Supporting Information for Low-Priority Substance Decanedioic Acid, 1,10-Dibutyl Ester (CASRN 109-43-3) (Dibutyl Sebacate) *Final Designation*

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1. Introduction

The Lautenberg amendments to the Toxic Substances Control Act (TSCA) require EPA to designate chemical substances as either High-Priority Substances for risk evaluation, or Low-Priority Substances for which risk evaluations are not warranted at this time (section 6(b)(1)(B) and implementing regulations (40 CFR 702.3)). A high-priority substance is defined as a chemical substance that the Administrator concludes, 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 the Administrator. If the Administrator concludes, based on information sufficient to establish, without consideration of costs or other non-risk factors, that the high-priority standard is not met, then the substance must be designated as a low-priority substance. Decanedioic acid, 1,10-dibutyl ester, referenced as dibutyl sebacate for the remainder of this document, is one of the 40 chemical substances initiated for prioritization as referenced in a March 21, 2019 notice (84 FR 10491)[1] and one of the 20 proposed as low-priority substances in an August 15, 2019 notice (84 FR 41712).[2]

As described under EPA's regulations at 40 CFR 702.9[3] and pursuant to section 6(b)(1)(A) of the statute, EPA generally used reasonably available information to screen the 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.

Designation of a low-priority substance is not a finding that the chemical substance does not present an unreasonable risk, but rather that the chemical does not meet the statutory criteria for a high-priority substance and that a risk evaluation is not warranted at the time. As explained in the preamble to the Prioritization Rule, "low-priority substance designations give the public notice of chemical substances for which the hazard and/or exposure potential is anticipated to be low or nonexistent and provides some insight into which chemical substances are likely not to need additional evaluation and risk management under TSCA." 82 FR 33753 at 33755. EPA is not precluded from later revising the designation based on reasonably available information, if warranted. 40 CFR 702.13; 702.15.

The screening review is not a risk evaluation, but rather a review of reasonably available information on the chemical substance that relates to the specific criteria and considerations in TSCA section 6(b)(1)(A)

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

[2] https://www.federalregister.gov/documents/2019/08/15/2019-17558/proposed-low-priority-substance-designation-under-the-toxic-substances-control-act-tsca-notice-of

[3] The prioritization process is explained in the *Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act* (82 FR 33753).

and 40 CFR 702.9. This paper documents the results of the screening review which supports the final designation of dibutyl sebacate as a low-priority substance. EPA has also prepared a general response to comments and, as applicable, chemical-specific responses to comments.

This screening-level review is organized as follows:

- *Section 1 (Introduction):* This section explains the requirements of the Lautenberg amendments to the Toxic Substances Control Act (TSCA) and implementing regulations – including the criteria and considerations -- pertinent to prioritization and designation of low-priority substances.

- *Section 2 (Background on the Low Priority Substance):* This section includes information on attributes of the chemical substance, including its structure, and relates them to its functionality.

- *Section 3 (Physical Chemical Properties):* This section includes a description of the physical-chemical properties of the chemical substance and explains how these properties lead to the chemical's fate, transport, and exposure potential.

- *Section 4 (Relevant Assessment History):* This section includes an overview of the outcomes of other governing entities' assessments of the chemical substance.

- *Section 5 (Conditions of Use):* This section presents the chemical substance's known, intended, and reasonably foreseen conditions of use under TSCA.

- *Section 6 (Hazard Characterization):* This section summarizes the reasonably available hazard information and screens the information against low-concern benchmarks.

- *Section 7 (Exposure Characterization):* This section includes a qualitative summary of potential exposures to the chemical substance.

- *Section 8 (Summary of Findings):* In this section, EPA presents information pertinent to prioritization against each of the seven statutory and regulatory criteria and considerations, and makes a conclusion based on that evidence.

- *Section 9 (Final Designation):* In this section, EPA presents the final designation for this chemical substance.

- *Appendix A (Conditions of Use Characterization):* This appendix contains a comprehensive list of TSCA and non-TSCA uses for the chemical substance from publicly available databases.

- *Appendix B (Hazard Characterization):* This appendix contains information on each of the studies used to support the hazard evaluation of the chemical substance.

- *Appendix C (Literature Search Outcomes):* This appendix includes literature search outcomes and rationales for studies that were identified in initial literature screening but were found to be off-topic or unacceptable for use in the screening-level review.

2. Background on Dibutyl Sebacate

Table 1 below provides the CAS number, synonyms, and other information on dibutyl sebacate.

Table 1: Dibutyl Sebacate at a Glance	
Chemical Name	Dibutyl Sebacate
CASRN	109-43-3
Synonyms	Dibutyl decanedioate; Butyl sebacate; Di-n-butyl sebacate, Decanedioic acid dibutyl ester, Bis(n-butyl) sebacate, Di-n-butylsebacate, Sebacic acid dibutyl ester, Bis(n-butyl)sebacate; Decanedioic acid, 1,10-dibutyl ester
Trade Name(s)	Polycizer DBS, Kodaflex DBS, Staflex DBS, Monoplex DBS
Molecular Formula	$C_{18}H_{34}O_4$
Representative Structure	

Dibutyl sebacate is an ester of sebacic acid - a saturated, straight-10-carbon-chain, naturally occurring dicarboxylic acid that is derived from castor oil. An ester is an organic chemical compound derived from an acid in which a hydroxyl (-OH) group is replaced by an alkoxy (-OR) group through the process of esterification. Shorter chain aliphatic diesters, such as dibutyl sebacate, function as plasticizers to give improved flexibility and resistance to cracking at low temperatures. A plasticizer is a substance that is added to a material to alter its physical properties, mainly to increase flexibility or decrease viscosity. These aliphatic diesters are also versatile solvents in that they are able to dissolve a wide range of organic compounds. Section 5 includes conditions of use for this chemical.

3. Physical-Chemical Properties

Table 2 lists physical-chemical properties for dibutyl sebacate. A chemical's physical-chemical properties provide a basis for understanding a chemical's behavior, including in the environment and in living organisms. These endpoints provide information generally needed to assess potential environmental release, exposure, and partitioning as well as insight into the potential for adverse toxicological effects.

Table 2: Physical-Chemical Properties for Dibutyl Sebacate

Source/Model	Data Type	Endpoint	Endpoint Value	Notes
Sigma Aldrich 2019	Experimental	Physical state at room temp	Liquid	
ATSDR 1995	Experimental	Molecular Weight	315 g/mol	
HSDB 2019	Experimental	Molecular Weight	314 g/mol	
EPISuite v.4.11[4]	Calculated	Molecular Weight	314 g/mol	
Reported to the ECHA database 2018	Experimental	Molar Volume	436 cm^3/mol	
HSDB 2019	Experimental	Melting Point	-10°C	
HSDB 2019	Experimental	Boiling Point	344.5°C	
HSDB 2019	Experimental	Water Solubility	40 mg/L at 20°C	
Reported to the ECHA database 2018	Experimental	Water Solubility	<0.05 mg/L at 20°C and pH 6.4	Column elution
EPISuite v.4.11	Estimated	Water Solubility	0.14 mg/L	K_{ow} method
HSDB 2018	Experimental	Water Solubility	$1.27x10^{-4}$ mol/L	
Reported to the ECHA database 2018	Experimental	Water Solubility	$1.59x10^{-7}$ mol/L	
EPISuite v.4.11	Estimated	Log K_{ow}	6.3	
EPISuite v.4.11	Estimated	Log K_{oa}	12	
EPISuite v.4.11	Estimated	Log K_{oc}	3.59 (MCI); 4.28 (K_{ow})	
ATSDR	Experimental	Vapor Pressure	3 mm Hg at 180°C	
HSDB 2019; Reported to the ECHA database 2018	Experimental	Vapor Pressure	$4.69x10^{-6}$ mm Hg at 25°C	ECHA source converted from $6.25x10^{-4}$ Pa

[4] EPI Suite Physical Property Inputs – Boiling Point = 344.5 deg C, Melting Point = -10 deg C, Vapor Pressure = 4.69E-06 mm Hg, Water Solubility = 40 mg/L, SMILES: O=C(OCCCC)CCCCCCCCC(=O)OCCCC

Table 2: Physical-Chemical Properties for Dibutyl Sebacate				
Source/Model	**Data Type**	**Endpoint**	**Endpoint Value**	**Notes**
EPISuite v.4.11	Estimated	Vapor Pressure	$1.78x10^{-4}$ mm Hg	
EPISuite v.4.11	Estimated	Henry's Law	$4.85x10^{-8}$ atm-m^3/mol	
EPISuite v.4.11	Estimated	Volatilization	892 days (river) 9740 days (lake)	
EPISuite v.4.11	Estimated	Photolysis (Indirect)	7.0 hours ($T_{1/2}$)	• OH rate constant 1.83E-11 cm^3/molecules-second (12 hour day; 1.5E6 OH/cm^3) • No ozone reaction estimation
EPISuite v.4.11	Estimated	Hydrolysis	4.5 years at pH 7 166 days at pH 8	Aqueous Base/Acid-Catalyzed Hydrolysis (25 deg C)
EPISuite v.4.11	Estimated	Biodegradation	Ready prediction: Yes	
EPISuite v.4.11	Estimated	Wastewater treatment plant removal	99.74% total removal (91.12% biodegradation, 8.62% sludge, 0% air)	Input parameters, based on analog dibutyl adipate: BIOP = 4, BioA = 1 and BioS = 1 based on 96% degradation after 28 d by CO2 analysis in an OECD 301E test; 86-95% degradation after 14 d by BOD analysis in a MITI 301C test; and 60% degradation after 28 d by BOD analysis in an OECD 301D test
EPISuite v.4.11	Estimated	Wastewater treatment plant removal	99.97% total removal (89.27% biodegradation, 10.71% sludge, 0% air)	Input parameters, based on analog diisopropyl sebacate: BIOP = 4, BioA = 1 and BioS = 1 based on 89.6% degradation after 28 d, with the 10 d window criterion satisfied, by CO2 analysis in an OECD 301B test
EPISuite v.4.11	Estimated	BAF	29	
EPISuite v.4.11	Estimated	BCF	281	From regression-based method

EPA's Sustainable Futures/P2 Framework Manual[5] was used to interpret the physical-chemical properties provided in Table 2. Based on its reported physical form and measured melting point (ATSDR, 1995), dibutyl sebacate is a liquid under ambient conditions. Liquids have the potential for exposure via direct dermal contact with the substance, ingestion, or by inhalation of aerosols if they are generated. Based on its measured vapor pressure (Reported to the ECHA database, 2018), dibutyl sebacate in its pure form is expected to have some volatility at ambient temperatures; however, if inhaled, absorption from the lungs is expected to be minimal based on its water solubility. Though dibutyl sebacate has limited solubility in water (Reported to the ECHA database, 2018), if it is present in aqueous products (e.g.., cleaning products), it is not expected to volatilize from water and aqueous solutions based on its estimated Henry's Law constant (EPI Suite, 2019). If orally ingested, limited absorption through the gastrointestinal tract is expected based on its low water solubility. Further, the ester functional groups are expected to undergo rapid metabolic transformation, which significantly decreases the potential for bioconcentration or bioaccumulation. Based on its estimated log K_{oc} (EPI Suite, 2019), dibutyl sebacate is expected to adsorb onto soil and sediment rather than be transported through soil to surface or ground water sources of drinking water. Estimated data indicate dibutyl sebacate is readily biodegradable in aerobic and anaerobic environments (discussed further in Section 6.3.1), meaning that it has the potential to break down in the environment into carbon dioxide and water.

3.1 References

ATSDR Toxicological Profile for Otto Fuel II and its Components, U.S. Dept. of Health and Human Services, 1995

European Chemicals Agency (ECHA). (2019). Dibutyl sebacate. Retrieved from https://echa.europa.eu/registration-dossier/-/registered-dossier/16127

Hazardous Substance Database (HSDB). (2006). Dibutyl Sebacate. Retrieved from. https://toxnet.nlm.nih.gov

Sigma Aldrich (2019). Dibutyl sebacate. Retrieved from https://www.sigmaaldrich.com/catalog/product/aldrich/84840?lang=en&region=US

U.S. EPA. (2019). Estimation Programs Interface Suite, v 4.11. United States Environmental Protection Agency, Washington, DC, USA

[5] https://www.epa.gov/sites/production/files/2015-05/documents/05.pdf

4. Relevant Assessment History

EPA assessed the toxicological profile of dibutyl sebacate and added the chemical to the Safer Choice Program's Safer Chemical Ingredients List (SCIL) in March 2017 under the functional classes of solvent, emollient, and skin conditioning agent. The SCIL[6] is a continuously updated list of chemicals that meet low-concern Safer Choice criteria.[7]

EPA also reviewed international assessments of dibutyl sebacate. EPA identified assessments by New Zealand's, Canada's and Germany's government agencies.

The Canadian Government, through an assessment of toxicity and exposure as part of its categorization of the Domestic Substance List, found that dibutyl sebacate did not meet its criteria for further attention.[8]

The German Environment Agency (UBA) designated dibutyl sebacate as "low hazard to waters" in August 2017 based on an assessment of ecotoxicity and environmental fate.[9]

New Zealand's Environmental Protection Authority (NZEPA) lists dibutyl sebacate in its Chemical Classification and Information Database (CCID), which includes hazard and physical information about single chemicals for use in hazard classifications and safety information. It has a classification description of "suspected human reproductive or developmental toxicants"; "harmful to human target organs or systems."[10] This description was used because, at the time of their determination in 2006 which was done by NZEPA's predecessor organization, the Environmental Risk Management Authority,[11] dibutyl sebacate was classified based on limited information indicating some potential for reproductive/developmental toxicity and target organ/systemic toxicity. U.S. EPA has identified a sufficient data set for dibutyl sebacate or closely-related analogs to make a low-concern determination for the areas of potential concern identified by New Zealand, as described in the remainder of this screening review.

[6] https://www.epa.gov/saferchoice/safer-ingredients

[7] https://www.epa.gov/sites/production/files/2013-12/documents/dfe_master_criteria_safer_ingredients_v2_1.pdf

[8] https://canadachemicals.oecd.org/ChemicalDetails.aspx?ChemicalID=942696DD-DD93-445B-8E6D-943CD2270E55

[9] https://webrigoletto.uba.de/rigoletto/public/searchDetail.do?kennummer=2198

[10] https://www.epa.govt.nz/database-search/chemical-classification-and-information-database-ccid/view/8231

[11] Dibutyl sebacate appears on page 1748 of the document (page 94 of the pdf document) under the name 'Decanedioic acid, dibutyl ester': https://www.epa.govt.nz/assets/Uploads/Documents/Hazardous-Substances/Policies/335c98365a/Hazardous-Substances-Chemicals-Transfer-Notice-2006.pdf

5. Conditions of Use

Per TSCA section 3(4), the term "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. EPA assembled information on all uses of dibutyl sebacate (Appendix A) to inform which uses would be determined conditions of use.[12] One source of information that EPA used to help determine conditions of use is 2016 Chemical Data Reporting (CDR). The CDR rule (previously known as the Inventory Update Rule, or IUR), under TSCA section 8, requires manufacturers (including importers) to report information on the chemical substances they produce domestically or import into the U.S., generally above a reporting threshold of 25,000 lb. per site per year. CDR includes information on the manufacturing, processing, and use of chemical substances with information dating to the mid-1980s. CDR may not provide information on other life-cycle phases such as the chemical substance's end-of-life after use in products (i.e., disposal).

According to CDR, dibutyl sebacate is manufactured domestically and imported. Based on CDR reporting, it is used in processing (incorporation into formulation, mixture or reaction and incorporation into article for plastic material and resin manufacturing, pharmaceutical and medicine manufacturing, wholesale and retail trade, plastics product manufacturing, and rubber product manufacturing); it is also used as a reactant in rubber product and synthetic rubber manufacturing. Dibutyl sebacate is used in a variety of industrial applications, including water supply and sewage treatment. Consumer and commercial uses include photographic supplies, film, and photo chemicals; ink, toner, and colorant products; arts, crafts, and hobby materials; laundry and dishwashing products; and cleaning and furnishing care products. Based on the known manufacturing, processing, and uses of this chemical substance, EPA assumes distribution in commerce. According to CDR, dibutyl sebacate was reported as recycled by at least one site. No information on disposal is found in CDR or through EPA's Toxics Release Inventory (TRI) Program[13] because dibutyl sebacate is not a TRI-reportable chemical. Although reasonably available information did not specify additional types of disposal, for purpose of this prioritization designation, EPA assumed end-of-life pathways that include releases to air, wastewater, surface water and land via solid and liquid waste based on the conditions of use (e.g., incineration, landfill).

To supplement CDR, EPA conducted research through the publicly available databases listed in Appendix A (Table A.2) and performed additional internet searches to clarify conditions of use or find additional occupational[14] and consumer uses. This research improved the Agency's understanding of the conditions of use for dibutyl sebacate. In the course of this research, EPA identified uses of dibutyl sebacate in various types of cleaning products, construction materials, cosmetics, coatings, oils, adhesives, and food and beverage manufacturing, among others. Although EPA identified uses of dibutyl sebacate in personal care products, the screening review covered TSCA conditions of use for the chemical substance and personal care products were not considered in EPA's assessment. Exclusions to TSCA's regulatory scope regarding "chemical substance" can be

[12] The prioritization process, including the definition of conditions of use, is explained in the *Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act* (82 FR 33753).

[13] https://www.epa.gov/toxics-release-inventory-tri-program

[14] Occupational uses include industrial and/or commercial uses

found at TSCA section 3(2). Table 3 lists the conditions of use for dibutyl sebacate considered for chemical substance prioritization, per TSCA section 3(4). Table 3 reflects the TSCA uses determined as conditions of use listed in Table A.3 (Appendix A).

Table 3: Conditions of Use for Dibutyl Sebacate			
Life Cycle Stage	**Category**	**Subcategory of Use**	**Source**
Manufacturing	Domestic manufacture	Domestic manufacture not reported although some information is withheld and/or CBI	EPA (2017b)
	Import	Import	
Processing	Processing-incorporation into formulation, mixture or reaction	Plasticizers– plastic material and resin manufacturing; pharmaceutical and medicine manufacturing, Wholesale and retail trade, Plastics product manufacturing, Rubber product manufacturing	EPA (2017b)
		Solvents (which become part of product formulation or mixture)– photographic film paper, plate, and chemical manufacturing, wholesale and retail trade	
		Pigments – printing ink manufacturing	
	Processing as a reactant	Plasticizers – rubber product manufacturing, synthetic rubber manufacturing	
	Processing-Incorporation into an article	Plasticizer – plastic product manufacturing, rubber product manufacturing, wholesale and retail trade	
	All other chemical product and preparation manufacturing	Chemicals, cosmetics, electrical machinery, explosives, furniture, metals, textile and leather, windmill, transportation equipment, and paint/varnish manufacturing	CPCat (2019); Reported to the ECHA database (2018)
	Recycling	Recycling	EPA (2017b)[15]
Distribution	Distribution	Distribution	EPA (2017b)
Industrial uses	Other	Ceramic extrusion	Synapse Information Resources (n.d.)
	Photographic supplies, film, and photo chemicals	Printing and reproduction of recorded media	CPCat (2019)
	Surfactant	Surface-active agent	CPCat (2019)

[15] According to CDR reports, at least one manufacturer indicates that the chemical is recycled onsite. No other information is available information to indicate that other recycling is taking place. Reasonably available information did not specify types of disposal, but EPA assumes these releases based on the conditions of use.

Table 3: Conditions of Use for Dibutyl Sebacate			
Life Cycle Stage	**Category**	**Subcategory of Use**	**Source**
	Utilities	Water supply and sewage treatment	Reported to the ECHA database (2018)
	Agriculture, forestry, fishing and hunting[16]		Reported to the ECHA database (2018)
Industrial/ commercial uses	Lubricants and greases	Lubricant additive, greases and lubricants	Reported to the ECHA database (2018)
	Paints and coatings	Coatings, metal treatment coatings, polyvinyl butyral resins	Synapse Information Resources (n.d.); Reported to the ECHA database (2018)
Industrial/ commercial/ consumer uses	Photographic supplies, film, and photo chemicals	Photographic supplies, film, and photo chemicals	EPA (2017b)
	Arts, crafts, and hobby materials	Art and hobby supplies, finger paints, modelling clay	Reported to the ECHA database (2018)
	Adhesives and sealant chemicals	Adhesive manufacturing, sealants	CPCat (2019); Reported to the ECHA database (2018)
	Fuels and related products	Motor oil; oil and gas drilling, torpedo fuel	CPCat (2019); Reported to the ECHA database (2018), ATSDR (1995)
	Food and beverage[17]	Food and beverage manufacturing; food-contact metallic article manufacturing; food-contact rubber articles; food packaging adhesives; food paper/paperboard packing	CPCat (2019); Reported to the ECHA database (2018), Synapse Information Resources (n.d.)
	Ink, toner, and colorant products	Ink, toner, and colorant products	EPA (2017b)

[16] Assumed to be a mix of TSCA and non-TSCA products. More representative uses that fall into this category are provided in Table A.3.

[17] TSCA use based on the assumption that the chemical is used in the manufacturing of products and not intended to be a component of food.

Table 3: Conditions of Use for Dibutyl Sebacate			
Life Cycle Stage	**Category**	**Subcategory of Use**	**Source**
	Automotive care products	Cleaning	Reported to the ECHA database (2018)
	Building/construction materials not covered elsewhere	Boat and ship construction, building construction materials, road construction, flooring materials	CPCat (2019); Reported to the ECHA database (2018)
	Cleaning and furnishing care products	Boat cleaners, carpet cleaners, wipes, descaler, floor cleaner/polish, wood/leather/glass cleaners, general cleaners, metal cleaners	Reported to the ECHA database (2018)
	Laundry and dishwashing products	Bleach products, dishwashing products, drain cleaner, fabric conditioner, detergents	Reported to the ECHA database (2018)
	Deicing and anti-icing products	Deicer	Reported to the ECHA database (2018)
	Fabric, textile, and leather products not covered elsewhere	Leather treatment products	Reported to the ECHA database (2018)
	Agricultural products (non-pesticidal)	Plant protection products	Reported to the ECHA database (2018)
	Adhesives, sealants	Adhesive	Reported to the ECHA database (2018)
Consumer	Odor agents	Fragrance,[18] air freshener	CPCat (2019), Reported to the ECHA database (2018)
	Fabric, textile, and leather products not covered elsewhere	Dyes and finishes	CPCat (2019)
Disposal	Releases to air, wastewater, solid and liquid wastes		Though not explicitly identified, releases from disposal were assumed to be reasonably foreseen[19]

[18] Potentially a non-TSCA category may contain both TSCA and non-TSCA uses; however, because information is insufficient to determine, it is assumed to be covered by TSCA.

[19] See Section 5 for a discussion on why releases were assumed to be reasonably foreseen for purposes of this prioritization designation.

6. Hazard Characterization

EPA reviewed primary literature and other data sources to identify reasonably available information. This literature review approach[20] is tailored to capture the reasonably available information associated with low-hazard chemicals. EPA also used this process to verify the reasonably available information for reliability, completeness, and consistency. EPA reviewed the reasonably available information to identify relevant, quality studies to evaluate the hazard potential for dibutyl sebacate against the endpoints listed below. EPA's New Chemicals Program has used these endpoints for decades to evaluate chemical substances under TSCA[21] and EPA toxicologists rely on these endpoints as key indicators of potential human health and environmental effects. These endpoints also align with internationally accepted hazard characterization criteria, such as the Globally Harmonized System of Classification and Labelling of Chemicals[22] as noted above in Section 4 and form the basis of the comparative hazard assessment of chemicals.

Human health endpoints evaluated: Acute mammalian toxicity, repeated dose toxicity, carcinogenicity, mutagenicity/genotoxicity, reproductive and developmental toxicity, neurotoxicity, skin sensitization, respiratory sensitization, immunotoxicity and eye and skin irritation.

Environmental fate and effects endpoints evaluated: Aquatic toxicity, environmental persistence, and bioaccumulation.

The low-concern criteria used to evaluate both human health and environmental fate and effects are included in Table 4 below.

Table 4: Low concern Criteria for Human Health and Environmental Fate and Effects

Human Health				
Acute Mammalian Toxicity[23]	**Very High**	**High**	**Moderate**	**Low**
Oral LD50 (mg/kg)	≤ 50	> 50 – 300	> 300 - 2000	> 2000
Dermal LD50 (mg/kg)	≤ 200	> 200 – 1000	> 1000 - 2000	> 2000
Inhalation LC50 (vapor/gas) (mg/L)	≤ 2	> 2 – 10	> 10 - 20	> 20
Inhalation LC50 (dust/mist/fume) (mg/L)	≤ 0.5	> 0.5 - 1.0	> 1.0 - 5	> 5

[20] Discussed in the document "Approach Document for Screening Hazard Information for Low-Priority Substances Under TSCA," which can be found at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0450-0002.

[21] https://www.epa.gov/sustainable-futures/sustainable-futures-p2-framework-manual

[22] https://www.unece.org/fileadmin/DAM/trans/danger/publi/ghs/ghs_rev07/English/ST_SG_AC10_30_Rev7e.pdf

[23] Values derived from GHS criteria (*Chapter 3.1: Acute Toxicity.* 2009, United Nations).

Table 4: Low concern Criteria for Human Health and Environmental Fate and Effects				
Repeated Dose Toxicity, Neurotoxicity, and Immunotoxicity (90-day study)[24]		**High**	**Moderate**	**Low**
Oral (mg/kg-bw/day)		< 10	10 - 100	> 100
Dermal (mg/kg-bw/day)		< 20	20 - 200	> 200
Inhalation (vapor/gas) (mg/L/6h/day)		< 0.2	0.2 - 1.0	> 1.0
Inhalation (dust/mist/fume) (mg/L/6h/day)		< 0.02	0.02 - 0.2	> 0.2
Reproductive and Developmental Toxicity[25]		**High**	**Moderate**	**Low**
Oral (mg/kg/day)		< 50	50 - 250	> 250
Dermal (mg/kg/day)		< 100	100 - 500	> 500
Inhalation (vapor, gas, mg/L/day)		< 1	1 - 2.5	> 2.5
Inhalation (dust/mist/fume, mg/L/day)		< 0.1	0.1 - 0.5	> 0.5
Mutagenicity/ Genotoxicity[26]	**Very High**	**High**	**Moderate**	**Low**
Germ cell mutagenicity	GHS Category 1A or 1B: Substances known to induce heritable mutations or to be regarded as if they induce heritable mutations in the germ cells of humans.	GHS Category 2: Substances which cause concern for humans owing to the possibility that they may induce heritable mutations in the germ cells of humans.	Evidence of mutagenicity support by positive results *in vitro* OR *in vivo* somatic cells of humans or animals	Negative for chromosomal aberrations and gene mutations, or no structural alerts.
Mutagenicity and Genotoxicity in Somatic Cells		OR Evidence of mutagenicity supported by positive results in *in vitro* AND		

[24] Values from GHS criteria for Specific Target Organ Toxicity Repeated Exposure (*Chapter 3.9: Specific Target Organ Toxicity Repeated* Exposure. 2009, United Nations).

[25] Values derived from the US EPA's Office of Pollution Prevention & Toxics criteria for HPV chemical categorizations (*Methodology for Risk-Based Prioritization Under ChAMP*), and the EU REACH criteria for Annex IV (2007).

[26] From GHS criteria (*Chapter 3.5: Germ Cells Mutagenicity.* 2009, United Nations) and supplemented with considerations for mutagenicity and genotoxicity in cells other than germs cells.

Table 4: Low concern Criteria for Human Health and Environmental Fate and Effects				
		in vivo somatic cells and/or germ cells of humans or animals.		
Carcinogenicity[27]	**Very High**	**High**	**Moderate**	**Low**
	Known or presumed human carcinogen (GHS Category 1A and 1B)	Suspected human carcinogen (GHS Category 2)	Limited or marginal evidence of carcinogenicity in animals (and inadequate[28] evidence in humans)	Negative studies or robust mechanism-based SAR
Sensitization[29]		**High**	**Moderate**	**Low**
Skin sensitization		High frequency of sensitization in humans and/or high potency in animals (GHS Category 1A)	Low to moderate frequency of sensitization in human and/or low to moderate potency in animals (GHS Category 1B)	Adequate data available and not GHS Category 1A or 1B
Respiratory sensitization		Occurrence in humans or evidence of sensitization in humans based on animal or other tests (equivalent to GHS Category 1A or 1B)	Limited evidence including the presence of structural alerts	Adequate data available indicating lack of respiratory sensitization
Irritation/ Corrosivity[30]	**Very High**	**High**	**Moderate**	**Low**
Eye Irritation/ Corrosivity	Irritation persists for >21 days or corrosive	Clearing in 8-21 days, severely irritating	Clearing in 7 days or less, moderately irritating	Clearing in less than 24 hours, mildly irritating
Skin Irritation/ Corrosivity	Corrosive	Severe irritation at 72 hours	Moderate irritation at 72 hours	Mild or slight irritation at 72 hours

[27] Criteria mirror classification approach used by the IARC (*Preamble to the IARC Monographs: B. Scientific Review and Evaluation: 6. Evaluation and rationale.* 2006*)* and incorporate GHS classification scheme (*Chapter 3.6: Carcinogenicity.* 2009, United Nations).

[28] EPA's approach to determining the adequacy of information is discussed in the document "Approach Document for Screening Hazard Information for Low-Priority Substances Under TSCA", also released at proposal.

[29] Incorporates GHS criteria (*Chapter 3.4: Respiratory or Skin Sensitization.* 2009, United Nations).

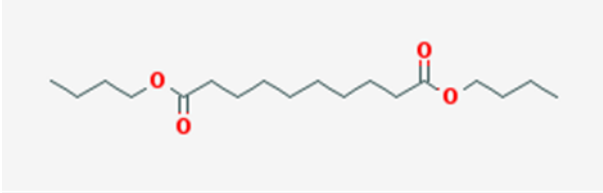
[30] Criteria derived from the Office of Pesticide Programs Acute Toxicity Categories (US EPA. *Label Review Manual.* 2010).

Table 4: Low concern Criteria for Human Health and Environmental Fate and Effects			
Environmental Fate and Effects			
Acute Aquatic Toxicity Value (L/E/IC50)[31]	**Chronic Aquatic Toxicity Value (L/E/IC50)[31]**	**Persistence (Measured in terms of level of biodegradation)[32]**	**Bioaccumulation Potential[33]**
May be low concern if ≤10 ppm…	…and ≤1 ppm…	…and the chemical meets the 10-day window as measured in a ready biodegradation test…	…and BCF/BAF < 1000.
Low concern if >10 ppm and <100 ppm…	…and >1 ppm and <10 ppm…	…and the chemical reaches the pass level within 28 days as measured in a ready biodegradation test	
Low concern if ≥100 ppm…	…and ≥ 10 ppm…	… and the chemical has a half-life < 60 days…	

6.1 Human Health Hazard

Below is a summary of the reasonably available information that EPA included in the hazard evaluation of dibutyl sebacate. In many cases, EPA used analogous chemicals to make findings for a given endpoint. Where this is case, use of the analog is explained. If the chemical studied is not named, the study is for dibutyl sebacate. Appendix B contains more information on each study.

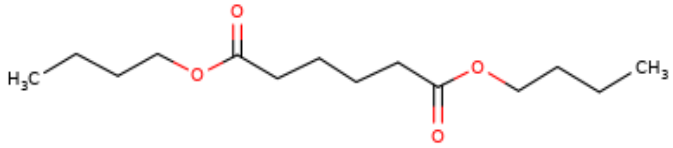
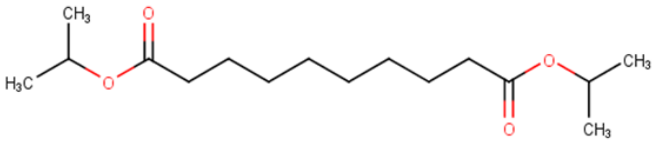
Dibutyl sebacate is an aliphatic diester. EPA used best professional judgement to select analogs for dibutyl sebacate based on similarity in structure, physical-chemical properties and functionality, with the assumption that these chemicals will have similar environmental transport and persistence characteristics, and bioavailability and toxicity profiles. As shown in Table 5, the selected analogs used to inform EPA's understanding of this chemical are aliphatic diesters like dibutyl sebacate. Dibutyl adipate has a shorter aliphatic chain length separating the ester groups than dibutyl sebacate. Diisopropyl sebacate has the same length aliphatic chain separating the ester groups as dibutyl sebacate, but diisopropyl sebacate's configuration of the ester groups are different than dibutyl sebacate's. Despite these subtle differences, the environmental and toxicological effects of dibutyl adipate and diisopropyl sebacate are expected to be very similar to those of dibutyl sebacate.

Table 5: Dibutyl Sebacate and Analog Structures		
CASRN	**Name**	**Structure**
109-43-3	**Dibutyl sebacate**	

[31] Derived from GHS criteria (*Chapter 4.1: Hazards to the Aquatic Environment.* 2009, United Nations), EPA OPPT New Chemicals Program (*Pollution Prevention (P2) Framework,* 2005*)* and OPPT's criteria for HPV chemical categorization (*Methodology for Risk Based Prioritization Under ChAMP. 2009).*

[32] Derived from OPPT's New Chemicals Program and DfE Master Criteria, and reflects OPPT policy on PBTs (*Design for the Environment Program Master Criteria for Safer Chemicals, 2010)*.

[33] Derived from OPPT's New Chemicals Program and Arnot & Gobas (2006) [Arnot, J.A. and F.A. Gobas, *A review of bioconcentration factor (BCF) and bioaccumulation factor (BAF) assessments for organic chemicals* in aquatic organisms. Environmental Reviews, 2006. 14: p. 257-297.]

Table 5: Dibutyl Sebacate and Analog Structures		
CASRN	**Name**	**Structure**
105-99-7	**Dibutyl adipate**	
7491-02-3	**Diisopropyl sebacate**	

6.1.1 Absorption, Distribution, Metabolism, and Excretion

To review absorption, distribution, metabolism and excretion (ADME) endpoints without adequate quality[34] experimental data, EPA used widely accepted new approach methodologies (NAMs), such as modeling and estimation tools often based on physical-chemical properties, which provided information sufficient to fill these endpoints.

Absorption

If ingested orally, dibutyl sebacate is expected to have low to moderate absorption from the gastrointestinal tract based on its molecular weight and low water solubility (Section 3). If inhaled as a vapor, aerosol, or dust, dibutyl sebacate is expected to have minimal absorption from the lungs based on its low water solubility (Section 3). The potential for dermal absorption of dibutyl sebacate is also predicted to be low based on the combination of its low water solubility and moderate log K_{ow} (Section 3).

Distribution

Experimental data determined to be of adequate quality[34] on dibutyl sebacate or closely related analogs were not reasonably available for the assessment of distribution potential. Based on the absorption, metabolism, and excretion information, it is expected that dibutyl sebacate will not be distributed or retained throughout the body. If ingested, it is expected to be metabolized and excreted (described further below).

Metabolism

Experimental data determined to be of adequate quality[35] on dibutyl sebacate or closely related analogs metabolite formation were not reasonably available. The Quantitative Structure-Activity

[34] The literature search and review process to determine studies of adequate quality for inclusion in the screening review is further discussed in the document "The Approach Document for Screening Hazard Information for Low-Priority Substances under TSCA." https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0450-0002

[35] The literature search and review process to determine studies of adequate quality for inclusion in the screening review is further discussed in the document "The Approach Document for Screening Hazard Information for Low-Priority Substances under TSCA." https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0450-0002

Relationship (QSAR) toolbox[36] was used to run the rat liver S9 metabolism simulator, the skin metabolism simulator, and the *in vivo* rat metabolism simulator. The metabolism simulators predicted hydrolysis of dibutyl sebacate to the corresponding monoester (sebacic acid monobutyl ester), releasing butanol. Butanol is further metabolized by alcohol dehydrogenase to butyraldehyde and by aldehyde dehydrogenase to butyric acid, which is subsequently metabolized via β-oxidation to carbon dioxide and water. Other metabolites predicted by the simulators include mono- and di- esters, carboxylic acids, and aldehydes.

Excretion

Based on the predicted metabolism of dibutyl sebacate and the excretion pathways observed with butanol (discussed in Metabolism), metabolites of this substance are expected to be excreted via the urine or further metabolized and exhaled as carbon dioxide.

6.1.2 Acute Toxicity

EPA assessed the potential for mammalian toxicity from acute exposure to dibutyl sebacate using experimental data. Rats exposed to a single dose of dibutyl sebacate via oral gavage showed no mortality, resulting in an LD_{50} greater than 4700 mg/kg (Reported to the ECHA database, 1976a). Rats exposed to dibutyl sebacate orally resulted in mortality only at very high doses with an LD_{50} in between 16,000 mg/kg and 32,000 mg/kg (Smith, 1953). These studies provide sufficient information to indicate low concern for acute toxicity with LD_{50}s above the low-concern benchmark of 2000 mg/kg for oral exposures.

6.1.3 Repeated Dose Toxicity

EPA assessed the potential for mammalian toxicity from repeated exposures to dibutyl sebacate using experimental data. Rats exposed to dibutyl sebacate in their diet for one year indicated no adverse effects, resulting in a no observed adverse effect level (NOAEL) of 870 mg/kg-day (WHO, 2000; Smith, 1953). A two-year diet study on rats also reported no effects at the highest dose (4400 mg/kg-day), resulting in a NOAEL of 4400 mg/kg-day (WHO, 2000; Smith, 1953). These results provide sufficient information to indicate low concern for mammalian toxicity from repeated exposures to dibutyl sebacate by exceeding the low-concern benchmark of 100 mg/kg-day.

6.1.4 Reproductive and Developmental Toxicity

EPA assessed the potential for mammalian reproductive toxicity using read-across from dibutyl adipate. Rats exposed to dibutyl adipate by oral gavage beginning two weeks prior to mating and through day 3 of lactation (for females) displayed no effects on reproductive parameters, resulting in a NOAEL of 1000 mg/kg-day (OECD, 1996). This study also examined a subset of developmental parameters, including pup number, pup sex ratio, live and dead pups, postnatal deaths, gross abnormalities, pup weight gain, physical and behavioral abnormalities, reflexology and gross necropsy. The F1 generation developmental NOAEL was 300 mg/kg-day and the LOAEL was 1000 mg/kg-day based on decreased pup weight and decreased viability. These results provide sufficient information to indicate low concern for reproductive and developmental toxicity by exceeding the low-concern benchmarks of 250 mg/kg-day for oral exposures.

[36] https://www.oecd.org/chemicalsafety/risk-assessment/oecd-qsar-toolbox.htm

6.1.5 Genotoxicity

EPA assessed experimental data on chromosomal aberrations and used read-across from dibutyl adipate for gene mutation as potential indicators of genotoxic carcinogenicity. An *in vivo* micronucleus study in mice exposed to dibutyl sebacate was negative for chromosomal aberrations (specifically, micronucleated polychromatic erythrocytes) (Wild et al., 1983). A sex-linked recessive lethal mutation study on *Drosophila* was also negative for dibutyl sebacate (Wild et al., 1983). Gene mutation studies on two bacteria species reported negative results with and without activation when exposed to dibutyl adipate (Reported to the ECHA database, 1996; OECD, 1996). These results provide sufficient information to indicate dibutyl sebacate has low concern for inducing genotoxicity.

6.1.6 Carcinogenicity

EPA assessed the potential for dibutyl sebacate to cause carcinogenicity using experimental data. Rats exposed to dibutyl sebacate orally for two years demonstrated no cancer-related effects at the highest dose tested of 4400 mg/kg-day, resulting in a negative finding for carcinogenicity (Smith, 1953). These results provide sufficient information to indicate low concern for carcinogenicity by dibutyl sebacate.

6.1.7 Neurotoxicity

While no guideline neurotoxicity studies were available for dibutyl sebacate or closely related analogs, EPA assessed the potential for neurotoxicity using relevant endpoints measured in repeated dose studies and accepted new approach methodologies (NAMs), such as predictions made by U.S. EPA's ToxCast.[37]

A one year, repeated dose study in rats exposed to dibutyl sebacate demonstrated dietary doses corresponding to 870 mg/kg-day did not produce histopathological lesions in the brain (Smith, 1953).

ToxCast results for dibutyl sebacate included 27 *in vitro* high throughput biochemical- and cell-based assays related to neurological functions.[38] Dibutyl sebacate induced bioactivity in 1 of the 27 assays; the active result was reported in the Novascreen Human Beta-site APP Cleaving Enzyme (NVS_ENZ_hBACE) assay, but dibutyl sebacate was inactive in the NVS_ENZ_hBACE_Activator assay. The protein used in this assay is the human Beta-secretase 1 protein, which targeted the beta-site APP-cleaving enzyme 1 (BACE1) gene. The activity detected from exposure to dibutyl sebacate indicates enzyme function and kinetic changes may occur in the BACE1 gene; however, an AC_{50} (concentration of 50% maximum activity) value could not be calculated for these data because the efficacy was below 50% at the highest concentration. Therefore, the results are only useful for a qualitative determination of active vs. inactive in this assay and only represent a potential molecular initiating event that does not appear to translate into adverse outcomes based on the low-hazard findings for repeated dose exposures. Further, the analog di-n-butyl adipate (105-99-7) did not induce

[37] https://comptox.epa.gov/dashboard. Chemical specific assay list can be found at https://comptox.epa.gov/dashboard/dsstoxdb/results?search=DTXSID1041847

[38] Identified by supplemental information in Chushak Y., Shows H., Gearhart J., Pangburn H. 2018. In silico identification of protein targets for chemical neurotoxins using Toxcast in vitro data and read-across within the QSAR toolbox. Toxicology Research issue 3. Supplemental files: https://pubs.rsc.org/en/content/articlelanding/2018/tx/c7tx00268h#!divAbstract.

activity in either the NVS_ENZ_hBACE or NVS_ENZ_hBACE_Activator assays (U.S. EPA ToxCast, 2019).

Applying expert scientific judgement based on the reasonably available information and weight of the scientific evidence, this information provides sufficient information to indicate there is low concern for neurotoxicity from dibutyl sebacate.

6.1.8 Skin Sensitization

Experimental data determined to be of adequate quality[39] on dibutyl sebacate or closely-related analogs were not reasonably available to assess the potential for dibutyl sebacate to cause skin sensitization. EPA used widely accepted NAMs, such as the QSAR Toolbox, Version 4.2 models which did not identify any structural alerts for protein binding potential of dibutyl sebacate for skin sensitization. These results provide sufficient information to indicate dibutyl sebacate is low concern for skin sensitization.

6.1.9 Respiratory Sensitization

Experimental data determined to be of adequate quality[40] on dibutyl sebacate or closely-related analogs were not reasonably available for the assessment of respiratory sensitization potential. To model respiratory sensitization for dibutyl sebacate, EPA used NAMs, such as the QSAR Toolbox version 4.2 models[41] for keratinocyte gene expression; protein binding potency h-CLAT; protein binding potency cysteine; protein binding potency lysine; and respiratory sensitization. No structural alerts were identified for dibutyl sebacate. The results from these NAMs and weight of the scientific evidence provide sufficient information to indicate low concern for respiratory sensitization.

6.1.10 Immunotoxicity

EPA reviewed the literature for immunotoxicity endpoints such as lymphoid organ weight, histopathology, and immune function. Specific endpoints included immune system function (e.g., T-cell dependent antibody response), immunophenotyping (e.g., changes in cell types), natural killer cell activity, host resistance assays, macrophage neutrophil function, and cell-mediated immunity assays. Experimental data determined to be of adequate quality[42] on dibutyl sebacate or closely related analogs were not reasonably available for the assessment of immunotoxicity potential.

Repeated dose testing is designed to be comprehensive in nature and is intended to address a wide range of possible impacts, including, but not limited to immunotoxicity. The testing required to address repeated dose toxicity typically includes routine clinical observations, hematology and clinical biochemistry, body weight/food and water consumption, as well as both gross necropsy and

[39] This process is further discussed in the document "Approach Document for Screening Hazard Information for Low-Priority Substances under TSCA."

[40] The literature search and review process to determine studies of adequate quality for inclusion in the screening review is further discussed in the document "Approach Document for Screening Hazard Information for Low-Priority Substances under TSCA." https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0450-0002

[41] The OECD QSAR Toolbox is one of EPA's listed new approach methodologies under TSCA 4(h)(2), available at https://www.epa.gov/sites/production/files/2019-12/documents/alternative_testing_nams_list_first_update_final.pdf

[42] The literature search and review process to determine studies of adequate quality for inclusion in the screening review is further discussed in the document "Approach Document for Screening Hazard Information for Low-Priority Substances under TSCA." https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0450-0002

histopathology involving organs and organ systems. For example, repeated dose studies can evaluate changes to the spleen or thymus, which with accompanying histological changes or changes in hematological parameters can indicate potential for immunological toxicity. Where immune system-related endpoints were measured in repeated dose studies, any adverse effects would be incorporated into the lowest observed adverse effect level used against the low-concern benchmarks. Therefore, EPA relied on this information from repeated dose studies when it was reasonably available. For dibutyl sebacate and the closely-related analogs dibutyl adipate and diisopropyl sebacate, the included repeated dose studies did not report changes in lymphoid organ weights (thymus, spleen, lymph nodes), with accompanying histopathology, or hematological changes due to exposure to this chemical substance in mammals. These results provide sufficient information to indicate low concern for immunotoxicity potential from dibutyl sebacate.

6.1.11 Skin Irritation

EPA assessed the potential of dibutyl sebacate to induce skin irritation using experimental data from two analogs, dibutyl adipate and diisopropyl sebacate. Rabbits dermally exposed to diisopropyl sebacate for 24 hours displayed slight erythema in two of six animals at 24 hours; however, these results were fully reversible by 72 hours and were classified as non-irritating (Reported to the ECHA database, 1976b). Rabbits exposed to dibutyl adipate for four hours showed slight to obvious erythema and very slight edema in three of three animals one hour following exposure (Reported to the ECHA database, 1989). These effects were reversed by day eight. Because the irritation duration varied for the two analogs with both resulting in reversibility, EPA investigated which analog is a better match for dibutyl sebacate for this endpoint. EPA determined diisopropyl sebacate is a stronger analog than dibutyl adipate to assess the potential for skin irritation. EPA makes this finding based on the following information. Diisopropyl sebacate is similar in size (dibutyl sebacate: 314.47 g/mol; diisopropyl sebacate: 286.42 g/mol; dibutyl adipate: 258.36 g/mol) and predicted to have similar hydrophobicity and water solubility to dibutyl sebacate (dibutyl sebacate: 0.14 mg/L, Log K_{ow} of 6.3; diisopropyl sebacate: 0.57 mg/L, Log K_{ow} of 5.17; dibutyl adipate: 13.6 mg/L, Log K_{ow} of 4.33). The irritation study results for the stronger analog, diisopropyl sebacate, provide sufficient information to indicate that dibutyl sebacate has low concern for skin irritation.

6.1.12 Eye Irritation

EPA assessed available experimental data on eye irritation. A study in rabbits demonstrated dibutyl sebacate induced slight eye irritation, but these effects were fully reversible within 48 hours (Reported to the ECHA database, 1991). These results indicate moderate concern for eye irritation from dibutyl sebacate. The weight of the scientific evidence for these results is discussed in Section 8.1.

6.1.13 Hazards to Potentially Exposed or Susceptible Subpopulations

The above information supports a low human health hazard finding for dibutyl sebacate based on low-concern criteria. This finding includes considerations such as the potential for developmental toxicity, reproductive toxicity, and acute or repeated dose toxicity that may impact potentially exposed or susceptible subpopulations. Based on the hazard information discussed in Section 6, EPA did not identify populations with greater susceptibility to dibutyl sebacate.

6.2 Environmental Hazard

To review environmental hazard endpoints without adequate quality[34] experimental data, EPA used widely accepted new approach methodologies (NAMs), such as modeling and estimation tools often based on physical-chemical properties, which provided information sufficient to fill these endpoints and form the basis for designation. EPA assessed environmental hazard for dibutyl sebacate based on estimated toxicity values using the Ecological Structure Active (ECOSAR) Predictive Model[43] and available experimental data from an analog, dibutyl adipate. Appendix B contains a summary of the reasonably available environmental hazard data.

6.2.1 Acute Aquatic Toxicity

EPA assessed aquatic toxicity from acute exposures using read-across from dibutyl adipate. Invertebrates exposed to dibutyl adipate had a reported EC_{50} greater than 5.2 mg/L (Reported to the ECHA database, 2014b), which exceeds some of the reported water solubilities for dibutyl sebacate (see Table 2). Further, the predicted log K_{ow} of 6.3 for dibutyl sebacate is greater than ECOSAR's acute benchmark[44] of log K_{ow} of 5. Chemicals with log K_{ow} values of 5 or greater are expected to result in no effects at saturation during a 48-hour to 96-hour test.[45] Thus, ECOSAR predicts that the physical-chemical properties of dibutyl sebacate, specifically the high octanol water partition coefficient and low water solubility, limit the dissolved (and bioavailable) concentration of the chemical in the water column to the extent that environmental toxicity is unlikely to be exhibited. Both ECOSAR and the experimental invertebrate evidence for dibutyl adipate suggest no effects at saturation are expected for aquatic vertebrates, invertebrates, and algae acutely exposed to dibutyl sebacate. However, even if dibutyl sebacate were soluble in water above the observed effect concentrations for dibutyl adipate (>5.2 mg/L as compared to dibutyl sebacate's highest measured water solubility of 40 mg/L, see Table 2), aerobic biodegradation is expected to quickly reduce the dissolved concentration in the environment (see Section 6.3.1, below). In particular, dibutyl sebacate has experimental data to show greater than 60% aerobic biodegradation within 10 days. These results provide sufficient information to indicate dibutyl sebacate meets the low-concern benchmarks outlined in Table 4 and is low concern for acute aquatic exposures.

6.2.2 Chronic Aquatic Toxicity

EPA assessed toxicity from chronic exposures using read-across from dibutyl adipate. Two 21-day studies on invertebrates exposed to dibutyl adipate reported a NOEC value of 1.5 mg/L and an LC_{50} of 4.3 mg/L (Reported to the ECHA database, 2014a, OECD, 1996).

EPA estimated the potential for dibutyl sebacate to cause chronic toxicity to aquatic vertebrates and algae using ECOSAR. ECOSAR estimated a chronic effect to fish at 0.004 mg/L and to algae at 0.04 mg/L. These estimations indicate high concern for chronic aquatic toxicity, while the experimental values for dibutyl adipate indicate moderate concern. For the purposes of this screening review, EPA

[43] https://www.epa.gov/tsca-screening-tools/ecological-structure-activity-relationships-ecosar-predictive-model

[44] The limits of each QSAR must be understood if the results are to be interpreted properly. In general, when the log Kow is ≤ 5.0 for fish and daphnid, or ≤ 6.4 for green algae, ECOSAR provides reliable estimates for acute effects. If the log Kow exceeds those limits, empirical data indicate that the decreased solubility of these lipophilic chemicals results in "no effects at saturation." Source: https://www.epa.gov/sites/production/files/2015-05/documents/06.pdf

[45] https://www.epa.gov/sites/production/files/2015-05/documents/06.pdf

assumes high concern for aquatic toxicity, meaning that effects may be seen at values of less than 1 mg/L, which is equivalent to 1 ppm. For a chemical with chronic aquatic toxicity values <1 ppm to be considered low concern for hazard, the chemical must reach 60% degradation within 10 days as measured in an aerobic ready biodegradation test without degradation products of concern. Given the expected low persistence of closely-related analogs for dibutyl sebacate (discussed in 6.3.1), these aquatic toxicity studies indicate low concern for chronic aquatic exposure because the aquatic toxicity data is accompanied by greater than 60% aerobic biodegradation within 10 days. Rapid aerobic biodegradation of dibutyl sebacate (discussed in Section 6.3.1) is expected to reduce the dissolved concentration in the environment, reducing the potential for chronic exposures and aquatic toxicity. Applying expert scientific judgement and weight of the scientific evidence, these results provide sufficient evidence to indicate dibutyl sebacate is low-concern for chronic aquatic toxicity.

6.2.3 Terrestrial Toxicity

EPA assessed the potential of dibutyl sebacate toxicity on a soil-dwelling organism, *Eisenia fetida,* using experimental data from dibutyl adipate. An OECD Guideline 207 study reported a no observed effect concentration (NOEC) of 1000 mg/kg following a 14-day exposure to dibutyl adipate (Reported to the ECHA database, 2013). These results provide sufficient information to indicate dibutyl sebacate has low concern for sub-chronic exposures to soil organisms.

6.3 Persistence and Bioaccumulation Potential

6.3.1 Persistence

EPA assessed the potential for dibutyl sebacate to be persistent using experimental data from two analogs, dibutyl adipate and diisopropyl sebacate. A study following OECD Guideline 301B reported diisopropyl sebacate to be readily biodegradable under aerobic conditions, with greater than 60% of the substance degraded in 10 days and 89.6% in 28 days based on CO_2 evolution (Reported to the ECHA database, 1998). A study following OECD Guideline 301E reported dibutyl adipate to be readily biodegradable under aerobic conditions, with 96% of the substance degraded within 28 days based on DOC (Reported to the ECHA database, 2000). Another study following OECD Guideline 301C, also known as the MITI test, reported dibutyl adipate to be readily biodegradable under aerobic conditions, with 95% degrading in 28 days based on BOD (OECD, 1996; Reported to the ECHA database, 1995). Further, an OECD Guideline 301D study reported dibutyl adipate degraded 60% in 28 days under aerobic conditions (Reported to the ECHA database, 1999). The available biodegradation results on analogs meet the low-concern benchmark of greater than 60% biodegradation in 10 days (based on the aquatic toxicity criteria) and provide sufficient information to indicate dibutyl sebacate will readily biodegrade in aerobic environments.

EPA assessed the potential for anaerobic biodegradation using BIOWIN 7, a model within EPISuite. This model predicted dibutyl sebacate would biodegrade quickly under anaerobic conditions, with a probability of 0.7490. Predictions with a probability greater than 0.5 are considered reliable under this model.

No degradation products of concern were identified for this chemical substance. These results on aerobic and anaerobic biodegradation provide sufficient information to indicate dibutyl sebacate has low persistence.

6.3.2 Bioaccumulation Potential

Based on the estimated bioaccumulation factor (BAF) value of 29 using the Estimation Programs Interface (EPI) Suite models,[46] EPA has sufficient information that dibutyl sebacate is expected to have low potential for bioaccumulation in the environment based on the low-concern benchmark of less than 1000.

[46] https://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface

7. Exposure Characterization

EPA considered reasonably available information on exposure for dibutyl sebacate. In general, there is limited information on exposure for low-hazard chemicals. EPA consulted sources of exposure and use information that include CDR and other databases and public sources (described in Table A.2). Of these sources, EPA determined that the CDR database contained the primary source of information on the conditions of use for this exposure characterization. EPA used these other databases and public sources (described in Table A.2) only where they augmented information from the CDR database to inform intended, known or reasonably foreseen uses (Section 5).

As shown in Tables 3 and A.3, dibutyl sebacate is a solvent used in processing (incorporation into an article and into a formulation, mixture, or product) in the plastic, rubber, and pharmaceutical manufacturing sectors. It is also used in a variety of industrial uses, such as water supply and sewage treatment, and commercial and consumer uses, such as ink, toner, and colorant products; laundry and dishwashing products; and cleaning and furnishing care products (Table 3). Non-TSCA uses, including those excluded under TSCA section 3(2), are beyond the scope of this assessment (See Table A.3).

Under the conditions of use identified in Table 3, EPA assessed the potential exposure to the following categories: the environment, the general population, and potentially exposed or susceptible subpopulations including workers, consumers, and children.

7.1 Production Volume Information

Production volume information for dibutyl sebacate is based on an analysis of CDR data reported from 1986 to 2015.[47] In reporting years 1986 and 1998-2014, aggregate production volume for dibutyl sebacate was between 1,000,000 lbs. and 10,000,000 lbs. In reporting years 1990, 1994 and 2015, aggregate product volume was comparatively less than other reporting years, at 500,000 lbs. to 1,000,000 lbs. In general, since 2011, production volume has remained relatively stable, with a slight decrease from 2014-2015.

7.2 Exposures to the Environment

EPA expects most exposures to the environment to occur during the manufacture, import, processing, and industrial, commercial, and consumer uses of dibutyl sebacate. Exposure is also reasonably foreseeable from other uses, such as distribution and disposal. These activities could result in releases of dibutyl sebacate to media including surface water, landfills, and air.

Given dibutyl sebacate's low water solubility, any releases to surface water are expected to result in dibutyl sebacate adsorbing onto sediment based on the estimated log K_{oc} (Table 2 of Section 3), potentially exposing benthic organisms. Further, EPA expects high levels of removal of dibutyl sebacate during wastewater treatment (either directly from the facility or indirectly via discharge to a municipal treatment facility or Publicly Owned Treatment Works (POTW), see Table 2). Dibutyl sebacate is expected to have low persistence aerobically and anaerobically (discussed in Section

[47] The CDR requires manufacturers (including importers) to report information on the chemicals they produce domestically or import into the U.S above 25,000 lb. per site per year.

6.3.1) and has the potential to break down in the environment to carbon dioxide and water. Therefore, any releases of the chemical to sediments or soils is expected to break down, reducing exposures to soil-dwelling and benthic organisms.

If disposed of in a landfill, this chemical is expected to biodegrade under aerobic and anaerobic conditions (aerobic and anaerobic biodegradation are discussed in Section 6.3.1).

If incineration releases during manufacturing and processing occur, EPA expects significant degradation of dibutyl sebacate to the point that it will not be present in air.

7.3 Exposures to the General Population

EPA expects the general population is unlikely be exposed to dibutyl sebacate from the potential environmental releases described above. Air exposure is unlikely from incineration. If dibutyl sebacate is present in air from volatilization, it is expected to be reduced by its atmospheric half-life of approximately 7 hours (Section 3). Dibutyl sebacate is unlikely to be present in surface water because of its low water solubility (discussed in Section 3), biodegradability (discussed in Section 6.3.1), adsorption to sediment (based on the log K_{oc}, discussed in Section 3), and removal through wastewater treatment, thus reducing the potential for the general population to be exposed by oral ingestion or dermal exposure. Further, given the predicted low concentration in the water column and predicted bioaccumulation and bioconcentration potential of dibutyl sebacate, oral exposure to dibutyl sebacate via fish ingestion is unlikely.

7.4 Exposures to Potentially Exposed or Susceptible Subpopulations

EPA identified workers, consumers, and children as potentially exposed or susceptible subpopulations based on greater exposure to dibutyl sebacate than the general population during manufacturing, processing, distribution, use, and disposal. EPA identified children (including any adults working closely with children) as a population that may experience greater exposure to dibutyl sebacate than the general population during use of art and hobby supplies, finger paints, and modelling clay. EPA also identified consumers as a population that may experience greater exposure to dibutyl sebacate than the general population through use of ink, toner, and colorant products; laundry and dishwashing products; and cleaning and furnishing care products, for example.

7.4.1 Exposures to Workers

Based on its reported physical form and measured melting point (Table 2), dibutyl sebacate is a liquid under ambient conditions. Based on dibutyl sebacate's conditions of use (Table 3), workers may be exposed to liquids through direct dermal contact with the substance and inhalation of aerosols if they are generated. Based on its measured vapor pressure, dibutyl sebacate is expected to have some volatility at ambient temperatures, and therefore workers may be exposed through inhalation of vapors. If inhaled, absorption through the lungs is expected to be minimal. However, if dibutyl sebacate is in a dilute form, the estimated Henry's Law constant for dibutyl sebacate indicates volatilization from water and aqueous solutions is expected to be minimal. Workers may be exposed to non-dilute dibutyl sebacate in manufacturing, processing, distribution, industrial use, and disposal.

7.4.3 Exposures to Consumers

Consumers may be exposed to dibutyl sebacate through the use of cleaning and furnishing care products, laundry and dishwashing products, and ink, toner, and colorants products, for example. For all these uses, if dermal contact does occur, dibutyl sebacate is expected to be minimally absorbed through the skin. If the chemical is in an aerosol product and inhalation exposure occurs, dibutyl sebacate's absorption from the lungs is expected to be minimal. EPA does not include intentional misuse, such as people drinking products containing this chemical, as part of the known, intended, or likely conditions of use that could lead to an exposure (82 FR 33726). Thus, oral exposures will be incidental (meaning inadvertent and low in volume). Dibutyl sebacate is expected to be rapidly metabolized and excreted, further reducing the duration of exposure.

7.4.2 Exposures to Children

Children may be exposed to dibutyl sebacate through use of art and hobby supplies, finger paints, or modelling clay. Given the molecular weight, water solubility, and partitioning coefficients in Table 2, this chemical is expected to be poorly absorbed through the skin. For use in arts and crafts supplies, dibutyl sebacate is assumed to only be present in aqueous solutions, such as finger paint solution. Based on the predicted Henry's Law constant (provided in Section 3), dibutyl sebacate's volatilization from aqueous solutions is expected to be minimal from these products, reducing inhalation exposures to children. While using these products, children may rub their eyes or incidentally ingest the product.

8. Summary of Findings

EPA has used reasonably available information on the following statutory and regulatory criteria and considerations to screen dibutyl sebacate against each of the priority designation considerations in 40 CFR 702.9(a), and discussed individually in this section, under its conditions of use:

- the hazard and exposure potential of the chemical substance (See Sections 6 and 7);
- persistence and bioaccumulation (See Section 6.3);
- potentially exposed or susceptible subpopulations (See Section 7.4);
- storage near significant sources of drinking water (See Section 8.4);
- conditions of use or significant changes in the conditions of use of the chemical substance (See Section 5);
- the chemical substance's production volume or significant changes in production volume (See Section 7.1); and
- other risk-based criteria that EPA determines to be relevant to the designation of the chemical substance's priority.

EPA conducted a risk-based, screening-level review based on the criteria and other considerations above and other relevant information described in 40 CFR 702.9(c) to inform the determination of whether the substance meets the standard of a high-priority substance. High-priority substance means 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 (40 CFR 702.3). Designation of a low-priority substance is not a finding that the chemical substance does not present an unreasonable risk, but rather that the chemical does not meet the statutory criteria for a high-priority substance and that a risk evaluation is not warranted at the time. This section explains the basis for the final designation and how EPA applied statutory and regulatory requirements, addressed issues, and reached conclusions.

8.1. Hazard and Exposure Potential of the Chemical Substance

Approach: EPA evaluated the hazard and exposure potential of dibutyl sebacate. EPA used this information to inform its determination of whether dibutyl sebacate meets the statutory criteria and considerations for final designation as a low-priority substance.

- **Hazard potential:**

For dibutyl sebacate's hazard potential, EPA gathered information for a broad set of human health and environmental endpoints described in detail in Section 6 of this document. EPA screened this information against low-concern benchmarks. EPA found that dibutyl sebacate is of low concern for human health and environmental hazard across the range of endpoints in these low-concern criteria.

- **Exposure potential:**

To understand exposure potential, EPA gathered information on physical-chemical properties, production volumes, and the types of exposures likely to be faced by workers, the general population, children, and consumers (discussed in Sections 3 and 7). EPA also gathered information on environmental releases. EPA identified workers, the general population, consumers, children, and the

environment as most likely to experience exposures. EPA determined that while the general population, consumers, and workers may be exposed to dibutyl sebacate, exposure by the dermal, ingestion, and inhalation pathways are limited by dibutyl sebacate's physical-chemical properties. If dibutyl sebacate is released into the environment, its exposure potential will be reduced through biodegradation under aerobic and anaerobic conditions.

Rationale: Although dibutyl sebacate may cause moderate eye irritation, the effects are reversible, thereby reducing concern for longer-term effects. TSCA conditions of use would be unlikely to result in frequent eye exposure because use patterns do not involve intentional eye exposure. Workers could be exposed during processing, manufacturing, distribution, use, and disposal through handling and splashing or hand-to-face and eye contact. Other uses covered under TSCA, especially consumer uses in cleaning and furnishing care products, potential use in finger paints, and laundry and dishwashing products, would be unlikely to result in more than incidental eye exposure. Eye irritation resulting from exposure in an occupational and consumer setting is mitigated by the reversible nature of the effects and furthermore by the strong likelihood that any exposures would be self-limiting, especially by those who experience eye irritation from eye exposure.

Conclusion: Based on an initial analysis of reasonably available hazard and exposure information, EPA concludes that the risk-based, screening-level review under 40 CFR 702.9(a)(1) does not support a finding that dibutyl sebacate meets the standard for a high-priority substance. The reasonably available hazard and exposure information described above provides sufficient information to support this finding. EPA does not find that unlikely, infrequent, and temporary occurrence of potential moderate eye irritation meets the standard for a high-priority substance (i.e., that the substance "may present an unreasonable risk of injury to health").

8.2. Persistence and Bioaccumulation

Approach: EPA has evaluated both the persistence and bioaccumulation potential of dibutyl sebacate based on a set of EPA and internationally accepted measurement tools and benchmarks that are indicators of persistence and bioaccumulation potential (described in Section 6). These endpoints are key components in evaluating a chemical's persistence and bioaccumulation potential.

Rationale: EPA's review of experimental data indicates dibutyl sebacate is readily biodegradable under aerobic conditions, with greater than 60 percent biodegradation expected within 10 days, and predicted to biodegrade under anaerobic conditions (Section 6.3.1). EPA's EPI Suite models indicate a low potential for bioaccumulation and bioconcentration (Section 6.3.2).

Conclusion: Based on an analysis of reasonably available information on persistence and bioaccumulation, EPA concludes that the screening level review under 40 CFR 702.9(a)(2) does not support a finding that dibutyl sebacate meets the standard for a high-priority substance. The reasonably available persistence and bioaccumulation information described above provides sufficient information to support this finding.

8.3. Potentially Exposed or Susceptible Subpopulations

Approach: 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 of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly." EPA identified workers engaged in the manufacturing, processing, distribution, use, and disposal of dibutyl sebacate as a potentially exposed or susceptible subpopulation (described in more detail in Section 7). EPA also identified children as a population that may experience greater exposure to dibutyl sebacate than the general population during use of art and hobby supplies, finger paints, or modelling clay. Consumers are also a potentially exposed subpopulation because of their use of products such as cleaning and furnishing care products, laundry and dishwashing products, and ink, toner, and colorants products, as shown in Table 3.

Rationale: EPA expects workers and consumers to have a higher exposure to dibutyl sebacate than the general population. Higher exposure to children (and adults working closely with children) could result from use of art and hobby supplies, finger paints, or modelling clay containing dibutyl sebacate, which might lead to inadvertent eye contact. Because of the chemical's low-concern hazard properties, this exposure does not pose a significant increase in risk.

Conclusion: Based on the Agency's understanding of the conditions of use and expected users such as potentially exposed or susceptible populations, EPA concludes that the screening-level review under 40 CFR 702.9(a)(3) does not support a finding that dibutyl sebacate meets the standard for a high-priority substance. The conditions of use could result in increased in exposures to certain populations. Even in light of this finding, the consistently low-concern hazard profile of dibutyl sebacate provides sufficient evidence to support a finding of low concern. The reasonably available information on conditions of use, hazard, and exposure described above provides sufficient information to support this finding.

8.4. Storage near Significant Sources of Drinking Water

Approach: In Sections 6 and 7 of this document, EPA explains its evaluation of the elements of risk relevant to the storage of dibutyl sebacate near significant sources of drinking water. EPA focused primarily on the chemical's potential human health hazards, including to potentially exposed or susceptible subpopulations, and environmental fate properties, and explored a scenario of a release to a drinking water source. EPA also investigated whether the chemical was monitored for and detected in a range of environmental media. This requirement to consider storage near significant sources of drinking water is unique to prioritization under TSCA Section 6(b)(1)(A).

Rationale: In terms of health hazards, dibutyl sebacate is expected to present low concern to the general population, including susceptible subpopulations, across a spectrum of health endpoints.

In the event of an accidental release into a surface drinking water source, dibutyl sebacate has limited solubility in water, which decreases its potential for exposure via ingestion of contaminated drinking water relative to more soluble substances. In the event of an accidental release to land, the estimated log K_{oc} indicates dibutyl sebacate is expected to adsorb onto soil and sediment rather than be transported through soil to surface, ground or well water supplies. The fate and transport evaluation indicates dibutyl sebacate is predicted to biodegrade under aerobic and anaerobic conditions and unlikely to bioaccumulate (see Section 6.3).

A sudden release of large quantities of the chemical near a drinking water source could have immediate effects on the usability of a surface drinking water source. If such a release were to occur, two primary factors would operate together to reduce concern. First, the chemical would be expected to present low concern to the general population, including susceptible subpopulations, across a spectrum of health endpoints (see Section 6). Second, dibutyl sebacate has low water solubility, would likely bind to sediments, and would degrade in aerobic and anaerobic environments (see Section 6). Together, these factors mean that any exposures to this chemical through drinking water sources would be short-lived, and that if ingestion were to take place, concern for adverse health effects would be low.

EPA also explored whether the chemical had been identified as a concern under U.S. environmental statutes in the past. EPA searched lists of chemicals and confirmed that dibutyl sebacate does not appear on these lists. The lists reviewed include EPA's List of Lists (https://www.epa.gov/sites/production/files/2015-03/documents/list_of_lists.pdf). EPA also searched the lists of chemicals included in the National Primary Drinking Water Regulations and the Unregulated Contaminant Monitoring Rule (UCMR) under the Safe Drinking Water Act (SDWA).

Conclusion: Based on a qualitative review of a potential release near a significant source of drinking water, EPA concludes that the screening-level review of dibutyl sebacate under 40 CFR 702.9(a)(4) does not support a finding that dibutyl sebacate meets the standard for a high-priority substance. The reasonably available information on storage near significant sources of drinking water described above provides sufficient information to support these findings.

8.5. Conditions of Use or Significant Changes in Conditions of Use of the Chemical Substance

Approach: EPA evaluated the conditions of use for dibutyl sebacate and related potential exposures.

Rationale: EPA evaluated the conditions of use of dibutyl sebacate (see Section 5 and Appendix A) and found it to have a broad range of conditions of use. EPA expects that even if the conditions of use were to expand beyond activities that are currently known, intended and likely, the outcome of the screening review would likely not change and would not alter the Agency's conclusion of low concern. EPA bases this expectation on dibutyl sebacate's consistently low-concern hazard characteristics across the spectrum of hazard endpoints and regardless of a change in the nature or extent of its use and resultant increased exposures.

Conclusion: EPA's qualitative evaluation of potential risk does not support a finding that dibutyl sebacate meets the standard for a high-priority substance, based on its low-hazard profile under the current conditions of use. EPA concludes that even if conditions of use broaden, resulting in an increase in the frequency or amount of exposures, the analysis conducted to support the screening-level review under 40 CFR 702.9(a)(5) would not change significantly. In particular, the analysis of concern for hazard, which forms an important basis for EPA's findings, would not be impacted by a change in conditions of use. Therefore, such changes would not support a finding that dibutyl sebacate meets the standard for a high-priority substance. The reasonably available information on conditions of use, or significant changes in conditions of use described above provides sufficient information to support this finding.

8.6. The Volume or Significant Changes in Volume of the Chemical Substance Manufactured or Processed

Approach: EPA evaluated the current production volumes of dibutyl sebacate (Section 7.1) and related potential exposures (Section 7.2 through 7.4).

Rationale: EPA used reasonably available information on production volume (see Appendix A) in considering potential risk. It is possible that designation of dibutyl sebacate as a low-priority substance could result in increased use and higher production volumes. EPA expects, however, that any changes in dibutyl sebacate's production volume would not alter the Agency's assessment of low concern given the chemical's low-hazard profile of the chemical. EPA bases this expectation on dibutyl sebacate's consistently low-concern hazard characteristics across the spectrum of hazard endpoints. This expectation would apply, even with a significant change in the volume of the chemical manufactured or processed and resultant increased exposures.

Conclusion: Based on this screening criteria under 40 CFR 702.9(a)(6), EPA concludes that even if production volumes increase, resulting in an increase in the frequency or level of exposure, dibutyl sebacate does not meet the standard for a high-priority substance. The reasonably available information on production volume, or significant changes in production volume described above provides sufficient information to support this finding.

8.7. Other Considerations

EPA did not identify other considerations for the screening review to support the final designation of dibutyl sebacate as a low-priority substance.

9. Final Designation

Based on a risk-based screening-level review of the chemical substance and relevant information received from the public and other information as appropriate and consistent with TSCA section 26(h), (i) and (j), EPA concludes that dibutyl sebacate does not meet the standard for a high-priority substance. The reasonably available information described above provides sufficient information to support this finding. Accordingly, EPA is designating dibutyl sebacate as a low-priority substance.

Appendix A: Conditions of Use Characterization

EPA gathered information on and related to conditions of use including uses of the chemical, products in which the chemical is used, types of users, and status (e.g., known, regulated).

A.1. CDR Manufacturers and Production Volume

The Chemical Data Reporting (CDR) rule (previously known as the Inventory Update Rule, or IUR), under TSCA section 8, requires manufacturers (including importers) to report information on the chemical substances they produce domestically or import into the U.S., generally above a reporting threshold of 25,000 lb. per site per year. According to the 2016 Chemical Data Reporting (CDR) database, eight companies manufactured or imported dibutyl sebacate at eight sites for reporting year 2015.

Table presents the historic production volume of dibutyl sebacate from the CDR (previously known as the Inventory Update Rule, or IUR) from 1986-2015. In reporting years 1986, and 1998-2014, aggregate production volume for dibutyl sebacate was between 1,000,000 lbs. and 10,000,000 lbs. In reporting years 1990, 1994 and 2015, aggregate product volume was comparatively less than other reporting years, at 500,000 lbs. to 1,000,000 lbs. In general, since 2011, production volume has remained relatively stable, with a slight decrease from 2014-2015.

Table A.1: 1986-2015 National Production Volume Data for Dibutyl Sebacate (Non-Confidential Production Volume in Pounds)

1986	1990	1994	1998	2002	2006	2011	2012	2013	2014	2015
>1M – 10M	>500K – 1M	>500K – 1M	>1M – 10M	>1M – 10M	1M – 10M	1M – 10M	1M – 10M	1M – 10M	1M – 10M	500K – 1M

Source(s):
EPA (2018a; 2017b; 2006; 2002, 2002)
Note(s):
K = Thousand; M = Million

A.2. Uses

A.2.1 Methods for Uses Products Table

Table A.3 provides a list of known uses of dibutyl sebacate, organized by category of use. To compile the uses, EPA searched publicly available databases listed in Table A.2 and conducted additional internet searches to clarify uses. Search terms differed among databases because of different search term requirements for each database (i.e., some databases search by CASRN while others search by chemical name).

Table A.2: Sources Searched for Uses of Dibutyl Sebacate

Title	Author and Year	Search Term(s)	Found Use Information? [1]
Sources searched for all use reports			
California Links to Pesticides Data	California Dept of Pesticide Regulation (2013)	Dibutyl sebacate	No
Canada Chemicals Management Plan information sheets	Government of Canada (2018)	Dibutyl sebacate	No
Chemical and Product Categories (CPCat)	CPCat (2019)	109-43-3	Yes
ChemView [2]	EPA (2018a)	109-43-3	Yes
Children's Safe Product Act Reported Data	Washington State Dept. of Ecology (2018)	109-43-3	No
Consumer Product Information Database (CPID)	DeLima Associates (2018)	109-43-3	No
Danish surveys on chemicals in consumer products	Danish EPA (2018)	Dibutyl sebacate	No
Datamyne	Descartes Datamyne (2018)	Dibutyl sebacate	No
DrugBank	DrugBank (2018)	109-43-3; Dibutyl sebacate	No
European Chemicals Agency (ECHA) Registration Dossier	EHCA (2018)	109-43-3	Yes
eChemPortal [2]	OECD (2018)	109-43-3	No
Envirofacts [2]	EPA (2018b)	109-43-3	No
Functional Use Database (FUse)	EPA (2017a)	109-43-3	No
Kirk-Othmer Encyclopedia of Chemical Technology	Kirk-Othmer (2006)	Dibutyl sebacate	No
Non-Confidential 2016 Chemical Data Reporting (CDR)	EPA (2017b)	109-43-3	Yes
PubChem Compound	Kim et al. (2016)	109-43-3	Yes
Safer Chemical Ingredients List (SCIL)	EPA (2018d)	109-43-3	Yes
Synapse Information Resources[2]	Synapse Information Resources (2009)	109-43-3	Yes

Table A.2: Sources Searched for Uses of Dibutyl Sebacate			
Title	**Author and Year**	**Search Term(s)**	**Found Use Information?** [1]
Resource Conservation and Recovery Act (RCRA)	EPA (2018c)	109-43-3	No
Scorecard: The Pollution Information Site	GoodGuide (2011)	109-43-3	No
Skin Deep Cosmetics Database	EWG (2018)	109-43-3; Dibutyl sebacate	No
Toxics Release Inventory (TRI)	EPA (2018e)	109-43-3	No
TOXNET [2]	NLM (2018)	109-43-3	Yes
Ullmann's Encyclopedia of Industrial Chemistry	Ullmann's (2000)	Dibutyl sebacate	No
Additional sources identified from reasonably available information			
Agency for Toxic Substances and Disease Registry (ATSDR)	ATSDR (1995)	Incidentally identified while researching details of this chemical's uses and products.	Yes
Amazon	Amazon.com (2018)		
Ceramic Industry	Ceramic Industry (2018)		
Eastman Chemical Company	Eastman Chemical Company (2017)		
Electronics Cooling	Mohapatra (2006)		
Pfizer	Pfizer (2016)		
Note(s): 1. If use information was found in the resource, it will appear in Table unless otherwise noted. 2. This source is a group of databases; thus the exact resource(s) it led to will be cited instead of the database as whole.			

The U.S. Patent and Trademark Office has an online database that shows 5,290 patents referencing "dibutyl sebacate" (USPTO 2018). Although patents could be useful in determining reasonably foreseen uses, it is difficult to confirm whether any of the patented technologies are currently in use. Uses inferred from patents containing dibutyl sebacate were not included in Table A.3. Note that the uses in Table A.3 that are covered under TSCA are included in Section 5, Table 3 of this document.

A.2.2 Uses of Dibutyl Sebacate

Table A.3: Uses of Dibutyl Sebacate		
Use	**Expected Users**	**Description of Use and References**
TSCA Conditions of Use: Cleaning Products		
Air freshener	Consumer	Reported to the ECHA database (2018) The ECHA registration dossier reports use of dibutyl sebacate in aerosol and non-aerosol air freshener products, including heated products including candles, diffusers. No further information about this specific use could be found and it is unknown whether this is an ongoing use in the United States. Expected users are consumer based on inclusion in ECHA's consumer uses.
Automotive care products	Consumer, commercial, industrial	Reported to the ECHA database (2018) The ECHA registration dossier reports use of dibutyl sebacate in washing and cleaning automotive care products, in spray and liquid forms, and in professional and industrial vehicle spray, rinse cleaning and wash products. No further information about this specific use could be found and it is unknown whether this is an ongoing use in the United States. Expected users are consumer, commercial and industrial based on inclusion in ECHA's consumer uses, uses by professional workers and uses at industrial sites.
Bleach products	Consumer	Reported to the ECHA database (2018) The ECHA registration dossier reports use of dibutyl sebacate in washing and cleaning bleach products, in powder, liquid and tablets forms. No further information about this specific use could be found and it is unknown whether this is an ongoing use in the United States. Expected users are consumer based on inclusion in ECHA's consumer uses.
Boat cleaners	Commercial, industrial	Reported to the ECHA database (2018) The ECHA registration dossier reports use of dibutyl sebacate in professional boat cleaning and washing product, in spray and wipe forms. No further information about this specific use could be found and it is unknown whether this is an ongoing use in the United States. Expected users are commercial and industrial based on inclusion in ECHA's uses by professional workers and uses at industrial sites.

Table A.3: Uses of Dibutyl Sebacate		
Use	**Expected Users**	**Description of Use and References**
Carpet cleaners	Consumer, commercial	Reported to the ECHA database (2018) The ECHA registration dossier reports use of dibutyl sebacate in washing and cleaning carpet cleaner products, in spray and liquid forms, and in professional carpet cleaning products. No further information about this specific use could be found and it is unknown whether this is an ongoing use in the United States. Expected users are consumer and commercial based on inclusion in ECHA's consumer uses and uses by professional workers.
Cleaning wipes	Consumer	Reported to the ECHA database (2018) The ECHA registration dossier reports use of dibutyl sebacate in washing and cleaning wipe products for use in the bathroom, kitchen and floor. No further information about this specific use could be found and it is unknown whether this is an ongoing use in the United States. Expected users are consumer based on inclusion in ECHA's consumer uses.
Descaler	Consumer, commercial	Reported to the ECHA database (2018) The ECHA registration dossier reports use of dibutyl sebacate in washing and cleaning descaler products and in professional descaling agents. No further information about this specific use could be found and it is unknown whether this is an ongoing use in the United States. Expected users are consumer and commercial based on inclusion in ECHA's consumer uses and uses by professional workers.

Table A.3: Uses of Dibutyl Sebacate		
Use	**Expected Users**	**Description of Use and References**
Dishwash	Consumer, commercial	Reported to the ECHA database (2018) The ECHA registration dossier reports use of dibutyl sebacate in washing and cleaning hand dishwashing products, in liquid form, and professional dishwash product and rinse aid. No further information about this specific use could be found and it is unknown whether this is an ongoing use in the United States. Expected users are consumer and commercial based on inclusion in ECHA's consumer uses and uses by professional workers.
Drain cleaner/ unblocker	Consumer, commercial	Reported to the ECHA database (2018) The ECHA registration dossier reports use of dibutyl sebacate in washing and cleaning drain products, in powder and gel forms, and in professional drain unblockers. No further information about this specific use could be found and it is unknown whether this is an ongoing use in the United States. Expected users are consumer and commercial based on inclusion in ECHA's consumer uses and uses by professional workers.
Fabric conditioners	Consumer, commercial	Reported to the ECHA database (2018) The ECHA registration dossier reports use of dibutyl sebacate in washing and cleaning fabric softener products, in liquid form and professional laundry conditioner (softener). No further information about this specific use could be found and it is unknown whether this is an ongoing use in the United States. Expected users are consumer and commercial based on inclusion in ECHA's consumer uses and uses by professional workers.
Floor cleaner, polish, stripper	Commercial	Reported to the ECHA database (2018) The ECHA registration dossier reports use of dibutyl sebacate in professional floor care products, in spray and wipe forms and floor polish and stripper products. No further information about this specific use could be found and it is unknown whether this is an ongoing use in the United States. Expected users are commercial based on inclusion in ECHA's uses by professional workers.

Table A.3: Uses of Dibutyl Sebacate		
Use	**Expected Users**	**Description of Use and References**
Furniture cleaner (leather care)	Consumer	Reported to the ECHA database (2018) The ECHA registration dossier reports use of dibutyl sebacate in "furniture floor and leather care" products, in spray and liquid forms. No further information about this specific use could be found and it is unknown whether this is an ongoing use in the United States. Expected users are consumer based on inclusion in ECHA's consumer uses.
Furniture cleaner (wooden)	Commercial	Reported to the ECHA database (2018) The ECHA registration dossier reports use of dibutyl sebacate in professional wooden furniture care products, in spray and wipe forms. No further information about this specific use could be found and it is unknown whether this is an ongoing use in the United States. Expected users are commercial based on inclusion in ECHA's uses by professional workers.
General purpose cleaner	Commercial	Reported to the ECHA database (2018) The ECHA registration dossier reports use of dibutyl sebacate in professional general purpose cleaners. No further information about this specific use could be found and it is unknown whether this is an ongoing use in the United States. Expected users are commercial based on inclusion in ECHA's uses by professional workers.
Glass cleaner	Commercial	Reported to the ECHA database (2018) The ECHA registration dossier reports use of dibutyl sebacate in professional glass cleaner, in spray and wipe forms. No further information about this specific use could be found and it is unknown whether this is an ongoing use in the United States. Expected users are commercial based on inclusion in ECHA's uses by professional workers.
Ironing aid	Consumer	Reported to the ECHA database (2018) The ECHA registration dossier reports use of dibutyl sebacate in ironing aids. No further information about this specific use could be found and it is unknown whether this is an ongoing use in the United States. Expected users are consumer based on inclusion in ECHA's consumer uses.

Table A.3: Uses of Dibutyl Sebacate		
Use	**Expected Users**	**Description of Use and References**
Kitchen cleaner	Commercial	Reported to the ECHA database (2018) The ECHA registration dossier reports use of dibutyl sebacate in professional kitchen surface cleaners. No further information about this specific use could be found and it is unknown whether this is an ongoing use in the United States. Expected users are commercial based on inclusion in ECHA's uses by professional workers.
Laundry detergent	Consumer, commercial, industrial	Dionisio et al. (2015); Reported to the ECHA database (2018) CPCat lists the use of dibutyl sebacate in cleaning washing detergent, as a surfactant. The ECHA registration dossier reports use of dibutyl sebacate in laundry cleaning and washing products both in powder and liquid forms, and in semi-automatic processes. No further information about this specific use could be found and it is unknown whether this is an ongoing use in the United States. Expected users are industrial based on inclusion in industrial sector categories and consumer and commercial based on inclusion in ECHA's consumer uses and uses by professional workers.
Leather treatment products	Consumer, commercial	Reported to the ECHA database (2018) The ECHA registration dossier reports use of dibutyl sebacate in leather treatment products; and professional leather care products. No further information about this specific use could be found and it is unknown whether this is an ongoing use in the United States. Expected users are consumer and commercial based on inclusion in ECHA's consumer uses and uses by professional workers.
Machine dishwasher cleaner	Consumer, commercial	Reported to the ECHA database (2018) The ECHA registration dossier reports use of dibutyl sebacate in washing and cleaning machine dishwashing products, in powder, liquid and tablet forms and in professional dishwashing products intended for semi-automatic use. No further information about this specific use could be found and it is unknown whether this is an ongoing use in the United States. Expected users are consumer and commercial based on inclusion in ECHA's consumer uses and uses by professional workers.

Table A.3: Uses of Dibutyl Sebacate		
Use	**Expected Users**	**Description of Use and References**
Metal cleaner	Commercial	Reported to the ECHA database (2018) The ECHA registration dossier reports use of dibutyl sebacate in professional metal cleaning agents, including silver and copper polishes. No further information about this specific use could be found and it is unknown whether this is an ongoing use in the United States. Expected users are commercial based on inclusion in ECHA's uses by professional workers.
Oven and grill cleaners	Consumer, commercial	Reported to the ECHA database (2018) The ECHA registration dossier reports use of dibutyl sebacate in cleaning and washing over cleaners, in spray and trigger forms, and in professional oven and grill cleaners. No further information about this specific use could be found and it is unknown whether this is an ongoing use in the United States. Expected users are consumer and commercial based on inclusion in ECHA's consumer uses and uses by professional workers.
Polishes and wax blends	Consumer, commercial	Reported to the ECHA database (2018) The ECHA registration dossier reports use of dibutyl sebacate in polishes and wax blends. No further information about this specific use could be found and it is unknown whether this is an ongoing use in the United States. Expected users are consumer and commercial based on inclusion in ECHA's consumer uses and uses by professional workers.

Table A.3: Uses of Dibutyl Sebacate		
Use	**Expected Users**	**Description of Use and References**
Stain remover	Commercial	Reported to the ECHA database (2018) The ECHA registration dossier reports use of dibutyl sebacate in professional laundry stain remover products. No further information about this specific use could be found and it is unknown whether this is an ongoing use in the United States. Expected users are commercial based on inclusion in ECHA's uses by professional workers.
Stainless steel cleaner	Commercial	Reported to the ECHA database (2018) The ECHA registration dossier reports use of dibutyl sebacate in professional stainless steel care. No further information about this specific use could be found and it is unknown whether this is an ongoing use in the United States. Expected users are commercial based on inclusion in ECHA's uses by professional workers.
Surface cleaner	Consumer	Reported to the ECHA database (2018) The ECHA registration dossier reports use of dibutyl sebacate in surface cleaner products, in liquid, powder, gel and spray forms. No further information about this specific use could be found and it is unknown whether this is an ongoing use in the United States. Expected users are consumer based on inclusion in ECHA's consumer uses.
Toilet cleaners	Consumer	Reported to the ECHA database (2018) The ECHA registration dossier reports use of dibutyl sebacate in cleaning and washing toilet cleaner products, in powder, liquid, gel and tablet forms. No further information about this specific use could be found and it is unknown whether this is an ongoing use in the United States. Expected users are consumer based on inclusion in ECHA's consumer uses.
Vehicle dewaxing	Commercial, industrial	Reported to the ECHA database (2018) The ECHA registration dossier reports use of dibutyl sebacate in vehicle dewaxing product. No further information about this specific use could be found and it is unknown whether this is an ongoing use in the United States. Expected users are commercial and industrial based on inclusion in ECHA's uses by professional workers and uses at industrial sites.

Table A.3: Uses of Dibutyl Sebacate		
Use	**Expected Users**	**Description of Use and References**
TSCA Conditions of Use: Construction		
Boat and ship construction	Industrial/ commercial/ consumer	CPCat (2019) CPCat lists the use of dibutyl sebacate in the building and repairing of ships, floating structures, and pleasure and sporting boats. No further information is available on its use in this industry. The expected users are assumed to be industrial, commercial, and consumer.
Building construction	Consumer, commercial, industrial	CPCat (2019); Reported to the ECHA database (2018) CPCat lists the use of dibutyl sebacate in the construction of buildings and "complete constructions and part thereof civil." and in construction materials. The ECHA registration dossier reports use of dibutyl sebacate in consumer and professional building construction adhesives and chemicals. No further information about this specific use could be found and it is unknown whether this is an ongoing use in the United States. Expected users are commercial and industrial based on inclusion in ECHA's uses by professional workers and uses at industrial sites.
Building materials	Industrial	CPCat (2019) CPCat lists the use of dibutyl sebacate in construction materials and plastic construction materials. No further information is available on its use in this industry. Expected users are industrial based on inclusion in industrial sector categories.
Flooring materials	Industrial/ commercial/ consumer	CPCat (2019) CPCat lists the use of dibutyl sebacate in flooring materials (joint-less floors). No further information is available on this use. The expected users are assumed to be industrial, commercial, and consumer.
Road construction	Commercial	Reported to the ECHA database (2018) The ECHA registration dossier reports use of dibutyl sebacate in road and construction applications. No further information about this specific use could be found and it is unknown whether this is an ongoing use in the United States. Expected users are commercial based on inclusion in ECHA's uses by professional workers.

Table A.3: Uses of Dibutyl Sebacate		
Use	**Expected Users**	**Description of Use and References**
TSCA Conditions of Use: Cosmetics and Personal Care Products		
Fragrances[1]	Consumer	CPCat (2019) CPCat lists the use of dibutyl sebacate in consumer product fragrances available for consumer use. Expected users are consumer based on its classification in product categories.
TSCA Conditions of Use: Fertilizer and Plant Products		
Agrochemicals	Consumer, commercial	Reported to the ECHA database (2018) The ECHA registration dossier reports use of dibutyl sebacate in agrochemicals, fertilizers. No further information about this specific use could be found and it is unknown whether this is an ongoing use in the United States. Expected users are consumer and commercial based on inclusion in ECHA's consumer uses and uses by professional workers.
Plant protection products	Consumer, commercial	Reported to the ECHA database (2018) The ECHA registration dossier reports use of dibutyl sebacate in plant protection products for outdoor and indoor spraying. No further information about this specific use could be found and it is unknown whether this is an ongoing use in the United States. Expected users are consumer and commercial based on inclusion in ECHA's consumer uses and uses by professional workers.
Pre-treated seeds	Consumer, commercial	Reported to the ECHA database (2018) The ECHA registration dossier reports use of dibutyl sebacate in the application of pre-treated seeds for outdoor use, and in the professional application of pre-treated seeds for indoor and outdoor use. No further information about this specific use could be found and it is unknown whether this is an ongoing use in the United States. Expected users are consumer and commercial based on inclusion in ECHA's consumer uses and uses by professional workers.
Seed treatment	Consumer, commercial	Reported to the ECHA database (2018) The ECHA registration dossier reports use of dibutyl sebacate in seed treatment products for outdoor use. No further information about this specific use could be found and it is unknown whether this is an ongoing use in the United States. Expected users are consumer and commercial based on inclusion in ECHA's consumer uses and uses by professional workers.

Table A.3: Uses of Dibutyl Sebacate		
Use	**Expected Users**	**Description of Use and References**
TSCA Conditions of Use: Food and Beverages		
Food and beverage manufacturing[2]	Industrial	Reported to the ECHA database (2018) The ECHA registration dossier reports use of dibutyl sebacate in industrial washing and cleaning and in food and beverage processing. No further information about this specific use could be found and it is unknown whether this is an ongoing use in the United States. Expected users are industrial based on inclusion in ECHA's uses at industrial sites.
Food-contact metallic article manufacturing[2]	Industrial	Synapse Information Resources (2009) Synapse Information Resources lists the use of dibutyl sebacate in food-contact coatings and as a surface lubricant for the manufacturing of food-contact metallic articles. No further information could be found on this use. Expected user is not stated, but it is most likely industrial for the manufacturing of food contact metallic articles.
Food-contact rubber articles[2]	Industrial/ commercial/ consumer	Synapse Information Resources (2009) Synapse Information Resources lists the use of dibutyl sebacate as a plasticizer in food-contact rubber articles for repeated use. No further information could be found on this use. The expected users are assumed to be industrial, commercial, and consumer.
Food packaging adhesives[2]	Industrial/ commercial/ consumer	Synapse Information Resources (2009) Synapse Information Resources lists the use of dibutyl sebacate in adhesives. No further information could be found on this use. The expected users are assumed to be industrial, commercial, and consumer.
Food paper/paperboard packing[2]	Industrial/ commercial/ consumer	Synapse Information Resources (2009) Synapse Information Resources lists the use of dibutyl sebacate in "paper/paperboard in contact with aq./fatty foods." The expected users are assumed to be industrial, commercial, and consumer.

Table A.3: Uses of Dibutyl Sebacate		
Use	**Expected Users**	**Description of Use and References**
TSCA Conditions of Use: Fuel		
Motor oil	Industrial/ commercial/ consumer	Synapse Information Resources (2009) Synapse Information Resources lists dibutyl sebacate in motor oils. No further information about this specific use could be found. The expected users are assumed to be industrial, commercial, and consumer.
Oil and gas drilling	Commercial, industrial	Reported to the ECHA database (2018) The ECHA registration dossier reports use of dibutyl sebacate in oil and gas field drilling and production operations. No further information about this specific use could be found and it is unknown whether this is an ongoing use in the United States. Expected users are commercial and industrial based on inclusion in ECHA's uses by professional workers and uses at industrial sites.
Torpedo fuel	Industrial	ATSDR (1995); CPCat (2019) CPCat lists the use of dibutyl sebacate in a product that is used as torpedo fuel by the United States military. The current use and manufacturing of this product is unknown. According to ATSDR, expected users of this chemical are industrial as the product is exclusively used by U.S. Navy personnel.
TSCA Conditions of Use: Manufacturing		
Adhesive manufacturing	Industrial	CPCat (2019) CPCat lists the use of dibutyl sebacate in adhesive manufacturing. No further information is available on its function in industrial adhesive manufacturing. However, other entries in this table show evidence of dibutyl sebacate in end-use adhesives, sealants, paint adhesives, food packaging adhesives, and building construction adhesives. Expected users are industrial based on inclusion in industrial sector categories.

Table A.3: Uses of Dibutyl Sebacate		
Use	**Expected Users**	**Description of Use and References**
Chemicals manufacturing	Industrial	CPCat (2019); Reported to the ECHA database (2018) CPCat lists the use of dibutyl sebacate in the manufacture of "chemicals and chemical products." The ECHA registration dossier reports use of dibutyl sebacate in chemical production. No further information about this specific use could be found and it is unknown whether this is an ongoing use in the United States. Expected users are industrial based on inclusion in industrial sector categories and inclusion in ECHA's uses at industrial sites
Electrical machinery manufacturing	Industrial	CPCat (2019) CPCat lists the use of dibutyl sebacate in the "manufacture of electrical machinery, equipment and apparatus." No further information is available on its use in this industry. Expected users are industrial based on inclusion in industrial sector categories.
Explosives manufacturing	Commercial	Reported to the ECHA database (2018) The ECHA registration dossier reports use of dibutyl sebacate in explosives manufacturing. No further information about this specific use could be found and it is unknown whether this is an ongoing use in the United States. Expected users are commercial based on inclusion in ECHA's uses by professional workers
Furniture manufacturing	Industrial	CPCat (2019) CPCat lists the use of dibutyl sebacate in the manufacture of furniture. No further information is available on its use in this industry. Expected users are industrial based on inclusion in industrial sector categories.
Machinery and equipment manufacturing	Industrial	CPCat (2019) CPCat lists the use of dibutyl sebacate in the manufacture of machinery and equipment. No further information is available on its use in this industry. Expected users are industrial based on inclusion in industrial sector categories.

Table A.3: Uses of Dibutyl Sebacate		
Use	**Expected Users**	**Description of Use and References**
Metals manufacturing	Industrial	CPCat (2019); Synapse Information Resources (2009) CPCat lists the use of dibutyl sebacate in the manufacturing of "fabricated metal products, except machinery." Synapse Information Resources lists the use of dibutyl sebacate as a lubricant in metalworking. No further information is available on its use in this industry. Expected users are industrial based on inclusion in industrial sector categories.
Paint and varnish manufacturing	Industrial	CPCat (2019) CPCat lists the reported use of dibutyl sebacate in the manufacture of "paints, varnishes, and other similar coating, print." Expected users are industrial based on inclusion in industrial sector categories.
Photographic film paper, plate, and chemical manufacturing	Industrial	EPA (2017b) CDR identified the use of dibutyl sebacate as a solvent in processing – incorporation into product formulation or mixture, in photographic film paper, plate and chemical manufacturing. Expected users are industrial based on identification in CDR's industrial processing and use report.
Plastic product, material and resin manufacturing	Industrial	EPA (2017b); Reported to the ECHA database (2018) CDR identified the use of dibutyl sebacate as a plasticizer in processing – incorporation into formulation, mixture or reaction product, and article, in plastics products, plastic material and resin manufacturing. The ECHA registration dossier reports use of dibutyl sebacate as an additive in plastics. Expected users are industrial based on inclusion in ECHA's uses at industrial sites.
Polymer processing	Industrial	Reported to the ECHA database (2018) The ECHA registration dossier reports use of dibutyl sebacate in polymer processing. No further information about this specific use could be found and it is unknown whether this is an ongoing use in the United States. Expected users are industrial based on inclusion in ECHA's uses at industrial sites.

Table A.3: Uses of Dibutyl Sebacate		
Use	**Expected Users**	**Description of Use and References**
Printing ink manufacturing	Industrial	EPA (2017b) CDR identified the use of dibutyl sebacate as a pigment in processing – incorporation into formulation, mixture or reaction product, in printing ink manufacturing. Expected users are industrial based on identification in CDR's industrial processing and use report.
Rubber product manufacturing	Industrial	EPA (2017b); CPCat (2019); Synapse Information Resources (2009); Reported to the ECHA database (2018) CDR identified the use of dibutyl sebacate as a plasticizer in processing – incorporation into article, and as a reactant, in rubber product manufacturing. CPCat lists the use of dibutyl sebacate in the manufacture of rubber and plastics products. Synapse Information Resources lists that dibutyl sebacate is used as a rubber softener. The ECHA registration dossier reports use of dibutyl sebacate in rubber production and processing. Expected users are industrial based on identification in CDR's industrial processing and use report.
Synthetic rubber manufacturing	Industrial	EPA (2017b) CDR identified the use of dibutyl sebacate as a plasticizer in processing as a reactant, in synthetic rubber manufacturing. Expected users are industrial based on identification in CDR's industrial processing and use report.
Textile and leather manufacturing	Industrial	Synapse Information Resources (2009); Reported to the ECHA database (2018) Synapse Information Resources lists the use of dibutyl sebacate as a fattening agent in textile and leather production. The ECHA registration dossier reports use of dibutyl sebacate in textile applications as a reactive processing aid. No further information about this specific use could be found and it is unknown whether this is an ongoing use in the United States. Expected users are industrial based on inclusion in ECHA's uses at industrial sites.
Transportation equipment manufacturing	Industrial	CPCat (2019) CPCat lists the reported use of dibutyl sebacate in the manufacture of "other transportation equipment." No further information is available on its use in this industry. Expected users are industrial based on inclusion in industrial sector categories.

Table A.3: Uses of Dibutyl Sebacate		
Use	**Expected Users**	**Description of Use and References**
Wholesale and retail trade	Industrial	EPA (2017b) CDR identified the use of dibutyl sebacate as a plasticizer and solvent in processing – incorporation into formulation, mixture or reaction product, and article, in wholesale and retail trade. Expected users are industrial based on identification in CDR's industrial processing and use report.
Windmill manufacturing	Industrial	CPCat (2019) CPCat lists the reported use of dibutyl sebacate in the manufacture of "windmills and parts of this." No further information is available on its use in this industry. Expected users are industrial based on inclusion in industrial sector categories.

Table A.3: Uses of Dibutyl Sebacate		
Use	**Expected Users**	**Description of Use and References**
TSCA Conditions of Use: Other Industrial Uses		
Agricultural crop, agricultural animal, hunting[3]	Industrial	CPCat (2019) CPCat lists the reported use of dibutyl sebacate as an agricultural crop, agricultural animals, and hunting. No further information is provided on current use and manufacturing. Expected users are industrial based on inclusion in industrial sector categories.
Ceramic extrusion	Industrial	Ceramic Industry (2018); Synapse Information Resources (2009) Synapse Information Resources lists the use of dibutyl sebacate in extrusion of ceramics. Ceramic extrusion is described as "the act or process of shaping by forcing through a die." Expected user is not stated, but it is most likely industrial for the cosmetics manufacturing.
Coatings	Commercial, industrial	Reported to the ECHA database (2018) The ECHA registration dossier reports use of dibutyl sebacate in coatings in various industrial and commercial processes. No further information about this specific use could be found and it is unknown whether this is an ongoing use in the United States. Expected users are commercial and industrial based on inclusion in ECHA's uses by professional workers and uses at industrial sites.
Dielectric liquid	Industrial	Mohapatra (2006); Synapse Information Resources (2009) Synapse Information Resources lists dibutyl sebacate as a dielectric liquid. Dielectric liquids are used as coolants for electronic. Expected users are industrial as this is used in the manufacturing of electronics.
Industrial cleaner	Industrial	Reported to the ECHA database (2018) The ECHA registration dossier reports use of dibutyl sebacate in industrial cleaners. No further information about this specific use could be found and it is unknown whether this is an ongoing use in the United States. Expected users are industrial based on inclusion in ECHA's uses at industrial sites.

Table A.3: Uses of Dibutyl Sebacate		
Use	**Expected Users**	**Description of Use and References**
Lubricant	Commercial, industrial	Reported to the ECHA database (2018) The ECHA registration dossier reports use of dibutyl sebacate in lubricants for miscellaneous industrial and commercial processes for vehicles or machinery. No further information about this specific use could be found and it is unknown whether this is an ongoing use in the United States. Expected users are commercial and industrial based on inclusion in ECHA's uses by professional workers and uses at industrial sites.
Metal treatment	Industrial	Reported to the ECHA database (2018) The ECHA registration dossier reports use of dibutyl sebacate in metal treatment coating product. No further information about this specific use could be found and it is unknown whether this is an ongoing use in the United States. Expected users are industrial based on inclusion in ECHA's uses at industrial sites.
Polyvinyl butyral resins	Commercial, industrial	Eastman Chemical Company (2017); Synapse Information Resources (2009) Dibutyl sebacate is listed as an ingredient component in a polyvinyl resin that is currently available for use. Polyvinyl butyral resin is a raw material that can be used in a variety of application including ceramic binders, inks/ dry toners, wood coatings, etc. Synapse Information Resources lists dibutyl sebacate as a plasticizer in polyvinyl butyral. Expected users are commercial and industrial, as the product information sheet lists that it can be used for commercial and industrial applications.
Printing and reproduction of recorded media	Industrial	CPCat (2019) CPCat lists the use of dibutyl sebacate in printing and reproduction of recorded media. Expected users are industrial based on inclusion in industrial sector categories.
Surfactant	Industrial	CPCat (2019) CPCat lists the reported use of dibutyl sebacate as a surface-active agent. Expected users are industrial based on inclusion in industrial sector categories.

Table A.3: Uses of Dibutyl Sebacate		
Use	**Expected Users**	**Description of Use and References**
Water treatment chemicals	Consumer, commercial, industrial	Reported to the ECHA database (2018) The ECHA registration dossier reports use of dibutyl sebacate in water treatment chemicals, and waste-water treatment, and in consumer water softener products, in powder, liquid and tablet forms. No further information about this specific use could be found and it is unknown whether this is an ongoing use in the United States. Expected users are commercial and industrial based on inclusion in ECHA's uses by professional workers and uses at industrial sites.
TSCA Conditions of Use: Miscellaneous		
Adhesives, sealants	Consumer	Reported to the ECHA database (2018) The ECHA registration dossier reports use of dibutyl sebacate in adhesives, sealants. No further information about this specific use could be found and it is unknown whether this is an ongoing use in the United States. Expected users are consumer based on inclusion in ECHA's consumer uses.
Deicing and anti-icing products	Consumer, commercial	Reported to the ECHA database (2018) The ECHA registration dossier reports use of dibutyl sebacate in deicing and anti-icing application products. No further information about this specific use could be found and it is unknown whether this is an ongoing use in the United States. Expected users are consumer and commercial based on inclusion in ECHA's consumer uses and uses by professional workers.
Fillers, putties, plasters, modelling clay	Consumer	Reported to the ECHA database (2018) The ECHA registration dossier reports use of dibutyl sebacate in fillers, putties, plasters, and modelling clay. No further information about this specific use could be found and it is unknown whether this is an ongoing use in the United States. Expected users are consumer based on inclusion in ECHA's consumer uses.
Finger paints	Consumer	Reported to the ECHA database (2018) The ECHA registration dossier reports use of dibutyl sebacate in finger paints. No further information about this specific use could be found and it is unknown whether this is an ongoing use in the United States. Expected users are consumer based on inclusion in ECHA's consumer uses.

Table A.3: Uses of Dibutyl Sebacate		
Use	**Expected Users**	**Description of Use and References**
Greases and lubricants	Consumer, commercial	Synapse Information Resources (2009); Reported to the ECHA database (2018) Synapse Information Resources lists dibutyl sebacate in greases. The ECHA registration dossier reports use of dibutyl sebacate in lubricants and greases, in vehicles and machinery. No further information about this specific use could be found and it is unknown whether this is an ongoing use in the United States. Expected users are consumer and commercial based on inclusion in ECHA's consumer uses and uses by professional workers
Ink, toner, and colorant products	Consumer, commercial	EPA (2017b); Reported to the ECHA database (2018) CDR identified the use of ink, toner, and colorant products containing dibutyl sebacate. The ECHA registration dossier reports use of dibutyl sebacate in ink and toners. Expected users are based on CDR's consumer/commercial classification and inclusion in ECHA's consumer uses.
Medical devices	Commercial	Reported to the ECHA database (2018) The ECHA registration dossier reports use of dibutyl sebacate in professionally used medical devices in spray and wipe processes. No further information about this specific use could be found and it is unknown whether this is an ongoing use in the United States. Expected users are commercial based on inclusion in ECHA's uses by professional workers.
Non-metal surface treatment products	Consumer	Reported to the ECHA database (2018) The ECHA registration dossier reports use of dibutyl sebacate in non-metal surface treatment products. No further information about this specific use could be found and it is unknown whether this is an ongoing use in the United States. Expected users are consumer based on inclusion in ECHA's consumer uses.

Table A.3: Uses of Dibutyl Sebacate		
Use	**Expected Users**	**Description of Use and References**
Paint adhesive and binding agent	Unknown	CPCat (2019) CPCat lists the use of dibutyl sebacate as a paint adhesive, binding agent. No further information is provided on current use and manufacturing. Expected users are unknown, due to the limited availability of information.
Paints, lacquers and varnishes	Consumer	CPCat (2019); Reported to the ECHA database (2018) CPCat lists the use of dibutyl sebacate in paints, lacquers, varnishes. The ECHA registration dossier reports use dibutyl sebacate in "coating and paints, thinners and paint removers." No further information about this specific use could be found and it is unknown whether this is an ongoing use in the United States. Expected users are consumer based on inclusion in ECHA's consumer uses.
Photographic supplies, film and photo chemicals	Consumer, Commercial	EPA (2017b); CPCat (2019) CDR identified the use of dibutyl sebacate in photographic supplies, film and photo chemicals containing dibutyl sebacate. CPCat lists the use of dibutyl sebacate as a photographic reprographic agent. Expected users are based on CDR's consumer/commercial classification.
Printing	Unknown	CPCat (2019) CPCat lists the use of dibutyl sebacate in printing inks. No further information is provided on current use and manufacturing. Expected users are unknown, due to the limited availability of information.
Surface treatment of metal	Unknown	CPCat (2019) CPCat lists the use of dibutyl sebacate in "other surface treatment of metal." No further information is provided on current use and manufacturing. Expected users are unknown, due to the limited availability of information.

Table A.3: Uses of Dibutyl Sebacate		
Use	**Expected Users**	**Description of Use and References**
Textile dyes	Consumer	Reported to the ECHA database (2018) The ECHA registration dossier reports use of dibutyl sebacate in "textile dyes, and impregnating products." No further information about this specific use could be found and it is unknown whether this is an ongoing use in the United States. Expected users are consumer based on inclusion in ECHA's consumer uses.
Non-TSCA Uses		
Biocidal products	Consumer	Reported to the ECHA database (2018) The ECHA registration dossier reports use of dibutyl sebacate in biocidal products including for pest control. No further information about this specific use could be found and it is unknown whether this is an ongoing use in the United States. Expected users are consumer based on inclusion in ECHA's consumer uses.
Cosmetics manufacturing	Industrial	Synapse Information Resources (2009) Synapse Information Resources lists the use of dibutyl sebacate as an emollient and film-former in cosmetics. Expected user is not stated, but it is most likely industrial for the cosmetics manufacturing.
Cosmetics products	Consumer	Reported to the ECHA database (2018) The ECHA registration dossier reports use of dibutyl sebacate in consumer end-use of cosmetics. No further information about this specific use could be found and it is unknown whether this is an ongoing use in the United States. Expected users are consumer based on inclusion in ECHA's consumer uses.
Food additive/ flavoring	Unknown	CPCat (2019); Synapse Information Resources (2009) CPCat lists the use of dibutyl sebacate as a food additive and flavoring. Synapse Information Resources lists dibutyl sebacate as a synthetic flavoring agent in food. The expected users are unknown, due to the limited availability of information.

Table A.3: Uses of Dibutyl Sebacate		
Use	**Expected Users**	**Description of Use and References**
Perfumes	Consumer	Synapse Information Resources (2009) Synapse Information Resources lists the use of dibutyl sebacate in perfumes. Expected users are consumer based on its classification in product categories.
Hand cleaner (skin disinfectant)	Commercial	Reported to the ECHA database (2018) The ECHA registration dossier reports use of dibutyl sebacate in professional hand cleaners (skin disinfectants). No further information about this specific use could be found and it is unknown whether this is an ongoing use in the United States. Expected users are commercial based on inclusion in ECHA's uses by professional workers.
Inactive drug ingredient	Industrial	CPCat (2019) CPCat lists the use of dibutyl sebacate as an inactive ingredient in a pharmaceutical drug and use in pharmaceutical medicine manufacturing. Expected users are industrial based on inclusion in industrial sector categories.
Insecticides	Consumer	Reported to the ECHA database (2018) The ECHA registration dossier reports use of dibutyl sebacate in insecticide and repellent products, in liquid and spray forms. No further information about this specific use could be found and it is unknown whether this is an ongoing use in the United States. Expected users are consumer based on inclusion in ECHA's consumer uses.
Pain medication	Consumer	Pfizer (2016) Dibutyl sebacate is listed as ingredient in a Troxyca ER, a medication currently available for use in the United States. The drug is used to treat severe pain. Expected users are consumer as the medication is a prescription pain medication that would be prescribed to consumers.

Table A.3: Uses of Dibutyl Sebacate		
Use		**Description of Use and References**
Pest control products	Consumer	Reported to the ECHA database (2018) The ECHA registration dossier reports use of dibutyl sebacate in pest control products, insecticides and repellents. No further information about this specific use could be found and it is unknown whether this is an ongoing use in the United States. Expected users are consumer based on inclusion in ECHA's consumer uses.
Pharmaceutical and medicine manufacturing	Industrial	EPA (2017b); Synapse Information Resources (2009) CDR identified the use of dibutyl sebacate as a plasticizer in processing – incorporation into formulation, mixture or reaction product, in pharmaceutical and medicine manufacturing. Synapse Information Resources lists the use of dibutyl sebacate in oral pharmaceuticals. Expected users are industrial based on identification in CDR's industrial processing and use report.
Skin cleansing oil	Consumer	Amazon.com (2018) Dibutyl sebacate is listed as an ingredient for a skin cleansing oil product currently available for use and purchase. Expected users are consumer as the product is available for consumer purchase.
Children's Products CDR reports did not include any uses in children's products. However, the ECHA registration dossier includes use in finger paints, which are likely to be used by children.		
Recycling and Disposal In the 2016 CDR, one facility reported recycling dibutyl sebacate (e.g., recycled, remanufactured, reprocessed, or reused). Two facilities reported not recycling dibutyl sebacate, two facilities withheld recycling information, and three facilities reported this information as CBI (EPA 2017b).		
Note(s): 1. Potentially a non-TSCA use as category may contain both TSCA and non-TSCA uses; however, because information is insufficient to determine, it is assumed to be covered by TSCA. 2. TSCA product based on the assumption that the chemical is used in the manufacturing of products and not intended to be a component of food. 3. Assumed to be a mix of TSCA and non-TSCA products. It is expected that more specifically defined uses in the table are representative of the uses that fall into this category.		

A.3 References

Agency for Toxic Substances and Disease Registry (ATSDR). (1995). Toxicological Profile for Otto Fuel II and its Components.

Amazon.com. (2018). Bb Laboratories Deep Clear Cleansing Oil 150ml. Retrieved from https://www.amazon.com/Laboratories-Deep-Clear-Cleansing-150ml/dp/B004M801KA

California Dept of Pesticide Regulation. (2013). DPR Databases. Retrieved from https://www.cdpr.ca.gov/dprdatabase.htm

Ceramic Industry. (2018). Extrusion Basics. Retrieved from https://www.ceramicindustry.com/articles/87808-extrusion-basics

Danish EPA. (2018). Danish surveys on chemicals in consumer products. Retrieved from https://eng.mst.dk/chemicals/chemicals-in-products/consumers-consumer-products/danish-surveys-on-consumer-products/

DeLima Associates. (2018). Consumer Product Information Database. Retrieved from https://www.whatsinproducts.com/

Dionisio, K. L. (CPCat), Frame, A. M., Goldsmith, M.-R., Wambaugh, J. F., Liddell, A., Cathey, T., . . . Judson, R. S. (2015). Exploring consumer exposure pathways and patterns of use for chemicals in the environment. *Toxicology Reports, 2*, 228-237. doi:http://dx.doi.org/10.1016/j.toxrep.2014.12.009

Eastman Chemical Company. (2017). Butvar Polyvinyl Resins Properties and Uses. Retrieved from https://www.eastman.com/Literature_Center/A/ADDBVR3978.pdf

European Chemicals Agency (ECHA). (2018). Dibutyl Sebacate. Retrieved from https://echa.europa.eu/registration-dossier/-/registered-dossier/16127/1

GoodGuide. (2011). Scorecard: The Pollution Information Site. Retrieved from http://scorecard.goodguide.com/chemical-profiles/index.tcl

Government of Canada. (2018). Chemical Substances: Services and Information. Retrieved from https://www.canada.ca/en/health-canada/services/chemical-substances.html

Kim, S., Thiessen, P. A., Bolton, E. E., Chen, J., Fu, G., Gindulyte, A., . . . Bryant, S. H. (2016). PubChem Substance and Compound databases. *Nucleic Acids Research, 44*(Database issue), D1202-D1213. doi:10.1093/nar/gkv951

Kirk-Othmer. (2006). Kirk-Othmer Encyclopedia of Chemical Technology.

Mohapatra, S. C. (2006). An Overview of Liquid Coolants for Electronics Cooling. Retrieved from https://www.electronics-cooling.com/2006/05/an-overview-of-liquid-coolants-for-electronics-cooling/#

Organisation for Economic Cooperation and Development (OECD). (2018). eChemPortal: Global Portal to Information on Chemical Substances. Retrieved from https://www.echemportal.org/echemportal/index.action

Pfizer. (2016). SAFETY DATA SHEET. Retrieved from https://www.pfizer.com/sites/default/files/products/material_safety_data/Oxycodone_HCl_Naltrexone_HCL_ER_tablets_26-Aug-2016.pdf

Synapse Information Resources. (2009). Specialty Chemicals Source Book. Fourth Edition. Volume 1.

U.S. Environmental Protection Agency (EPA). (2002). 1986-2002 Historical IUR Data. Retrieved from Excel File

U.S. Environmental Protection Agency (EPA). (2006). 2006 IUR Public Database.

U.S. Environmental Protection Agency (EPA). (2017a). *Functional Use Database (FUse)*. Retrieved from https://catalog.data.gov/dataset/functional-use-database-fuse

U.S. Environmental Protection Agency (EPA). (2017b). Non-Confidential 2016 Chemical Data Reporting (CDR). Retrieved from https://www.epa.gov/chemical-data-reporting

U.S. Environmental Protection Agency (EPA). (2018a). ChemView. Retrieved from https://chemview.epa.gov/chemview

U.S. Environmental Protection Agency (EPA). (2018b). Envirofacts Multisystem Search. Retrieved from https://www3.epa.gov/enviro/facts/multisystem.html

U.S. Environmental Protection Agency (EPA). (2018c). Look up table for BR Waste Code (National Biennial RCRA Hazardous Waste Report). Retrieved from https://iaspub.epa.gov/enviro/brs_codes_v2.waste_lookup

U.S. Environmental Protection Agency (EPA). (2018d). Safer Chemical Ingredients List. Retrieved from https://www.epa.gov/saferchoice/safer-ingredients

U.S. Environmental Protection Agency (EPA). (2018e). TRI-Listed Chemicals. Retrieved from https://www.epa.gov/toxics-release-inventory-tri-program/tri-listed-chemicals

U.S. National Library of Medicine (NLM). (2017). Haz-Map. Retrieved from https://hazmap.nlm.nih.gov/category-details?id=4753&table=copytblagents

U.S. National Library of Medicine (NLM). (2018). TOXNET® (TOXicology Data NETwork). Retrieved from https://toxnet.nlm.nih.gov/

U.S. Patent and Trademark Office (USPTO). (2018). USPTO Patent Full-Text and Image Database. Retrieved from http://patft.uspto.gov/netahtml/PTO/search-adv.htm

Ullmann's. (2000). ULLMANN'S Encyclopedia of Industrial Chemistry.

Washington State Dept. of Ecology. (2018). Children's Safe Product Act Reported Data. Retrieved from https://fortress.wa.gov/ecy/cspareporting/

Appendix B: Hazard Characterization

Table B.1: Human Health Hazard

Acute Mammalian Toxicity

Source	Exposure Route	Species & Strain (if available)	Duration	Doses and Replicate Number	Effect	Study Details
4867875	Oral (gavage)	Albino rat	Single exposure	**Dose:** 4,700 mg/kg **Replicates:** 5 per sex	LD50 > 4700 mg/kg	**Methods:** • Test substance reported as CASRN 109-43-3 • Purity not reported • Equivalent to OECD Guideline 401 • Predates GLP compliance
61578	Oral	Sprague-Dawley rat	Single exposure observed for 7 days	**Doses and replicates:** • 1,000 mg/kg (3 males) • 5,000 mg/kg (9 males) • 16,000 mg/kg (6 males) • 32,000 mg/kg (6 males)	LD50 estimated to be between 16000 mg/kg-32000 mg/kg	**Methods:** • Test substance reported as CASRN 109-43-3 • Purity not reported • Predates GLP compliance **Mortality Results:** • 1000 mg/kg: 0/3 males • 5000 mg/kg: 0/9 males • 16000 mg/kg: 0/6 males • 32000 mg/kg: 6/6 males

Repeated Dose Toxicity

Source	Exposure Route	Species & Strain (if available)	Duration	Doses and Replicate Number	Effect	Study Details
4829109, 61578	Oral	Sprague-Dawley rat	1 year	**Doses:** 0, 7, 35, 170, and 870 mg/kg-day **Replicates**: 10 males per group	NOAEL: 870 mg/kg-day	**Methods:** • Test substance reported as CASRN 109-43-3 • Purity not reported • Doses reported in percent diet and mg/kg-day but no basis for conversion was provided; these doses are based on percent diet and EPA reference values for body weight and food consumption

Table B.1: Human Health Hazard						
						• Predates GLP compliance
4829109, 61578	Oral	Sprague-Dawley rat	2 year	**Doses:** 0, 7, 35, 170, 870, and 4400 mg/kg-day **Replicates:** 16 males per group	NOAEL: 4400 mg/kg-day	**Methods:** • Test substance reported as CASRN 109-43-3 • Purity not reported • Doses reported in percent diet and mg/kg-day but no basis for conversion was provided; these doses are based on percent diet and EPA reference values for body weight and food consumption • Predates GLP compliance
Reproductive Toxicity						
Source	**Exposure Route**	**Species & Strain (if available)**	**Duration**	**Doses and Replicate Number**	**Effect**	**Study Details**
5077960	Oral (gavage)	Sprague-Dawley rats	2 weeks prior to mating through day 3 of lactation (for females) or 42 days (for males)	**Doses:** 0, 100, 300, and 1000 mg/kg-day **Replicates:** 13 per sex per group	NOAEL: 1000 mg/kg-day	**Methods:** • Test substance reported as CASRN 105-99-7 • Purity > 99% • GLP compliant

Table B.1: Human Health Hazard						
Developmental Toxicity						
Source	**Exposure Route**	**Species & Strain (if available)**	**Duration**	**Doses and Replicate Number**	**Effect**	**Study Details**
5077960	Oral (gavage)	Sprague-Dawley rats	2 weeks prior to mating through day 3 of lactation (for females) or 42 days (for males)	**Doses:** 0, 100, 300, and 1000 mg/kg-day **Replicates:** 13 per sex per group	NOAEL: 300 mg/kg-day, LOAEL: 1000 mg/kg-day based on decreased pup weight and decreased viability	**Methods:** • Test substance reported as CASRN 105-99-7 • Purity > 99% • GLP compliant **Endpoints evaluated:** • Pup number, pup sex ratio, live and dead pups, postnatal deaths, gross abnormalities, pup weight gain, physical and behavioral abnormalities, reflexology and gross necropsy.
Cancer						
Source	**Exposure Route**	**Species & Strain (if available)**	**Duration**	**Doses and Replicate Number**	**Effect**	**Study Details**
61578	Oral	Sprague-Dawley rat	2 year	**Doses:** 0, 7, 35, 170, 870, 4400 mg/kg-day **Replicates:** 16 males per group	Negative	**Methods:** • Test substance reported as CASRN 109-43-3 • Purity not reported • Doses reported in percent diet and mg/kg-day but no basis for conversion was provided; these doses are based on percent diet and EPA reference values for body weight and food consumption • Predates GLP compliance

Table B.1: Human Health Hazard						
Genotoxicity						
Source	**Test Type & endpoint**	**Species & Strain (if available)**	**Metabolic Activation**	**Doses and Controls**	**Results**	**Study Details**
2207709	BASC test on *Drosophila*, Sex linked recessive lethal mutation	*Drosophila*	N/A	**Dose:** 19 mM	Negative	**Methods:** • Test substance reported as CASRN 109-43-3 • Purity not reported • GLP compliance not reported
2207709	Chromosomal aberration (*in vivo)*	NMRI Mice	N/A	**Doses:** 0, 943, 1886, or 2829 mg/kg **Replicates:** 4 per group	Negative	**Methods:** • Test substance reported as CASRN 109-43-3 • Purity not reported • GLP compliance not reported
5077960	Gene mutation (*in vitro*)	Salmonella typhimurium TA 98, TA 100, TA 1535 and TA 1537	With and without	**Doses:** 0, 312.5, 625, 1250, 2500, and 5000 µg/plate	Negative	**Methods:** • Test substance reported as CASRN 105-99-7 • Purity > 99% • Equivalent to OECD Guideline 471 • GLP compliant
5077960	Gene mutation (*in vitro*)	E. Coli strain WP2	With and without	**Doses:** 0, 312.5, 625, 1250, 2500, and 5000 µg/plate	Negative	**Methods:** • Test substance reported as CASRN 105-99-7 • Purity > 99% • Equivalent to OECD Guideline 472 • GLP compliant
5077960	Gene mutation (*in vitro*)	Salmonella typhimurium TA 98, TA 100, TA 1535, TA 1537, and TA 1538	With and without	**Doses:** Experiment 1: 8, 40, 200, 1000 and 5000 µg/plate Experiment 2: 50, 125, 250, 500 and 1000 µg/plate	Negative	**Methods:** • Test substance reported as CASRN 105-99-7 • Purity > 99% • Equivalent to OECD Guideline 471 • GLP compliant

Table B.1: Human Health Hazard						
Irritation						
Source	**Exposure Route**	**Species & Strain (if available)**	**Duration**	**Doses**	**Effect**	**Study Details**
5077950	Skin	Small White Russian rabbits	4 hour exposure, observed for 8 days	**Doses:** 0.5 mL of undiluted test material **Replicates:** 3 male rabbits	Irritating	**Methods:** • Test substance reported as CASRN 105-99-7 • Purity approximately 99.7% • OECD Guideline 404 • GLP compliance not reported **Results:** • Slight to obvious erythema and very slight edema observed in 3/3 animals 1 hour following exposure • Observed effects were fully reversed 8 days following exposure
5077953	Skin	Rabbits	24 hour exposure, observed for 3 days	**Doses:** 0.5 mL of undiluted test material **Replicates:** 3 rabbits per sex	Non-irritating	**Methods:** • Test substance reported as CASRN 7491-02-3 • Purity not reported • Equivalent to OECD Guideline 404 • Not GLP compliant **Results:** • Slight erythema was observed in 2/6 animals 24 hours following the exposure period • Observed effects were fully reversed 3 days following exposure

Table B.1: Human Health Hazard						
4867885	Ocular	Kleinrussen, Chbb:HM rabbits	72 hours	**Doses:** Undiluted test material **Replicates:** 3 male rabbits	Non-irritating	**Methods:** • Test substance reported as CASRN 109-43-3 • Purity not reported • OECD Guideline 405 • GLP compliant **Results:** • 2/3 animals had slight conjunctiva prior to 48 hours • 1/3 animals had slight chemosis prior to 48 hours • All effects fully reversible by 48 hours

Table B.2: Environmental Hazard					
Aquatic Toxicity: Experimental					
Source	**Species & Strain (if available)**	**Duration**	**Doses and Replicate Number**	**Effect**	**Study Details**
5077961	Daphnia magna	5 days	**Doses**: 0.045, 0.16, 0.48, 1.5 and 5.2 mg/L (measured)	EC50 > 5.2 mg/L	• Test substance reported as CASRN 105-99-7 • Purity: 99.7% • OECD Guideline 211 • GLP compliant
5077960	Daphnia magna	21 days	**Doses:** 5 nominal concentrations (0.18-18 mg/L) **Replicates:** 10 organisms per group	LC50: 4.3 mg/L	• Test substance reported as CASRN 105-99-7 • Purity: 99% • OECD Guideline 202 • Not GLP compliant
5077962	Daphnia magna	21 days	**Doses:** 0.045, 0.16, 0.48, 1.5 and 5.2 mg/L (measured) **Replicates:** 1 organism per vessel, 10 vessels per test concentration, 20 vessels per control	NOEC: 1.5 mg/L	• Test substance reported as CASRN 105-99-7 • Purity: 99.7% • OECD Guideline 211 • GLP compliant

Table B.2: Environmental Hazard					
5077963	Eisenia fetida	14 days	**Doses:** 1000 mg/kg soil	NOEC > 1000 mg/kg soil	• Test substance reported as CASRN 105-99-7 • Purity: 100% • OECD Guideline 207 • GLP compliant
Aquatic Toxicity: Estimated					
Model	**Endpoint**	**Species**	**Predicted Effect Level**	**Notes**	
ECOSAR v2.0 (Class: Esters)	Acute	Freshwater fish	LC50 = 0.1 mg/L	NES. Estimated Log K_{ow} exceeds the endpoint specific cutoff.	
ECOSAR v2.0 (Class: Esters)	Acute	Daphnia magna	LC50 = 0.2 mg/L	NES. Estimated Log K_{ow} exceeds the endpoint specific cutoff.	
ECOSAR v2.0 (Class: Esters)	Acute	Green algae	EC50 = 0.04 mg/L	NES. Estimated Log K_{ow} exceeds the endpoint specific cutoff.	
ECOSAR v2.0 (Class: Esters)	Chronic	Freshwater fish	ChV = 0.004 mg/L		
ECOSAR v2.0 (Class: Esters)	Chronic	Daphnia magna	ChV = 0.03 mg/L		
ECOSAR v2.0 (Class: Esters)	Chronic	Green algae	ChV = 0.04 mg/L		

Table B.3: Fate					
Environmental Fate: Experimental					
Source	**Endpoint**	**Duration**	**Doses and number of replicates**	**Results**	**Study Details**
5077969	CO_2 evolution	28 days	**Doses:** 20 mg/L	Biodegradable	**Methods:** • Test substance reported as CASRN 7491-02-3 • Purity not reported • OECD Guideline 301B • GLP compliance not reported **Biodegradation kinetics:** • 89.6% in 28 days; met the 10-day window
5077966	DOC	28 days	**Doses:** 20 mg/L	Biodegradable	**Methods:** • Test substance reported as CASRN 105-99-7

Table B.3: Fate					
					• Purity not reported • OECD Guideline 301E • Not GLP compliant **Biodegradation kinetics:** • 96% in 28 days
5077960, 5077964	BOD	28 days	**Doses:** 100 mg/L	Biodegradable	**Methods:** • Test substance reported as CASRN 105-99-7 • Purity not reported • OECD Guideline 301C • GLP compliant **Biodegradation kinetics:** • 86-95% in 28 days
5077965	Sludge inoculum	28 days	**Doses:** 2.62 mg/L	Biodegradable	• Test substance reported as CASRN 105-99-7 • Purity: 99.6% • OECD Guideline 301D • GLP compliant **Biodegradation kinetics:** • 60% in 28 days
Environmental Fate: Modelled					
Model	**Data Type**	**Endpoint**	**Predicted Endpoint**	**Notes**	
EPISuite v.4.11	Estimated	BAF	29	From Arnot-Gobas method	
EPISuite v.4.11	Estimated	BCF	281	From regression-based method	
EPISuite v.4.11 (BIOWIN 7)	Estimated	Anaerobic biodegradation	Predicted to biodegrade under anaerobic conditions	Predicted probability of 0.7490. Fragment representation is valid. Fast degradation is defined as predicted probability >0.5. Note: the prediction for this chemical is outside of the estimation domain	

B.1 References

Reported to the ECHA (European Chemicals Agency) database. (1976a). Dibutyl sebacate: acute toxicity: oral 001 key | experimental result. https://echa.europa.eu/registration-dossier/-/registered-dossier/16127/7/3/2

Reported to the ECHA (European Chemicals Agency) database. (1976b). Diisopropyl sebacate: skin irritation/corrosion: 001 key | experimental result. https://echa.europa.eu/registration-dossier/-/registered-dossier/10094/7/4/2/?documentUUID=73ffea54-2c63-4fd4-9828-d1c1b3bbe883

Reported to the ECHA (European Chemicals Agency) database. (1989). Dibutyl adipate: skin irritation/corrosion: 001 key | experimental result. https://echa.europa.eu/registration-dossier/-/registered-dossier/5939/7/4/2

Reported to the ECHA (European Chemicals Agency) database. (1991). Dibutyl sebacate: eye irritation: in vivo: 001 key | experimental result. https://echa.europa.eu/registration-dossier/-/registered-dossier/16127/7/4/3/?documentUUID=ce4ed65c-e5bc-47f6-ac52-9dd56ac25091

Reported to the ECHA (European Chemicals Agency) database. (1995). Dibutyl adipate: biodegradation in water: screening tests: 001 key | experimental result. https://echa.europa.eu/registration-dossier/-/registered-dossier/5939/5/3/2/?documentUUID=641f54ba-5881-4a20-882a-050195db28c6

Reported to the ECHA (European Chemicals Agency) database. (1996). Dibutyl adipate: genetic toxicity: in vitro. 003 supporting | experimental result. https://echa.europa.eu/registration-dossier/-/registered-dossier/5939/7/7/2/?documentUUID=6cab85c9-7d5e-4d3a-83fe-9f060a93c915

Reported to the ECHA (European Chemicals Agency) database. (1998). Diisopropyl sebacate: biodegradation in water: screening tests: 001 key | Experimental result. https://echa.europa.eu/registration-dossier/-/registered-dossier/10094/5/3/2/?documentUUID=c6b2ff26-0a23-4757-85e9-e807fe353faa

Reported to the ECHA (European Chemicals Agency) database. (1999). Dibutyl adipate: biodegradation in water: screening tests: 002 other | experimental result. https://echa.europa.eu/registration-dossier/-/registered-dossier/5939/5/3/2/?documentUUID=45cb1a62-2c54-4e1a-a73d-55c0350325b8

Reported to the ECHA (European Chemicals Agency) database. (2000). Dibutyl adipate: biodegradation in water: screening tests: 003 other | experimental result. https://echa.europa.eu/registration-dossier/-/registered-dossier/5939/5/3/2/?documentUUID=f298b3f7-59a1-452b-a0d2-4a27dd712afa

Reported to the ECHA (European Chemicals Agency) database. (2013). Dibutyl adipate: Toxicity to soil macroorganisms except arthropods: 001 key | experimental result. https://echa.europa.eu/registration-dossier/-/registered-dossier/5939/6/4/2/?documentUUID=e16a9c12-49c2-4809-82c8-c1aa947eb7ac

Reported to the ECHA (European Chemicals Agency) database. (2014a). Dibutyl adipate: long-term toxicity to aquatic invertebrates: 001 key | experimental result. https://echa.europa.eu/registration-dossier/-/registered-dossier/5939/6/2/5/?documentUUID=514a687a-f8c7-4060-98b9-fecd7a40529c

Reported to the ECHA (European Chemicals Agency) database. (2014b). Dibutyl adipate: short-term toxicity to aquatic invertebrates: 001 weight of evidence | experimental result. https://echa.europa.eu/registration-dossier/-/registered-dossier/5939/6/2/4/?documentUUID=01907b80-5be6-4d6e-9e56-b7729dd20c20

OECD (Organisation for Economic Co-operation and Development). (1996). Dibutyl adipate: CAS No:105-99-7. Geneva: UNEP Publications. http://www.inchem.org/documents/sids/sids/105997.pdf

Smith, CC. (1953). Toxicity of butyl stearate, dibutyl sebacate, dibutyl phthalate, and methoxyethyl oleate. AMA Arch Ind Hyg Occup Med 7: 310-318.

WHO (World Health Organization). (2000). Safety evaluation of certain food additives and contaminants. Aliphatic primary alcohols, aldehydes, carboxylic acids, acetals, and esters containing additional oxygenated functional groups. In WHO Food Additives Series (pp. 229-260). Geneva, Switzerland.

Wild, D; King, MT; Gocke, E; Eckhardt, K. (1983). Study of artificial flavoring substances for mutagenicity in the salmonella/microsome, basc and micronucleus tests. Food Chem Toxicol 21: 707-719. http://dx.doi.org/https://doi.org/10.1016/0278-6915(83)90202-8

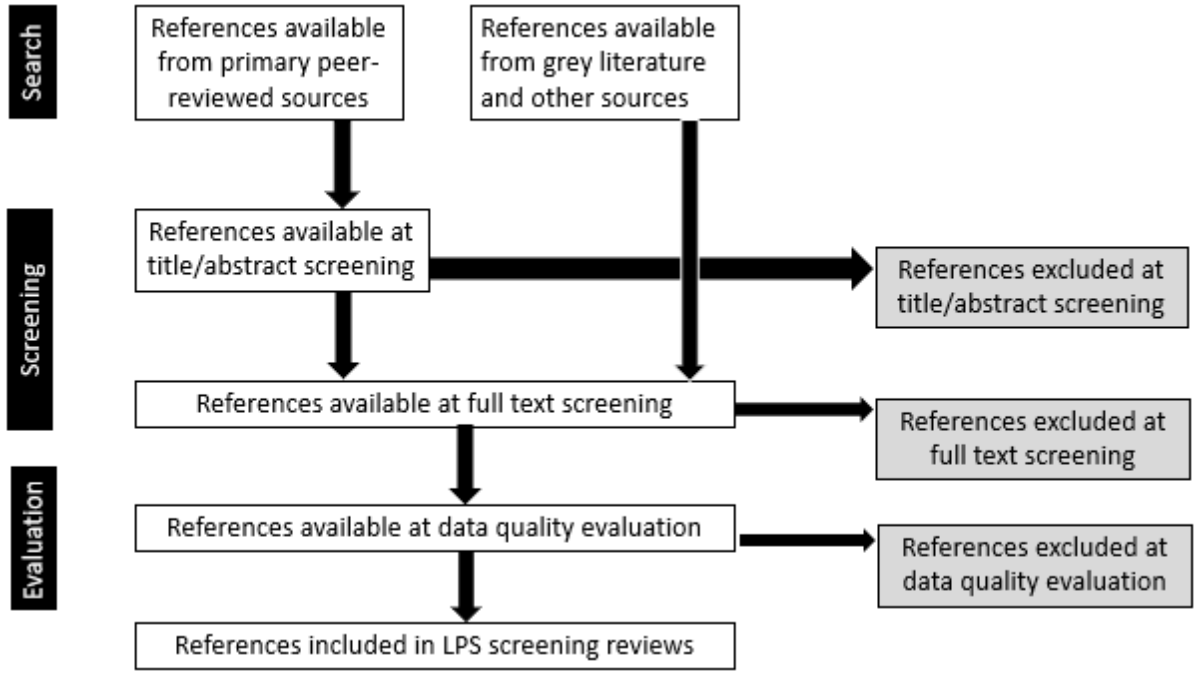
Appendix C: Literature Search Outcomes

C.1 Literature Search and Review

This section briefly describes the literature search and review process, search terms, and search outcomes for the hazard and fate screening of dibutyl sebacate. Search outcomes and reference details are provided on the candidate's HERO[48] project page.

EPA created a fit-for-purpose process to transparently document the literature search and review[49] of available hazard and fate information for low-priority substance (LPS) candidates. References from peer-reviewed primary sources, grey sources,[50] and other sources were identified, screened at the title/abstract and full-text level, and evaluated for data quality based on discipline-specific criteria. An overview of the literature search and review process is illustrated in Figure C1.

Figure C.1: Overview of the Literature Search and Review Process



[48] The HERO low-priority substance candidate project pages are accessible to the public at https://hero.epa.gov/hero/.

[49] Discussed in the document "Approach Document for Screening Hazard Information for Low-Priority Substances Under TSCA."

[50] Grey literature and additional sources are the broad category of studies not found in standard, peer-reviewed literature database searches. This includes U.S. and international government agency websites, non-government organization (NGO) websites, and data sources that are difficult to find, or are not included, in the peer-reviewed databases, such as white papers, conference proceedings, technical reports, reference books, dissertations, and information on various stakeholder websites.

C.1.1 Search for Analog Data

To supplement the information on the candidate chemical, dibutyl sebacate, the following analogs were used for designation: dibutyl adipate (CASRN 105-99-7) and diisopropyl sebacate (CASRN 7491-02-3). For more details and justification on analogs, see section 6.1.1. Analogs were used to fill data gaps on endpoints for which dibutyl sebacate lacked quality data, such as developmental toxicity, or to add to the weight of the scientific evidence. EPA collected reasonably available information for these endpoints by searching specific grey literature and other secondary sources, listed on Table C.1. If information related to the identified analogs were available in these sources, the references were screened and evaluated using the same process as references on dibutyl sebacate described above.[49]

Table C.1: Sources Used for Analog Search

Resource	URL
ATSDR	http://www.atsdr.cdc.gov/toxprofiles/index.asp
ChemID (EPA – HPVIS via ChemID)	http://chem.sis.nlm.nih.gov/chemidplus/
CIR	http://www.cir-safety.org/ingredients
ECHA	http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances
ECOTOX	https://cfpub.epa.gov/ecotox/quick_query.htm
EPA – ChemView (incl. TSCATS, RBP/HC, and HPV/HPVIS)	https://chemview.epa.gov/chemview
European Food Safety Authority (EFSA)	http://www.efsa.europa.eu/
FDA	https://www.fda.gov/default.htm
HERA	http://www.heraproject.com/RiskAssessment.cfm
NICNAS	http://www.nicnas.gov.au/
NITE (J-CHECK)	http://www.safe.nite.go.jp/jcheck/search.action?request_locale=en
NTP	https://ntpsearch.niehs.nih.gov/home
OECD/SIDS	https://hpvchemicals.oecd.org/UI/Search.aspx; http://webnet.oecd.org/hpv/ui/SponsoredChemicals.aspx

C.1.2 Search Terms and Results

EPA began the literature review process for the hazard screening of dibutyl sebacate by developing search terms. To gather publicly available information, specific search terms were applied for each discipline and across databases and grey literature sources. Table C.2 lists the search terms used in the database search of peer -reviewed literature for dibutyl sebacate. For grey literature and other secondary sources, Table C.3 lists the search terms used for dibutyl sebacate and analogs.

Table C.2: Search Terms Used in Peer Reviewed Databases

Discipline	Database	Search terms
Human Health	PubMed	109-43-3[rn] OR "Bis(n-butyl) sebacate"[tw] OR "Bis(n-butyl)sebacate"[tw] OR "Butyl sebacate"[tw] OR "DECANEDIOATE, DIBUTYL"[tw] OR "Decanedioic acid dibutyl ester"[tw] OR "Decanedioic acid, 1,10-dibutyl ester"[tw] OR "Decanedioic acid, dibutyl ester"[tw] OR "Decanedioic acid, dibutyl ester"[tw] OR "Decanodioic acid, dibutyl ester"[tw] OR "Di-n-Butyl sebacate"[tw] OR "Di-n-butylsebacate"[tw] OR "Dibutyl 1,8-

Table C.2: Search Terms Used in Peer Reviewed Databases		
Discipline	**Database**	**Search terms**
		octanedicarboxylate"[tw] OR "Dibutyl decanedioate"[tw] OR "Dibutyl sebacate"[tw] OR "Dibutyl sebacinate"[tw] OR "Dibutylsebacat"[tw] OR "Ergoplast SDB"[tw] OR "Kodaflex DBS"[tw] OR "Monoplex DBS"[tw] OR "Otto Fuel II"[tw] OR "Polycizer DBS"[tw] OR "Reomol DBS"[tw] OR "Sebacic acid di-n-butyl ester"[tw] OR "Sebacic acid, dibutyl ester"[tw] OR "Staflex DBS"[tw] OR "Uniflex DBS"[tw] OR "PX 404"[tw]
	Toxline	((109-43-3 [rn] OR "bis n-butyl sebacate" OR "butyl sebacate" OR "decanedioate dibutyl" OR "decanedioic acid dibutyl ester" OR "decanedioic acid 1 10-dibutyl ester" OR "decanedioic acid dibutyl ester" OR "decanedioic acid dibutyl ester" OR "decanodioic acid dibutyl ester" OR "di-n-butyl sebacate" OR "di-n-butylsebacate" OR "dibutyl 1 8-octanedicarboxylate" OR "dibutyl decanedioate" OR "dibutyl sebacate" OR "dibutyl sebacinate" OR "dibutylsebacat" OR "ergoplast sdb" OR "kodaflex dbs" OR "monoplex dbs" OR "otto fuel ii" OR "polycizer dbs" OR "reomol dbs" OR "sebacic acid di-n-butyl ester" OR "sebacic acid dibutyl ester" OR "staflex dbs" OR "uniflex dbs" OR "px 404") AND (aneupl [org] OR biosis [org] OR cis [org] OR dart [org] OR emic [org] OR epidem [org] OR fedrip [org] OR heep [org] OR hmtc [org] OR ipa [org] OR riskline [org] OR mtgabs [org] OR niosh [org] OR ntis [org] OR pestab [org] OR ppbib [org])) AND NOT PubMed [org] AND NOT pubdart [org]
	TSCATS 1	109-43-3[rn] AND tscats[org]
	WOS	TS=("109-43-3" OR "Bis(n-butyl) sebacate" OR "Bis(n-butyl)sebacate" OR "Butyl sebacate" OR "DECANEDIOATE, DIBUTYL" OR "Decanedioic acid dibutyl ester" OR "Decanedioic acid, 1,10-dibutyl ester" OR "Decanedioic acid, dibutyl ester" OR "Decanedioic acid, dibutyl ester" OR "Decanodioic acid, dibutyl ester" OR "Di-n-Butyl sebacate" OR "Di-n-butylsebacate" OR "Dibutyl 1,8-octanedicarboxylate" OR "Dibutyl decanedioate" OR "Dibutyl sebacate" OR "Dibutyl sebacinate" OR "Dibutylsebacat" OR "Ergoplast SDB" OR "Kodaflex DBS" OR "Monoplex DBS" OR "Otto Fuel II" OR "Polycizer DBS" OR "Reomol DBS" OR "Sebacic acid di-n-butyl ester" OR "Sebacic acid, dibutyl ester" OR "Staflex DBS" OR "Uniflex DBS" OR "PX 404")
Environmental Hazard	WOS	Same as human health strategy synonyms only
	Toxline	Same as human health strategy synonyms only
	TSCATS 1	Same as human health strategy CASRN only
	Proquest	Title=("109-43-3" OR "Bis n-butyl sebacate" OR "Butyl sebacate" OR "DECANEDIOATE, DIBUTYL" OR "Decanedioic acid dibutyl ester" OR "Decanedioic acid, 1,10-dibutyl ester" OR "Decanedioic acid, dibutyl ester" OR "Decanedioic acid, dibutyl ester" OR "Decanodioic acid, dibutyl ester" OR "Di-n-Butyl sebacate" OR "Di-n-butylsebacate" OR "Dibutyl 1,8-octanedicarboxylate" OR "Dibutyl decanedioate" OR "Dibutyl sebacate" OR "Dibutyl sebacinate" OR "Dibutylsebacat" OR "Otto Fuel II" OR "Sebacic acid di-n-butyl ester" OR "Sebacic acid, dibutyl ester") Abstract=("109-43-3" OR "Bis n-butyl sebacate" OR "Butyl sebacate" OR "DECANEDIOATE, DIBUTYL" OR "Decanedioic acid dibutyl ester" OR "Decanedioic acid, 1,10-dibutyl ester" OR "Decanedioic acid, dibutyl ester" OR "Decanedioic acid, dibutyl ester" OR "Decanodioic acid, dibutyl ester" OR "Di-n-Butyl sebacate" OR "Di-n-butylsebacate" OR "Dibutyl 1,8-octanedicarboxylate" OR "Dibutyl decanedioate" OR "Dibutyl sebacate" OR "Dibutyl sebacinate" OR "Dibutylsebacat" OR "Otto Fuel II" OR "Sebacic acid di-n-butyl ester" OR "Sebacic acid, dibutyl ester") Subject=("109-43-3" OR "Bis n-butyl sebacate" OR "Butyl sebacate" OR "DECANEDIOATE, DIBUTYL" OR "Decanedioic acid dibutyl ester" OR "Decanedioic acid, 1,10-dibutyl ester" OR "Decanedioic acid, dibutyl ester" OR "Decanedioic acid,

Table C.2: Search Terms Used in Peer Reviewed Databases		
Discipline	**Database**	**Search terms**
		dibutyl ester" OR "Decanodioic acid, dibutyl ester" OR "Di-n-Butyl sebacate" OR "Di-n-butylsebacate" OR "Dibutyl 1,8-octanedicarboxylate" OR "Dibutyl decanedioate" OR "Dibutyl sebacate" OR "Dibutyl sebacinate" OR "Dibutylsebacat" OR "Otto Fuel II" OR "Sebacic acid di-n-butyl ester" OR "Sebacic acid, dibutyl ester") Title=("Ergoplast SDB" OR "Kodaflex DBS" OR "Monoplex DBS" OR "Polycizer DBS" OR "Reomol DBS" OR "Staflex DBS" OR "Uniflex DBS") OR Abstract=("Ergoplast SDB" OR "Kodaflex DBS" OR "Monoplex DBS" OR "Polycizer DBS" OR "Reomol DBS" OR "Staflex DBS" OR "Uniflex DBS") OR Subject=("Ergoplast SDB" OR "Kodaflex DBS" OR "Monoplex DBS" OR "Polycizer DBS" OR "Reomol DBS" OR "Staflex DBS" OR "Uniflex DBS")
Fate	WOS	Same as human health strategy synonyms only

Table C.3: Search Terms Used in Grey Literature and Additional Sources	
Chemical	**Search terms**
Dibutyl Sebacate	Searched as a string or individually depending on resource: "109-43-3" OR "Bis(n-butyl) sebacate" OR "Bis(n-butyl)sebacate" OR "Butyl sebacate" OR "DECANEDIOATE, DIBUTYL" OR "Decanedioic acid dibutyl ester" OR "Decanedioic acid, 1,10-dibutyl ester" OR "Decanedioic acid, dibutyl ester" OR "Decanedioic acid, dibutyl ester" OR "Decanodioic acid, dibutyl ester" OR "Di-n-Butyl sebacate" OR "Di-n-butylsebacate" OR "Dibutyl 1,8-octanedicarboxylate" OR "Dibutyl decanedioate" OR "Dibutyl sebacate" OR "Dibutyl sebacinate" OR "Dibutylsebacat" OR "Ergoplast SDB" OR "Kodaflex DBS" OR "Monoplex DBS" OR "Otto Fuel II" OR "Polycizer DBS" OR "Reomol DBS" OR "Sebacic acid di-n-butyl ester" OR "Sebacic acid, dibutyl ester" OR "SEBACINSAEURE-DIBUTYLESTER" OR "Staflex DBS" OR "Uniflex DBS"
Analogs searched	di-n-butyl adipate (105-99-7); diisopropyl sebacate (7491-02-3)

After the search terms were applied, more than 290 references were returned by all search efforts across peer-reviewed databases and grey literature sources. The total number of references include database results, additional strategies, and analog searches. All references from the search efforts were screened and evaluated through the LPS literature search and review process.[49] Of these, 7 references were included for data evaluation and used to support the designation of dibutyl sebacate as LPS. The included hazard and fate references are listed in the bibliography of Appendix B.

C.2 Excluded Studies and Rationale

This section lists the excluded references, by HERO ID, found to be off-topic or unacceptable for use in the hazard screening of dibutyl sebacate. The excluded references are organized by discipline (human health hazard, environmental hazard, and fate), presented along with a rationale based on exclusion criteria. The criteria[49] was used to determine off-topic references in the title/abstract or full text screening and to determine unacceptable references in the data quality evaluation are provided in the form of questions.

C.2.1 Human Health Hazard Excluded References

For the screening review of dibutyl sebacate, EPA excluded a total of 231 references when assessing human health hazard. Off-topic references (e.g., studies that did not contain information relevant to human health) were excluded at either title/abstract screening (see Table C.4), or full-text screening (see

Table C.5). Unacceptable references (e.g., studies that did not meet data quality metrics) were excluded at full-text screening (see Tables C.6 and C.7). Off-topic and unacceptable references are displayed next to the corresponding exclusion criteria.

Table C.4: Off-Topic References Excluded at *Title/Abstract Screening* for Human Health Hazard

Reference excluded (HERO ID) because the reference did NOT contain information needs[51] relevant to human health hazard									
470461	4828910	4829077	1940287	4829005	1332794	4828991	4829102	3539768	4829025
675047	4828911	4829078	1955077	4829006	1332863	4828992	4829103	4725770	4829026
788806	4828913	4829079	1955671	4829007	1332864	4828995	4829104	4828873	4829030
789457	4828914	4829081	1964710	4829008	1332951	4828996	4829105	4828874	4829031
789500	4828915	4829082	1964712	4829009	1338440	4828997	4829107	4828875	4829032
789607	4828917	4829083	2035549	4829011	1341409	4828998	4829108	4828876	4829035
789865	4828918	4829084	2219907	4829012	1341532	4828999	4829110	4828877	4829036
1035976	4828919	4829085	2303476	4829013	1342285	4829000	4829111	4828878	4829037
1048860	4828920	4829088	2309930	4829015	1342303	4829001	4829114	4828879	4829038
1049870	4828921	4829090	2749721	4829016	1585256	4829002	4829116	4828880	4829040
1197952	4828922	4829091	2952365	4829017	1764374	4829004	4829185	4828881	4829041
1249977	4828923	4829092	3039434	4829018	4828898	4829063	4828892	4828882	4829042
1312288	4828924	4829093	3040068	4829019	4828899	4829064	4828893	4828883	4829043
1315808	4828925	4829095	3040761	4829020	4828900	4829065	4828894	4828884	4829044
1323131	4828926	4829096	3046807	4829021	4828901	4829066	4828895	4828885	4829045
1325374	4828927	4829097	3046989	4829022	4828902	4829067	4828896	4828886	4829046
1325731	4828929	4829100	3363559	4829023	4828903	4829068	4828897	4828887	4829049
1325814	4828930	4829101	3493667	4829024	4828904	4829069	4829056	4828888	4829051
4828908	4829074	4829061	4829054	4828890	4828905	4829070	4829058	4828889	4829053
4828909	4829076	4829062	4829055	4828891	4828906	4829072	4829059	4829073	4829060
4828907									
Reference excluded (HERO ID) because the reference primarily contained *in silico* data									
N/A.									

Table C.5: Screening Questions and Off-Topic References Excluded at *Full Text Screening* for Human Health Hazard

Question	Off-topic if answer is:	References excluded (HERO ID)
Does the reference contain information pertaining to a low-priority substance candidate?	No	789535 4861538 4867872 4829099
What type of source is this reference?	Review article or book chapter that contains only citations to primary literature sources	3042030 4860775 4861081 4862652

[51] The information needs for human health hazard includes a list of study characteristics pertaining to the study population/test organism, types of exposures and routes, use of controls, type and level of effects. A complete list of the information needs is provided in Table A1 of the "Approach Document for Screening Hazard Information for Low-Priority Substances Under TSCA". These information needs helped guide the development of questions for title/abstract and full-text screening.

Table C.5: Screening Questions and Off-Topic References Excluded at *Full Text Screening* for Human Health Hazard		
Question	**Off-topic if answer is:**	**References excluded (HERO ID)**
What kind of evidence does this reference primarily contain?	*In silico* studies that DO NOT contain experimental verification	N/A
The following question apply to HUMAN evidence only		
Does the reference report an exposure route that is or is presumed to be by an inhalation, oral, or dermal route?	No	N/A
Does the reference report both test substance exposure(s) AND related health outcome(s)?	No	N/A
If the reference reports an exposure to a chemical mixture, are measures of the test substance or related metabolite(s) reported independently of other chemicals? Note: If the paper does not pertain to mixtures, choose "Not Applicable".	No	N/A
The following question apply to ANIMAL evidence only		
Does the reference report an exposure route that is by inhalation, oral, or dermal route?	No	N/A
Does the reference report both test substance-related exposure(s) AND related health outcome(s)?	No	4867876 4867877 4867886 4867892
Does the reference report the duration of exposure?	No	N/A
Does the reference report an exposure to the test substance only (i.e. no mixtures with the exception of aqueous solutions and reasonable impurities and byproducts)?	No	4829192
Does the paper report a negative control that is a vehicle control or no treatment control?	No[52]	4867877 4867886 4867876 4867892 4861922
The following questions apply to MECHANISTIC/ALTERNATIVE TEST METHODS evidence only		
Does the reference report a negative control that is a vehicle control or no treatment control?	No	4862652 1335403 4828912 4829112

[52] Except for acute mammalian toxicity and skin and eye irritation studies, where the use of a negative control may not be required (e.g., OECD 403 Acute Inhalation Toxicity Guidelines).

Table C.5: Screening Questions and Off-Topic References Excluded at *Full Text Screening* for Human Health Hazard		
Question	**Off-topic if answer is:**	**References excluded (HERO ID)**
		4867878
Does the reference report an exposure to the test substance only (i.e. no mixtures with the exception of aqueous solutions and reasonable impurities and byproducts)?	No	1335403
For genotoxicity studies only: Does the study use a positive control?	No	4862652 4828912 4829112 1335403 4867879

Table C.6: Data Quality Metrics and Unacceptable References Excluded at *Data Quality Evaluation* for Human Health Hazard – Animal		
Data Quality Metric	**Unacceptable if:**	**References excluded (HERO ID)**
Metric 1: Test Substance Identity	• The test substance identity cannot be determined from the information provided (e.g., nomenclature was unclear and CASRN or structure were not reported). **OR** • For mixtures, the components and ratios were not characterized or did not include information that could result in a reasonable approximation of components.	N/A
Metric 2: Negative and Vehicle Controls	A concurrent negative control group was not included or reported. **OR** The reported negative control group was not appropriate (e.g., age/weight of animals differed between control and treated groups).	2207709 4829115
Metric 3: Positive Controls	When applicable, an appropriate concurrent positive control (i.e., inducing a positive response) was not used.	N/A
Metric 4: Reporting of Doses/Concentrations	Doses/concentrations were not reported and could not be calculated using default or reported estimates of body weight and diet/water intake (e.g., default intake values are not available for pregnant animals).	4829115 4867862 4867874 4867889
Metric 5: Exposure Duration	The duration of exposure was not reported. **OR** The reported exposure duration was not suited to the study type and/or outcome(s) of interest (e.g., <28 days for repeat dose).	2207709 61578 4829071 4867861
Metric 6:	The test animal species was not reported. **OR**	N/A

Table C.6: Data Quality Metrics and Unacceptable References Excluded at *Data Quality Evaluation* for Human Health Hazard – Animal		
Data Quality Metric	**Unacceptable if:**	**References excluded (HERO ID)**
Test Animal Characteristics	The test animal (species, strain, sex, life-stage, source) was not appropriate for the evaluation of the specific outcome(s) of interest (e.g., genetically modified animals, strain was uniquely susceptible or resistant to one or more outcome of interest).	
Metric 7: Number of Animals Per Group	The number of animals per study group was not reported. **OR** The number of animals per study group was insufficient to characterize toxicological effects (e.g., 1-2 animals in each group).	2207709 4867861 4867889 30540
Metric 8: Outcome Assessment Methodology	The outcome assessment methodology was not sensitive for the outcome(s) of interest (e.g., evaluation of endpoints outside the critical window of development, a systemic toxicity study that evaluated only grossly observable endpoints, such as clinical signs and mortality, etc.).	2207709 4867889 61578 4829071 4829115 4867862 2303428
Metric 9: Reporting of Data	Data presentation was inadequate (e.g., the report does not differentiate among findings in multiple exposure groups). **OR** Major inconsistencies were present in reporting of results.	4829115

Table C.7: Data Quality Metrics and Unacceptable References Excluded at *Data Quality Evaluation* for Human Health Hazard – In Vitro		
Data Quality Metric	**Unacceptable if:**	**References excluded (HERO ID)**
Metric 1: Test Substance Identity	The test substance identity or description cannot be determined from the information provided (e.g., nomenclature was unclear and CASRN or structure were not reported). **OR** For mixtures, the components and ratios were not characterized or did not include information that could result in a reasonable approximation of components.	N/A
Metric 2: Negative Controls	A concurrent negative control group was not included or reported. **OR** The reported negative control group was not appropriate (e.g., different cell lines used for controls and test substance exposure).	2303428

Table C.7: Data Quality Metrics and Unacceptable References Excluded at *Data Quality Evaluation* for Human Health Hazard – In Vitro		
Data Quality Metric	**Unacceptable if:**	**References excluded (HERO ID)**
Metric 3: Positive Controls	A concurrent positive control or proficiency group was not used.	N/A
Metric 4: Assay Type	The assay type was not reported. **OR** The assay type was not appropriate for the study type or outcome of interest (e.g., *in vitro* skin corrosion protocol used for *in vitro* skin irritation assay).	N/A
Metric 5: Reporting of Concentration	The exposure doses/concentrations or amounts of test substance were not reported.	2303428
Metric 6: Exposure Duration	No information on exposure duration(s) was reported. **OR** The exposure duration was not appropriate for the study type and/or outcome of interest (e.g., 24 hours exposure for bacterial reverse mutation test).	1335402 2303428
Metric 7: Metabolic Activation	No information on the characterization and use of a metabolic activation system was reported. **OR** The exposure duration was not appropriate for the study type and/or outcome of interest (e.g., 24 hours exposure for bacterial reverse mutation test).	2303428
Metric 8: Test Model	The test model was not reported **OR** The test model was not routinely used for evaluation of the specific outcome of interest.	1335402
Metric 9: Outcome Assessment Methodology	The outcome assessment methodology was not reported. **OR** The assessment methodology was not appropriate for the outcome(s) of interest (e.g., cells were evaluated for chromosomal aberrations immediately after exposure to the test substance instead of after post-exposure incubation period).	1335402

C.2.2 Environmental Hazard

For the screening review of LPS candidate dibutyl sebacate, EPA excluded a total of 223 references when assessing environmental hazard. Off-topic environmental hazard references excluded at title/abstract screening are listed in Table C.8, and those excluded at full-text screening are listed in Table C.9. References in Table C.10 represent unacceptable studies based on specific data quality metrics for environmental hazard. Off-topic and unacceptable references are displayed next to the corresponding exclusion criteria.

Table C.8: Off-Topic References Excluded at *Title/Abstract Screening* for Environmental Hazard

Reference excluded (HERO ID) because the reference did NOT contain information needs[53] relevant to environmental hazard									
470461	4829004	4828908	4829102	4829043	1342303	4829036	4828999	4829193	4829073
675047	4829005	4828909	4829103	4829044	1598314	4829037	4829000	4829196	4829074
788806	4829006	4828911	4829104	4829045	1764374	4829038	4829001	4829197	4829076
789457	4829007	4828912	4829105	4829046	1940287	4829040	4829002	4829201	4829077
789500	4829008	4828913	4829107	4829049	1955671	4829041	4828893	4828877	4829078
789535	4829009	4828914	4829108	4829051	1964710	4829042	4828895	4828878	4829079
789865	4829011	4828915	4829110	4829053	1964712	3493667	4828896	4828879	4829081
1035976	4829012	4828917	4829111	4829054	1965786	3539768	4828897	4828881	4829082
1049870	4829013	4828918	4829112	4829055	2035549	4455565	4828898	4828882	4829083
1197952	4829015	4828919	4829113	4829056	2219907	4725770	4828899	4828883	4829084
1249977	4829016	4828920	4829114	4829058	2303476	4828874	4828901	4828884	4829085
1312288	4829017	4828921	4829116	4829059	2309930	4828875	4828902	4828885	4829088
1315808	4829018	4828922	4829128	4829060	2749721	4828876	4828903	4828886	4829090
1323131	4829019	4828923	4829130	4829061	2952365	4829097	4828904	4828887	4829091
1325374	4829020	4828925	4829131	4829062	3039434	4829098	4828905	4828888	4829092
1325731	4829021	4828926	4829135	4829063	3040068	4829099	4828906	4828889	4829093
1325814	4829022	4828927	4829138	4829064	3040761	4829100	4828907	4828890	4829094
1332794	4829023	4828929	4829139	4829065	3046807	4829101	1341409	4828891	4829095
1332863	4829024	4828930	4829143	4829066	3046989	4829175	4829070	4828892	4829096
1332864	4829025	4828991	4829150	4829067	3363559	4829031	4828996	4829185	4829072
1332951	4829026	4828992	4829165	4829068	1341532	4829032	4828997	4829180	4829071
1338440	4829030	4828995	4829173	4829069	1342285	4829035	4828998		
Reference excluded (HERO ID) because the reference did NOT present quantitative environmental hazard data									
N/A.									

Table C.9: Screening Questions and Off-Topic References Excluded at *Full Text Screening* for Environmental Hazard

Question	Off-topic if answer is:	References excluded (HERO ID)
Does the reference contain information pertaining to a low-priority substance candidate?	No	61578 1335403 3042030 4829109

[53] The information needs for environmental hazard includes a list of study characteristics pertaining to the test organism/species, type and level of effects, and use of controls. A complete list of the information needs is provided in Table A2 of the "Approach Document for Screening Hazard Information for Low-Priority Substances Under TSCA". These information needs helped guide the development of questions for title/abstract and full-text screening.

Table C.9: Screening Questions and Off-Topic References Excluded at *Full Text Screening* for Environmental Hazard		
Question	**Off-topic if answer is:**	**References excluded (HERO ID)**
What type of source is this reference?	Review article or book chapter that contains only citations to primary literature sources	N/A
Is quantitative environmental hazard data presented?	No	N/A
Is this primarily a modeling/simulation study? [Note: select "No" if experimental verification was included in the study]	Yes	N/A
Is environmental hazard data presented for standard or non-standard aquatic or terrestrial species (fish, invertebrates, microorganisms, non-mammalian terrestrial species)?	No	N/A
Is exposure measured for the target substance or is the test substance a mixture (except for reasonable impurities, byproducts, and aqueous solutions) or formulated product?	Mixture	N/A
	Formulated Product	N/A
Does the reference report a duration of exposure?	No	N/A
Does the reference report a negative control that is a vehicle control or no treatment control?	No	N/A
Does the reference include endpoints in the information needs?	No	N/A

Table C.10: Data Quality Metrics and Unacceptable References Excluded at *Data Quality Evaluation* for Environmental Hazard		
Question	**Unacceptable if:**	**References excluded (HERO ID)**
Metric 1: Test Substance Identity	The test substance identity or description cannot be determined from the information provided (e.g., nomenclature was unclear, CASRN or structure were not reported, substance name/ description does not match CASRN). **OR** For mixtures, the components and ratios were not characterized or did not include information that could result in a reasonable approximation of components.	N/A
Metric 2: Negative Controls	A concurrent negative control group was not included or reported.	N/A

Table C.10: Data Quality Metrics and Unacceptable References Excluded at *Data Quality Evaluation* for Environmental Hazard		
Question	**Unacceptable if:**	**References excluded (HERO ID)**
Metric 3: Experimental System	The experimental system (e.g., static, semi-static, or flow-through regime) was not described.	N/A
Metric 4: Reporting of Concentrations	Test concentrations were not reported.	N/A
Metric 5: Exposure Duration	The duration of exposure was not reported. **OR** The reported exposure duration was not suited to the study type and/or outcome(s) of interest (e.g., study intended to assess effects on reproduction did not expose organisms for an acceptable period of time prior to mating).	N/A
Metric 6: Test Organism Characteristics	The test species was not reported. **OR** The test species, life stage, or age was not appropriate for the outcome(s) of interest.	N/A
Metric 7: Outcome Assessment Methodology	The outcome assessment methodology was not reported.	4867859
Metric 8: Reporting of Data	Data presentation was inadequate. **OR** Major inconsistencies were present in reporting of results.	N/A

C.2.3 Fate

For the screening review of LPS candidate dibutyl sebacate, EPA excluded a total of 175 references when assessing environmental fate. Off-topic fate references excluded at title/abstract screening are listed in Table C.11, and those excluded at full-text screening are listed in Table C.12. References in Table C.13 represent unacceptable studies based on specific data quality metrics for fate. Off-topic and unacceptable references are displayed next to the corresponding exclusion criteria.

Table C.11: Off-Topic References Excluded at Initial Screening for Fate									
Reference excluded (HERO ID) because the reference did NOT contain information needs[54] relevant to environmental fate									
470461	4829063	4829030	4828921	3539768	1332794	4829079	4829054	4829000	4828888
675047	4829064	4829031	4828922	4725770	1332863	4829081	4829055	4829001	4828890
788806	4829065	4829032	4828923	4828874	1332864	4829082	4829056	4829002	4828892
789457	4829066	4829035	4828925	4828875	1338440	4829083	4829058	4829004	4828893

[54] The information needs for fate includes a list of study characteristics pertaining to the associated media and exposure pathways, associated processes, and use of controls. A complete list of the information needs is provided in Table A3 of the "Approach Document for Screening Hazard Information for Low-Priority Substances Under TSCA". These information needs helped guide the development of questions for title/abstract and full-text screening.

Table C.11: Off-Topic References Excluded at Initial Screening for Fate									
789500	4829067	4829036	4828926	4828876	1341409	4829084	4829059	4829005	4828895
789535	4829068	4829037	4828927	4828877	1341532	4829085	4829060	4829006	4828896
789865	4829069	4829038	4828929	4828878	1342285	4829088	4829061	4829007	4828897
1035976	4829070	4829040	4828930	4828879	1342303	4828920	4829062	4829008	4828899
1197952	4829071	4829041	4828991	4828881	1598314	4829019	4828911	4829009	4828901
1249977	4829072	4829043	4828992	4828882	1764374	4829020	4828912	4829011	4828902
1315808	4829073	4829044	4828995	4828883	1940287	4829021	4828913	4829012	4828903
1323131	4829074	4829045	4828996	4828884	1955671	4829022	4828914	4829013	4828904
1325374	4829076	4829046	4828997	4828885	1964710	4829023	4828915	4829015	4828905
1325731	4829077	4829051	4828998	4828886	1964712	4829025	4828917	4829016	4828907
1325814	4829078	4829053	4828999	4828887	2035549	4829026	4828918	4829017	4828908
2303476	3040068	2309930	3046807	2952365	2219907	3039434	4828919	4829018	4828909
2749721	3493667								
Reference excluded (HERO ID) because the reference did NOT present quantitative environmental fate data									
N/A.									

Table C.12: Screening Questions and Off-Topic References Excluded at *Full Text Screening* for Fate		
Question	**Off-topic if answer is:**	**References excluded (HERO ID)**
Does the reference contain information pertaining to a low-priority substance candidate?	No	3042030 1049870 2218126 3363559 4829042 4829049 4860842 4861922 4884530 4829143 4829173 4860893
What type of source is this reference?	Review article or book chapter that contains only citations to primary literature sources	4861922
Is quantitative fate data presented?	No	2218126
Is this primarily a modeling/simulation study? [Note: Select "Yes" only if there is no experimental verification]	Yes	N/A

Table C.13: Data Quality Metrics and Unacceptable References Excluded at *Data Quality Evaluation* for Fate		
Data quality metric	**Unacceptable if:**	**References excluded (HERO ID)**
Metric 1: Test Substance Identity	The test substance identity or description cannot be determined from the information provided (e.g., nomenclature was unclear and CASRN or structure were not reported). **OR**	N/A

Table C.13: Data Quality Metrics and Unacceptable References Excluded at *Data Quality Evaluation* for Fate		
Data quality metric	**Unacceptable if:**	**References excluded (HERO ID)**
	For mixtures, the components and ratios were not characterized or did not include information that could result in a reasonable approximation of components.	
Metric 2: Study Controls	The study did not include or report crucial control groups that consequently made the study unusable (e.g., no positive control for a biodegradation study reporting 0% removal). **OR** The vehicle used in the study was likely to unduly influence the study results.	N/A
Metric 3: Test Substance Stability	There were problems with test substance stability, homogeneity, or preparation that had an impact on concentration or dose estimates and interfered with interpretation of study results.	N/A
Metric 4: Test Method Suitability	The test method was not reported or not suitable for the test substance. **OR** The test concentrations were not reported. **OR** The reported test concentrations were not measured, and the nominal concentrations reported greatly exceeded the substances water solubility, which would greatly inhibit meaningful interpretation of the outcomes.	N/A
Metric 5: Testing Conditions	Testing conditions were not reported, and the omission would likely have a substantial impact on study results. **OR** Testing conditions were not appropriate for the method (e.g., a biodegradation study at temperatures that inhibit the microorganisms).	N/A
Metric 6: System Type and Design- Partitioning	Equilibrium was not established or reported, preventing meaningful interpretation of study results. **OR** The system type and design (e.g. static, semi-static, and flow-through; sealed, open) were not capable of appropriately maintaining substance concentrations, preventing meaningful interpretation of study results.	N/A
Metric 7: Test Organism-Degradation	The test organism, species, or inoculum source were not reported, preventing meaningful interpretation of the study results.	N/A
Metric 8: Test Organism-Partitioning	The test organism information was not reported. **OR** The test organism is not routinely used and would likely prevent meaningful interpretation of the study results.	N/A
Metric 9: Outcome Assessment Methodology	The assessment methodology did not address or report the outcome(s) of interest.	4829024

Table C.13: Data Quality Metrics and Unacceptable References Excluded at *Data Quality Evaluation* for Fate		
Data quality metric	**Unacceptable if:**	**References excluded (HERO ID)**
Metric 10: Data Reporting	Insufficient data were reported to evaluate the outcome of interest or to reasonably infer an outcome of interest. **OR** The analytical method used was not suitable for detection or quantification of the test substance. **OR** Data indicate that disappearance or transformation of the parent compound was likely due to some other process.	N/A
Metric 11: Confounding Variables	There were sources of variability and uncertainty in the measurements and statistical techniques or between study groups.	4829024
Metric 12: Verification or Plausibility of Results	Reported value was completely inconsistent with reference substance data, related physical chemical properties, or otherwise implausible, suggesting that a serious study deficiency exists (identified or not).	N/A