



United States
Environmental Protection Agency

Office of Chemical Safety and
Pollution Prevention

**Proposed Designation of
Butyl Benzyl Phthalate
(CASRN 85-68-7)
as a High-Priority
Substance for Risk
Evaluation**

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Acronyms and Abbreviations

Term	Description
ACGIH	American Conference of Governmental Industrial Hygienists
BBP	Butyl benzyl phthalate
BP	Boiling point
CAA	Clean Air Act
CASRN	Chemical Abstracts Service Registry Number
CBI	Confidential Business Information
CDR	Chemical Data Reporting
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
CFR	Code of Federal Regulations
CWA	Clean Water Act
EPCRA	Emergency Planning and Community Right-to-Know Act
IUR	Inventory Update Reporting
M	Million
MITI	Ministry of International Trade and Industry, Japan
MP	Melting point
N/A	Not applicable
NIH	National Institutes of Health
NIOSH	National Institute for Occupational Safety and Health
NOC	Not otherwise categorized
NR	Not reported
OECD	Organisation for Economic Co-operation and Development
OSHA	Occupational Safety and Health Administration
PEL	Permissible Exposure Limit
PPE	Personal protective equipment
RCRA	Resource Conservation and Recovery Act
REL	Recommended Exposure Limit
RY	Reporting year

Term	Description
SMILES	Simplified molecular-input line-entry system
TBD	To be determined
TLV	Threshold Limit Value
TRI	Toxics Release Inventory
TSCA	Toxic Substances Control Act
VP	Vapor pressure
WS	Water solubility

1. Introduction

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

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

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

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

Butyl benzyl phthalate (BBP) is one of the 40 chemical substances initiated for prioritization as referenced in the March 21, 2019 notice (84 FR 1049)². EPA has determined that BBP is a suitable candidate for the proposed designation as a high-priority substance. The proposed designation is based on the results of the review against the aforementioned criteria and considerations as well as review of the reasonably available information on BBP, including relevant information received from the public and other information as appropriate.

¹ For all 40 CFR 702 citations, please refer to:

<https://www.govinfo.gov/content/pkg/CFR-2018-title40-vol33/xml/CFR-2018-title40-vol33-part702.xml> and <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0654-0108>

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

EPA will take comment on this proposed designation for 90 days before finalizing its designation of BBP. The docket number for providing comments on BBP is EPA-HQ-OPPT-2018-0501 and is available at www.regulations.gov.

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

- *Section 1 (Introduction):* This section explains the requirements of the amended TSCA and implementing regulations – including the criteria and considerations -- pertinent to the prioritization and designation of high-priority chemical substances.
- *Section 2 (Production volume or significant changes in production volume):* This section presents information and analysis on national aggregate production volume of the chemical substance.
- *Section 3 (Conditions of use or significant changes in conditions of use):* This section presents information and analysis regarding the chemical substance's conditions of use under TSCA.
- *Section 4 (Potentially exposed or susceptible subpopulations):* This section presents information and analysis regarding potentially exposed or susceptible subpopulations, including children, women of reproductive age, and workers, with respect to the chemical substance.
- *Section 5 (Persistence and bioaccumulation):* This section presents information and analysis regarding the physical and chemical properties of the chemical substance and the chemical's fate characteristics.
- *Section 6 (Storage near significant sources of drinking water):* This section presents information and analysis considered regarding the risk from the storage of the chemical substance near significant sources of drinking water.
- *Section 7 (Hazard potential):* This section presents the hazard information relevant to the chemical substance.
- *Section 8 (Exposure potential):* This section presents information and analysis regarding the exposures to the chemical substance.
- *Section 9 (Other risk-based criteria):* This section presents the extent to which EPA identified other risk-based criteria that are relevant to the designation of the chemical substance's priority.
- *Section 10 (Proposed designation):* Based on the results of the review performed and the information and analysis presented, this section describes the basis used by EPA to support the proposed designation.

2. Production volume or significant changes in production volume

Approach

EPA considered current volume or significant changes in volume of the chemical substance using information reported by manufacturers (including importers). EPA assembled reported information for years 1986 through 2015 on the production volume for BBP reported under the Inventory Update Reporting (IUR) rule and Chemical Data Reporting (CDR) rule.³ The national aggregate production volume, which is presented as a range to protect individual site production volumes that are confidential business information (CBI), is presented in Table 1.

Results and Discussion

Production volume of BBP in 2015, as reported to EPA during the 2016 CDR reporting period, was between 10 and 50 million pounds. Production volume of BBP as reported to EPA has decreased very substantially since 1990. It has decreased further since 2011 and has not changed since 2012 consistently ranging from 10 to 50 million pounds per year (Table 1).

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

Chemical ID	1986	1990	1994	1998	2002	2006	2011	2012	2013	2014	2015
Butyl Benzyl Phthalate (85-68-7)	>50M to 100M	>100M to 500M	>50M to 100M	>100M to 500M	>50M to 100M	50M to <100M	50M to 100M	10M to 50M	10M to 50M	10M to 50M	10M to 50M
Note: M = million Reference: U.S. EPA (2013) and U.S. EPA (2017)											

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

Approach

EPA assembled information to determine conditions of use or significant changes in conditions of use of the chemical substance. TSCA section 3(4) defines the term “conditions of use” to mean the circumstances, as determined by the Administrator, under which a chemical substance is

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

intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.

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

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

CDR Tables

Based on the publicly available⁴ manufacturing information, industrial processing and use information, and consumer and commercial use information reported under CDR, EPA developed a list of conditions of use for the 2016 and 2012 reporting cycles (Table 2 and Table 3 respectively).

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

Table 2. Butyl Benzyl Phthalate (85-68-7) Categories and Subcategories of Conditions of Use⁵ (2016 CDR Reporting Cycle)

Life-Cycle Stage	Category	Subcategory of Use	Reference
Manufacturing	Domestic manufacturing/Import	CBI	U.S. EPA (2019a)
	Import	Import	U.S. EPA (2019a)
Processing	Incorporation into formulation, mixture, or reaction product	Fillers in: – Custom compounding of purchased resin	U.S. EPA (2019a)
	Incorporation into article	Plasticizers in: – Adhesive manufacturing – Plastics product manufacturing	U.S. EPA (2019a)
Distribution in Commerce ^{a,b}	Distribution in commerce		
Commercial Uses	Adhesives and sealants	Adhesives and sealants	U.S. EPA (2019a)
	Floor coverings	Floor coverings	U.S. EPA (2019a)
	Paints and coatings	Paints and coatings	U.S. EPA (2019a)
Consumer Uses	Adhesives and sealants	Adhesives and sealants	U.S. EPA (2019a)
	Floor coverings	Floor coverings	U.S. EPA (2019a)
Disposal ^a	Disposal		
<p>^a CDR includes information on the manufacturing, processing, and use of chemical substances. CDR may not provide information on other life-cycle phases such as distribution or chemical end-of-life after use in products (i.e., disposal). The table row is highlighted in gray to indicate that no information is provided for this life-cycle stage.</p> <p>^b EPA is particularly interested in information from the public on distribution in commerce.</p>			

⁵ Certain other uses that are excluded from TSCA are not captured in this table.

Table 3. Butyl Benzyl Phthalate (85-68-7) Categories and Subcategories of Conditions of Use⁶ (2012 CDR Reporting Cycle)

Life-Cycle Stage	Category	Subcategory of Use	Reference
Manufacturing	Domestic manufacturing/Import	CBI	U.S. EPA (2019a)
	Import	Import	U.S. EPA (2019a)
Processing	Processing – incorporating into articles	Plasticizers in: – Adhesive manufacturing – Plastics product manufacturing	U.S. EPA (2019a)
Distribution in Commerce ^{a,b}	Distribution in commerce		
Commercial Uses	Adhesives and sealants	Adhesives and sealants	U.S. EPA (2019a)
	Floor coverings	Floor coverings	U.S. EPA (2019a)
Consumer Uses	Adhesives and sealants	Adhesives and sealants	U.S. EPA (2019a)
	Floor coverings	Floor coverings	U.S. EPA (2019a)
Disposal ^a	Disposal		http://www.epa.gov/cdr/
<p>^a CDR includes information on the manufacturing, processing, and use of chemical substances. CDR may not provide information on other life-cycle phases such as distribution or chemical end-of-life after use in products (i.e., disposal). The table row is highlighted in gray to indicate that no information is provided for this life-cycle stage.</p> <p>^b EPA is particularly interested in information from the public on distribution in commerce.</p>			

CDR and TRI Summary and Additional Information on Conditions of Use

BBP was removed from the TRI chemical list; reporting year (RY) 1993 was the last RY for this chemical. In the 2016 CDR reporting cycle, BBP was reported as used in manufacturing commercial and consumer products. Two sites reported use of BBP in adhesives and sealants. One site reported use of BBP in floor coverings. Two sites reported use of BBP in commercial paints and coatings. Three facilities reported that BBP was not recycled (e.g., not recycled, remanufactured, reprocessed, or reused).

Industrial uses of BBP in adhesive and plastic product manufacturing were consistent between the 2012 and 2016 CDR reporting cycles. In the 2012 CDR data, three sites reported non-specific industrial processing, whereas in the 2016 CDR data, only one site reported non-specific

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

industrial processing and one site reported processing of BBP in the custom compounding of resin.

Consumer and commercial uses of BBP in adhesives and sealants, as well as floor coverings were consistent between 2012 and 2016; however, the product concentrations changed significantly for adhesives and sealants. In 2012, there were two non-specific consumer or commercial uses reported, whereas in 2016 two sites reported a use of BBP in commercial paints and coatings.

CDR data show that consumer and commercial uses have not changed significantly between 2012 and 2016. Consumer uses were also identified in additional databases, which are included in the Exposure Potential section (Section 8).

According to one public comment received, BBP is used in adhesives, lacquers, coatings, and processing aids in the aerospace industry. BBP has been identified within lacquer compounds, topcoats, spray paint and potting compounds. There are also very specific applications such as in adhesives critical to electrical/circuit boards, in printed wire assemblies, and processing aids such as parting lacquers, primer surfacer, and maskings used in the temporary protection of aircraft parts. Other uses found were as a catalyst in composite air ducts, as a dielectric paste, or within silicone rubber coated fiberglass (EPA-HQ-OPPT-2018-0501-0004 (Aerospace Industries Association)).

According to another public comment, BBP is used in trace amounts as a plasticizer and additive in clear coatings and industrial wood coatings, some of which are designed for spray application and consumer use. BBP is also used in adhesives and sealants. It's also used in adhesives and sealants. The amounts used in coatings manufacturing is extremely low (below 2,500 pounds per year), if used at all. The amount of BBP in products are typically negligible, although some specialty adhesives and sealants may contain amounts above 10%, but below 50% (EPA-HQ-OPPT-2018-0501-0003 (American Coatings Association)).

According to an additional comment, BBP is used in coatings and construction materials (EPA-HQ-OPPT-2018-0501-0008 (BASF)). Additionally, BASF reported importing this substance in the 2016 CDR for the RY 2015 and 2018 and does not expect to report this chemical in their 2020 CDR. In their comments, BASF redacted specific amount of lbs imported in the 2016 CDR and in 2018.

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

4. Potentially exposed or susceptible subpopulations

Approach

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

Results and Discussion

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

Children

EPA used data reported to the 2012 and 2016 CDR to identify uses in products and articles intended for children over time for BBP. The 2012 and 2016 CDR did not report any use in children's products. In the existing assessments reviewed, there was no discussion on the susceptibility of children to BBP. EPA identified potential developmental hazards that would impact any stage of children's development.

Women of reproductive age (e.g., pregnant women per TSCA statute)

EPA identified studies that observed developmental and reproductive effects following exposure to BBP (Section 7, Table 6). Pregnant women are therefore included as a susceptible subpopulation with respect to BBP.

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

Workers

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

Consumers

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

5. Persistence and bioaccumulation

Approach

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

Physical and Chemical Properties and Environmental Fate Tables

Table 4 and Table 5 summarize the physical and chemical properties and environmental fate characteristics of BBP, respectively.

Table 4. Physical and Chemical Properties of Butyl Benzyl Phthalate

Property or Endpoint	Value ^a	Reference
Molecular Formula	C ₁₉ H ₂₀ O ₄	CRC Handbook (Haynes, 2014)
Molecular Weight	312.360 g/mole	CRC Handbook (Haynes, 2014)
Physical State	Liquid	CRC Handbook (Haynes, 2014)
Physical Form	Clear, oil liquid	HSDB (2015) citing Lewis (2012)
Purity	>98.5% w/w; impurities include <1.0% dibenzyl phthalate, <0.5% benzyl benzoate, <0.5% dibutyl phthalate, <2 ppm α-chlorotoluen and <2 ppm α-α-diclorotoluen; additives include <0.5 ppm pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	ECB (2007)
Melting Point	-35 °C	HSDB (2015) ; Lewis (2012)
	-40.5 °C	Physprop (2012)
Boiling Point	370 °C	CRC Handbook (Haynes, 2014); HSDB (2015) citing Lewis (2012)
Density	1.12 g/cm ³ at 25 °C	HSDB (2015) citing CRC Handbook (Haynes, 2014); Lewis (2012)
Vapor Pressure	8.25 × 10 ⁻⁶ mm Hg at 25 °C	HSDB (2015) citing Howard et al. (1985)
Vapor Density	10.8 (relative vapor density to air = 1)	HSDB (2015) citing Lewis (2012)
Water Solubility	2.69 mg/L at 25 °C	HSDB (2015) citing Howard (1985)

Property or Endpoint	Value ^a	Reference
Log Kow	4.73	HSDB (2015) citing Ellington and Floyd (1996)
Henry's Law Constant	1.26×10^{-6} atm-m ³ /mole at 25 °C (calculated from measured vapor pressure and water solubility data) ^b	EPI Suite (2012)
Flash Point	199 °C (closed cup)	HSDB (2015) citing NFPA (2010)
Auto Flammability	425 °C (autoignition temperature)	ECB (2007) citing Bayer AG (1999)
Viscosity	42 mPa s at 25 °C	ECHA (2018) citing Ferro (2008)
Refractive Index	1.535–1.540 at 25 °C	HSDB (2015) citing IARC 1982
Dielectric Constant	TBD	TBD
Surface Tension	34 dynes/cm (0.034 N/M) at 20 °C	HSDB (2015) citing CHRIS (1984)
Notes: ^a Measured unless otherwise noted; ^b EPI Suite™ physical property inputs: Log Kow = 4.73, BP = 370 °C, MP = -40.5 °C, VP = 8.25×10^{-6} mm Hg, WS = 2.69 mg/L BioP = 4, BioA = 1 and BioS = 1 SMILES O=C(OCC(c1ccccc1)c1c(c(ccc2)C(=O)OCCCC)c2); TBD = to be determined, if reasonably available. EPA is particularly interested in information from the public on these properties or endpoints.		

Table 5. Environmental Fate Characteristics of Butyl Benzyl Phthalate

Property or Endpoint	Value ^a	Reference
Direct Photodegradation	0%/10 days; 43%/28 days	ECB (2007) citing Monsanto (1979)
	<5%/28 days	ECB (2007) citing Monsanto (1980)
	t _{1/2} > 100 days	ECB (2007) citing Gledhill et al. (1980)
Indirect Photodegradation	t _{1/2} = 11.6 hours at 25 °C based on ·OH rate constant of 1.1×10^{-11} cm ³ /molecule second and 1.5×10^6 ·OH/cm ³ ; estimated) ^b	EPI Suite (2012)
Hydrolysis	t _{1/2} > 100 days	ECHA (2018) citing Gledhill et al. (1980)
Biodegradation (Aerobic)	74–79%/10–50 days at 25 °C (activated sludge)	HSDB (2015) citing Desai (1992)

Property or Endpoint	Value ^a	Reference
	t _{1/2} = 5 days (lake water/sediment microcosm)	HSDB (2015) citing Carson et al. (1990)
	81%/2 weeks based on BOD (MITI test)	HSDB (2015) citing NITE (2015)
Biodegradation (Anaerobic)	t _{1/2} = 107 hours (sewage sludge)	HSDB (2015) citing Ziogou et al. (1989)
	98.3%/120 days at 35 °C	HSDB (2015) citing Parker et al. (1994)
Wastewater Treatment	80% of sewage treatment plants had a 90% removal of 1,2-benzenedicarboxylic acid, 1-butyl 2-(phenylmethyl) ester in secondary sewage treatment plant, whereas 10% had less than 40% removal	ECB (2007) citing U.S. EPA (1982)
	100% total removal (90% biodegradation, 10% sludge, 0% air; estimated) ^b	EPI Suite (2012)
Bioconcentration Factor	663 and 772 (<i>Lepomis macrochirus</i>)	HSDB (2015) citing Carr et al. (1997)
	0.13 to 45 (<i>Ipomoea aquatica</i>)	HSDB (2015) citing Cai et al. (2006)
Soil Organic Carbon:Water Partition Coefficient (Log K _{oc})	3.3 at pH 4.8	HSDB (2015) citing Zurmuehl et al. (1991)
	3.21	HSDB (2015) citing Sablijic et al. (1995)
Notes:		
^a Measured unless otherwise noted		
^b EPI Suite™ physical property inputs: Log Kow = 4.73, BP = 370 °C, MP = -40.5 °C, VP = 8.25 × 10 ⁻⁶ mm Hg, WS = 2.69 mg/L BioP = 4, BioA = 1 and BioS = 1 SMILES O=C(OCc(ccc1)c1)c(c(ccc2)C(=O)OCCCC)c2		
·OH = hydroxyl radical; OECD: Organisation for Economic Co-operation and Development; SIDS = screening information data sets; MITI = Ministry of International Trade and Industry, Japan; BOD = biochemical oxygen demand; K _{oc} = organic carbon-water partition coefficient		

Results and Discussion

BBP is a clear, oily liquid with moderate water solubility (2.69 mg/L). Based on its calculated Henry's Law constant (1.26 × 10⁻⁶ atm·m³/mole), BBP has moderate potential to volatilize from water or moist soil surfaces; however, its measured vapor pressure (8.25 × 10⁻⁶ mm Hg) indicates only low potential to volatilize from dry soil. BBP's measured soil adsorption coefficient (log K_{oc} 3.21–3.3) suggests moderate mobility in soil, which would increase the possibility of migration of this chemical to groundwater. If released directly to air, BBP in the vapor phase will be susceptible to both direct (measured half-life >100 days) and indirect (estimated half-life of 11.6 hours for reaction with photochemically-generated hydroxy radicals) photodegradation, whereas particulate BBP may be removed via wet and dry precipitation.

BBP reached 74–79 percent biodegradation in 10–50 days in aerobic activated sludge and 81 percent biodegradation in 14 days in a Japanese Ministry of International Trade and Industry (MITI) test. Measured aerobic and anaerobic degradation half-lives of 5 and 4.5 days were reported for BBP in lake water/sediment microcosm and sewage sludge, respectively. These data suggest that BBP has low potential to persist in the environment. Based on the measured bioconcentration factors of 663 and 772 in bluegill, BBP is expected to have low potential to bioaccumulate.

6. Storage near significant sources of drinking water

Approach

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

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

Results and Discussion

BBP is a Priority Pollutant under the CWA. EPA has not established a Maximum Contaminant Level Goal (MCLG) or Maximum Contaminant Level (MCL) for BBP.

BBP is not subject to reporting requirements under EPCRA. It was on the original TRI chemical list in 1987 but delisted in calendar year 1994. EPA considers it as a hazardous substance under CERCLA and releases of BBP in excess of 100 pounds are subject to reporting to the National Response Center. It is also listed on the Superfund Amendments and Reauthorization Act of 1986, a list that includes substances most commonly found at facilities on the CERCLA National Priorities List that have been deemed to pose the greatest threat to public health.

BBP is listed as a hazardous constituent under the Resource Conservation and Recovery Act (RCRA). RCRA directs EPA to develop and promulgate criteria for identifying the characteristics of hazardous waste, and for listing hazardous waste, taking into account toxicity,

persistence, and degradability in nature, potential for accumulation in tissue and other related factors such as flammability, corrosiveness, and other hazardous characteristics

7. Hazard potential

Approach

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

Because there are very few publicly available assessments for BBP with cited environmental hazard data (Table 7). EPA used the infrastructure of ECOTOXicology knowledgebase (ECOTOX) to identify single chemical toxicity data for aquatic and terrestrial life ([U.S. EPA, 2018](#)). It uses a comprehensive chemical-specific literature search of the open literature that is conducted according to the Standard Operating Procedures (SOPs)⁷. The environmental hazard information was populated in ECOTOX and is available to the public. In comparison to the approach used to survey human health hazard data, EPA also used a read-across approach to identify additional environmental hazard data for isomers of BBP, if available, to fill in potential data gaps when there were no reported observed effects for specific taxa exposed to BBP (Table 7).

Potential Human Health and Environmental Hazard Tables

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

⁷ The ECOTOX Standard Operating Procedures (SOPs) can be found at: <https://cfpub.epa.gov/ecotox/help.cfm?helptabs=tab4>

Table 6. Potential Human Health Hazards Identified for Butyl Benzyl Phthalate

Human Health Hazards	Tested for Specific Effect	Effect Observed	Reference
Acute Toxicity	X		NICNAS (2015) , NICNAS (2008) , ECB (2007) , NTP (2003) , RIVM (2001) , Environment Canada (2000)
Repeated Dose Toxicity	X	X	NICNAS (2015) , CPSC (2014) , CPSC (2010) , NICNAS (2008) , ECB (2007) , RIVM (2001) , IRIS (1989)
Genetic Toxicity	X	X	NICNAS (2015) , OEHHA (2013) , NICNAS (2008) , ECB (2007) , NTP (2003) , U.S. EPA (2002) , RIVM (2001) , Environment Canada (2000) , IARC (1999) , NTP (1997) , IRIS (1989)
Reproductive Toxicity	X	X	UNEP (2016) , CPSC (2014) , CPSC (2010) , ECHA (2010) , NICNAS (2008) , ECB (2007) , NTP (2003) , RIVM (2001) , IRIS (1989)
Developmental Toxicity	X	X	UNEP (2016) , CPSC (2014) , OEHHA (2013) , OEHHA (1986) , CPSC (2010) , NICNAS (2008) , ECB (2007) , NTP (2003) , Environment Canada (2000) , IARC (1999)
Toxicokinetic	X	X	NICNAS (2015) , OEHHA (1986) , CPSC (2010) , NICNAS (2008) ; NTP (2003) , U.S. EPA (2002) , RIVM (2001) , Environment Canada (2000) , IARC (1999)
Irritation/ Corrosion	X		NICNAS (2008) , ECB (2007) , NTP (2003) , Environment Canada (2000)
Dermal Sensitization	X		NICNAS (2015) , NICNAS (2008) , ECB (2007) , NTP (2003)
Respiratory Sensitization	X	X	UNEP (2016)
Carcinogenicity	X	X	NICNAS (2015) , OEHHA (2013) , Lowell Center (2011) , CPSC (2010) , NICNAS (2008) , ECB (2007) , U.S. EPA (2002) , RIVM (2001) , Environment Canada (2000) , IARC (1999) , NTP (1997) , IRIS (1989)
Immunotoxicity			
Neurotoxicity	X		ECB (2007) , Environment Canada (2000)
Epidemiological Studies or Biomonitoring Studies	X	X	CPSC (2017) , UNEP (2016) , NICNAS (2015) , CSPC (2015) , OEHHA (2013) , ECHA (2010) , OEHHA (1986) , ECB (2007) , NTP (2003)

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

Table 7. Potential Environmental Hazards Identified for Butyl Benzyl Phthalate

Media	Study Duration	Taxa Groups	High-Priority Chemical Candidate		Isomers of Butyl Benzyl Phthalate 1,2-Benzene-Dicarboxylic Acid, 1-Butyl 2(Phenylmethyl) Ester (CASRN 85-68-7)		Reference
			Butyl Benzyl Phthalate 1,2-Benzene-Dicarboxylic Acid, 1-Butyl 2(Phenylmethyl) Ester (CASRN 85-68-7)	NONE	Number of Studies	Observed Effects	
Aquatic	Acute exposure	Vegetation	3	X	–		Adams et al. (1995); Jonsson and Baun (2003); Nendza and Wenzel (2006)
		Invertebrate	20	X	–		Adams and Heidolph (1985); Adams et al. (1995); Barera and Adams (1983); Herrero et al. (2015); Horne and Oblad (1983); Jonsson and Baun (2003); LeBlanc (1980); Liu et al. (2009); Martinez-Guitarte et al. (2012); Mayer (1987); Monsanto Co. (1986) ; Morales et al. (2011); Planello et al. (2011) ; Wang et al. (2011) ; Zaroogian (1981)
		Fish	12	X	–		Adams et al. (1995) ; Buccafusco et al. (1981) ; Carr et al. (1997) ; E.G. and G. Bionomics (1983) ; Heitmuller et al. (1981) ; Jarmolowicz et al. (2010) LeBlanc (1984) ; Ozretich et al. (1983) Randall et al. (1983)
		Non-fish vertebrate (i.e., amphibians, reptiles, mammals)	–		–		
		Vegetation	1	X	–		Chen et al. (2011)

Media	Study Duration	Taxa Groups	High-Priority Chemical Candidate Butyl Benzyl Phthalate 1,2-Benzene-Dicarboxylic Acid, 1-Butyl 2(Phenylmethyl) Ester (CASRN 85-68-7)		Isomers of Butyl Benzyl Phthalate 1,2-Benzene-Dicarboxylic Acid, 1-Butyl 2(Phenylmethyl) Ester (CASRN 85-68-7)		Reference
			Number of Studies	Observed Effects	Number of Studies	Observed Effects	
Aquatic	Chronic exposure	Invertebrate	3	X	–		Adams and Heidolph (1985); E.G. and G. Bionomics (1979); Rhodes et al. (1995)
		Fish	8	X	–		Barrows et al. (1978); Harries et al. (2000); Hicks (2008); Kaplan et al. (2013); LeBlanc (1984); Ozretich et al. (1983); Wibe et al. (2002); Zhang et al. (2014)
		Non-fish vertebrate (i.e., amphibians, reptiles, mammals)	1	X	–		Sugiyama et al. (2005)
Terrestrial	Acute exposure	Vegetation	–		–		
		Invertebrate	3	X	–		Boyd et al. (2016) ; Lenoir et al. (2014); Valencia et al. (1985)
		Vertebrate	1	X	–		Wilson et al. (2004)
	Chronic exposure	Vegetation	–		–		
		Invertebrate	–		–		
		Vertebrate	1	X	–		Larsen et al. (2003)

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

8. Exposure potential

Approach

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

Release Potential for Environmental and Human Health Exposure

EPA considered conditions of use reported in CDR and the physical and chemical properties to inform the release potential of BBP.

Worker/Occupational exposure and consumer exposure

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

General population exposure

EPA identified environmental concentration and ecological biomonitoring data to inform BBP's exposure potential to the general population (Table 9).

Results and Discussion

Release Potential for Environmental and Human Health Exposure

BBP was removed from the TRI chemical list in 1994. RY 1993 was the last RY for this chemical.

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

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

Worker/Occupational exposure

Worker exposures to this chemical may be affected by many factors, including but not limited to volume produced, processed, distributed, used, and disposed of; physical form and concentration; processes of manufacture, processing, and use; chemical properties such as vapor pressure, solubility, and water partition coefficient; local temperature and humidity; and

exposure controls such as engineering controls, administrative controls, and the existence of a personal protective equipment (PPE) program.

BBP has a vapor pressure of 8.25×10^{-6} mm Hg at 25 °C/77 °F. EPA assumes negligible inhalation exposure to vapors generated from liquids with vapor pressures below 0.001 mm Hg at ambient room temperature conditions. BBP does not have an OSHA Permissible Exposure Limit (PEL) ([OSHA 2009](#)), a NIOSH Recommended Exposure Limit (REL) ([NIOSH 2005](#)), or the TLV set by ACGIH.

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

Consumer exposure

CDR reporting and information from the National Institutes of Health (NIH) Household Products Database and the Chemical and Products Database ([CPDat](#)) indicate that BBP is used in a number of consumer products (Table 8) and exposure can occur following the use of these products ([U.S. EPA 2019b](#), [NTP 2003](#)). Once incorporated into products intended for consumer use, BBP is not bound within the matrix and can migrate from the polymeric material and be released ([ECB 2007](#)). Consumer exposure can come from food and food packaging, fragrances, baby products, children's toys, and indoor dust ([OEHHA 2013](#)).

Table 8. Exposure Information for Consumers

Chemical Identity	Consumer Product Database
	Consumer Uses (List)
Butyl Benzyl Phthalate (85-68-7)	Adhesive, apparel bags, arts crafts paint, arts crafts products, automotive, automotive care, binding, building material, carpet, caulk/sealant, casting agent, cleaner, clothing, colorant, decor, electronics, filler, filler building material, finish spray, fixative, flooring, fluid property modulator, footwear, grout sealer, hardener, insulation, lubricant, metal surface treatment, paint, paint automotive, paint binding, paint exterior, paper surface treatment, photographic, plastic building material, plastic, plastic softener, polish, primer, printing, printing ink, putty or filler, rubber, seal material, softener, surface treatment, toothbrush, toys, viscous liquid building material, wall building material, writing ink

Reference: [CPDat](#)

General population exposure

Releases of BBP from certain conditions of use, such as manufacturing, disposal, or waste treatment activities, may result in general population exposures via ingestion, dermal contact, and inhalation from air releases. Based on a review of the available literature, there is ecological aquatic, non-mammalian biomonitoring data available; however, no human biomonitoring was identified (Table 9).

BBP has been identified in air, water, sediment, and soil samples ([ECB 2007](#), [Environment Canada 2000](#)), as well as in food stuffs (i.e., carcass meat, poultry, eggs, and milk) ([NTP 2003](#), [CPSC 2010](#)). The general population is primarily exposed via ingestion ([NTP 2003](#), [IARC 1999](#), [CPSC 2010](#)).

Table 9. Exposure Information for the Environment and General Population

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

^a Concen.= concentration

^b Biomon.= biomonitoring

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

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

10. Proposed designation and Rationale

Proposed Designation: High-priority substance

Rationale: EPA identified and analyzed reasonably available information for exposure and hazard and is proposing to find that BBP may present an unreasonable risk of injury to health and/or the environment, including potentially exposed or susceptible subpopulations (e.g., workers, consumers, women of reproductive age, children). This is based on the potential hazard and potential exposure of BBP under the conditions of use described in this document to support the prioritization designation. Specifically, EPA expects that the manufacturing, processing, distribution, use, and disposal of BBP may result in presence of the chemical in surface water and groundwater, ingestion of the chemical in drinking water, inhalation of the chemical from air releases, exposure to workers, exposure to consumers, and exposure to the general population, including children. In addition, EPA identified potential environmental (e.g., aquatic toxicity, terrestrial toxicity) and human health hazards (e.g., repeated dose toxicity, genetic toxicity, reproductive toxicity, developmental toxicity, respiratory sensitization, carcinogenicity, and observations in epidemiologic and/or biomonitoring studies).

11. References

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

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