rich) branched alkyl phthalates" OR "Di(isononyl) phthalate branched" OR "Diacizer DINP" OR "Diisononyl phthalate" OR "Di-isononyl phthalate" OR "Diisononyl phthalate (mixed isomers)" OR "Diisononylphthalate" OR "DINP" OR "DINP branched" OR "Isononyl alcohol, phthalate (2:1)" OR "JAY-DINP" OR "Jayflex DINP" OR "Monocizer DINP" OR "Palatinol DINP" OR "Palatinol DN" OR "Palatinol N" OR "PHTHALATE, DIISONONYL" OR "Phthalic acid diisononyl ester" OR "Phthalic acid, diisononyl ester" OR "Phthalisocizer DINP" OR "Sansocizer DINP" OR "Vestinol 9" OR "Vestinol NN" OR "Vinycizer 90" OR "Vinylcizer 90" OR "Witamol 150") AND STYPE("Scholarly Journals" OR Reports OR Thesis OR "Government Documents") AND LA(ENG)
N = 686

PROQUEST Dissertations and Theses: (https://search.proquest.com/)
General search terms applied to the search strategy for ProQuest Dissertations and Theses
Date Searched:08/29/2019
Date Range of Search: 1900 to Present
N = 2

ALL("1,2-Benzenedicarboxylic acid diisononyl ester" OR "1,2-Benzenedicarboxylic acid, 1,2-diisononyl ester" OR "1,2-Benzenedicarboxylic acid, diisononyl ester" OR "1,2-Benzenedicarboxylic acid, di-isononyl ester" OR "Baylectrol 4200" OR "BIS-ISONONYL PHTHALATE" OR "Di(C8-10, C9 rich) branched alkyl phthalates" OR "Di(isononyl) phthalate branched" OR "Diacizer DINP" OR "Diisononyl phthalate" OR "Di-isononyl phthalate" OR "Diisononyl phthalate (mixed isomers)" OR "Diisononylphthalate" OR "DINP" OR "DINP branched" OR "Isononyl alcohol, phthalate (2:1)" OR "JAY-DINP" OR "Jayflex DINP" OR "Monocizer DINP" OR "Palatinol DINP" OR "Palatinol DN" OR "Palatinol N" OR "PHTHALATE, DIISONONYL" OR "Phthalic acid diisononyl ester" OR "Phthalic acid, diisononyl ester" OR "Phthalisocizer DINP" OR "Sansocizer DINP" OR "Vestinol 9" OR "Vestinol NN" OR "Vinycizer 90" OR "Vinylcizer 90" OR "Witamol 150") AND LA(ENG)

SCIENCE DIRECT: www.sciencedirect.com)
General search terms applied to the search strategy for Science Direct
Date Searched: 08/28/19
Date Range of Search: 1823 to Present
N = 334

Science Direct 01:
"1,2-Benzenedicarboxylic acid diisononyl ester" OR "1,2-Benzenedicarboxylic acid, 1,2-diisononyl ester" OR "1,2-Benzenedicarboxylic acid, diisononyl ester" OR "1,2-Benzenedicarboxylic acid, di-isononyl ester" OR "Baylectrol 4200" OR "BIS-ISONONYL PHTHALATE" OR "Di(C8-10, C9 rich) branched alkyl phthalates" OR "Di(isononyl) phthalate branched" OR "Diacizer DINP"
N = 0

Science Direct 02:
"Diisononyl phthalate" OR "Di-isononyl phthalate" OR "Diisononyl phthalate (mixed isomers)" OR "Diisononylphthalate" OR "DINP" OR "DINP branched" OR "Isononyl alcohol, phthalate (2:1)" OR "JAY-DINP" OR "Jayflex DINP"
N = 331

Science Direct 03:
"Monocizer DINP" OR "Palatinol DINP" OR "Palatinol DN" OR "Palatinol N" OR "PHTHALATE, DIISONONYL" OR "Phthalic acid diisononyl ester" OR "Phthalic acid, diisononyl ester" OR "Phthalisocizer DINP" OR "Sansocizer DINP"
N = 3

Science Direct 04:
"Vestinol 9" OR "Vestinol NN" OR "Vinycizer 90" OR "Vinylcizer 90" OR "Witamol 150"
N = 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: 08/29/2019

Date Range of Search: 15th century to the Present
N = 149

Agricola 01:
1,2-Benzenedicarboxylic acid diisononyl ester
1,2-Benzenedicarboxylic acid, 1,2-diisononyl ester
1,2-Benzenedicarboxylic acid, diisononyl ester
1,2-Benzenedicarboxylic acid, di-isononyl ester
Baylectrol 4200
BIS-ISONONYL PHTHALATE
Di(C8-10, C9 rich) branched alkyl phthalates
Di(isononyl) phthalate branched
Diacizer DINP
Diisononyl phthalate

Agricola 02:
Di-isononyl phthalate
Diisononyl phthalate (mixed isomers)
Diisononylphthalate
DINP
DINP branched
Isononyl alcohol, phthalate (2:1)
JAY-DINP
Jayflex DINP
Monocizer DINP
Palatinol DINP
Agricola 03:
Palatinol DN
Palatinol N
PHTHALATE, DIISONONYL
Phthalic acid diisononyl ester
Phthalic acid, diisononyl ester
Phthalisocizer DINP
Sansocizer DINP
Vestinol 9
Vestinol NN
Vinycizer 90
Agricola 04:
Vinylcizer 90
Witamol 150

TOXNET: (https://www.nlm.nih.gov/toxnet/index.html)
General search terms applied to the search strategy for TOXNET.
Date Searched: 08/28/19
Date Range of Search: 1900 to Present
N = 401

TOXNET 01:

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28553-12-0 OR 68515-48-0 OR 58033-90-2 OR 105009-97-0 OR 41375-91-1
N = 401

Search	Database	Query	Time	Result
# 1	toxline	(("diisononyl phthalate" OR "enj 2065" OR "di isononyl phthalate" OR "witamol 150" OR "vestinol nn" OR "sansocizer dinp" OR "palatinol n" OR "palatinol dn" OR dinp OR 28553-12-0 [rn]) OR ("ec 271 090 9" OR 68515-48-0 [rn]) OR 58033-90-2 [rn] OR 105009-97-0 [rn] OR 41375-91-1 [rn]) AND (eng [la]) AND (BIOSIS [org] OR NTIS [org] OR PESTAB [org] OR PubMed [org] OR TSCATS [org])	13:47:46	401

PubMed: (https://pubmed.ncbi.nlm.nih.gov/)
Below are the search terms compiled from the Chemical Report for Di-isononyl Phthalate and used on the PubMed "advanced search" page using the "Title" and the "Title/Abstract" fields.
Date Searched: 08/28/2019
Date Range of Search: 1900 to present
N = 363

"1,2-Benzenedicarboxylic acid diisononyl ester" OR "1,2-Benzenedicarboxylic acid, 1,2-diisononyl ester" OR "1,2-Benzenedicarboxylic acid, diisononyl ester" OR "1,2-Benzenedicarboxylic acid, di-isononyl ester" OR "Baylectrol 4200" OR "BIS-ISONONYL PHTHALATE" OR "Di(C8-10, C9 rich) branched alkyl phthalates" OR "Di(isononyl) phthalate branched" OR "Diacizer DINP" OR "Diisononyl phthalate" OR "Di-isononyl phthalate" OR "Diisononyl phthalate (mixed isomers)" OR "Diisononylphthalate" OR "DINP" OR "DINP Below are the search terms compiled from the Chemical Report for Di-isononyl Phthalate and used on the PubMed "advanced search" page using the "Title" and the "Title/Abstract" fields. branched" OR "Isononyl alcohol, phthalate (2:1)" OR "JAY-DINP" OR "Jayflex DINP" OR "Monocizer DINP" OR "Palatinol DINP" OR "Palatinol DN" OR "Palatinol N" OR "PHTHALATE, DIISONONYL" OR "Phthalic acid diisononyl ester" OR "Phthalic acid, diisononyl ester" OR "Phthalisocizer DINP" OR "Sansocizer DINP" OR "Vestinol 9" OR "Vestinol NN" OR "Vinycizer 90" OR "Vinylcizer 90" OR "Witamol 150"
N = 363

ECOTOX UNIFY:
This is an internal EPA database that is not accessible to the public. Results from the ECOTOX Unify search strategy.
Date Searched: 08/29/2019
Date Range of Search: All years
N = 41

Chemical(s) of Concern:
DINP

UNIFY Title Search String:
1,2-Benzenedicarboxylic acid diisononyl ester|1,2-Benzenedicarboxylic acid, 1,2-diisononyl ester|1,2-Benzenedicarboxylic acid, diisononyl ester|1,2-Benzenedicarboxylic acid, di-isononyl ester|Baylectrol 4200|BIS-ISONONYL PHTHALATE|Di(C8-10, C9 rich) branched alkyl phthalates|Di(isononyl) phthalate branched|Diacizer DINP|Diisononyl phthalate|Di-isononyl phthalate|Diisononyl phthalate (mixed isomers)|Diisononylphthalate|DINP|DINP branched|Isononyl

alcohol, phthalate (2:1)|JAY-DINP|Jayflex DINP|Monocizer DINP|Palatinol DN|Palatinol N|PHTHALATE, DIISONONYL|Phthalic acid diisononyl ester|Phthalic acid, diisononyl ester|Phthalisocizer DINP|Sansocizer DINP|Vestinol 9|Vestinol NN|Vinycizer 90|Vinylcizer 90|Witamol 150

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

In brief, SWIFT Review has pre-set literature search strategies ("filters") developed by information specialists that can be applied to identify studies that are more likely to be useful for identifying human health and ecotoxicity content from those that likely do not (*e.g.,* analytical methods). The filters function like a typical search strategy where studies are tagged as belonging to a certain filter if the terms in the filter literature search strategy appear in title, abstract, keyword or medical subject headings (MeSH*)* fields content. The applied SWIFT Review filters focused on lines of evidence: human, animal models for human health, ecological taxa (which includes ecotoxicological animal models, plants, and other taxa), and *in vitro* studies. The details of the search strategies that underlie the filters are available online. Studies not retrieved using these filters were not considered further. Studies that included one or more of the search terms in the title, abstract, keyword, or MeSH fields were exported as a RIS file for screening in Swift-ActiveScreener or DistillerSR.[9]

A.1.2.3 Data Prioritization for Occupational Exposures and Environmental Releases and Gen Pop, 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 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.

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

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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 DINP effects on human health and environmental hazard is presented in Table_Apx A-3. In addition to the PECO criteria, studies containing potentially relevant supplemental material were tracked and categorized during the literature screening process as outlined in Table_Apx A-4.

Table_Apx A-3. Hazards Title and Abstract and Full-Text PECO Criteria for DINP

PECO Element	Evidence
Population	• **Human:** Any population and life stage (*e.g.,* occupational or general population, including children and other sensitive populations). • **Animal:** Aquatic and terrestrial species (live, whole organism) from any life stage (*e.g.,* preconception, in utero, lactation, peripubertal, and adult stages). Animal models will be inventoried according to the categorization below: – Human health models: Rat, mouse, rabbit, dog, hamster, guinea pig, cat, non-human primate, pig, hen (neurotoxicity only) – Ecotoxicological models: Invertebrates (*e.g.,* insects, spiders, crustaceans, mollusks, and worms) and vertebrates (*e.g.,* mammals and all amphibians, birds, fish, and reptiles). All hen studies (including neurotoxicity studies) will be included for ecotoxicological models.

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PECO Element	Evidence
	• **Plants:** All aquatic and terrestrial species (live), including algal, moss, lichen, and fungi species. **Screener note:** • To identify human health and environmental hazards, other organisms not listed above in their respective categories can also be used. Non-mammalian model systems are increasingly used to identify potential human health hazards (*e.g., Xenopus*, zebrafish), and traditional human health models (*e.g.,* rodents) can be used to identify potential environmental hazard. Neurotoxicity studies performed in hens (*e.g.,* OECD 418 and 419) are considered relevant to both human and eco hazard • PECO considerations should be directed toward effects on target species only and not on the indirect effects expressed in taxa as a result of chemical treatment (*e.g.,* substance is lethal to a targeted pest species leading to positive effects on plant growth due to diminished presence of the targeted pest species). • Tests of the single toxicants in *in vitro* and *ex vivo* systems or on gametes, embryos, or plant or fungal sections capable of forming whole, new organisms will be tagged as potentially supplemental (mechanistic studies). Bacteria and yeast studies specific for assessing genotoxicity or mutagenicity (*e.g.,* Ames assay) will also be tagged as potentially supplemental (mechanistic studies), but are otherwise excluded. Studies on viruses are excluded.

Exposure	**Relevant forms:**
	• Dibutyl phthalate (DBP) (CASRN 84-74-2)
	• Butyl benzyl phthalate (BBP) (CASRN 85-68-7)
	• Diethylhexyl phthalate (DEHP) (CASRN 117-81-7)
	  – *Isomer:* Isooctyl phthalate – CASRN 27554-26-3
	• Di-isobutyl phthalate (DIBP) (CASRN 84-69-5)
	• Dicyclohexyl phthalate (CASRN 84-61-7)
	• Diisodecyl phthalate (DIDP) (CASRN 26761-40-0)
	  – *Isomer:* DIDP (mixed isomers) – CASRN 68515-49-1
	• Diisononyl phthalate (DINP) (CASRN 28553-12-0)
	  – *Isomer:* DINP (mixed isomers) – CASRN 68515-48-0
	
	For synonyms see the USEPA Chemistry Dashboard.
	• No isomers were included for DBP, BBP, DIBP, or dicyclohexyl phthalate.
	• **Human:** Any exposure to DBP, BBP, DEHP, DIBP, dicyclohexyl phthalate, DIDP, and/or DINP singularly or in mixture, including exposure as measured by internal concentrations of these chemicals or metabolites of these chemicals in a biological matrix (*e.g.,.,* urine, blood, semen). See list of common metabolites for each phthalate below.
	• **Animal:** Any exposure to DBP, BBP, DEHP, DIBP, dicyclohexyl phthalate, DIDP and/or DINP, including via water (including environmental aquatic exposures), soil or sediment, diet, gavage, injection, dermal, and inhalation.

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PECO Element	Evidence
	• **Plants:** Any exposure to DBP, BBP, DEHP, DIBP, dicyclohexyl phthalate, DIDP, and/or DINP including via water, soil, or sediment. **Screener note:** • Field studies with media concentrations (surface water, interstitial water, soil, sediment) and/or body/tissue concentrations of animals or plants are to be identified as *Supplemental* if any biological effects are reported. • Animal and plant studies involving exposures to mixtures will be *included* only if they also include exposure to DBP, BBP, DEHP, DIBP, dicyclohexyl phthalate, DIDP and/or DINP alone. Otherwise, animal and plant mixture studies will be tagged as *Supplemental*. Human mixture studies are *included*. • Controlled outdoor experimental studies (*e.g.,* controlled crop/greenhouse studies, mesocosm studies, artificial stream studies) are considered to be laboratory studies (not field studies) because there is a known and prescribed exposure dose(s) and an evaluation of hazardous effect(s). Whereas field studies (*e.g.,* biomonitoring) where there is no prescribed exposure dose(s) will be excluded if there is no evaluated hazardous effect, and tagged as supplemental field, if there is an evaluated hazardous effect.
Comparator	• **Human:** A comparison or referent population exposed to lower levels (or no exposure/exposure below detection limits) of DBP, BBP, DEHP, DIBP, dicyclohexyl phthalate, DIDP, and/or DINP, or exposure to DBP, BBP, DEHP, DIBP, dicyclohexyl phthalate, DIDP, and/or DINP for shorter periods of time. • **Animal and plants:** A concurrent control group exposed to vehicle-only treatment and/or untreated control (control could be a baseline measurement). **Screener note:** • If no control group is explicitly stated or implied (*e.g.,* by mention of statistical results that could only be obtained if a control group was present), the study will be marked as *Unclear* during Title/Abstract Screening. • All case series and case studies describing findings in a sample size of less than 20 people in any setting (*e.g.,* occupation, general population) will be tracked as *Supplemental* Case-control, case-crossover, case-referent, case-only, case-specular, case-cohort, case-parent, nested case-control study designs are all *Included*.
Outcome	• **Human:** All health outcomes (cancer and non-cancer) at the organ level or higher. • **Animal and plants:** All apical biological effects (effects measured at the organ level or higher) and bioaccumulation from laboratory studies with concurrently measured media and/or tissue concentrations). Apical endpoints include, but are not limited to, reproduction, survival, and growth. **Screener note:**

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PECO Element	Evidence
	• Measurable biological effects relevant for humans, animals and plants may include but are not limited to: mortality, behavioral, population, physiological, growth, reproduction, systemic, and point of contact (irritation and sensitization) effects. • Effects measured at the cellular level of biological organization and below are to be tagged as supplemental, mechanistic.

Table_Apx A-4. Major Categories of "Potentially Relevant" Supplemental Materials for DINP

Category	Evidence
Mechanistic studies	All studies that report results at the cellular level and lower in both mammalian and non-mammalian model systems, including *in vitro*, *in vivo*, *ex vivo*, and *in silico* studies. These studies include assays for genotoxicity or mutagenicity using bacteria or yeast.
ADME, PBPK, and toxicokinetic	Studies designed to capture information regarding ADME, toxicokinetic studies, or PBPK models.
Case reports or case series	Case reports ($n \leq 3$ cases) and case series (non-occupational) will be tracked as potentially relevant supplemental information.
Potentially exposed or susceptible subpopulations (no health outcome)	Studies that identify potentially exposed or susceptible subpopulations; for example, studies that focus on a specific demographic, life stage, or genotype. This tag applies primarily during full-text screening. **Screener note:** If biological susceptibility issues are clearly present or *strongly* implied in the title/abstract, this supplemental tag may be applied at the title abstract level. If uncertain at title/abstract, do not apply this tag to the reference during title/abstract screening.
Mixture studies	Experimental mixture studies that are not considered PECO-relevant because they do not contain an exposure or treatment group assessing only the chemical of interest. Human health animal model and environmental animal model/plant will be tagged separately for mixture studies.
Records with no original data	Records that do not contain original data, such as other agency assessments, informative scientific literature reviews, editorials, or commentaries.
Conference abstracts	Records that do not contain sufficient documentation to support study evaluation and data extraction.
Field studies	Field studies with media concentrations (*e.g.,* surface water, interstitial water, soil, sediment) and/or body/tissue concentrations of animals or plants if biological effects reported.

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Category	Evidence
Isomer	PECO-relevant studies with an exposure to one of the identified isomers, if any.

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

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

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

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

Chemical	Drinking Water	Ambient Air	Air Disposal	Land Disposal	Underground Disposal	Groundwater
DINP	–	–	–	–	–	–

[a] "Supplemental pathways" refers to pathways addressed by other EPA-administered statutes. Studies tagged under these pathways provide media information that is not prioritized in the screening process.

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A.2.1.3 RESO for Occupational Exposure and Environmental Releases

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

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

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

RESO Element	Evidence
Receptors	• Human: Workers, including ONUs • Environment: All environmental receptors (relevant release estimates input to Exposure) Please refer to the conceptual models for more information about the environmental and human receptors included in the TSCA risk evaluation.
Exposure	• Worker exposure to and relevant environmental releases of the chemical substance from occupational scenarios: Dermal and inhalation exposure routes (as indicated in the conceptual model) Oral route (as indicated in the conceptual model) Please refer to the conceptual models for more information about the routes and media/pathways included in the TSCA risk evaluation.
Setting or Scenario	• Any occupational setting or scenario resulting in worker exposure and relevant environmental releases (includes all manufacturing, processing, use, disposal.
Outcomes	• Quantitative estimates[a] of worker exposures and of relevant environmental releases from occupational settings • General information and data related and relevant to the occupational estimates*
[a] Metrics (*e.g.,* mg/kg/day or mg/m^3 for worker exposures, kg/site/day for releases) are determined by toxicologists for worker exposures and by exposure assessors for releases; also, the Engineering, Release and Occupational Exposure Data Needs (Table_Apx A-8) provides a list of related and relevant general information.	

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

Objective Determined during Scoping	Type of Data[a]
General engineering assessment (may apply to occupational exposures and/or environmental releases)	Description of the life cycle of the chemical(s) of interest, from manufacture to end-of-life (*e.g.,* each manufacturing, processing, or use step), and material flow between the industrial and commercial life cycle stages. The total annual U.S. volume (lb/yr or kg/yr) of the chemical(s) of interest manufactured, imported, processed, and used; and the share of total annual manufacturing and import volume that is processed or used in each life cycle step. Description of processes, equipment, and unit operations during each industrial/ commercial life cycle step. Material flows, use rates, and frequencies (lb/site-day or kg/site-day and days/yr; lb/site-batch and batches/yr) of the chemical(s) of interest during each industrial/ commercial life cycle step. Note: if available, include weight fractions of the chemicals(s) of interest and material flows of all associated primary chemicals (especially water). Number of sites that manufacture, process, or use the chemical(s) of interest for each industrial/commercial life cycle step and site locations. Concentration of the chemical of interest.
Occupational exposures	Description of worker activities with exposure potential during the manufacture, processing, or use of the chemical(s) of interest in each industrial/commercial life cycle stage. Potential routes of exposure (*e.g.,* inhalation, dermal). Physical form of the chemical(s) of interest for each exposure route (*e.g.,* liquid, vapor, mist) and activity. Breathing zone (personal sample) measurements of occupational exposures to the chemical(s) of interest, measured as time-weighted averages (TWAs), short-term exposures, or peak exposures in each occupational life cycle stage (or in a workplace scenario similar to an occupational life cycle stage). Area or stationary measurements of airborne concentrations of the chemical(s) of interest in each occupational setting and life cycle stage (or in a workplace scenario similar to the life cycle stage of interest). For solids, bulk and dust particle size characterization data. Dermal exposure data. Exposure duration (hr/day). Exposure frequency (days/yr). Number of workers who potentially handle or have exposure to the chemical(s) of interest in each occupational life cycle stage. PPE types employed by the industries associated with the conditions of use examined in the risk evaluation. Engineering controls employed to reduce occupational exposures in each occupational life cycle stage (or in a workplace scenario similar to the life cycle stage of interest), and associated data or estimates of exposure reductions.
Environmental releases (to relevant environmental media)	Description of sources of potential environmental releases, including cleaning of residues from process equipment and transport containers, involved during the manufacture, processing, or use of the chemical(s) of interest in each life cycle stage.

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

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 category of chemical substances undergoing risk evaluation.

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

PESO Element	Evidence
Pathways and Processes	Environmental fate, transport, partitioning, and degradation behavior across environmental media to inform exposure pathways of the chemical substance of interest. Exposure pathways included in the conceptual models: air, surface water, groundwater, wastewater, soil, sediment, and biosolids. Processes associated with the target exposure pathways Bioconcentration and bioaccumulation Destruction and removal by incineration Please refer to the conceptual models for more information about the exposure pathways included in each TSCA risk evaluation.
Exposure	Environmental exposure of environmental receptors (*i.e.,* aquatic and terrestrial organisms) to the chemical substance of interest, mixtures including the chemical substance, and/or its degradation products and metabolites. Environmental exposure of human receptors, including any potentially exposed or susceptible subpopulations, 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
Setting or Scenario	Any setting or scenario resulting in releases of the chemical substance of interest into the natural or built environment (*e.g.,* buildings including homes or workplaces, or wastewater treatment facilities) that would expose environmental (*i.e.,* aquatic and terrestrial organisms) or human receptors (*i.e.,* general population, and potentially exposed or susceptible subpopulation)
Outcomes	Fate properties which allow assessments of exposure pathways: Abiotic and biotic degradation rates, mechanisms, pathways, and products Bioaccumulation magnitude and metabolism rates Partitioning within and between environmental media (see Pathways and Processes)

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

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

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

A.2.1.5 Generation of Hazard Heat Maps

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

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

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

A.3 Gray Literature Search and Screening Strategies

EPA conducted a gray literature search for reasonably available information to support the manufacturer requested 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, 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.

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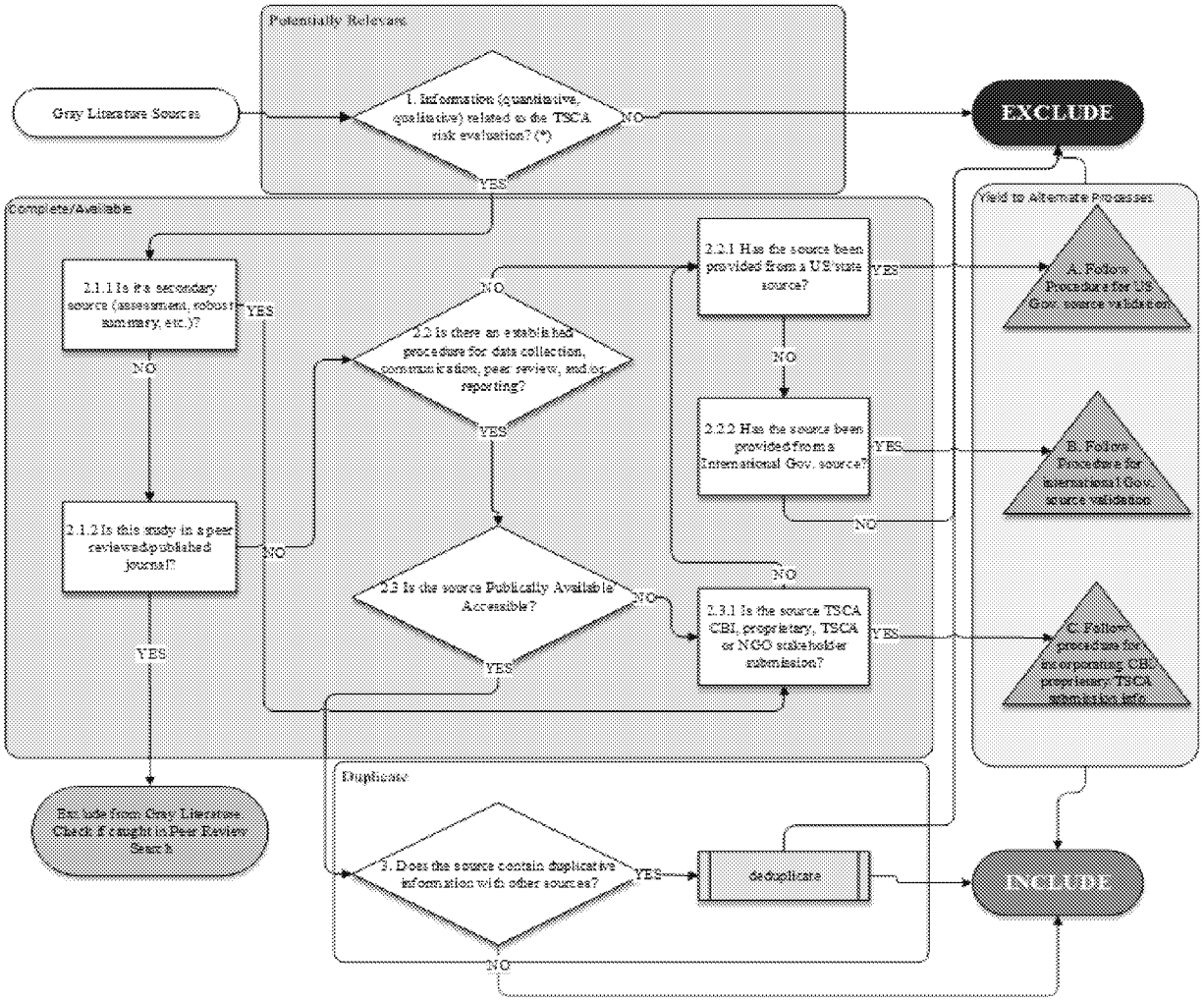
A.3.1 Screening of Gray Literature

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.

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Table_Apx A-11. Decision Logic Tree Overview

Step	Metric	Questions to Consider
1	Potential relevance	Does the result have information (qualitative or quantitative) related to TSCA risk evaluations?[a]
2.1.1	Complete/available	Is it a secondary data source (assessment, robust summary, TSCA submission databases, etc.)?
2.1.2		Is the document from a peer-reviewed/published journal?
2.2		Is there an established procedure for data collection, communication, peer review, and/or reporting?
2.2.1		Has the data been provided by a U.S. 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?
[a] Apply discipline relevancy metric		

Results of the gray literature search and decision tree process are included in Appendix A.3.3.

A.3.3 TSCA Submission Searching and Title Screening

EPA screens non-CBI and CBI 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 move to data evaluation. If the title is not clear regarding the document's contents, EPA obtains the full text and advances to the next steps.

After full texts are obtained, EPA will review 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

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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 DINP

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

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

Source Agency	Source Name	Source Type	Source Category	Source Website
ATSDR	ATSDR Toxicological Profiles (Original Publication)	Other U.S. Agency Resources	Assessment or Related Document	https://www.atsdr.cdc.gov/toxprofiles/index.asp
Aus. Assm.	NICNAS Assessments (human health, Tier I, II or III)	International Resources	Assessment or Related Document	https://www.nicnas.gov.au/chemical-information/imap-assessments/imap-assessments
CAL EPA	Technical Support Documents for regulations: Proposition 65, Cancer	Other U.S. Agency Resources	Assessment or Related Document	https://oehha.ca.gov/chemicals
CPSC	Chronic Hazard Advisory Panel Reports	Other U.S. Agency Resources	Assessment or Related Document	https://www.cpsc.gov/chap
CPSC	Technical Reports: Exposure/Risk Assessment	Other U.S. Agency Resources	Assessment or Related Document	https://www.cpsc.gov/Research--Statistics/Chemicals
CPSC	Technical Reports: Toxicity Review	Other U.S. Agency Resources	Assessment or Related Document	https://www.cpsc.gov/Research--Statistics/Chemicals
ECHA	Annex XV Restriction Report	International Resources	Assessment or Related Document	https://echa.europa.eu/current-activities-on-restrictions

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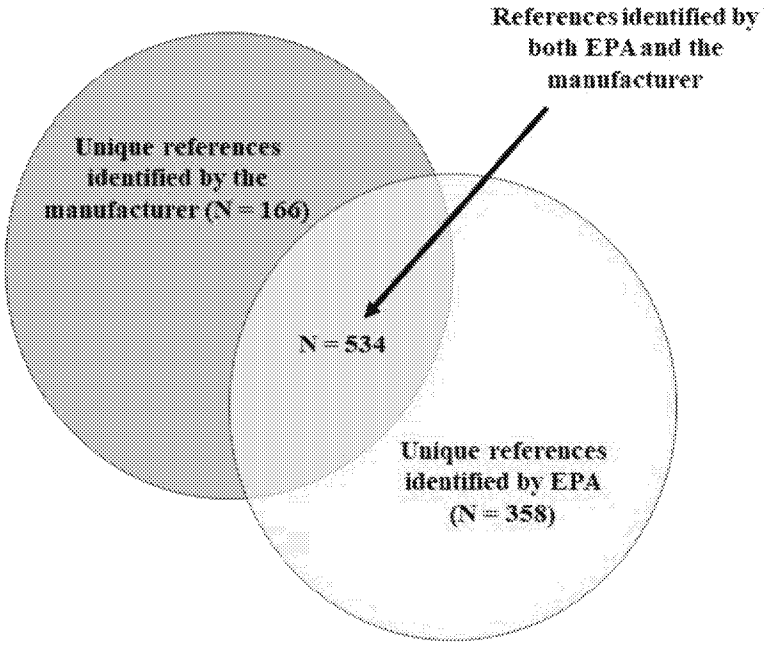
Source Agency	Source Name	Source Type	Source Category	Source Website
ECHA	Annex XVII Restriction Reports	International Resources	Assessment or Related Document	https://echa.europa.eu/substances-restricted-under-reach
ECHA	ECHA Documents	International Resources	Assessment or Related Document	https://echa.europa.eu/information-on-chemicals
ECHA	European Union Risk Assessment Report	International Resources	Assessment or Related Document	https://echa.europa.eu/information-on-chemicals/information-from-existing-substances-regulation
ECHA	Substance Infocard	International Resources	Fact Sheet	https://echa.europa.eu/da/substance-information
Env Canada	Canada Substance Grouping Pages	International Resources	Assessment or Related Document	http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=D7A631FF-1
EPA	OPPT: TSCATS database maintained at SRC (TSCA submissions)	U.S. EPA Resources	Database	http://chem.sis.nlm.nih.gov/chemidplus/chemidheavy.jsp
EPA	OPPT: Chemview (TSCA submissions – chemical test rule data and substantial risk reports)	U.S. EPA Resources	Database	https://chemview.epa.gov/chemview
EPA	OPPT: CIS (CBI LAN) (TSCA submissions)	U.S. EPA Resources	Database	
EPA	EPA: Generic Scenario	U.S. EPA Resources	Assessment or Related Document	https://www.epa.gov/tsca-screening-tools/chemsteer-chemical-screening-tool-exposures-and-environmental-releases#genericscenarios

Source Agency	Source Name	Source Type	Source Category	Source Website
EPA	Office of Water: Code of Federal Regulations (CFRs)	U.S. EPA Resources	Regulatory Document or List	https://www.epa.gov/eg/industrial-effluent-guidelines
EPA	Office of Air: Code of Federal Regulations (CFRs) and Dockets	U.S. EPA Resources	Regulatory Document or List	https://www.epa.gov/stationary-sources-air-pollution
EPA	Office of Air: Air Emission Factors (AP-42)	U.S. EPA Resources	Regulatory Document or List	https://www.epa.gov/air-emissions-factors-and-quantification/ap-42-compilation-air-emissions-factors
EPA	Other EPA: Misc Sources	U.S. EPA Resources	General Search	https://www.epa.gov/
KOECT	Kirk-Othmer Encyclopedia of Chemical Technology Journal Article	Other Resources	Encyclopedia	https://onlinelibrary.wiley.com/doi/book/10.1002/0471238961
NIOSH	CDC NIOSH: Health Hazard Evaluations (HHEs)	Other U.S. Agency Resources	Assessment or Related Document	https://www2a.cdc.gov/hhe/search.asp
NIOSH	CDC NIOSH – Publications and Products	Other U.S. Agency Resources	Assessment or Related Document	https://www2a.cdc.gov/nioshtic-2/
NLM	National Library of Medicine's Hazardous Substance Databank	Other U.S. Agency Resources	Database	https://www.nlm.nih.gov/databases/download/hsdb.html
NLM	National Library of Medicine's HazMap	Other U.S. Agency Resources	Database	https://haz-map.com/
NTP	Additional NTP Reports	Other U.S. Agency Resources	Assessment or Related Document	https://ntp.niehs.nih.gov/publications/index.html
NTP	Office of Health Assessment and	Other U.S. Agency Resources	Assessment or Related Document	https://ntp.niehs.nih.gov/pubhealt

Source Agency	Source Name	Source Type	Source Category	Source Website
	Translation (OHAT) Monographs			h/hat/noms/evals.html
OECD	OECD Substitution and Alternatives Assessment	International Resources	Assessment or Related Document	http://www.oecdsaatoolbox.org/
OECD	OECD: General Site	International Resources	General Search	https://www.oecd.org/
OECD	OECD: Emission Scenario Documents	International Resources	Assessment or Related Document	http://www.oecd.org/document/46/0,2340,en_2649_201185_2412462_1_1_1_1,00.html
RIVM	RIVM Reports: Risk Assessments	International Resources	Assessment or Related Document	https://www.rivm.nl/en
UNEP	Risk Profile/Stockholm Convention	International Resources	Assessment or Related Document	http://chm.pops.int/TheConvention/ThePOPs/AllPOPs/tabid/2509/Default.aspx

A.4 Summary of Literature Cited in the ACC HPP Submission

As part of the ACC HPP submission requesting the risk evaluation for DINP (Docket ID: EPA-HQ-OPPT-2018-0436), data were submitted to EPA separately from the systematic review search process outlined for peer-reviewed and gray literature data in Appendix A.2 and Appendix A.3, respectively. Data from the ACC HPP submission were compared to the search results from the systematic review process to determine the overlap in the reference pools. Following deduplication of references within the submission and removal of CFR's and U.S.C.'s, the final list of manufacturer-submitted references totaled 700, 534 of which were also identified by EPA in a separate literature search for DINP. The Venn diagram in Figure_Apx A-2 below shows the numbers in each of these pools (yellow and blue circles) along with the number common to both in green. The remaining 166 references provided by the manufacturer that were not captured in EPA's literature search for DINP data will undergo the appropriate systematic review steps.



Figure_Apx A-2. Venn Diagram of Literature Identified by EPA vs. the ACC HPP Submission
Gray literature from the ACC HPP submission was also de-duplicated with the EPA gray literature search results and is included in the figure totals for each pool (numbers are of June 15, 2021).

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Appendix B PHYSICAL AND CHEMICAL PROPERTIES OF DINP

Table_Apx B-1 summarizes statistics for the physical and chemical property values identified through systematic review as of June 2020. The "N" column indicates the number of unique primary sources of data for that endpoint. That is, if multiple sources presented equivalent values and cited the same primary source, only one of those was included in these statistics and included in the statistical calculations. All physical and chemical property values that were extracted and evaluated as of June 2020 are presented in the supplemental file *Data Extraction and Data Evaluation Tables for Physical and Chemical Property Studies* (Docket ID: EPA-HQ-OPPT-2018-0436).

Table_Apx B-1. Summary Statistics for Reviewed Physical Properties

Property or Endpoint	N	Unit	Mean	Standard Deviation	Min	Max
Molecular formula	–	–	NA	NA	NA	NA
Molecular weight	–	g/mol	NA	NA	NA	NA
Physical state	2	–	NA	NA	NA	NA
Physical properties	1	–	NA	NA	NA	NA
Melting point	1	°C	−48	–	−48	−48
Boiling point	1	°C	252	–	252	252
Density	3	g/cm^3	0.973	0.002	0.972	0.97578
Vapor pressure	5	mm Hg	8.10	17.8	$5.40E\times10^{-7}$	40
Vapor density	0	–	–	–	–	–
Water solubility	2	mg/L	0.2	0	0.2	0.2
Octanol/water partition coefficient (log Kow)	2	–	9.37	0	9.37	9.37
Henry's Law constant	0	$atm\cdot m^3/mol$	–	–	–	–
Flash point	1	°C	213	–	213	213
Auto flammability	0	°C	–	–	–	–
Viscosity	1	cP	55.334	–	55.334	55.334
Refractive index	4	–	1.496	0.019	1.486	1.524
Dielectric constant	0	–	–	–	–	–

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Appendix C ENVIRONMENTAL FATE AND TRANSPORT PROPERTIES OF DINP

Table_Apx C-1 provides the environmental fate characteristics that EPA identified and considered in developing the scope for DINP. This table may be updated as EPA collects additional information through systematic review methods and by reviewing information provided in the ACC HPP submission requesting the risk evaluation for DINP (Docket ID: EPA-HQ-OPPT-2018-0436).

Table_Apx C-1. Environmental Fate and Transport Properties of DINP

Property or Endpoint	Value[a]	Reference
Direct photodegradation	Contains chromophores that absorb at wavelengths >290 nm, may be susceptible to direct photodegradation	(NLM, 2020) citing (Lyman et al., 1990)
Indirect photodegradation	$t_{1/2}$ = 0.35 days at OH radical concentration of 1×10^6 molecules/cm^3	(Mackay et al., 2006) citing (Peterson and Staples, 2003)
Hydrolysis	$t_{1/2}$ at pH 7 = 4 years; $t_{1/2}$ at pH 8 = 150 days (estimated)[b]	(U.S. EPA, 2012b)
Biodegradation (aerobic)	Water: $t_{1/2}$ = 5.31 days in acclimated shake flask CO_2 evaluation test	(Mackay et al., 2006) citing (Sugatt et al., 1984)
	Water: 74%/4 weeks (Japanese MITI test)	(NITE, 2018)
	Soil: $t_{1/2}$ = 51 days	(ECHA, 2019)
Wastewater treatment	94% total removal (0.78% by biodegradation, 93% by sludge and 0% by volatilization to air; estimated)[b]	(U.S. EPA, 2012b)
Bioconcentration factor (BCF)	1,860 (*Arca zebra)*	(Mackay et al., 2006) citing (Solbakken et al., 1985)
Bioaccumulation factor (BAF)	16 (estimated)[b]	(U.S. EPA, 2012b)
Soil organic carbon:water partition coefficient (Log K_{oc})	6.0 (K_{ow} method); 5.4 (MCI method) (estimated)[b]	(U.S. EPA, 2012b)

[a] Measured unless otherwise noted
[b] EPI Suite Physical Property Inputs: MP = −48 °C, VP = 5.4×10^{-7} mm Hg, WS = 0.2 mg/L, SMILES CCC(C)CC(C)CCOC(=O)c1ccccc1C(=O)OCC(C)CCC(C)CC (representative structure)

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Appendix D REGULATORY HISTORY

The category of chemical substances, DINP, 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 DINP are listed in Table_Apx D-3.

D.1 Federal Laws and Regulations

Table_Apx D-1. Federal Laws and Regulations

Statute/Regulation	Description of Authority/Regulation	Description of Regulation
EPA statutes/regulations		
Toxic Substances Control Act (TSCA) – section 8(a)	The TSCA section 8(a) CDR Rule requires manufacturers (including importers) to give EPA basic exposure-related information on the types, quantities, and uses of chemical substances produced domestically and imported into the United States.	DINP manufacturing (including importing), processing, and use information is reported under the CDR rule (85 FR 5081620122, April 9, 2020).
Toxics 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.	1,2-Benzenedicarboxylic acid, 1,2-diisononyl ester (CASRN 28553-12-0) and 1,2-benzenedicarboxylic acid, di-C8-10-branched alkyl esters, C9-rich (CASRN 68515-48-0)) were on the initial TSCA Inventory and therefore were not subject to EPA's new chemicals review process under TSCA section 5 (60 FR 16309, March 29, 1995).
Toxic Substances Control Act (TSCA) – section 8(e)	Manufacturers (including importers), processors, and distributors must immediately notify EPA if they obtain information that supports the conclusion that a chemical substance or mixture presents a substantial risk of injury to health or the environment.	Four substantial risk reports were received for CASRN 28553-12-0 and 12 substantial risk reports were received for CASRN 68515-48-0 (1991-1998) (U.S. EPA, ChemView. Accessed May 18, 2020).
Toxic Substances Control Act (TSCA) – section 4	Provides EPA with authority to issue rules, enforceable consent agreements, and orders requiring manufacturers (including importers) and processors to test chemical substances and mixtures.	Two chemical data submissions from test rules received for CASRN 28553-12-0 for biodegradation (U.S. EPA, ChemView. Accessed May 18, 2020).
Federal Food, Drug, and Cosmetic Act (FFDCA) – section 408	FFDCA governs the allowable residues of pesticides in food. Section 408 of the FFDCA provides EPA with the authority to set tolerances (rules that establish maximum allowable residue limits), or exemptions from the requirement of a	CASRN 28553-12-0 is approved for non-food use (InertFinder, Accessed May 18, 2020).

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Statute/Regulation	Description of Authority/Regulation	Description of Regulation
	tolerance, for pesticide residues (including inert ingredients) on food. Prior to issuing a tolerance or exemption from tolerance, EPA must determine that the pesticide residues permitted under the action are "safe." Section 408(b) of the FFDCA defines "safe" to mean a reasonable certainty that no harm will result from aggregate, nonoccupational exposures to the pesticide. Pesticide tolerances or exemptions from tolerance that do not meet the FFDCA safety standard are subject to revocation under FFDCA section 408(d) or (e). In the absence of a tolerance or an exemption from tolerance, a food containing a pesticide residue is considered adulterated and may not be distributed in interstate commerce.	
Clean Water Act (CWA) – Sections 301, 304, 306, 307, and 402	CWA 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 401.15. The "priority pollutants" specified by those families are listed in 40 CFR part 423 Appendix A. These are pollutants for which best available technology effluent limitations must be established on either a national basis through rules (sections 301(b), 304(b), 307(b), 306) or on a case-by-case best professional judgement basis in NPDES permits, see section 402(a)(1)(B). EPA identifies the best available technology that is economically achievable for that industry after considering statutorily prescribed factors and sets regulatory requirements based on the performance of that technology.	As a phthalate ester, DINP is designated as a toxic pollutant under section 307(a)(1) of the CWA, and as such is subject to effluent limitations.
Comprehensive Environmental Response, Compensation and Liability Act (CERCLA)	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.	As a phthalate ester, DINP is designated as a hazardous substance under CERCLA. No reportable quantity is assigned to the generic or broad class (40 CFR 302.4).
Other federal statutes/regulations		
Federal Food, Drug, and Cosmetic Act (FFDCA)	Provides the Food and Drug Administration (FDA) with authority to	CASRN 28553-12-0 is listed as an Indirect Additive used in

Statute/Regulation	Description of Authority/Regulation	Description of Regulation
	oversee the safety of food, drugs, and cosmetics.	Food Contact Substances (21 CFR 178.3740).
Consumer Product Safety Improvement Action 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 childcare articles at concentrations >0.1%.	Children's toys and childcare articles that contain concentrations of >0.1% of DINP are prohibited. The interim prohibition on the use of DINP in children's toys and child care articles (15 U.S.C. 2057(c), August 14, 2008) became permanent in the final rule and was expanded to prohibit all children's toys (not just those that can be placed in a child's mouth) and child care articles that contain concentrations > 0.1% of DINP (16 CFR part 1307, October 27, 2017).

D.2 State Laws and Regulations

Table_Apx D-2. State Laws and Regulations

State Action	Description of Action
State Right-to-Know Acts	Pennsylvania (P.L. 734, No. 159 and 34 Pa. Code § 323) includes phthalate esters on the hazardous substance list as an environmental hazard but does not specifically list DINP.
Chemicals of High Concern to Children	Several states have adopted reporting laws for chemicals in children's products containing DINP (CASRN 28553-12-0), including Minnesota (Toxic Free Kids Act Minn. Stat. 116.9401 to 116.9407), Oregon (Toxic-Free Kids Act, Senate Bill 478, 2015), Vermont (18 V.S.A § 1776) and Washington State (Wash. Admin. Code 173-334-130).
Other	California listed DINP on Proposition 65 in 2013 due to potential to cause cancer. (Cal Code Regs. Title 27, § 27001). DINP (CASRN 28553-12-0) is listed as a Candidate Chemical under California's Safer Consumer Products Program (Health and Safety Code § 25252 and 25253). California lists DINP as a designated priority chemical for biomonitoring (California SB 1379). Minnesota designated DINP (28553-12-0) as a chemical of high concern (Toxic Free Kids Act Minn. Stat. 116.9401 to 116.9407.

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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	CASRNs 28553-12-0 and 68515-48-0 are on the Canadian Domestic Substances List (Government of Canada. Managing substances in the environment. Substances search. Database accessed May 18, 2020).
European Union	CASRN 28553-12-0 (EC/List no.: 249-079-5) and CASRN 68515-48-0 (EC/List no.: 271-090-9) are registered for use in the EU (European Chemicals Agency (ECHA) database. Accessed May 18, 2020). DINP was added to the Annex XVII of REACH (Conditions of restriction) (European Union Chemical Agency [ECHA] database. Accessed May 18, 2020).
Australia	CASRNs 28553-12-0 and 68515-48-0 were assessed under Human Health Tier II of the Inventory Multi-Tiered Assessment and Prioritisation (IMAP). (National Industrial Chemicals Notification and Assessment Scheme [NICNAS], 2015, *Diisononyl phthalates and related compounds: Human health tier II assessment*. Accessed January 27, 2021) CASRNs 28553-12-0 and 68515-48-0 are listed on the Chemical Inventory and subject to secondary notifications when importing or manufacturing the chemical in Australia. (Australian Inventory of Industrial Chemicals database. Accessed January 27, 2021)
Japan	CASRNs 28553-12-0 and 68515-48-0 are 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]) CASRN 28553-12 is also regulated under the following legislation: • Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof • Industrial Safety and Health Act (ISHA) • Air Pollution Control Law • Water Pollution Control Law • Soil Contamination Countermeasures Act • Poisonous and Deleterious Substances Control Act Act on the Protection of the Ozone Layer through the Control of Specified Substances and Other Measures (National Institute of Technology and Evaluation [NITE] Chemical Risk Information Platform [CHIRP]. Accessed May 18, 2020).
Denmark, Ireland, New Zealand, United Kingdom	Occupational exposure limits for DINP (CASRN 28553-12-0) (GESTIS International limit values for chemical agents (occupational exposure limits, OELs database. Accessed May 18, 2020).

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Country/ Organization	Requirements and Restrictions
Additional information	SPILLAGE DISPOSAL CLASSIFICATION & LABELLING Collect leaking and spilled liquid in covered containers as far as possible. Routes of exposure. The substance can be absorbed into the body by inhalation of its aerosol. NOTES Other melting points: between −40 °C and −46 °C. The recommendations on this Card also apply to 1,2-benzenecarboxylic acid, di-C8-10-branched alkyl esters, C9-rich (CAS 68515-48-0) (DINP 1 is a trade name) http://www.inchem.org/.

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Appendix E PROCESS, RELEASE, AND OCCUPATIONAL EXPOSURE INFORMATION

This appendix provides information and data found in preliminary data gathering for DINP.

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 41 facilities that submitted activity data for 2015. Twenty of these facilities stated that they imported DINP in 2015, four stated that they manufactured DINP in 2015, and the remaining 17 facilities' 2015 manufacture or import activity is withheld or claimed as CBI (U.S. EPA, 2020a). According to 2016 public CDR data, DINP is imported into the United States in liquid or pellet form and manufactured in liquid form (U.S. EPA, 2020a).

E.1.1.1 Domestic Manufacturing

DINP is generally produced through esterification of phthalic anhydride with isononyl alcohol in a closed system at high temperatures, and usually over an acid catalyst. Following esterification, excess alcohol is removed under reduced pressure and the product is typically neutralized, washed, and filtered (ECPI, 2015).

Of note, DINP exists in two forms (hence, the two CASRN numbers), reflecting the two possible routes for isononanol precursor production. DINP (CASRN 28553-12-0) is manufactured from a C9 alcohol fraction that is n-butene based while DINP (CASRN 68515-48-0) is manufactured from a C8-C10 alcohol fraction through the "Polygas" process (ECPI, 2015).

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. If DINP is imported (activity claimed as CBI), it is shipped in liquid or pellet form according to 2016 CDR. All facilities that claimed import/manufacture as CBI also claimed "import never at site" as CBI (U.S. EPA, 2020a).

E.1.2 Processing and Distribution

E.1.2.1 Reactant or Intermediate

Processing as a reactant or intermediate is the use of DINP as a feedstock in the production of another chemical via a chemical reaction in which DINP is consumed to form the product. Four companies reported to the 2016 CDR that DINP was processed as a reactant or intermediate to produce plastic material and resin, processing aids not otherwise listed (*e.g.,* mixed metal stabilizer), plastic products, synthetic rubber, or rubber products (U.S. EPA, 2020a).

Exact operations for the use of DINP 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 DINP (if any exists).

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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 DINP into a chemical formulation, mixture, or reaction product are dependent on the specific manufacturing process or processes involved. Companies reported to 2016 CDR that DINP is used as a plasticizer for the manufacture of various end products, including plastic materials and resins, paints and coatings, and adhesives and sealants (U.S. EPA, 2020a). Data reported to the 2016 CDR also indicates that DINP is used as a heat stabilizer in plastic products (U.S. EPA, 2020a). Various companies have also reported DINP as an additive and/or constituent in laboratory chemicals (Spex Certiprep, 2019; TCI America, 2019).

The exact processes used to formulate products containing DINP are not known at this time; however, several ESDs published by the OECD and Generic Scenarios published by EPA have been identified that provide general process descriptions for these types of products. EPA plans to further investigate processing uses of DINP 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 DINP-containing formulations or reaction products are dependent on the article. The majority of companies reported through 2016 CDR that DINP is used as a plasticizer in the manufacture of plastic articles for multiple types of end uses, such as plastics products, rubber products, textiles, furniture, and electrical equipment (U.S. EPA, 2020a).

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 from a bulk storage container into smaller containers.

E.1.2.5 Recycling

In 2016 CDR, 18 facilities reported that DINP was not recycled, three facilities reported that DINP was recycled, and 20 facilities withheld recycling information or indicated it was not known or reasonably ascertainable. EPA plans to further investigate the potential for recycling of DINP and pre- and post-consumer recycling of resins containing DINP during risk evaluation.

E.1.3 Uses

E.1.3.1 Plastic and Rubber Products

As described in Section E.1.2.3, DINP is used to increase the flexibility of plastic and rubber products, which may be used industrially, commercially, and by consumers. DINP is used in plastics such as wires and cables used in the building and construction and automotive industries, floor and wall coverings (such as poly(vinyl chloride) [PVC] materials), electronic products, furniture and furnishings, toys, playgrounds, sporting equipment, mold-making for munitions/weapon systems, and other miscellaneous plastic and rubber products (Euclid Chemical, 2020, EPA-HQ-OPPT-2018-0436-0016; (U.S. EPA, 2020a)). DINP is likely entrained in the products; however, DINP may be available for exposure depending on the application of the end use products, such as if building and construction materials are cut prior to installation. EPA plans to further investigate processing uses of DINP during risk evaluation.

E.1.3.2 Building/Construction Materials Not Covered Elsewhere

DINP is a constituent of construction materials (U.S. EPA, 2020a). DINP is found in plastic products, adhesives, sealants, paints, and coatings manufactured for construction end uses (U.S. EPA, 2020a). Additionally, companies have indicated that DINP is a constituent of patching pastes (Gardner-Gibson, 2015), caulking materials (DAP Products, 2019), and grout (AVM Industries Inc, 2017; Polygem, 2015).

E.1.3.3 Adhesives, Sealants, Paints, and Coatings

DINP is used in a variety of adhesive, sealant, paint, and coating products. Specifically, DINP is typically found in consumer and commercial adhesives, sealants, paints, and coatings typically at concentrations of less than 1% to less than 60% (U.S. EPA, 2020a). These adhesives, sealants, paints, and coatings are used in products such as plastic products, fabrics and textiles, and furniture and furnishings (U.S. EPA, 2020a).

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 and electron beam radiation) (OECD, 2010). Specifically, DINP is used as an industrial adhesive sealant for automotive care products (3M, 2019).

E.1.3.4 Ink, Toner, and Colorant Products

DINP is used in printing ink, one stamp product, and pigments (Identity Group, 2017; Era Polymers Pty Ltd, 2015; Nazdar, 2015; Porelon, 2007). Printing inks consist of colorants (*e.g.,* pigments, dyes, and toners) dispersed in a formulation to form a paste, liquid, or solid, which can be applied to a substrate's surface and dried (OECD, 2010). Industrial printing processes can be categorized as lithographic, flexographic, gravure, letterpress, screen printing, or digital printing. Commercial printing may involve lithographic, flexographic, gravure, and letterpress printing—all of which involve the transfer of images from printing plates to a substrate. Screen printing requires a mesh screen to transfer the ink to a substrate, whereas digital printing allows for the transfer of a digital image directly onto a substrate. Inkjet printing is the most common form of digital printing. It involves the application of small drops of ink onto a substrate with direct contact between the ink nozzle and the substrate (OECD, 2010).

E.1.3.5 Other Uses

Multiple facilities reported DINP as present in: cleaning solvent for lithographic presses (Gans Ink, 2018); laboratory chemicals (Spex Certiprep, 2019; TCI America, 2019); solvents (for cleaning or degreasing) (Green Mountain International, 2008); arts, crafts, and hobby materials (U.S. EPA, 2020a); paper products (Nazdar Company, 2015); cleaning and furniture care products (U.S. EPA, 2020a); foam seating and bedding products (CPSC, 2015b); air care products (Rustic Escentuals, 2015); hydraulic fluid (EPA-HQ-OPPT-2018-0436-0019); and pigment for leak detector products (EPA-HQ-OPPT-2018-0436-0019).

EPA plans to further investigate these uses of DINP during risk evaluation.

E.1.4 Disposal

Each of the conditions of use of DINP may generate waste streams of the chemical that are collected and transported to third-party sites for disposal, treatment, or recycling. Industrial sites that treat or dispose onsite wastes that they themselves generate are assessed in each condition of use assessment. Similarly, point source discharges of DINP to surface water are assessed in each condition of use assessment (point

source discharges are exempt as solid wastes under RCRA). Wastes of DINP that are generated during a condition of use and sent to a third-party site for treatment, disposal, or recycling may include the following:

- Wastewater: DINP may be contained in wastewater discharged to POTW or other, non-public treatment works for treatment. Industrial wastewater containing DINP 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 DINP is included in each of the condition of use assessments.
- Solid wastes: Solid wastes are defined under RCRA as any material that is discarded by being: abandoned; inherently waste-like; a discarded military munition; or recycled in certain ways (certain instances of the generation and legitimate reclamation of secondary materials are exempted as solid wastes under RCRA). DINP is not a listed hazardous waste under RCRA, and as non-hazardous solid waste, it is regulated under the less stringent requirements of Subtitle D of RCRA.
- Wastes exempted as solid wastes under RCRA: Certain conditions of use of DINP may generate wastes of DINP that are exempted as solid wastes under 40 CFR 261.4(a).

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. DINP does not have an OSHA Integrated Management Information System (IMIS) code. As such, OSHA has not collected monitoring data for this chemical.

Table_Apx E-1. Summary of NIOSH HHEs with Monitoring for DINP[a]

Year of Publication	Report Number	Facility Description
1984	HETA 79-034-1440	Plastic/Resin Products Manufacturing – Coating, Laminating, Printing, and Solvent Use
[a] Table includes HHEs identified to date		

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

Life Cycle Stage	Category	Subcategory	Release/Exposure Scenario	Exposure Pathway	Exposure Route	Receptor/Population	Plans to Evaluate	Rationale
Manufacture	Domestic Manufacture	Domestic Manufacture	Manufacture and Packaging	Liquid Contact	Dermal	Workers	Yes	2016 CDR references manufacture in liquid form. Thus, the potential for exposures to workers exists during manufacturing.
				Solid Contact	Dermal	Workers	Yes	2016 CDR references manufacture in unknown forms (information withheld). Thus, the potential for exposures to workers exists during manufacturing if DINP is in solid form.
				Vapor	Inhalation	Workers, ONUs	No	Due to DINP's vapor pressure (VP = 5.4×10^{-7} mm Hg) at room temperature, potential for vapor generation is low.
				Mist	Inhalation/Dermal	Workers, ONUs	No	Mist generation is not expected during manufacturing.
				Dust	Inhalation/Dermal	Workers, ONUs	Yes	2016 CDR references manufacture in unknown forms (information withheld). Thus, the potential for exposures to workers exists during manufacturing if DINP is in solid form.
				Liquid/Solid Contact	Dermal	ONUs	No	Exposure is expected to be primarily restricted to workers who are directly

Life Cycle Stage	Category	Subcategory	Release/Exposure Scenario	Exposure Pathway	Exposure Route	Receptor/Population	Plans to Evaluate	Rationale
								involved in working with the category of chemical substances. ONUs are not expected to come in direct contact with the category of chemical substances.
	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. Thus, the potential for exposures to workers exists during import, but exposure will only occur in the event the imported material is repackaged.
				Vapor	Inhalation	Workers, ONUs	No	Due to DINP's vapor pressure (VP = 5.4×10^{-7} mm Hg) at room temperature, potential for vapor generation is low.
				Mist	Inhalation/ Dermal	Workers, ONUs	No	Mist generation is not expected during repackaging of import containers.
				Dust	Inhalation/ Dermal	Workers, ONUs	Yes	2016 CDR references import in pellet form, which may form dust. Thus, the potential for exposures to workers exists during import, but exposure will only occur

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Life Cycle Stage	Category	Subcategory	Release/Exposure Scenario	Exposure Pathway	Exposure Route	Receptor/Population	Plans to Evaluate	Rationale
								in the event the imported material is repackaged.
				Liquid/Solid Contact	Dermal	ONUs	No	Exposure is expected to be primarily restricted to workers who are directly involved in working with the category of chemical substances. ONUs are not expected to come in direct contact with the category of chemical substances.
Processing	Processing as a Reactant	Adhesives and sealants chemicals (*e.g.,* adhesive manufacturing); Plasticizers (*e.g.,* plastic material and resin manufacturing; plastic product manufacturing; rubber product manufacturing; synthetic rubber manufacturing); processing aids not otherwise listed (*e.g.,* mixed metal stabilizer)	Processing as a reactant	Liquid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during manufacturing of other chemicals, as DINP may be in liquid form.
				Solid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during manufacturing of other chemicals, as DINP may be in solid form.
				Vapor	Inhalation	Workers, ONUs	Yes	Due to DINP's vapor pressure (VP = 5.4×10^{-7} 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, ONUs	No	Mist generation is not expected during processing as a reactant.
				Dust	Inhalation/ Dermal	Workers, ONUs	Yes	The potential for dust exposures to workers and

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Life Cycle Stage	Category	Subcategory	Release/Exposure Scenario	Exposure Pathway	Exposure Route	Receptor/Population	Plans to Evaluate	Rationale
								ONUs exists during manufacturing of other chemicals, as DINP may be in solid form.
				Liquid/Solid Contact	Dermal	ONUs	No	Exposure is expected to be primarily restricted to workers who are directly involved in working with the category of chemical substances. ONUs are not expected to come in direct contact with the category of chemical substances.
	Incorporation into formulation, mixture or reaction product	Adhesives and sealants chemicals (*e.g.,* adhesive and sealant manufacturing; construction; wholesale and retail trade); Intermediates (*e.g.,* adhesive manufacturing; all other chemical products and preparation manufacturing; plastic material and resin manufacturing); Laboratory chemicals; Other (*e.g.,* all other chemical products and preparation manufacturing); Paint additives not described by other categories (*e.g.,* wholesale and retail trade); Plasticizers (*e.g.,* adhesive manufacturing; custom compounding of	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 DINP may be in liquid form.
				Solid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during processing (incorporation into formulation, mixture, or reaction product), as DINP may be in solid form.
				Vapor	Inhalation	Workers, ONUs	Yes	Due to DINP's vapor pressure (VP = 5.4×10^{-7} mm Hg) at room temperature, potential for vapor generation is low. However, some of these operations may occur at elevated temperatures, which increase the potential for vapor generation.

Life Cycle Stage	Category	Subcategory	Release/Exposure Scenario	Exposure Pathway	Exposure Route	Receptor/Population	Plans to Evaluate	Rationale
		purchased resin; paint and coating manufacturing; plastic product manufacturing; plastic material and resin manufacturing; synthetic rubber manufacturing; transportation equipment manufacturing; wholesale and retail trade); Processing aids, not otherwise listed (*e.g.,* all, other basic organic chemical manufacturing; furniture and related product manufacturing); Process regulators (*e.g.,* paint and coating manufacturing); Not known or reasonably ascertainable (*e.g.,* petroleum refineries); Viscosity adjustors (*e.g.,* wholesale and retail trade)		Mist	Inhalation/ Dermal	Workers, ONUs	No	Mist generation is not expected during processing (incorporation into formulation, mixture, or reaction product).
				Dust	Inhalation/ Dermal	Workers, ONUs	Yes	The potential for dust exposures to workers and ONUs exists during processing as DINP may be in solid form.
				Liquid/Solid Contact	Dermal	ONUs	No	Exposure is expected to be primarily restricted to workers who are directly involved in working with the category of chemical substances. ONUs are not expected to come in direct contact with the category of chemical substances.
	Incorporation into articles	Finishing agents (*e.g.,* all other chemical products and preparation manufacturing); Plasticizers (*e.g.,* electrical equipment, appliance, and component manufacturing; miscellaneous manufacturing; paint	Plastics and Rubber product manufacturing (Plastic Converting) Other article manufacturing	Liquid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during incorporation into articles, as DINP may be in liquid form.
				Solid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during processing (incorporation into articles), as DINP may be in solid form, such as for resins.

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Life Cycle Stage	Category	Subcategory	Release/Exposure Scenario	Exposure Pathway	Exposure Route	Receptor/Population	Plans to Evaluate	Rationale
		and coating manufacturing; plastics product manufacturing; plastic material and resin manufacturing; rubber product manufacturing; textile, apparel, and leather manufacturing)		Vapor	Inhalation	Workers, ONUs	Yes	Due to DINP's vapor pressure (VP = 5.4×10^{-7} 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, ONUs	No	Mist generation is not expected during incorporation into article.
				Dust	Inhalation/ Dermal	Workers, ONUs	Yes	The potential for exposures to workers exists during processing (incorporation into articles), as DINP may be in solid form, such as for resins.
				Liquid/Solid Contact	Dermal	ONUs	No	Exposure is expected to be primarily restricted to workers who are directly involved in working with the category of chemical substances. ONUs are not expected to come in direct contact with the category of chemical substances.
	Non-incorporative activities	Adhesive and sealant chemicals (*e.g.,* adhesive manufacturing); Plasticizers (*e.g.,* plastic material and resin manufacturing, wholesale and retail trade)	Processing – non-incorporative activities	Liquid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during manufacturing of other chemicals, as DINP may be in liquid form.
				Solid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during

Life Cycle Stage	Category	Subcategory	Release/Exposure Scenario	Exposure Pathway	Exposure Route	Receptor/Population	Plans to Evaluate	Rationale
								manufacturing of other chemicals, as DINP may be in solid form.
				Vapor	Inhalation	Workers, ONUs	Yes	Due to DINP's vapor pressure (VP = 5.4×10^{-7} 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, ONUs	No	Mist generation is not expected during processing (non-incorporative activities).
				Dust	Inhalation/ Dermal	Workers, ONUs	Yes	The potential for dust exposures to workers and ONUs exists during manufacturing of other chemicals, as DINP may be in solid form.
				Liquid/Solid Contact	Dermal	ONUs	No	Exposure is expected to be primarily restricted to workers who are directly involved in working with the category of chemical substances. ONUs are not expected to come in direct contact with the category of chemical substances.
	Repackaging	Repackaging	Repackaging into large and small containers	Liquid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during repackaging, as DINP may be in liquid form.

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Life Cycle Stage	Category	Subcategory	Release/Exposure Scenario	Exposure Pathway	Exposure Route	Receptor/Population	Plans to Evaluate	Rationale
				Solid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during repackaging, as DINP may be incorporated into products in solid form.
				Vapor	Inhalation	Workers, ONUs	No	Due to DINP's vapor pressure (VP = 5.4×10^{-7} mm Hg) at room temperature, potential for vapor generation is low.
				Mist	Inhalation/ Dermal	Workers, ONUs	No	Mist generation is not expected during repackaging.
				Dust	Inhalation/ Dermal	Workers, ONUs	Yes	The potential for dust exposures to workers and ONUs exists during processing (repackaging), as DINP may be incorporated into products in solid form.
				Liquid/Solid Contact	Dermal	ONUs	No	Exposure is expected to be primarily restricted to workers who are directly involved in working with the category of chemical substances. ONUs are not expected to come in direct contact with the category of chemical substances.
	Recycling	Recycling	Recycling of DINP and products containing DINP	Liquid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during this use as liquid formulations may be recycled.
				Solid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during this use as

Life Cycle Stage	Category	Subcategory	Release/Exposure Scenario	Exposure Pathway	Exposure Route	Receptor/Population	Plans to Evaluate	Rationale
								solid formulations may be recycled.
				Vapor	Inhalation	Workers, ONUs	No	Due to DINP's vapor pressure (VP = 5.4×10^{-7} mm Hg) at room temperature, potential for vapor generation is low.
				Mist	Inhalation/ Dermal	Workers, ONUs	No	Mist generation is not expected during recycling of liquid wastes.
				Dust	Inhalation/ Dermal	Workers, ONUs	Yes	Dust generation is possible during recycling of solid wastes.
				Liquid/Solid Contact	Dermal	ONUs	No	Exposure is expected to be primarily restricted to workers who are directly involved in working with the category of chemical substances. ONUs are not expected to come in direct contact with the category of chemical substances.
Industrial/ Commercial Use	Adhesives and sealants; Paints and coatings; Cleaning and furniture care products; Solvents (for cleaning or degreasing); Air care products	Adhesives and sealants; Paints and coatings; Cleaning and furniture care products; Solvents (for cleaning or degreasing); Air 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 DINP used in these products.
				Solid Contact	Dermal	Workers	No	The potential for exposures to solid DINP is not expected during the use of these products because they are in liquid form.
				Vapor	Inhalation	Workers, ONUs	No	Due to DINP's vapor pressure (VP = 5.4×10^{-7} mm Hg) at room temperature, potential for vapor generation is low.

Life Cycle Stage	Category	Subcategory	Release/Exposure Scenario	Exposure Pathway	Exposure Route	Receptor/Population	Plans to Evaluate	Rationale
				Mist	Inhalation/ Dermal	Workers, ONUs	Yes	Mist generation is possible during application of these products.
				Dust	Inhalation/ Dermal	Workers, ONUs	No	The potential for exposures to solid DINP is not expected during the use of these products because they are in liquid form.
				Liquid/Solid Contact	Dermal	ONUs	No	Exposure is expected to be primarily restricted to workers who are directly involved in working with the category of chemical substances. ONUs are not expected to come in direct contact with the category of chemical substances.
	Automotive care products; Arts, crafts, and hobby materials; Ink, toner, and colorant products; Hydraulic fluid; Pigment for leak detector products	Automotive care products; Arts, crafts, and hobby materials; Ink, toner, and colorant products; Hydraulic fluid; Pigment for leak detector products	Use of automotive care products Use of arts, crafts, and hobby materials Use of ink, toner, and colorant products (*e.g.*, printing) Use of hydraulic fluid Use of pigment for leak detector products	Liquid Contact	Dermal	Workers	Yes	These products are in liquid form; therefore, exposures to workers exists for DINP used in these products.
				Solid Contact	Dermal	Workers	No	The potential for exposures to solid DINP is not expected during the use of these products because they are in liquid form.
				Vapor	Inhalation	Workers, ONUs	No	Due to DINP's vapor pressure (VP = 5.4×10^{-7} mm Hg) at room temperature, potential for vapor generation is low.
				Mist	Inhalation/ Dermal	Workers, ONUs	No	Mist generation is not expected during use of these products.

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Life Cycle Stage	Category	Subcategory	Release/Exposure Scenario	Exposure Pathway	Exposure Route	Receptor/Population	Plans to Evaluate	Rationale
				Dust	Inhalation/ Dermal	Workers, ONUs	No	The potential for exposures to solid DINP does not exist during the use of these products because they are in liquid form.
				Liquid/Solid Contact	Dermal	ONUs	No	Exposure is expected to be primarily restricted to workers who are directly involved in working with the category of chemical substances. ONUs are not expected to come in direct contact with the category of chemical substances.
	Plastic and rubber products not covered elsewhere (including lawn and garden products, automotive care products); Building/construction materials not covered elsewhere; Floor coverings; Fabric, textile and leather products not covered elsewhere; Foam seating and bedding products;	Plastic and rubber products not covered elsewhere (including lawn and garden products, automotive care products); Building/construction materials not covered elsewhere; Floor coverings; Fabric, textile and leather products not covered elsewhere; Foam seating and bedding products; Furniture and furnishings not covered elsewhere; Toys, playground, and sporting equipment; Electrical and electronic products; Paper products; Mold-making for munitions/weapon systems	Use of articles made using DINP	Liquid Contact	Dermal	Workers	No	The potential for exposures to liquid DINP is not expected during the use of these products because they are solid articles.
				Solid Contact	Dermal	Workers	Yes	These products may include solid articles in which DINP is entrained; therefore, DINP exposures to workers is unlikely but may occur if cutting /sawing / other machining operations occur.
				Vapor	Inhalation	Workers, ONUs	No	Due to DINP's vapor pressure (VP = 5.4×10^{-7} mm Hg) at room temperature, potential for vapor generation is low.
				Mist	Inhalation/ Dermal	Workers, ONUs	No	Mist generation is not expected during use of these products.
				Dust	Inhalation/ Dermal	Workers, ONUs	Yes	These products may include solid articles in

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Life Cycle Stage	Category	Subcategory	Release/Exposure Scenario	Exposure Pathway	Exposure Route	Receptor/Population	Plans to Evaluate	Rationale
	Furniture and furnishings not covered elsewhere; Toys, playground, and sporting equipment; Electrical and electronic products; Paper products; Mold-making for munitions/weapon systems							which DINP is entrained; therefore, DINP exposures to workers and ONUs is unlikely but may occur if cutting /sawing / other machining operations occur.
				Liquid/Solid Contact	Dermal	ONUs	No	Exposure is expected to be primarily restricted to workers who are directly involved in working with the category of chemical substances. ONUs are not expected to come in direct contact with the category of chemical substances.
Disposal	Disposal	Disposal of DINP 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, ONUs	No	Due DINP's vapor pressure (VP = 5.4×10^{-7} mm Hg) at room temperature, potential for vapor generation is low.
				Mist	Inhalation/ Dermal	Workers, ONUs	No	Mist generation is not expected during disposal of liquid wastes.
				Dust	Inhalation/ Dermal	Workers, ONUs	Yes	Dust generation is possible during disposal of solid wastes.

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Life Cycle Stage	Category	Subcategory	Release/Exposure Scenario	Exposure Pathway	Exposure Route	Receptor/Population	Plans to Evaluate	Rationale
				Liquid/Solid Contact	Dermal	ONUs	No	Exposure is expected to be primarily restricted to workers who are directly involved in working with the category of chemical substances. ONUs are not expected to come in direct contact with the category of chemical substances.

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Table_Apx G-1. Consumer Exposure Conceptual Model Supporting Table

Life Cycle Stage	Category	Subcategory	Release from Source	Exposure Pathway	Route	Receptor	Plans to Evaluate	Rationale
Consumer Use	Construction, Paint, Electrical, and Metal Products	Building/Construction Materials not Covered Elsewhere (Article)	Direct contact through handling of articles containing chemical	Direct Contact	Dermal	Consumers	Yes	Dermal exposure may occur for this condition of use
			Direct contact through mouthing of articles containing chemical	Mouthing	Oral	Consumers	Yes	Oral exposure may occur for this condition of use
			Long-term emission/mass-transfer, Abrasion, Transfer to Dust	Dust	Dermal, Inhalation, Oral	Consumers, Bystanders	Yes	Dermal, oral, and inhalation exposure from this condition of use may occur
Consumer Use	Construction, Paint, Electrical, and Metal Products	Electrical and Electronic Products (Article)	Direct contact through handling of articles containing chemical	Direct Contact	Dermal	Consumers	Yes	Dermal exposure may occur for this condition of use
			Direct contact through mouthing of articles containing chemical	Mouthing	Oral	Consumers	Yes	Oral exposure may occur for this condition of use
			Long-term emission/mass-transfer, Abrasion, Transfer to Dust	Dust	Dermal, Inhalation, Oral	Consumers, Bystanders	Yes	Dermal, oral, and inhalation exposure from this condition of use may occur
Consumer Use	Furnishing, Cleaning, Treatment/Care Products	Fabric, Textile, and Leather Products not Covered Elsewhere (Article)	Direct contact through handling of articles containing chemical	Direct Contact	Dermal	Consumers	Yes	Dermal exposure may occur for this condition of use
			Direct contact through mouthing of articles containing chemical	Mouthing	Oral	Consumers	Yes	Oral exposure may occur for this condition of use
			Long-term emission/mass-transfer, Abrasion, Transfer to Dust	Dust	Dermal, Inhalation, Oral	Consumers, Bystanders	Yes	Dermal, oral, and inhalation exposure from this condition of use may occur

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Life Cycle Stage	Category	Subcategory	Release from Source	Exposure Pathway	Route	Receptor	Plans to Evaluate	Rationale
Consumer Use	Furnishing, Cleaning, Treatment/Care Products	Floor Coverings (Article)	Direct contact through handling of articles containing chemical	Direct Contact	Dermal	Consumers	Yes	Dermal exposure may occur for this condition of use.
			Direct contact through mouthing of articles containing chemical	Mouthing	Oral	Consumers	Yes	Oral exposure may occur for this condition of use.
			Long-term emission/mass-transfer, Abrasion, Transfer to Dust	Dust	Dermal, Inhalation, Oral	Consumers, Bystanders	Yes	Dermal, oral, and inhalation exposure from this condition of use may occur.
Consumer Use	Furnishing, Cleaning, Treatment/Care Products	Furniture and Furnishings not Covered Elsewhere (Article)	Direct contact through handling of articles containing chemical	Direct Contact	Dermal	Consumers	Yes	Dermal exposure may occur for this condition of use.
			Direct contact through mouthing of articles containing chemical	Mouthing	Oral	Consumers	Yes	Oral exposure may occur for this condition of use.
			Long-term emission/mass-transfer, Abrasion, Transfer to Dust	Dust	Dermal, Inhalation, Oral	Consumers, Bystanders	Yes	Dermal, oral, and inhalation exposure from this condition of use may occur.
Consumer Use	Furnishing, Cleaning, Treatment/Care Products	Foam Seating and Bedding Products (Article)	Direct contact through handling of articles containing chemical	Direct Contact	Dermal	Consumers	Yes	Dermal exposure may occur for this condition of use.
			Direct contact through mouthing of articles containing chemical	Mouthing	Oral	Consumers	Yes	Oral exposure may occur for this condition of use.
			Long-term emission/mass-transfer, Abrasion, Transfer to Dust	Dust	Dermal, Inhalation, Oral	Consumers, Bystanders	Yes	Dermal, oral, and inhalation exposure from this condition of use may occur.
Consumer Use	Packaging, Paper, Plastic, Hobby Products	Paper Products (Article)	Direct contact through handling of articles containing chemical	Direct Contact	Dermal	Consumers	Yes	Dermal exposure may occur for this condition of use.
			Direct contact through mouthing of articles containing chemical	Mouthing	Oral	Consumers	Yes	Oral exposure may occur for this condition of use.

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Life Cycle Stage	Category	Subcategory	Release from Source	Exposure Pathway	Route	Receptor	Plans to Evaluate	Rationale
			Long-term emission/mass-transfer, Abrasion, Transfer to Dust	Dust	Dermal, Inhalation, Oral	Consumers, Bystanders	Yes	Dermal, oral, and inhalation exposure from this condition of use may occur.
Consumer Use	Packaging, Paper, Plastic, Hobby Products	Plastic and Rubber Products not Covered Elsewhere (Article)	Direct contact through handling of articles containing chemical	Direct Contact	Dermal	Consumers	Yes	Dermal exposure may occur for this condition of use.
			Direct contact through mouthing of articles containing chemical	Mouthing	Oral	Consumers	Yes	Oral exposure may occur for this condition of use.
			Long-term emission/mass-transfer, Abrasion, Transfer to Dust	Dust	Dermal, Inhalation, Oral	Consumers, Bystanders	Yes	Dermal, oral, and inhalation exposure from this condition of use may occur.
Consumer Use	Packaging, Paper, Plastic, Hobby Products	Toys, Playground, and Sporting Equipment (Article)	Direct contact through handling of articles containing chemical	Direct Contact	Dermal	Consumers	Yes	Dermal exposure may occur for this condition of use.
			Direct contact through mouthing of articles containing chemical	Mouthing	Oral	Consumers	Yes	Oral exposure may occur for this condition of use.
			Long-term emission/mass-transfer, Abrasion, Transfer to Dust	Dust	Dermal, Inhalation, Oral	Consumers, Bystanders	Yes	Dermal, oral, and inhalation exposure from this condition of use may occur.
Consumer Use	Furnishing, Cleaning, Treatment/Care Products	Air Care Products (Products)	Long-term emission/mass-transfer, Abrasion, Transfer to Dust	Dust	Dermal, Inhalation, Oral	Consumers, Bystanders	Yes	Dermal, oral, and inhalation exposure from this condition of use may occur.
			Direct contact through application or use of products	Liquid Contact	Dermal	Consumers	Yes	Exposure is expected to be primarily restricted to consumer who are directly involved in using the chemical.
			Long-term emission/mass-transfer through application or use of products	Vapor	Inhalation	Consumers, Bystanders	Yes	Inhalation is possible.

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

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Life Cycle Stage	Category	Subcategory	Release from Source	Exposure Pathway	Route	Receptor	Plans to Evaluate	Rationale
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.
			Direct contact through application or use of products	Liquid Contact	Dermal	Consumers	Yes	Exposure is expected to be primarily restricted to consumer who are directly involved in using the chemical.
			Long-term emission/mass-transfer through application or use of products	Vapor	Inhalation	Consumers, Bystanders	Yes	Inhalation is possible.
			Direct contact through application or use of products	Mist	Inhalation and Dermal	Consumers, Bystanders	Yes	If product is applied as a mist, inhalation and dermal exposure would be expected.
Consumer Use	Furnishing, Cleaning, Treatment/Care Products	Cleaning and Furniture Care Products (Product)	Long-term emission/mass-transfer, Abrasion, Transfer to Dust	Dust	Dermal, Inhalation, Oral	Consumers, Bystanders	Yes	Dermal, oral, and inhalation exposure from this condition of use may occur.
			Direct contact through application or use of products	Liquid Contact	Dermal	Consumers	Yes	Exposure is expected to be primarily restricted to consumer who are directly involved in using the chemical.
			Long-term emission/mass-transfer through application or use of products	Vapor	Inhalation	Consumers, Bystanders	Yes	Inhalation is possible.
			Direct contact through application or use of products	Mist	Inhalation and Dermal	Consumers, Bystanders	Yes	If product is applied as a mist, inhalation and dermal exposure would be expected.
Consumer Use	Furnishing, Cleaning,	Foam Seating and Bedding Products (Products)	Direct contact through handling of articles containing chemical	Direct Contact	Dermal	Consumers	Yes	Dermal exposure may occur for this condition of use

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

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Life Cycle Stage	Category	Subcategory	Release from Source	Exposure Pathway	Route	Receptor	Plans to Evaluate	Rationale
			Direct contact through application or use of products	Mist	Inhalation and Dermal	Consumers, Bystanders	Yes	If product is applied as a mist, inhalation and dermal exposure would be expected.
Consumer Handling of Disposal and Waste	Wastewater, Liquid wastes and solid wastes	Wastewater, Liquid wastes and solid wastes	Long-term emission/mass-transfer, Abrasion, Transfer to Dust	Dust	Dermal, Inhalation, Oral	Consumers, Bystanders	Yes	Dust generation is possible during the handling of solid waste.
			Direct contact through handling or disposal of products	Liquid Contact	Dermal	Consumers	Yes	Exposure is expected to be primarily restricted to consumers who are directly involved in handling and disposal of the chemical.
			Long-term emission/mass-transfer through application or use of products	Vapor	Inhalation	Consumers, Bystanders	Yes	Inhalation is possible.
			Direct contact through application or use of products	Mist	Inhalation and Dermal	Consumers, Bystanders	No	Mist generation is not expected during the handling or disposal.

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

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

Life Cycle Stage	Category	Release	Exposure Pathway/ Media	Exposure Routes	Receptor/ Population	Plans to Evaluate	Rationale
All	Emissions to Air	Emissions to Air	Near facility ambient air concentrations	Inhalation	General Population	Yes	DINP deposition to nearby bodies of water and soil are expected exposure pathways.
			Indirect deposition to nearby bodies of water and soil catchments	Oral Dermal	General Population	Yes	
				TBD	Aquatic and Terrestrial Receptors	Yes	
	Wastewater or Liquid Wastes	Industrial pre-treatment and wastewater treatment, or POTW	Direct release into surface water and indirect partitioning to sediment	TBD	Aquatic and Terrestrial Receptors	Yes	Release of DINP into surface water and indirect partitioning to sediment exposure pathways to aquatic and terrestrial receptors will be analyzed.
				Oral Dermal	General Population	Yes	Release of DINP into surface water and indirect partitioning to sediment and bioaccumulation exposure pathways to the general population will be analyzed.
			Drinking Water via Surface or Groundwater	Oral Dermal Inhalation (*e.g.*, showering)	General Population	Yes	Release of DINP into surface water and indirect partitioning to drinking water is an expected exposure pathway.
			Biosolids: application to soil and/or migration to groundwater and/or surface water	Oral (*e.g.*, ingestion of soil) Inhalation	General Population	Yes	EPA plans to analyze the pathway from biosolids to the general population, aquatic and terrestrial species.
				TBD	Aquatic and Terrestrial Receptors	Yes	

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Life Cycle Stage	Category	Release	Exposure Pathway/ Media	Exposure Routes	Receptor/ Population	Plans to Evaluate	Rationale
Disposal	Solid and Liquid Wastes	Municipal landfill and other land disposal	Leachate to soil, groundwater and/or migration to surface water	Oral Dermal	General Population	Yes	EPA plans to analyze the pathway from municipal landfills and other land disposal to the general population, aquatic and terrestrial receptors.
				TBD	Aquatic and Terrestrial Receptors		

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