United States
Environmental Protection Agency

Office of Chemical Safety and
Pollution Prevention

Proposed Designation of Di-isobutyl Phthalate (DIBP) (CASRN 84-69-5) as High-Priority Substance for Risk Evaluation

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Table of Contents

List of Tables

Acronyms and Abbreviations

Term	Description
ACGIH	American Conference of Governmental Industrial Hygienists
AGD	Anogenital Distance
AGI	Anogenital Index
BAF	Bioaccumulation Factor
BCF	Bioconcentration Factor
CAA	Clean Air Act
CBI	Confidential Business Information
CDR	Chemical Data Reporting
CERCLA	Comprehensive Environmental Response, Compensation and Liability Act
CFR	U.S. Code of Federal Regulations
CHAP	Chronic Hazard Advisory Panel
CPDat	Chemical and Products Database
CPSC	U.S. Consumer Product Safety Commission
CWA	Clean Water Act
DIBP	Di-isobutyl Phthalate
EPCRA	Emergency Planning and Community Right-to-Know Act
IUR	Inventory Update Reporting
K	Thousand
M	Million
MIBP	Monoisobutyl Phthalate
NHANES	National Health and Nutrition Examination Survey
NICNAS	National Industrial Chemicals Notification and Assessment Scheme (Australia)
NIH	National Institutes of Health (NIH)
NIOSH	National Institute for Occupational Safety and Health
OECD	Organisation for Economic Co-operation and Development
OSHA	Occupational Safety and Health Administration
PEL	Permissible Exposure Limit

PPE	Personal Protective Equipment
REL	Recommended Exposure Limit
TBD	To be determined
TLV	Threshold Limit Value
TSCA	Toxic Substances Control Act
TRI	Toxics Release Inventory
WH	Withheld

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).

Di-isobutyl phthalate (DIBP) 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 DIBP is a suitable candidate for the proposed designation as a high-priority 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 information on DIBP, including relevant information received from the public and other information as appropriate.

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[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

EPA will take comment on this proposed designation for 90 days before finalizing its designation of DIBP. The docket number for providing comments on DIBP is EPA-HQ-OPPT-2018-0434 and is available at www.regulations.gov.

The information, analysis and basis used 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 DIBP reported under the Inventory Update Reporting (IUR) rule and Chemical Data Reporting (CDR) rule[3]. 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.

Results and Discussion

National aggregate production volume for DIBP generally declined from 1986 to 2011, after which this information was withheld. From 1986 to 1998, aggregate production volume was between 1 million and 10 million pounds. In 2002 and 2006, aggregate production volume was between 500 thousand and 1 million pounds, and in reporting year 2011, 453,710 pounds of this chemical was manufactured or produced (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
Di-isobutyl Phthalate (84-69-5)	>1M to 10M	>1M to 10M	>1M to 10M	>1M to 10M	>500K to 1M	>500K to 1M	453,710	WH	WH	WH	WH

K = thousand, M = million, WH = withheld[4]
Reference: U.S. EPA (2013) and U.S. EPA (2017)

[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).

[4] This information is withheld, because EPA is releasing the 2016 CDR data in stages. EPA released the initial 2016 CDR data in May 2017. The initial data included national production volume (released in ranges), other manufacturing information, and processing and use information, except for information claimed by the submitter to be confidential business information (CBI) or information that EPA is withholding to protect claims of CBI. EPA anticipates releasing additional data after completion of an effort to obtain CBI substantiation required by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which amended the Toxic Substances Control Act.

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 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 DIBP 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 lbs per site, except if certain TSCA actions apply (in which case the reporting requirement is greater than 2,500 lbs 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.

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. DIBP 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, wastewater, and solid and liquid waste based on the conditions of use.

CDR Tables

Based on the publicly available[5] 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).

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

Table 2. Di-isobutyl phthalate (84-69-5) Categories and Subcategories of Conditions of Use[6] (2016 CDR Reporting Cycle)

Life-Cycle Stage	Category	Subcategory	Reference
Manufacturing	Domestic manufacturing	Domestic manufacturing	U.S. EPA (2019)
Manufacturing	Import	Import	U.S. EPA (2019)
Processing	Incorporating into article	Plasticizers – construction; plastics product manufacturing; transportation equipment manufacturing	U.S. EPA (2019)
Processing	Incorporating into formulation, mixture, or reaction product	Plasticizers – adhesive manufacturing; plastics product manufacturing	U.S. EPA (2019)
Distribution in Commerce [a,b]	Distribution in commerce		
Commercial Uses	Adhesives and sealants	Adhesives and sealants	U.S. EPA (2019)
Commercial Uses	Plastic and rubber products not covered elsewhere	Plastic and rubber products not covered elsewhere	U.S. EPA (2019)
Consumer Uses	Adhesives and sealants	Adhesives and sealants	U.S. EPA (2019)
Disposal [a]	Disposal		

[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.

[6] Certain other uses that are excluded from TSCA are not captured in this table.

Table 3. Di-isobutyl phthalate (84-69-5) Categories and Subcategories of Conditions of Use[7] (2012 CDR Reporting Cycle)

Life-Cycle Stage	Category	Subcategory	Reference
Manufacturing	Domestic manufacturing	Domestic manufacturing	U.S. EPA (2019)
Processing	Incorporating into formulation, mixture, or reaction product	Solvents (which become part of product formulation or mixture) – plastics material and resin manufacturing	U.S. EPA (2019)
Distribution in Commerce [a,b]	Distribution in commerce		
Commercial Uses	Catalyst solvent	Catalyst solvent	U.S. EPA (2019)
Disposal [a]	Disposal		

[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

There was an increase in reporting conditions of use for DIBP from the 2012 to 2016 CDR cycle. In the 2016 CDR data, one site reported use of DIBP in consumer and commercial adhesives and sealants, and another site reported use of this chemical in commercial plastic and rubber products, neither of which was reported in 2012. In the 2012 CDR data, only one site reported a commercial use of DIBP as a catalyst solvent. One site reported a single industrial use of DIBP in the 2012 CDR cycle for plastic material and resin manufacturing. A single site reported the same use in 2016, albeit for the functional category of plasticizers instead of solvents. Use of DIBP for industrial adhesive and transportation equipment manufacturing and construction was also reported in 2016. In the 2016 CDR data, two facilities reported that DIBP was not recycled (e.g., remanufactured, reprocessed, or reused). In the 2012 CDR data, one facility reported that DIBP was not recycled. Consumer uses were also identified in additional databases, which are included in the Exposure Potential section (Section 8).

One public commenter (EPA-HQ-OPPT-2018-0434-0004) asserted that DIBP is present as an additive and impurity in adhesives in amounts less than 0.1 percent. Another commenter (EPA-HQ-OPPT-2018-0434-0005) mentioned that DIBP is often a by-product or intermediate in the production of phthalate-containing plastics.

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.

[7] Certain other uses that are excluded from TSCA are not captured in this table.

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 may be potentially exposed or other susceptible subpopulations may be 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 DIBP.

Children

EPA used data reported to the 2012 and 2016 CDR to identify uses in products and articles intended for children over time for DIBP. The 2012 and 2016 CDR did not report any use of DIBP 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 DIBP (Section 7, Table 6). Thus, women of reproductive age were identified as a potentially exposed or susceptible subpopulation.

Consideration of women of reproductive age as a potentially exposed or susceptible subpopulation was also based on exposure because women of reproductive age are potential workers in the manufacturing, processing, distribution in commerce, use, or disposal of the chemical substance.

Workers

Please refer to the Exposure Potential section (Section 8) for 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 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 DIBP'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 DIBP, respectively.

Table 4. Physical and Chemical Properties of Di-isobutyl Phthalate

Property or Endpoint	Value[a]	Reference
Molecular Formula	$C_{16}H_{22}O_4$	CRC Handbook (Haynes, 2014)
Molecular Weight	278.344 g/mole	CRC Handbook (Haynes, 2014)
Physical State	Liquid	CRC Handbook (Haynes, 2014)
Physical Form	Liquid	HSDB (2013) citing Lewis (2007)
Purity	>99%; impurities include water	HSDB (2013) citing CPSC (2011)
Melting Point	−64 ºC	Physprop (2012)
Boiling Point	296.5 ºC	Physprop (2012); HSDB (2013) citing CRC Handbook (Haynes, 2014)
Density	1.049 g/cm^3	HSDB (2013) citing Haynes (2010); CRC Handbook (Haynes, 2014)
Vapor Pressure	4.76×10^{-5} at 25 ºC	HSDB (2013) citing Daubert and Danner (1989)
Vapor Density	TBD	TBD
Water Solubility	6.2 mg/L at 24 ºC[b]	PhysProp (2012); HSDB (2013) citing Yalkowsky et al. (2010)
	11.5 mg/L at −25 ºC	ECHA (2019)
Log K_{OW}	4.11	HSDB (2013) citing Hansch et al. (1995)
Henry's Law Constant	2.8×10^{-6} atm-m^3/mole (calculated from measured vapor pressure and water solubility)	EPI Suite (2012)
Flash Point	185 ºC (open cup)	HSDB (2013) citing NFPA (2010)

Property or Endpoint	Value[a]	Reference
Auto Flammability	432 ºC (autoignition temperature)	HSDB (2013) citing NFPA (2010)
Viscosity	41 mPa · second at 20 ºC	HSDB (2013) citing Gerhartz (1985)
Refractive Index	1.49 at 25 ºC	HSDB (2013) citing Lewis (2007)
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 Di-isobutyl Phthalate

Property or Endpoint	Value[a]	Reference
Direct Photodegradation	May be susceptible due to potential absorption	HSDB (2013)
Indirect Photodegradation	$t_{1/2}$ = 1.2 days (12-hour day at 1.5 × 10^6 OH/cm^3) based on OH rate constant of 9.3 × 10^{-12} cm^3/molecule-second at 25 ºC; estimated)[b]	EPI Suite (2012)
Hydrolysis	$t_{1/2}$ = 5,730 days (at pH = 8, based on a rate constant of 0.0014 M^{-1} $second^{-1}$)	Wolfe et al. (1980)
Biodegradation (Aerobic)	98%/4 weeks (OECD 302C)	HSDB (2013) citing Sedykh and Klopman (2007)
	100%/6 days (die-away tests)	HSDB (2013) citing Hattori et al. (1975)
	40%/28 days OECD 301B (CO_2 evolution)	ECHA (2019)
Biodegradation (Anaerobic)	0–30%/96 days (sewage sludge and swamp water) 0–30%/56 days (marine sediment)	HSDB (2013) citing Madsen et al. (1995)
Wastewater Treatment	99.5% total removal (92% by biodegradation, 7.5% by sludge adsorption, and 0% by volatilization to air; estimated)[b]	EPI Suite (2012)

Property or Endpoint	Value[a]	Reference
Bioconcentration Factor	240 (log BCF = 2.4; estimated)[b]	EPI Suite (2012)
Bioaccumulation Factor	26 (log BAF = 1.4; estimated)[b]	EPI Suite (2012)
Soil Organic Carbon:Water Partition Coefficient (Log K_{OC})	3.14	HSDB (2013) citing Sabljic et al. (1995)

Notes:
[a]Measured unless otherwise noted
[b]EPI Suite™ physical property inputs: Log K_{OW} = 4.11, BP = 296.5 ºC, MP = -64 ºC, VP = 4.76 × 10^{-5} mm Hg, WS = 6.2 mg/L, BioP = 4, BioA = 1, Bio S = 1 SMILES O=C(OCC(C)C)c(c(ccc1)C(=O)OCC(C)C)c1
Bioconcentration factor = BCF; Bioaccumulation factor = BAF

Results and Discussion
DIBP is a volatile liquid. Based on its vapor pressure (4.76 × 10^{-5} mm Hg) and calculated Henry's Law constant (2.8 × 10^{-6} atm-m^3/mole), DIBP is expected to volatilize from water and moist soil surfaces, but not dry soils. It is expected to have low mobility in soil (log K_{OC} 3.14).

DIBP is expected to biodegrade based on studies that demonstrated 98% degradation of DIBP in 4 weeks (OECD 302C) and 100% degradation in 6 days (die-away test). DIBP in the air will be in the particulate and vapor phases and is expected to react with hydroxyl radicals at a rate that corresponds to a half-life of 1.2 days. Additionally, respective estimated BCF and BAF values of 240 and 26, and a measured log K_{OW} of 4.11 indicate that DIBP has 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

As a phthalate ester, DIBP is designated as a toxic pollutant under 40 CFR 401.15, and as such, is subject to effluent limitations. Specifically, DIBP is categorized as an "aromatic organic chemical," as applicable to the process wastewater discharges resulting from the manufacture of bulk organic chemicals (40 CFR 414.70). Additionally, several states have adopted water pollution discharge programs which categorize DIBP as an "aromatic organic chemical," as applicable to the process wastewater discharges resulting from the manufacture of bulk organic chemicals, including Illinois (35 Ill. Adm. Code 307-2406) and Wisconsin (Wis. Adm. Code § NR 235.60).

7. Hazard potential

Approach

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

Because there are very few publicly available assessments for DIBP 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, 2018a). It uses a comprehensive chemical-specific literature search of the open literature that is conducted according to the Standard Operating Procedures (SOPs)[8]. 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 DIBP, if available, to fill in potential data gaps when there were no reported observed effects for specific taxa exposed to the DIBP (Table 7).

Potential Human Health and Environmental Hazard Tables

EPA identified human health and environmental hazards based on a review of the reasonable available information on DIBP (Tables 6 and 7, respectively).

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

Table 6. Potential Human Health Hazards Identified for Di-isobutyl Phthalate

Human Health Hazards	Tested for Specific Effect	Effect Observed	Reference
Acute Toxicity	X		NICNAS (2008a); NICNAS (2016); CPSC (2011); NICNAS (2008b)
Repeated Dose Toxicity	X	X	NICNAS (2008a); NICNAS (2016); CPSC (2011); NICNAS (2008b)
Genetic Toxicity	X		NICNAS (2008a); NICNAS (2016); NICNAS (2008b)
Reproductive Toxicity	X	X	NICNAS (2008a); NICNAS (2016); CPSC (2011); CPSC (2014); NICNAS (2008b)
Developmental Toxicity	X	X	NICNAS (2008a); NICNAS (2016); CPSC (2011); CPSC (2014); NICNAS (2008b)
Toxicokinetic	X		NICNAS (2008a); CPSC (2011); CPSC (2014)
Irritation/Corrosion	X		NICNAS (2008a); NICNAS (2016); CPSC (2011); NICNAS (2008b)
Dermal Sensitization	X		NICNAS (2008a); NICNAS (2016); CPSC (2011); NICNAS (2008b)
Respiratory Sensitization	X		CPSC (2011)
Carcinogenicity	X		NICNAS (2008a); NICNAS (2016); CPSC (2011); NICNAS (2008b)
Immunotoxicity			
Neurotoxicity	X		CPSC (2011); CPSC (2014)
Epidemiological Studies or Biomonitoring Studies	X		CPSC (2014)

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 Di-isobutyl Phthalate

Media	Study Duration	Taxa Groups	High-Priority Chemical Candidate Di-isobutyl Phthalate (1,2-Benzene- dicarboxylic acid, 1,2- bis-(2methylpropyl) ester) (DIBP) (CASRN 84-69-5)		Isomers of Di-isobutyl Phthalate (1,2-Benzene- dicarboxylic acid, 1,2- bis-(2methylpropyl) ester) (DIBP) (CASRN 84-69-5) NONE		Reference
			Number of Studies	Observed Effects	Number of Studies	Observed Effects	
Aquatic	Acute exposure	Vegetation	–		–		
		Invertebrate	1	X	–		Linden et al., 1979
		Fish	1	X	–		Geiger et al., 1985
		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	2	X	–		Boyd et al. (2016); Lenoir et al. (2014)
		Vertebrate	–		–		
	Chronic exposure	Vegetation	–		–		
		Invertebrate	–		–		
		Vertebrate	2	X	–		Hardin et al. (1987); Oishi and Hiraga (1980)

The dash indicates that no studies relevant for environmental hazard were identified during this initial screening and thus the "Observed Effects" column is left blank. The X in the Observed Effects column indicates when a hazard effect was reported by one or more of the referenced studies. 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 screen potential environmental, worker/occupational, consumer, and general population exposures for DIBP.

Release potential for environmental and human health exposure
DIBP 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 DIBP.

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 DIBP to inform occupational and consumer exposure potential. The results of this review are detailed in the following tables.

General population exposure
EPA identified environmental concentration data to inform DIBP's exposure potential to the general population (Table 9).

Results and Discussion

Release potential for environmental and human health exposure
DIBP is not included on the TRI chemical list.

When chemical substances are incorporated into formulations, mixtures, or reaction products, the industrial releases may be 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.

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.

DIBP does not have an Occupational Safety and Health Administration (OSHA) Permissible Exposure Limit (PEL) (OSHA 2019), a National Institute for Occupational Safety and Health (NIOSH) Recommended Exposure Limit (REL) (NIOSH 2018), or the Threshold Limit Value (TLV) set by American Conference of Governmental Industrial Hygienists (ACGIH).

DIBP has a vapor pressure of 4.76×10^{-5} 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.

DIBP is indicated as being used in adhesives and sealants. Products used as adhesive and sealants may be applied via spray or roll application methods. These methods may generate mists to which workers may be exposed.

Consumer exposure
CDR reporting and information from the National Institutes of Health Household Products Database do not report any use of DIBP in consumer products. However, the EPA Chemical and Products Database (CPDat) as well as available assessments indicate that DIBP has been used in consumer products such as adhesives, building materials, cleaners, paints, lubricants and building materials (CPSC 2015) (Table 8). Internal consumer exposure has been estimated to account for 0.1 to 8 µg/kg bodyweight per day for infants and 0.05 to 2 µg/kg bodyweight per day in adults (CPSC 2011).

Table 8. Exposure Information for Consumers

Chemical Identity	Consumer Product Database
	Consumer Uses (List)
Di-isobutyl Phthalate (84-69-5)	Adhesive, automotive, automotive care, building material, catalyst, cleaner, colorant, filler, filler building material, flooring, footwear, fragrance, hardener, metal surface treatment, paint, paint binding, paint hardener, paper, photographic, plastic, plastic hardener, rubber, seal material, solvent, stain remover, toys, viscous liquid building material, wall building material

Reference: CPDat

General population exposure
A review of the available literature suggests that environmental concentration data are available (Table 9). Releases of DIBP from certain conditions of use, such as manufacturing, disposal, or waste treatment activities, may result in general population exposures via drinking water ingestion, dermal contact, and inhalation from air releases (CPSC 2011).

Available assessments reviewed indicate that diet has been reported the primary source of exposure to DIBP with indoor air also contributing to total DIBP exposure (CPSC 2014). In the United States, urinary DIBP levels have increased over the past four National Health and Nutrition Examination Survey (NHANES) surveys (2001–2002; 2003–2004; 2005–2006; 2007–2008) in all age groups, genders, and races, and in total (CPSC 2014).

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.

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	yes	no	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

10. Proposed designation and Rationale

Proposed designation: High-priority substance

Rationale: EPA identified and analyzed reasonably available information and concluded that DIBP 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 DIBP 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 DIBP may result in presence of the chemical in surface water, 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 environmental (e.g., aquatic toxicity, terrestrial toxicity), and human health hazards (e.g., repeated dose toxicity, reproductive toxicity, developmental toxicity).

11. References

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

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