United States
Environmental Protection Agency

Office of Chemical Safety and
Pollution Prevention

Proposed Designation of Dicyclohexyl Phthalate (CASRN 84-61-7) as a High-Priority Substance for Risk Evaluation

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Acronyms and Abbreviations

Term	Definition
ACGIH	American Conference of Governmental Industrial Hygienists
BAF	Bioaccumulation Factor
BOD	Biochemical Oxygen Demand
CAA	Clean Air Act
CASRN	Chemical Abstracts Service Registry Number
CBI	Confidential Business Information
CDR	Chemical Data Reporting
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
CFR	Code of Federal Regulations
CWA	Clean Water Act
EPCRA	Emergency Planning and Community Right-to-Know Act
GC	Gas Chromatography
IUR	Inventory Update Reporting
K	Thousand
M	Million
MITI	Ministry of International Trade and Industry, Japan
MP	Melting Point
N/A	Not Applicable
NHANES	National Health and Nutrition Examination Survey
NIOSH	National Institute for Occupational Safety and Health
OSHA	Occupational Safety and Health Administration
·OH	Hydroxyl Radical
PEL	Permissible Exposure Limit
PPE	Personal Protective Equipment
PVC	Polyvinyl Chloride
REL	Recommended Exposure Limit
SMILES	Simplified Molecular-Input Line-Entry System
TBD	To be determined

Term	Definition
TLV	Threshold Limit Value
TRI	Toxics Release Inventory
TSCA	Toxic Substances Control Act
VP	Vapor Pressure
WS	Water Solubility

1. Introduction

In section 6(b)(1)(B) of the Toxic Substances Control Act (TSCA), as amended, and in the U.S. Environmental Protection Agency's (EPA) implementing regulations (40 CFR 702.3)[1], a high-priority substance for risk evaluation is defined as a chemical substance that EPA determines, without consideration of costs or other non-risk factors, may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the conditions of use, including an unreasonable risk to potentially exposed or susceptible subpopulations identified as relevant by EPA.

Before designating prioritization status, under EPA's regulations at 40 CFR 702.9 and pursuant to TSCA section 6(b)(1)(A), EPA will generally use reasonably available information to screen the candidate chemical substance under its conditions of use against the following criteria and considerations:

- the hazard and exposure potential of the chemical substance;
- persistence and bioaccumulation;
- potentially exposed or susceptible subpopulations;
- storage near significant sources of drinking water;
- conditions of use or significant changes in the conditions of use of the chemical substance;
- the chemical substance's production volume or significant changes in production volume; and
- other risk-based criteria that EPA determines to be relevant to the designation of the chemical substance's priority.

This document presents the review of the candidate chemical substance against the criteria and considerations set forth in 40 CFR 702.9 for a may present risk finding. The information sources used are relevant to the criteria and considerations and consistent with the scientific standards of TSCA section 26(h), including, as appropriate, sources for hazard and exposure data listed in Appendices A and B of the *TSCA Work Plan Chemicals: Methods Document* (February 2012) (40 CFR 702.9(b)). EPA uses scientific information that is consistent with the best available science. Final designation of the chemical substance as a high-priority chemical substance would immediately initiate the risk evaluation process as described in the EPA's final rule, *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act* (40 CFR 702).

Dicyclohexyl phthalate is one of the 40 chemical substances initiated for prioritization as referenced in the March 21, 2019 notice (84 FR 10491)[2]. EPA has determined that dicyclohexyl phthalate is a suitable candidate for the proposed designation as a high-priority chemical substance. The proposed designation is based on the results of the review against the aforementioned criteria and considerations as well as review of the reasonably available

[1] For all 40 CFR 702 citations, please refer to: https://www.govinfo.gov/content/pkg/CFR-2018-title40-vol33/xml/CFR-2018-title40-vol33-part702.xml and https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0654-0108

[2] https://www.federalregister.gov/documents/2019/03/21/2019-05404/initiation-of-prioritization-under-the-toxic-substances-control-act-tsca

information on dicyclohexyl phthalate, including relevant information received from the public and other information as appropriate.

EPA will take comment on this proposed designation for 90 days before finalizing its designation of dicyclohexyl phthalate. The docket number for providing comments on dicyclohexyl phthalate is EPA-HQ-OPPT-2018-0504 and is available at www.regulations.gov

The information, analysis, and basis for the review of the chemical is organized as follows:

- *Section 1 (Introduction)*: This section explains the requirements of the amended TSCA and implementing regulations - including the criteria and considerations -- pertinent to the prioritization and designation of high-priority chemical substances.

- *Section 2 (Production volume or significant changes in production volume)*: This section presents information and analysis on national aggregate production volume of the chemical substance.

- *Section 3 (Conditions of use or significant changes in conditions of use)*: This section presents information and analysis regarding the chemical substance's conditions of use under TSCA.

- *Section 4 (Potentially exposed or susceptible subpopulations)*: This section presents information and analysis regarding potentially exposed or susceptible subpopulations, including children, women of reproductive age, and workers, with respect to the chemical substance.

- *Section 5 (Persistence and bioaccumulation)*: This section presents information and analysis regarding the physical and chemical properties of the chemical substance and the chemical's fate characteristics.

- *Section 6 (Storage near significant sources of drinking water)*: This section presents information and analysis considered regarding the risk from the storage of the chemical substance near significant sources of drinking water.

- *Section 7 (Hazard potential)*: This section presents the hazard information relevant to the chemical substance.

- *Section 8 (Exposure potential)*: This section presents information and analysis regarding the exposures to the chemical substance.

- *Section 9 (Other risk-based criteria)*: This section presents the extent to which EPA identified other risk-based criteria that are relevant to the designation of the chemical substance's priority.

- *Section 10 (Proposed designation)*: Based on the results of the review performed and the information and analysis presented, this section describes the basis used by EPA to support the proposed designation.

2. Production volume or significant changes in production volume

Approach

EPA considered current volume or significant changes in volume of the chemical substance using information reported by manufacturers (including importers). EPA assembled reported information for years 1986 through 2015 on the production volume for dicyclohexyl phthalate reported under the Inventory Update Reporting (IUR) rule and Chemical Data Reporting (CDR) rule[3].

Results and Discussion

The national aggregate production volume, which is presented as a range to protect individual site production volumes that are confidential business information (CBI), is presented in Table 1.

Table 1. 1986–2015 National Aggregate Production Volume Data (Production Volume in Pounds)

Chemical ID	1986	1990	1994	1998	2002	2006	2011	2012	2013	2014	2015
Dicyclohexyl Phthalate (84-61-7)	>1M to 10M	>1M to 10M	>1M to 10M	>500K to 1M	>500K to 1M	<500K	500K to 1M	500K to 1M	500K to 1M	500K to 1M	500K to 1M

Note: K = thousand; M = million
Reference: U.S. EPA (2013) and U.S. EPA (2017)

Production volume of dicyclohexyl phthalate in 2015, as reported to EPA during the 2016 CDR reporting period, was between 500,000 and 1 million pounds. Production volume of for dicyclohexyl phthalate for reporting years 1986 to 1994 was 1 million to 10 million pounds. The production volume decreased for the following reporting years, in which 500 thousand to 1 million pounds of dicyclohexyl phthalate was manufactured or imported, except for 2006 when less than 500,000 pounds was reported (Table 1).

[3] Over time, the requirements for reporting frequency, production volume thresholds, and chemical substances under the Chemical Data Reporting (CDR) rule have changed. CDR was formerly known as the Inventory Update Rule (IUR). The first IUR collection occurred in 1986 and continued every four years through 2006. As part of two rulemakings in 2003 and 2005, EPA made a variety of changes to the IUR, including to change the reporting frequency to every five years to address burdens associated with new reporting requirements. Additional changes to reporting requirements were made in 2011, including to suspend and replace the 2011 submission period with a 2012 submission period, return to reporting every four years, and require the reporting of all years beginning with 2011 production volumes. The reporting of production volumes for all years was added because of the mounting evidence that many chemical substances, even larger production volume chemical substances, often experience wide fluctuations in production volume from year to year. In addition, also as part of the 2011 IUR Modifications final rule (76 FR 50816, Aug 16, 2011), EPA changed the name of the regulation from IUR to CDR to better reflect the distinction between this data collection (which includes exposure-related data) and the TSCA Inventory itself (which only involves chemical identification information).

3. Conditions of use or significant changes in conditions of use

Approach

EPA assembled information to determine conditions of use or significant changes in conditions of use of the chemical substance. TSCA section 3(4) defines the term "conditions of use" to mean the circumstances, as determined by the EPA Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.

A key source of reasonably available information that EPA considered for determining the conditions of use for dicyclohexyl phthalate was submitted by manufacturers (including importers) under the 2012 and 2016 CDR reporting cycles. CDR requires manufacturers (including importers) to report information on the chemical substances they produce domestically or import into the United States greater than 25,000 pounds per site, except if certain TSCA actions apply (in which case the reporting requirement is greater than 2,500 pounds per site). CDR includes information on the manufacturing, processing, and use of chemical substances. Based on the known manufacturing, processing and uses of this chemical substance, EPA assumes distribution in commerce. CDR may not provide information on other life-cycle phases such as distribution or chemical end-of-life after use in products (i.e., disposal). While EPA may be aware of additional uses, CDR submitters are not required to provide information on chemical uses that are not regulated under TSCA. Based on the publicly available[4] manufacturing information, industrial processing and use information, and consumer and commercial use information reported under CDR, EPA developed a list of conditions of use for the 2016 and 2012 reporting cycles (Tables 2 and 3, respectively).

For chemical substances under review that are included on the Toxics Release Inventory (TRI) chemical list, information disclosed by reporting facilities in Part II Section 3 ("Activities and Uses of the Toxic Chemical at the Facility") of their TRI Form R reports was used to supplement the CDR information on conditions of use. There is not a one-to-one correlation between conditions of use reported under CDR and information reported in Part II Section 3 of the TRI Form R because facilities are not required to disclose in their Form R submissions the specific uses of TRI chemical substances they manufactured on-site or imported. Dicyclohexyl phthalate is not included on the TRI chemical list. For purposes of this proposed prioritization designation, EPA assumed end-of-life pathways that include releases to air and solid waste based on the conditions of use.

[4] Some specific chemical uses may be claimed by CDR submitters as confidential business information (CBI) under section 14 of TSCA. In these cases, EPA indicated that the information is CBI.

Table 2. Dicyclohexyl Phthalate (84-61-7) Categories and Subcategories of Conditions of Use[5] (2016 CDR Reporting Cycle)

Life-Cycle Stage	Category	Subcategory	Reference
Manufacturing	Domestic Manufacturing/Import	CBI[6]	U.S. EPA (2019b)
Manufacturing	Domestic Manufacturing	Domestic Manufacturing	U.S. EPA (2019b)
Processing	Processing as a reactant	Processing aids not otherwise listed in miscellaneous manufacturing	U.S. EPA (2019b)
	Processing as a reactant	Process regulator in: – Paint and coating manufacturing – Plastic material and resin manufacturing – Plastics product manufacturing – Rubber product manufacturing	U.S. EPA (2019b)
	Processing – incorporation into formulation, mixture or reaction product	Filler in rubber product manufacturing	U.S. EPA (2019b)
	Processing – incorporation into formulation, mixture or reaction product	Adhesive and sealant chemical in adhesive manufacturing	U.S. EPA (2019b)
	Processing – incorporation into formulation, mixture or reaction product	Processing aids not otherwise listed in services	U.S. EPA (2019b)
	Processing – incorporation into formulation, mixture or reaction product	Plasticizer in: – Plastics product manufacturing – Printing ink manufacturing	U.S. EPA (2019b)
	Processing – incorporation into article	Plasticizer in plastics product manufacturing	U.S. EPA (2019b)
Distribution in Commerce [a,b]	Distribution in commerce		
Commercial Uses	Plastic and rubber products not covered elsewhere	Plastic and rubber products not covered elsewhere	U.S. EPA (2019b)
Consumer Uses	Plastic and rubber products not covered elsewhere	Plastic and rubber products not covered elsewhere	U.S. EPA (2019b)

[5] Certain other uses that are excluded from TSCA are not captured in this table.
[6] At this time, "CBI" indicates that a data element has been claimed CBI by the information submitter; it does not reflect the result of an EPA substantiation review.

Life-Cycle Stage	Category	Subcategory	Reference
Disposal [a]	Disposal		

[a] CDR includes information on the manufacturing, processing, and use of chemical substances. CDR may not provide information on other life-cycle phases such as distribution or chemical end-of-life after use in products (i.e., disposal). The table row is highlighted in gray to indicate that no information is provided for this life-cycle stage.
[b] EPA is particularly interested in information from the public on distribution in commerce.

Table 3. Dicyclohexyl Phthalate (84-61-7) Categories and Subcategories of Conditions of Use [7] (2012 CDR Reporting Cycle)

Life-Cycle Stage	Category	Subcategory	Reference
Manufacturing	Domestic Manufacturing/Import	CBI[8]	U.S. EPA (2019b)
Manufacturing	Domestic Manufacturing	Domestic Manufacturing	U.S. EPA (2019b)
Processing	Processing as a reactant	Process regulators in: – Plastics material and resin manufacturing – Plastics product manufacturing	U.S. EPA (2019b)
Processing	Processing – incorporating into formulation, mixture or reaction product	Process regulator in: – Adhesive manufacturing	U.S. EPA (2019b)
Processing	Processing – incorporating into formulation, mixture or reaction product	Adhesives and sealant chemical in adhesive manufacturing	U.S. EPA (2019b)
Processing	Processing – incorporating into formulation, mixture or reaction product	Paint additives and coating additives not described by other categories in print ink manufacturing	U.S. EPA (2019b)
Distribution in Commerce [a,b]	Distribution in commerce		
Commercial Uses	Building/construction materials not covered elsewhere	Building/construction materials not covered elsewhere	U.S. EPA (2019b)
Commercial Uses	Adhesives and sealants	Adhesives and sealants	U.S. EPA (2019b)
Disposal [a]	Disposal		

[7] Certain other uses that are excluded from TSCA are not captured in this table.
[8] At this time, "CBI" indicates that a data element has been claimed CBI by the information submitter; it does not reflect the result of an EPA substantiation review.

Life-Cycle Stage	Category	Subcategory	Reference
[a] CDR includes information on the manufacturing, processing, and use of chemicals. CDR may not provide information on other life-cycle phases such as distribution or chemical end-of-life after use in products (i.e., disposal). The table row is highlighted in gray to indicate that no information is provided for this life-cycle stage. **[b] EPA is particularly interested in information from the public on distribution in commerce.**			

CDR Summary and Additional Information on Conditions of Use

Other than two sites that reported unspecified consumer or commercial use of dicyclohexyl phthalate in 2012 and 2016, consumer and commercial uses were not similar between those two years. The 2012 CDR data show one site that used dicyclohexyl phthalate for commercial adhesives and sealants, and one site that used this chemical for commercial building or construction materials. The 2016 CDR data show a single site that used dicyclohexyl phthalate for consumer and commercial plastic and rubber products. CDR data do not show any use of dicyclohexyl phthalate in children's products. Consumer uses were also identified in additional databases, which are included in the Exposure Potential section (Section 8).

Use of dicyclohexyl phthalate in industrial adhesive and printing ink manufacturing is consistent between 2012 CDR and 2016 CDR data. Both the 2012 and 2016 CDR data show use of this chemical at a single site each for industrial manufacture (processing as a reactant) of plastic products and plastic material and resin. The 2016 CDR data, however, showed additional industrial uses in paint and coating, rubber, and miscellaneous manufacturing, as well as services (one site each).

Should the Agency decide to make a final decision to designate this chemical substance as a high-priority substance, further characterization of relevant TSCA conditions of use will be undertaken as part of the process of developing the scope of the risk evaluation.

4. Potentially exposed or susceptible subpopulations

Approach

In this review, EPA considered reasonably available information to identify potentially exposed or susceptible subpopulations, such as children, women of reproductive age, workers, consumers or the elderly. EPA analyzed processing and use information included on the CDR Form U. These data provide an indication about whether children or other susceptible subpopulations may be potentially exposed. EPA also used human health hazard information to identify potentially exposed or susceptible subpopulations.

Results and Discussion

At this stage, EPA identified children, women of reproductive age, consumers and workers as subpopulations who may be potentially exposed or susceptible subpopulations for dicyclohexyl phthalate.

Children

EPA used data reported to the 2012 and 2016 CDR to identify uses in products and articles intended for children over time for dicyclohexyl phthalate. The 2012 and 2016 CDR did not report any use of dicyclohexyl phthalate in children's products. EPA also identified potential developmental hazards that would impact any stage of children's development.

Women of reproductive age (e.g., pregnant women per TSCA statute)
EPA identified studies that observed developmental and reproductive effects following exposure to dicyclohexyl phthalate (Section 7, Table 6). Thus, women of reproductive age were identified as a potentially exposed or susceptible subpopulation with respect to dicyclohexyl phthalate.

Workers
Please refer to the Exposure Potential section (Section 8) for a summary of potential occupational exposures, which EPA indicates that workers are potentially exposed or susceptible subpopulations based on greater exposure.

Consumers
Please refer to the Exposure Potential section (Section 8) for a summary of potential consumer exposures, which EPA indicates that consumers are potentially exposed or susceptible subpopulations based on greater exposure.

5. Persistence and bioaccumulation

Approach
EPA reviewed reasonably available information, such as physical and chemical properties and environmental fate characteristics, to understand dicyclohexyl phthalate's persistence and bioaccumulation.

Physical and Chemical Properties and Environmental Fate Tables

Tables 4 and 5 summarize the physical and chemical properties and the environmental fate characteristics of dicyclohexyl phthalate, respectively.

Table 4. Physical and Chemical Properties of Dicyclohexyl Phthalate

Property or Endpoint	Value[a]	Reference
Molecular Formula	$C_{20}H_{26}O_4$	Haynes (2014)
Molecular Weight	330.418 g/mole	Haynes (2014)
Physical State	Solid	Haynes (2014)
Physical Form	Granular solid, crystalline solid; prisms from alcohol	Haynes (2014); HSDB (2015)
Purity	>99% reported in studies	ECHA (2019)
Melting Point	66 ºC	U.S. EPA (2012); HSDB (2015) citing CRC (2014)
Boiling Point	322.3 ºC (differential scanning calorimetry method ASTM E537-07)[b]	ECHA (2019)
	224 ºC at 4 mm Hg	U.S. EPA (2012)
	225 ºC at 4 mm Hg	Haynes (2014)
	222–228 ºC at 3.75 mm Hg	IPCS (2005)

Property or Endpoint	Value[a]	Reference
Density	1.383 g/cm^3 at 20 ºC	HSDB (2015) citing Haynes (2014)
Vapor Pressure	8.69 × 10^{-7} mm Hg at 25 ºC	U.S. EPA (2012); ECHA (2019) citing Werner (1952)
Vapor Density	TBD	TBD
Water Solubility	4 mg/L at 24 ºC[b]	U.S. EPA (2012) citing Yalkowsky and Dannenfleser (1992)
	1.02 mg/L at 20 ºC and pH 7 (OECD 105)	ECHA (2019)
Log K_{OW}	4.82 at 25 ºC (OECD 117, HPLC method)	ECHA (2019)
Henry's Law Constant	9.4 × 10^{-8} atm-m^3/mole (calculated from measured vapor pressure and water solubility)	U.S. EPA (2012)
Flash Point	TBD	TBD
Auto Flammability	TBD	TBD
Viscosity	TBD	TBD
Refractive Index	1.431 at 20 ºC	HSDB (2015) citing Haynes (2014)
Dielectric Constant	TBD	TBD
Surface Tension	TBD	TBD

Notes: [a]Measured unless otherwise noted; [b]Selected value;
TBD = To be determined, if reasonably available. **EPA is particularly interested in information from the public on these properties or endpoints.**

Table 5. Environmental Fate Characteristics of Dicyclohexyl Phthalate

Property or Endpoint	Value[a]	Reference
Direct Photodegradation	Contains chromophores that absorb at wavelengths >290 nm and, therefore, may be susceptible to direct photolysis by sunlight	HSDB (2015) citing Lyman et al. (1990)
Indirect Photodegradation	$t_{1/2}$ = 0.441 day (based on a 12-hour day with 1.5 × 10^6 ·OH/cm^3 and ·OH rate constant of 2.43 × 10^{-11} cm^3/molecule-second; estimated)[b]	U.S. EPA (2012)
Hydrolysis	Not expected to undergo hydrolysis due to the lack of functional groups that hydrolyze under environmental conditions	HSDB (2015) citing Lyman et al. (1990)
Biodegradation (Aerobic)	Water: 68.5%/4 weeks based on BOD and 91%/4 weeks based on GC (Japanese MITI test at an initial test substance concentration of 100 ppm with sludge at concentrations of 30 ppm)	NITE (2019)
	Sediment: $t_{1/2}$ = 11.1 days calculated in 6 river sediment samples from Taiwan under aerobic conditions	HSDB (2015) citing Yuan et al. (2002)

Property or Endpoint	Value[a]	Reference
Biodegradation (Anaerobic)	Sediment: $t_{1/2}$ = 26.4 days calculated in 6 river sediment samples from Taiwan under anaerobic conditions	HSDB (2015) citing Yuan et al. (2002)
Wastewater Treatment	100% total removal (89% by biodegradation, 11% by sludge adsorption, and 0% by volatilization to air; estimated)[b]	U.S. EPA (2012)
Bioconcentration Factor	1.2–3.2 and 0.5–6.9 (*Cyprinus caprio*); test substance concentrations of 0.4 and 0.04 mg/L, respectively	SYKE (2018)
Bioaccumulation Factor	137 (log BAF = 2.1; estimated)[b]	U.S. EPA (2012)
Soil Organic Carbon:Water Partition Coefficient (Log K_{OC})	4.2 (estimated)[b]	U.S. EPA (2012)

Notes:
[a]Measured unless otherwise noted;
[b]EPI Suite™ physical property inputs: MP = 66 ºC, VP = 8.69 × 10^{-7} mm Hg, WS = 4 mg/L, BioP = 4, BioA = 1 and BioS = 1, SMILES: O=C(OC(CCCC1)C1)c(c(ccc2)C(=O)OC(CCCC3)C3)c2
·OH = hydroxyl radical; MITI = Ministry of International Trade and Industry; BOD = biochemical oxygen demand; BAF = bioaccumulation factor; K_{OC} = organic carbon-water partition coefficient

Results and Discussion

Dicyclohexyl phthalate is a granular solid with a melting point of 66 °C. Based on its vapor pressure (8.69 × 10^{-7} mm Hg) and estimated Henry's Law Constant (9.4 × 10^{-8} atm-m^3/mole), dicyclohexyl phthalate is not expected to volatilize from water or soil. It is expected to be immobile in soil (estimated log K_{OC} 4.2).

It is readily biodegradable based on measured data reporting 68.5 and 91 percent degradation over 28 days by biochemical oxygen demand (BOD) and gas chromatography (GC) using the Japanese Ministry of International Trade and Industry (MITI) test. Aerobic and anaerobic degradation half-lives of 11.1 and 26.4 days were recorded in sediment. Based on these studies, dicyclohexyl phthalate is not expected to persist in the environment.

Dicyclohexyl phthalate in the air will be in the particulate form, which will be removed by wet and dry precipitation. Small amounts will be in the vapor phase, which may directly and indirectly photodegrade (half-life 5.3 hours). Bioconcentration factors of 0.5–6.9 and an estimated bioaccumulation factor of 137 indicate that dicyclohexyl phthalate has a low potential to bioaccumulate.

6. Storage near significant sources of drinking water

Approach

To support the proposed designation, EPA screened each chemical substance under its conditions of use with respect to the seven criteria in TSCA section 6(b)(1)(A) and 40 CFR 702.9. The statute specifically requires the Agency to consider the chemical substance's storage near significant sources of drinking water, which EPA interprets as direction to focus on the chemical substance's potential human health hazard and exposure.

EPA reviewed reasonably available information, specifically looking to identify certain types of existing regulations or protections for the proposed chemical substances. EPA considered the chemical substance's potential human health hazards, including to potentially exposed or susceptible subpopulations, by identifying existing National Primary Drinking Water Regulations under the Safe Drinking Water Act (40 CFR Part 141) and regulations under the Clean Water Act (CWA; 40 CFR 401.15). In addition, EPA considered the consolidated list of chemical substances subject to reporting requirements under the Emergency Planning and Community Right-to-Know Act (EPCRA; Section 302 Extremely Hazardous Substances and Section 313 Toxic Chemicals), the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA; Hazardous Substances), and the Clean Air Act (CAA) Section 112(r) (Regulated Chemicals for Accidental Release Prevention). Regulation by one of these authorities is an indication that the substance is a potential health or environmental hazard which, if released near a significant source of drinking water, could present an unreasonable risk of injury to human health or the environment.

Results and Discussion

Dicyclohexyl phthalate is not currently subject to the federal regulations named in the previous paragraph.

7. Hazard potential

Approach

EPA considered reasonably available information from peer-reviewed assessments and databases to identify potential human health and environmental hazards for dicyclohexyl phthalate (Tables 6 and 7, respectively).

Because there are very few publicly available assessments for dibutyl phthalate with cited environmental hazard data, EPA used the infrastructure of ECOTOXicology knowledgebase (ECOTOX) to identify single chemical toxicity data for aquatic and terrestrial life (U.S. EPA, 2018). It uses a comprehensive chemical-specific literature search of the open literature that is conducted according to the Standard Operating Procedures (SOPs)[9]. The environmental hazard information was populated in ECOTOX and is available to the public. In comparison to the approach used to survey human health hazard data, EPA also used a read-across approach to identify additional environmental hazard data for isomers of dicyclohexyl phthalate, if available, to fill in potential data gaps when there were no reported observed effects for specific taxa

[9] The ECOTOX Standard Operating Procedures (SOPs) can be found at: https://cfpub.epa.gov/ecotox/help.cfm?helptabs=tab4

exposed to dicyclohexyl phthalate. There were no environmental hazard information identified for dicyclohexyl phthalate (Table 7).

Potential Human Health and Environmental Hazard Tables

EPA identified human health hazards based on a review of the reasonable available information on dicyclohexyl phthalate (Table 6). EPA is particularly interested in information from the public on environmental hazards.

Table 6. Potential Human Health Hazards Identified for Dicyclohexyl Phthalate

Human Health Hazards	Tested for Specific Effect	Effect Observed	Reference
Acute Toxicity	X		CPSC (2010), NICNAS (2016)
Repeated Dose Toxicity	X	X	CPSC (2010), NICNAS (2016)
Genetic Toxicity	X	X	CPSC (2010), NICNAS (2016)
Reproductive Toxicity	X	X	CPSC (2010), CPSC (2014), ECHA (2019), NICNAS (2016)
Developmental Toxicity	X	X	CPSC (2010), CPSC (2014), ECHA (2019), NICNAS (2016)
Toxicokinetic	X	X	CPSC (2010), NICNAS (2016)
Irritation/Corrosion	X	X	CPSC (2010), NICNAS (2016)
Dermal Sensitization	X		CPSC (2010), NICNAS (2016)
Respiratory Sensitization	X		CPSC (2010)
Carcinogenicity			CPSC (2010), NICNAS (2016)
Immunotoxicity			CPSC (2010)
Neurotoxicity			CPSC (2010)
Epidemiological Studies or Biomonitoring Studies	X	X	CPSC (2010)

Note: The "X" in the "Effect Observed" column indicates when a hazard effect was reported by one or more of the referenced studies. Blank rows indicate when information was not identified during EPA's review of reasonably available information to support the proposed designation.

Table 7. Potential Environmental Hazards Identified for Dicyclohexyl Phthalate

Media	Study Duration	Taxa Groups	High-Priority Chemical Candidate Dicyclohexyl Phthalate (CASRN 84-61-7)		Isomers of Dicyclohexyl Phthalate (CASRN 84-61-7) NONE		Reference
			Number of Studies	Observed Effects	Number of Studies	Observed Effects	
Aquatic	Acute exposure	Vegetation	–		–		
		Invertebrate	–		–		
		Fish	–		–		
		Non-fish vertebrate (i.e., amphibians, reptiles, mammals)	–		–		
	Chronic exposure	Vegetation	–		–		
		Invertebrate	–		–		
		Fish	–		–		
		Non-fish vertebrate (i.e., amphibians, reptiles, mammals)	–		–		
Terrestrial	Acute exposure	Vegetation	–		–		
		Invertebrate	–		–		
		Vertebrate	–		–		
	Chronic exposure	Vegetation	–		–		
		Invertebrate	–		–		
		Vertebrate	–		–		

The dash indicates that no studies relevant for environmental hazard were identified during the initial review and thus the "Observed Effects" column is left blank. The N/A in the Observed Effects column indicates when a hazard effect was not reported by one of the referenced studies' abstract (full reference review has not been conducted).

8. Exposure potential

Approach

EPA considered reasonably available information to identify potential environmental, worker/occupational, consumer, and general population exposures for dicyclohexyl phthalate.

Release potential for environmental and human health exposure

Dicyclohexyl phthalate is not included on the TRI chemical list. EPA considered conditions of use reported in CDR and the physical and chemical properties to inform the release potential of dicyclohexyl phthalate.

Worker/Occupational and consumer exposure

EPA's approach for assessing exposure potential was to review the physical and chemical properties, conditions of use reported in CDR, and information from the National Institutes of Health Consumer Product Database and the Chemical and Products Database (CPDat) for dicyclohexyl phthalate to inform occupational and consumer exposure potential. The results of this review are detailed in the following tables.

General population exposure

EPA identified human biomonitoring data to inform dicyclohexyl phthalate's exposure potential to the general population (Table 9).

Results and Discussion

Release potential for environmental and human health exposure

When chemical substances are used as a reactant, the industrial releases that are a relatively low percentage of the production volume. Lower percentage releases occur when a high percentage of the chemical reacts without excess loss during its use as an intermediate. The actual percentages, quantities, and media of releases of the reported chemical associated with this processing or use are not known.

When chemical substances are incorporated into formulations, mixtures, or reaction products, the industrial releases that are a relatively low percentage of the production volume. Lower percentage releases occur when a high percentage of the volume is incorporated without significant process losses during its incorporation into a formulation, mixture, or product. The actual percentages, quantities, and media of releases of the reported chemical associated with this processing or use are not known.

When chemical substances have commercial or consumer use as adhesive and sealants, they can have variable release percentages. If the chemical is used as a solvent, it may evaporate to the air during the drying or curing of the adhesive or sealant. Other additives may be entrained in the dried or cured adhesive or sealant but may be released to the environment due to abrasion of the adhesive or sealant. The actual percentage and quantity of release of the reported chemical associated with this category are not known but could be high.

Worker/occupational exposure

Worker exposures to this chemical may be affected by many factors, including but not limited to volume produced, processed, distributed, used, and disposed of; physical form and

concentration; processes of manufacture, processing, and use; chemical properties such as vapor pressure, solubility, and water partition coefficient; local temperature and humidity; and exposure controls such as engineering controls, administrative controls, and the existence of a personal protective equipment (PPE) program.

Dicyclohexyl phthalate does not have an Occupational Safety and Health Administration (OSHA) Permissible Exposure Limit (PEL) (OSHA 2009), a National Institute for Occupational Safety and Health (NIOSH) Recommended Exposure Limit (REL) (NIOSH 2010), or the Threshold Limit Value (TLV) set by American Conference of Governmental Industrial Hygienists (ACGIH).

Dicyclohexyl phthalate has a vapor pressure of 8.69×10^{-7} mm Hg at 25 ºC/77 °F. EPA assumes that inhalation exposure is negligible when vapors are generated from liquids with vapor pressures below 0.001 mm Hg at ambient room temperature conditions. Some handling activities of dicyclohexyl phthalate may generate dust, particularly when handled as a dry powder. Workers may be exposed to aerosolized particles.

Dicyclohexyl phthalate is indicated as being used in adhesives and sealants, and paint additives and coating additives. Products used as adhesive and sealants and paints additives may be applied via spray or roll application methods. These methods may generate mists to which workers may be exposed.

Consumer exposure
CDR reporting does not report any use of dicyclohexyl phthalate in consumer products. However, the National Institutes of Health Household Products Database and the EPA's Chemical and Products Database (CPDat) list uses of dicyclohexyl phthalate in consumer products, such as adhesives, paints, and printing ink (Table 8). Available assessments reviewed also indicate that dicyclohexyl phthalate is found in several additional consumer products, due to its use as a plasticizer, heat sealer for cellulose, and in paper finishes, (CPSC 2010, CPSC 2014).

Table 8. Exposure Information for Consumers

Chemical Identity	Consumer Product Database
	Consumer Uses (List)
Dicyclohexyl Phthalate (84-61-7)	Adhesive, arts crafts products, building material, filler, filler building material, flooring, hardener, insulation, paint, paper, photographic, plastic hardener, printing, printing ink, wall building material

Reference: U.S. EPA (2019a)

General population exposure
EPA anticipates releases of dicyclohexyl phthalate into the environment based on the conditions of use for dicyclohexyl phthalate, particularly activities associated with the chemical's manufacturing and use in a number of products as a plasticizer and as a heat sealer (CPSC 2010). Based on fate properties, such as vapor pressure and water solubility, EPA anticipates possible presence of dicyclohexyl phthalate in water and soil. A review of the available literature suggests

that human biomonitoring data are available; however, no environmental concentration data or ecological biomonitoring data were identified (Table 9).

Releases of dicyclohexyl phthalate from certain conditions of use, such as manufacturing, disposal, or waste treatment activities, may result in general population exposures mainly via dermal contact and inhalation from air releases (CPSC 2010). Dicyclohexyl phthalate is used in polyvinyl chloride (PVC) and other plastics, adhesives, printing inks, paper, etc. (CPSC 2010, TERA 2015). In the United States, the 2001–2002 National Health and Nutrition Examination Survey (NHANES) measured metabolites of dicyclohexyl phthalate in urine at concentrations ranging from below the level of detection (50^{th} percentile) up to 0.400 µg/L creatinine (90^{th} percentile) (CPSC 2010).

Table 9. Exposure Information for the Environment and General Population

Database Name	Env. Concen. Data Present?	Human Biomon. Data Present?	Ecological Biomon. Data Present?	Reference
California Air Resources Board	no	no	no	CARB (2005)
Comparative Toxicogenomics Database	no	yes	no	MDI (2002)
EPA Ambient Monitoring Technology Information Center – Air Toxics Data	no	no	no	U.S. EPA (1990)
EPA Discharge Monitoring Report Data	no	no	no	U.S. EPA (2007)
EPA Unregulated Contaminant Monitoring Rule	no	no	no	U.S. EPA (1996)
FDA Total Diet Study	no	no	no	FDA (1991)
Great Lakes Environmental Database	no	no	no	U.S. EPA (2018b)
Information Platform for Chemical Monitoring Data	no	no	no	EC (2018)
International Council for the Exploration of the Sea	no	no	no	ICES (2018)
OECD Monitoring Database	no	no	no	OECD (2018)
Targeted National Sewage Sludge Survey	no	no	no	U.S. EPA (2006)
The National Health and Nutrition Examination Survey	no	no	no	CDC (2013)
USGS Monitoring Data –National Water Quality Monitoring Council	no	no	no	USGS (1991a)
USGS Monitoring Data –National Water Quality Monitoring Council, Air	no	no	no	USGS (1991b)
USGS Monitoring Data –National Water Quality Monitoring Council, Ground Water	no	no	no	USGS (1991c)
USGS Monitoring Data –National Water Quality Monitoring Council, Sediment	no	no	no	USGS (1991d)

USGS Monitoring Data –National Water Quality Monitoring Council, Soil	no	no	no	USGS (1991e)
USGS Monitoring Data –National Water Quality Monitoring Council, Surface Water	no	no	no	USGS (1991f)
USGS Monitoring Data –National Water Quality Monitoring Council, Tissue	no	no	no	USGS (1991g)

[a] Concen.= concentration
[b] Biomon.= biomonitoring

9. Other risk-based criteria that EPA determines to be relevant to the designation of the chemical substance's priority

EPA did not identify other risk-based criteria relevant to the designation of the chemical substance's priority.

10. Proposed designation and Rationale

Proposed designation: High-priority substance

Rationale: EPA identified and analyzed reasonably available information for exposure and hazard and is proposing to find that dicyclohexyl phthalate may present an unreasonable risk of injury to health and/or the environment, including potentially exposed or susceptible subpopulations, (e.g., workers, consumers, women of reproductive age, consumers, children). This is based on the potential hazard and potential exposure of dicyclohexyl phthalate under the conditions of use described in this document to support the prioritization designation. Specifically, EPA expects that the manufacturing, processing, distribution, use and disposal of dicyclohexyl phthalate may result in presence of the chemical in surface water, and groundwater, ingestion of the chemical in drinking water, inhalation of the chemical from air releases, exposure to workers, exposure to consumers and exposure to the general population, including exposure to children. In addition, EPA expects potential human health hazards (e.g., repeated dose toxicity, genetic toxicity, reproductive toxicity, developmental toxicity, toxicokinetic, and irritation/corrosion). EPA has not identified environmental hazard concerns for aquatic or terrestrial organisms due to exposures to dicyclohexyl phthalate.

11. References

Note: All hyperlinked in-text citations are also listed below

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