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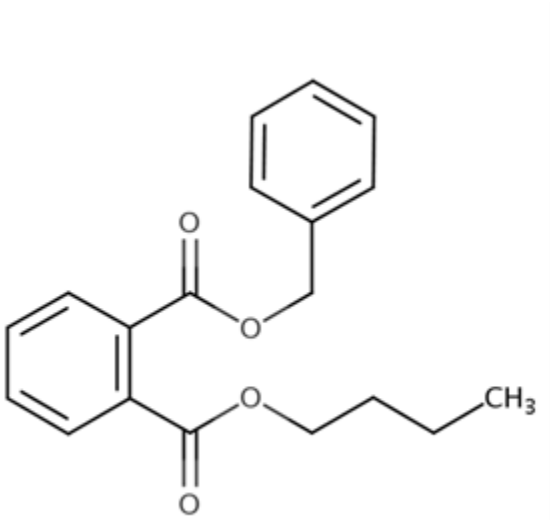
Office of Chemical Safety and
Pollution Prevention

United States
Environmental Protection Agency

Draft Scope of the Risk Evaluation for Butyl Benzyl Phthalate (1,2-Benzenedicarboxylic acid, 1-butyl 2-(phenylmethyl) ester)

CASRN 85-68-7



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Docket

Supporting information can be found in public docket: [Docket ID: EPA-HQ-OPPT-2018-0501].

Disclaimer

Reference herein to any specific commercial products, process or service by trade name, trademark, manufacturer or otherwise does not constitute or imply its endorsement, recommendation or favoring by the U.S. Government.

ABBREVIATIONS AND ACRONYMS

ACGIH	American Conference of Governmental Industrial Hygienists
ADME	Absorption, Distribution, Metabolism, and Excretion
AEGL	Acute Exposure Guideline Level
AICS	Australian Inventory for Chemical Substances
ATSDR	Agency for Toxic Substances and Disease Registry
BAF	Bioaccumulation Factor
BCF	Bioconcentration Factor
BMF	Biomagnification Factor
BOD	Biochemical oxygen demand
BP	Boiling point
BW	Body weight
CAA	Clean Air Act
CASRN	Chemical Abstracts Service Registry Number
CBI	Confidential Business Information
CDR	Chemical Data Reporting
CEHD	Chemical Exposure Health Data
CERCLA	Comprehensive Environmental Response, Compensation and Liability Act
CFR	Code of Federal Regulations
CHRIP	Chemical Risk Information Platform
COC	Concentration of Concern
CPCat	Chemical and Product Categories
CPSC	Consumer Product Safety Commission
CSCL	Chemical Substances Control Law
CWA	Clean Water Act
DMR	Discharge Monitoring Report
EC	Engineering Controls
EC_x	Effective Concentration
ECB	European Chemicals Bureau
ECHA	European Chemicals Agency
EPA	Environmental Protection Agency
EPCRA	Emergency Planning and Community Right-to-Know Act
ERG	Eastern Research Group
ESD	Emission Scenario Document
EU	European Union
FDA	Food and Drug Administration
FYI	For Your Information
FR	Federal Register
GDIT	General Dynamics Information Technology
GESTIS	International Occupational Exposure Limit Database
GS	Generic Scenario
Hg	Mercury
HHE	Health Hazard Evaluation
HMTA	Hazardous Materials Transportation Act
IARC	International Agency for Research on Cancer
ICF	ICF is a global consulting services company
IECCU	Indoor Environmental Concentrations in Buildings with Conditioned and Unconditioned Zones

IMAP	Inventory Multi-Tiered Assessment and Prioritisation (Australia)
K_{OC}	Organic Carbon: Water Partition Coefficient
K_{OW}	Octanol: Water Partition Coefficient
KOECT	Kirk-Othmer Encyclopedia of Chemical Technology
LC_x	Lethal Concentration
LOAEL	Lowest Observed Adverse Effect Level
LOEC	Lowest Observed Effect Concentration
MACT	Maximum Achievable Control Technology
MDI	MDI Biological Laboratory
MITI	Ministry of International Trade and Industry
MOA	Mode of Action
MP	Melting point
NASA	National Air and Space Administration
NEI	National Emissions Laboratory
NICNAS	National Industrial Chemicals Notification and Assessment Scheme (Australia)
NIOSH	National Institute for Occupational Safety and Health
NITE	National Institute of Technology and Evaluation
NLM	National Library of Medicine
NOAEL	No Observed Adverse Effect Level
NOEC	No Observed Effect Concentration
NPDES	National Pollutant Discharge Elimination System
NPL	National Priorities List
NPRI	National Pollutant Release Inventory
NTP	National Toxicology Program
OCSPP	Office of Chemical Safety and Pollution Prevention
OECD	Organisation for Economic Co-operation and Development
OEHHA	Office of Environmental Health Hazard Assessment (California)
OEL	Occupational Exposure Limit
ONU	Occupational Non-User
OPPT	Office of Pollution Prevention and Toxics
OSHA	Occupational Safety and Health Administration
OW	Office of Water
PBPK	Physiologically Based Pharmacokinetic
PBT	Persistent, Bioaccumulative, Toxic
PPE	Personal Protective Equipment
P-Chem	Physical-Chemical
PECO	Population, Exposure, Comparator and Outcome
PESS	Potentially Exposed or Susceptible Populations
POD	Point of Departure
POTW	Publicly Owned Treatment Works
RCRA	Resource Conservation and Recovery Act
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals (European Union)
RIVM	Dutch National Institute for Public Health and the Environment
RQ	Risk Quotient
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
SDWA	Safe Drinking Water Act
SRC	SRC Inc., formerly Syracuse Research Corporation

STORET	STORage and RETrieval (water quality data warehouse)
SVOC	Semivolatile Organic Compound
TBD	To be determined
TERA	Toxicology in Risk Assessment
TIAB	Title and Abstract
TMF	Trophic Magnification Factors
TRI	Toxics Release Inventory
TSCA	Toxic Substances Control Act
TURA	Toxics Use Reduction Act (Massachusetts)
UNEP	United Nations Environment Programme
USGS	United States Geological Survey
VP	Vapor Pressure
WS	Water solubility
WQX	Water Quality Exchange
WWT	Wastewater Treatment

EXECUTIVE SUMMARY

In December 2019, EPA designated butyl benzyl phthalate (CASRN 85-68-7) as a high-priority substance for risk evaluation following the prioritization process as required by Section 6(b) of the Toxic Substances Control Act (TSCA) and implementing regulations (40 CFR 702) (Docket ID: EPA-HQ-OPPT-2018-0501). The first step of the risk evaluation process is the development of the scope document and this document fulfills the TSCA regulatory requirement to issue a draft scope document as described in 40 CFR 702.41(c)(7). The draft scope for butyl benzyl phthalate includes the following information: the conditions of use, potentially exposed or susceptible subpopulations (PESS), hazards, and exposures that EPA plans to consider in this risk evaluation, along with a description of the reasonably available information, conceptual model, analysis plan and science approaches, and plan for peer review for this chemical substance. EPA is providing a 45-day comment period on the draft scope. Comments received on this draft scope document will help inform development of the final scope document and the risk evaluation.

General Information. Butyl benzyl phthalate is a clear, oily liquid with a total production volume in the United States between 10 and 50 million pounds.

Reasonably Available Information. EPA leveraged the data and information sources already described in the document supporting the High-Priority Substance designation for butyl benzyl phthalate to inform the development of this draft scope document. To further develop this draft scope document, EPA conducted a comprehensive search to identify and screen multiple evidence streams (i.e., chemistry, fate, release and engineering, exposure, hazard) and the search and screening results are provided in Section 2.1. EPA is seeking public comment on this draft scope document and will consider additional information identified following publication of this draft scope document, as appropriate, in developing the final scope document. EPA is using the systematic review process described in the *Application of Systematic Review in TSCA Risk Evaluations* document (U.S. EPA, 2018a) to guide the process of searching for and screening reasonably available information, including information already in EPA's possession, for inclusion in the risk evaluation. EPA is applying these systematic review methods to collect reasonably available information regarding the hazards, exposures, PESS, and conditions of use that may help inform the risk evaluation for butyl benzyl phthalate.

Conditions of Use. EPA plans to evaluate industrial, commercial and consumer, distribution, and disposal uses of butyl benzyl phthalate in the risk evaluation. Butyl benzyl phthalate is manufactured within the U.S. as well as imported into the United States. Production volumes were reported to the Chemical Data Reporting (CDR) in 2016. The chemical is processed as a reactant, incorporated into a formulation, mixture, or reaction product, and incorporated into articles. The identified processing activities also include the repackaging and recycling of butyl benzyl phthalate. Several industrial and commercial uses were identified that included adhesives and sealants, floor coverings, paints and coatings, and use in plastic and rubber products. Multiple consumer uses were also reported to CDR.

Conceptual Model. The conceptual models for butyl benzyl phthalate are presented in Section 2.6. Conceptual models are graphical depictions of the actual or predicted relationships of conditions of use, exposure pathways (e.g., media), exposure routes (e.g., inhalation, dermal, oral), hazards, and receptors throughout the life cycle of the chemical substance—from manufacturing, processing, distribution in commerce, storage, or use, to release or disposal. EPA plans to focus the risk evaluation for butyl benzyl phthalate on the following exposures, hazards, and receptors, however, EPA also plans to consider comments received on this draft scope and other reasonably available information when finalizing this

scope document, and to adjust the exposure pathways, exposure routes and hazards included in the scope document as needed.

- *Exposures (Pathways and Routes), Receptors and PESS.* EPA plans to analyze both human and environmental exposures resulting from the conditions of use of butyl benzyl phthalate that EPA plans to consider in the risk evaluation. Exposures for butyl benzyl phthalate are discussed in Section 2.3. EPA identified environmental monitoring data reporting the presence of butyl benzyl phthalate in air, water, sediment, and soil (U.S. EPA, 2019a). Additional information gathered through the results of systematic review searches will also inform expected exposures.

  EPA's plan as to evaluating environmental exposure pathways in the draft scope document considers whether and how other EPA-administered statutes and regulatory programs address the presence of butyl benzyl phthalate in media pathways falling under the jurisdiction of those authorities. Section 2.6.3 discusses those pathways that may be addressed pursuant to other Federal laws. In Section 2.6.4, EPA presents the conceptual model describing the identified exposures (pathways and routes), receptors and hazards associated with the conditions of use of butyl benzyl phthalate within the scope of the risk evaluation.

  Preliminarily, EPA plans to evaluate the following exposure pathways, receptors and PESS in the risk evaluation. However, EPA plans to consider comments received on this draft scope and other reasonably available information when finalizing this scope document, and to adjust the exposure pathways, exposure routes and hazards included in the scope document as needed.
  - *Occupational exposures associated with industrial and commercial conditions of use*: EPA plans to evaluate exposures to workers and/or occupational non-users (ONUs) via the inhalation route and exposures to workers via the dermal route associated with the manufacturing, processing, use or disposal of butyl benzyl phthalate.
  - *Consumer and bystander exposures associated with consumer conditions of use:* EPA plans to evaluate the oral, inhalation and dermal exposure to butyl benzyl phthalate when consumers and bystanders are using and/or handling adhesives and sealants products, automotive care products, arts, crafts, and hobby materials, cleaning and furnishing care products, fabric, textile, and leather products, floor coverings, paints and coatings, plastic and rubber products, toys, playground and sporting equipment, and ink, toner, and colorant products.
  - *General population exposures:* EPA plans to evaluate exposure to butyl benzyl phthalate via oral route from drinking water or groundwater, and soil for the general population and via the inhalation route for ambient air.
  - *Receptors and PESS:* EPA plans to evaluate children, women of reproductive age, (e.g.., pregnant women), workers and consumers as receptors and PESS in the risk evaluation.
  - *Environmental exposures:* EPA plans to evaluate exposure to butyl benzyl phthalate for aquatic and terrestrial receptors.

- *Hazards.* Hazards for butyl benzyl phthalate are discussed in Section 2.4. EPA completed preliminary reviews of information from peer-reviewed assessments and databases to identify potential environmental and human health hazards for butyl benzyl phthalate as part of the prioritization process. Environmental hazard effects were identified for aquatic and terrestrial organisms. Information collected through systematic review methods and public comments may identify additional environmental hazards that warrant inclusion in the environmental hazard assessment of the risk evaluation.

EPA will use systematic review methods to evaluate the epidemiological and toxicological literature for butyl benzyl phthalate. Relevant mechanistic evidence will also be considered, if reasonably available, to inform the interpretation of findings related to potential human health effects and the dose-repose assessment. EPA plans to evaluate all the potential human health hazards for butyl benzyl phthalate identified in Section 2.4.2. The broad health effect categories include reproductive and developmental, immunological, nervous system, genotoxicity, carcinogenicity, absorption, distribution, metabolism, and excretion (ADME), and irritation effects.

Analysis Plan. The analysis plan for butyl benzyl phthalate is presented in Section 2.7. The analysis plan outlines the general scientific approaches that EPA plans to use for the various information streams (i.e., chemistry, fate, release and engineering, exposure, hazard) supporting the risk evaluation. The analysis plan is based on EPA's knowledge of butyl benzyl phthalate to date which includes a partial, but ongoing, review of identified information as described in Section 2.1. EPA plans to continue to consider new information submitted by the public. Should additional data or approaches become reasonably available, EPA may update its analysis plan in the final scope document.

EPA plans to seek public comments on the systematic review methods supporting the risk evaluation for butyl benzyl phthalate, including the methods for assessing the quality of data and information and the approach for evidence synthesis and evidence integration supporting the exposure and hazard assessments. The details will be provided in a supplemental document that EPA anticipates releasing for public comment prior to the finalization of the scope document.

Peer Review. The draft risk evaluation for butyl benzyl phthalate will be peer reviewed. Peer review will be conducted in accordance with EPA's regulatory procedures for chemical risk evaluations, including using EPA's Peer Review Handbook and other methods consistent with Section 26 of TSCA (See 40 CFR 702.45).

1 INTRODUCTION

This document presents for comment the draft scope of the risk evaluation to be conducted for butyl benzyl phthalate under the Frank R. Lautenberg Chemical Safety for the 21st Century Act. The Frank R. Lautenberg Chemical Safety for the 21st Century Act amended the Toxic Substances Control Act (TSCA) on June 22, 2016. The new law includes statutory requirements and deadlines for actions related to conducting risk evaluations of existing chemicals.

TSCA § 6(b) and 40 CFR Part 702, Subpart A require the Environmental Protection Agency (EPA) to designate chemical substances as high-priority substances for risk evaluation or low-priority substances for which risk evaluations are not warranted at the time, and upon designating a chemical substance as a high-priority substance, initiate a risk evaluation on the substance. TSCA § 6(b)(4) directs EPA, in conducting risk evaluations for existing chemicals, to "determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use."

TSCA § 6(b)(4)(D) and implementing regulations require that EPA publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use and potentially exposed or susceptible subpopulations, that the Administrator expects to consider within 6 months after the initiation of a risk evaluation. In addition, a draft scope is to be published pursuant to 40 CFR 702.41. In December 2019, EPA published a list of 20 chemical substances that have been designated high priority substances for risk evaluations (84 FR 71924), as required by TSCA § 6(b)(2)(B), which initiated the risk evaluation process for those chemical substances. Butyl benzyl phthalate is one of the chemicals designated as a high-priority substance for risk evaluation.

2 SCOPE OF THE EVALUATION

2.1 Reasonably Available Information

EPA conducted a comprehensive search for reasonably available information[1] to support the development of this draft scope document for butyl benzyl phthalate. EPA leveraged the data and information sources already identified in the documents supporting the chemical substance's high-priority substance designation. In addition, EPA searched for additional data and information on physical and chemical properties, environmental fate, engineering, exposure, environmental and human health hazards that could be obtained from the following general categories of sources:

1. Databases containing publicly available, peer-reviewed literature;
2. Gray literature, which is defined as the broad category of data/information sources not found in standard, peer-reviewed literature databases.
3. Data and information submitted under TSCA Sections 4, 5, 8(e), and 8(d), as well as "for your information" (FYI) submissions.

Following the comprehensive search, EPA performed a title and abstract screening to identify information potentially relevant for the risk evaluation process. This step also classified the references

[1] *Reasonably available information* means information that EPA possesses or can reasonably generate, obtain, and synthesize for use in risk evaluations, considering the deadlines specified in TSCA Section 6(b)(4)(G) for completing such evaluation. Information that meets the terms of the preceding sentence is reasonably available information whether or not the information is confidential business information, that is protected from public disclosure under TSCA Section 14 (40 CFR § 702.33).

into useful categories or tags to facilitate the sorting of information through the systematic review process. The search and screening processes were conducted based on EPA's general expectations for the planning, execution and assessment activities outlined in the *Application of Systematic Review in TSCA Risk Evaluations* document (U.S. EPA, 2018a). EPA will publish supplemental documentation on the systematic review methods supporting the butyl benzyl phthalate risk evaluation to explain the literature and screening process presented in this document in the form of literature inventory trees. Please note that EPA focuses on the data collection phase (consisting of data search, data screening, and data extraction) during the preparation of the TSCA scope document, whereas the data evaluation and integration stages will occur during the development of the draft risk evaluation and thus are not part of the scoping activities described in this document.

The subsequent sections summarize the data collection activities completed to date for the general categories of sources and topic areas (or disciplines) using systematic review methods. EPA plans to seek public comments on the systematic review methods supporting the risk evaluation for butyl benzyl phthalate upon publication of the supplemental documentation of those methods.

2.1.1 Search of Gray Literature

EPA surveyed the gray literature[2] and identified 89 search results relevant to EPA's risk assessment needs for butyl benzyl phthalate. Appendix A lists the gray literature sources that yielded 89 discrete data or information sources relevant to butyl benzyl phthalate. EPA further categorized the data and information into the various topic areas (or disciplines) supporting the risk evaluation (e.g., physical chemistry, environmental fate, environmental hazard, human health hazard, exposure, engineering) and the breakdown is shown in Figure 2-1. EPA is currently identifying additional reasonable available information (e.g., public comments), and the reported numbers in Figure 2-1 may change.

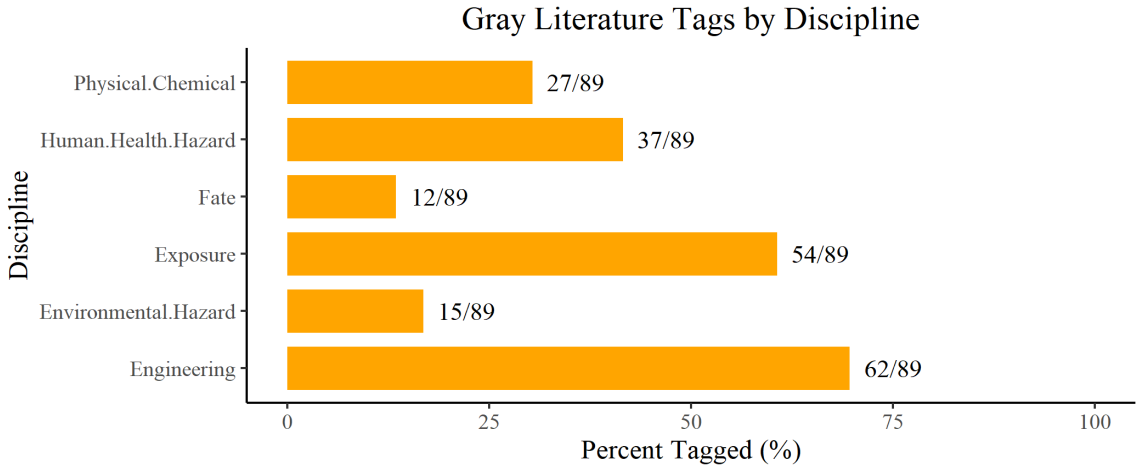

Figure 2-1 Gray Literature Search Results for Butyl Benzyl Phthalate
The percentages across disciplines do not add up to 100%, as each source may provide data or information for various topic areas (or disciplines).

[2] Gray literature is defined as the broad category of data/information sources not found in standard, peer-reviewed literature databases (e.g., PubMed and Web of Science). Gray literature includes data/information sources such as white papers, conference proceedings, technical reports, reference books, dissertations, information on various stakeholder websites, and other databases.

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

EPA is currently conducting a systematic review of the reasonably available literature. This includes performing a comprehensive search of the reasonably available peer review literature on physical-chemical (p-chem) properties, environmental fate and transport, engineering (environmental release and occupational exposure), exposure (environmental, general population and consumer) and environmental and human health hazards of butyl benzyl phthalate. Eligibility criteria were applied in the form of PECO (population, exposure, comparator, outcome) statements. Included references met the PECO criteria, whereas excluded references did not meet the criteria (i.e., not relevant), and supplemental material was considered as potentially relevant. EPA plans to analyze the reasonably available information identified for each discipline during the development of the risk evaluation. The literature inventory trees depicting the number of references that were captured and those that were included, excluded, or tagged as supplemental material during the screening process for each discipline area are shown in Figure 2-2 through Figure 2-6. "TIAB" in these figures refers to title and abstract screening. Note that in some figures the sum of the numbers for the various sub-categories may be larger than the broader category because some studies may be included under multiple sub-categories. In other cases, the sum of the various sub-categories may be smaller than the main category because some studies may not be depicted in the sub-categories if their relevance to the risk evaluation was unclear.

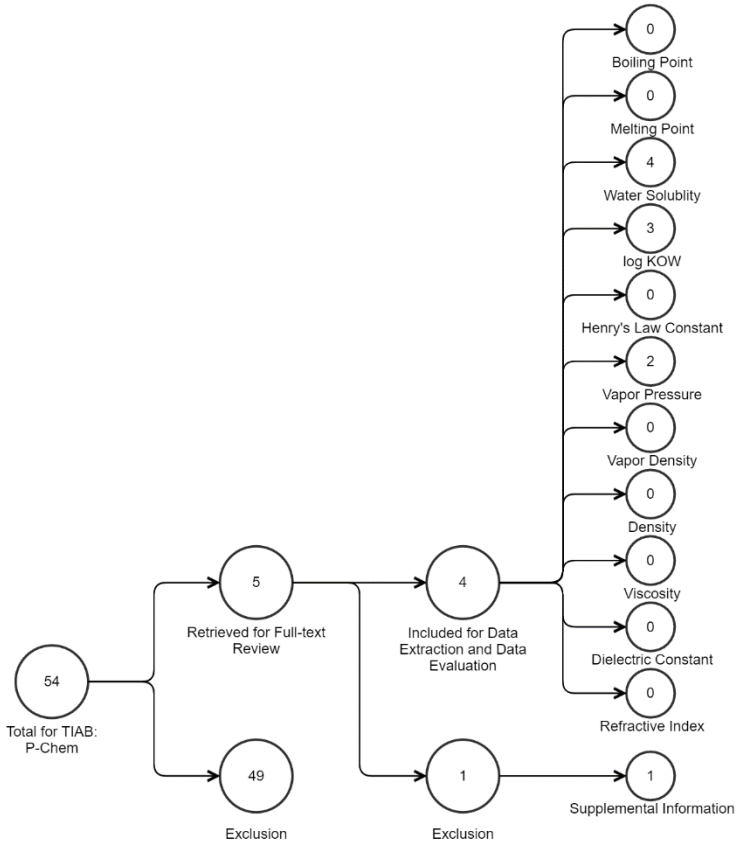

Figure 2-2 Peer-reviewed Literature - Physical-Chemical Properties Search Results for Butyl Benzyl Phthalate

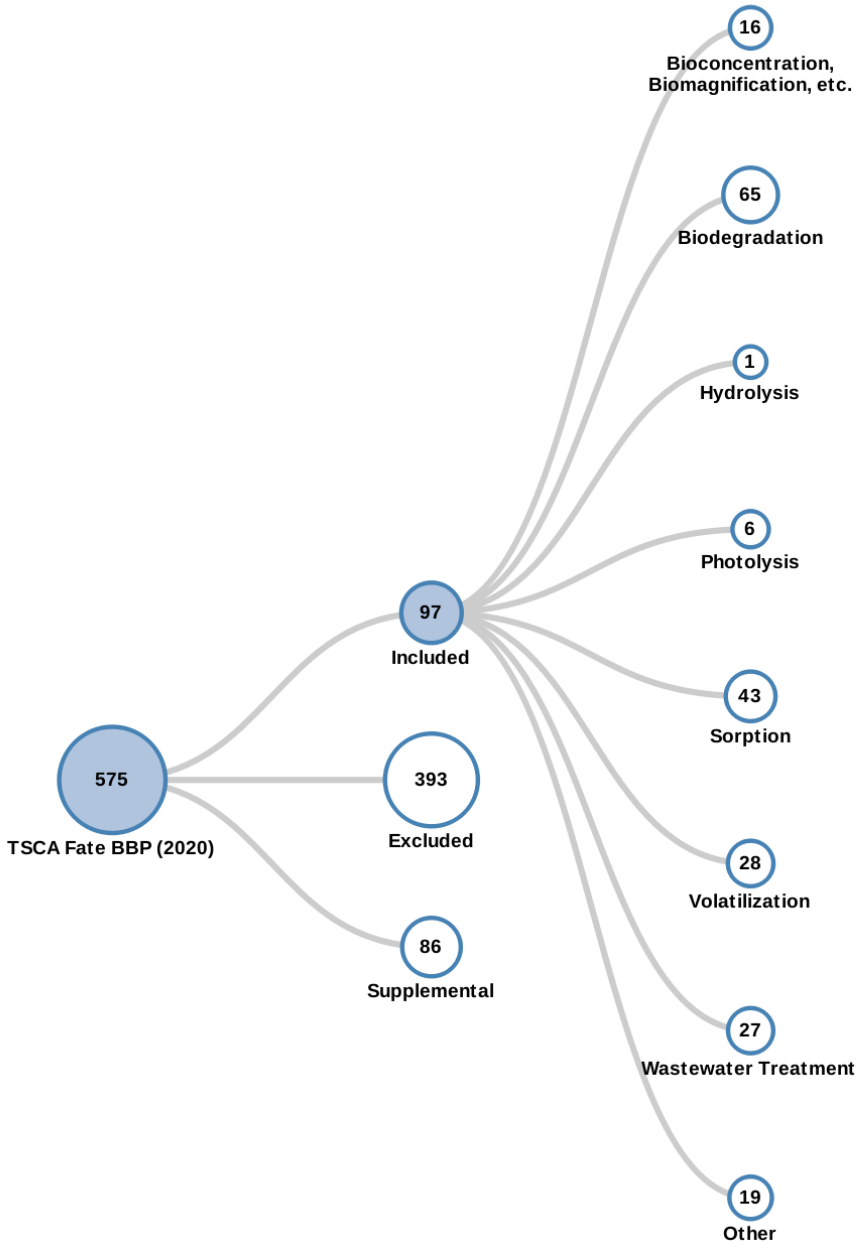

Figure 2-3 Peer-reviewed Literature - Fate and Transport Search Results for Butyl Benzyl Phthalate

Click here for interactive Health Assessment Workplace Collaborative (HAWC) diagram.

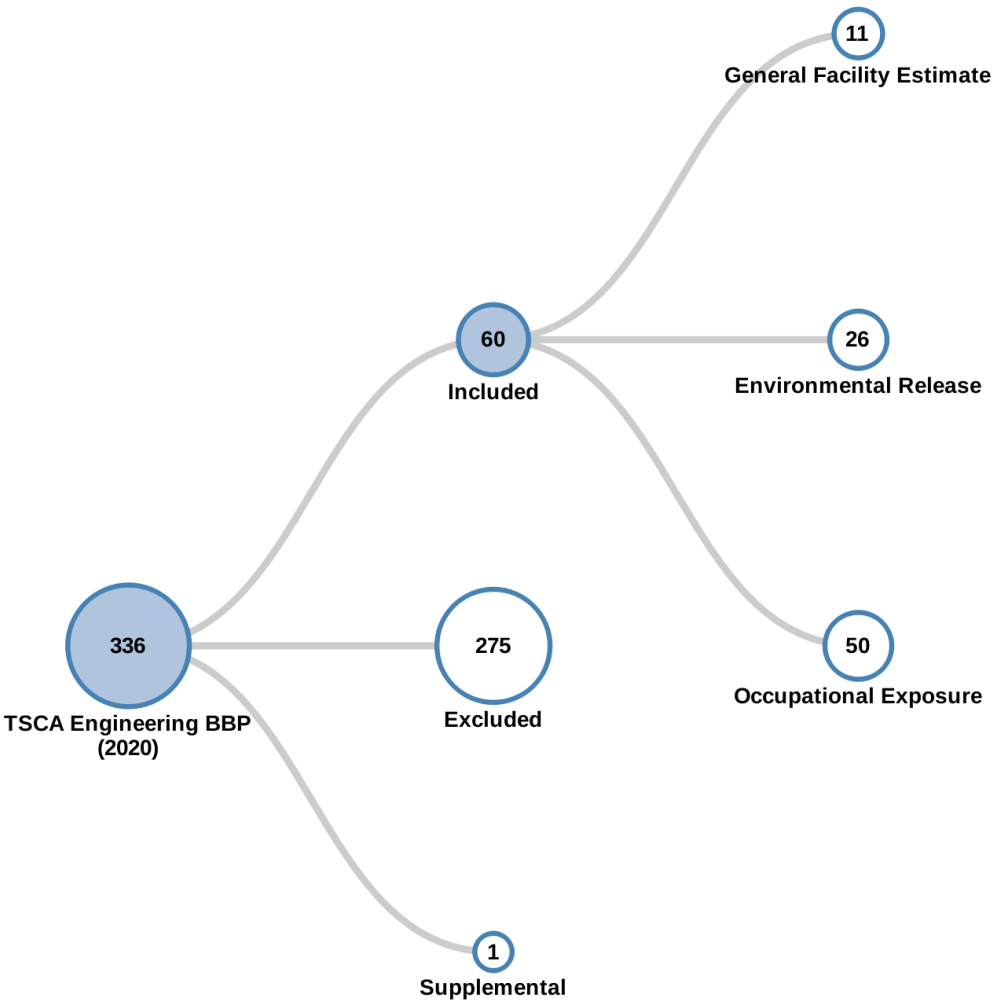

Figure 2-4 Peer-reviewed Literature - Engineering Search Results for Butyl Benzyl Phthalate
Click here for interactive HAWC diagram.

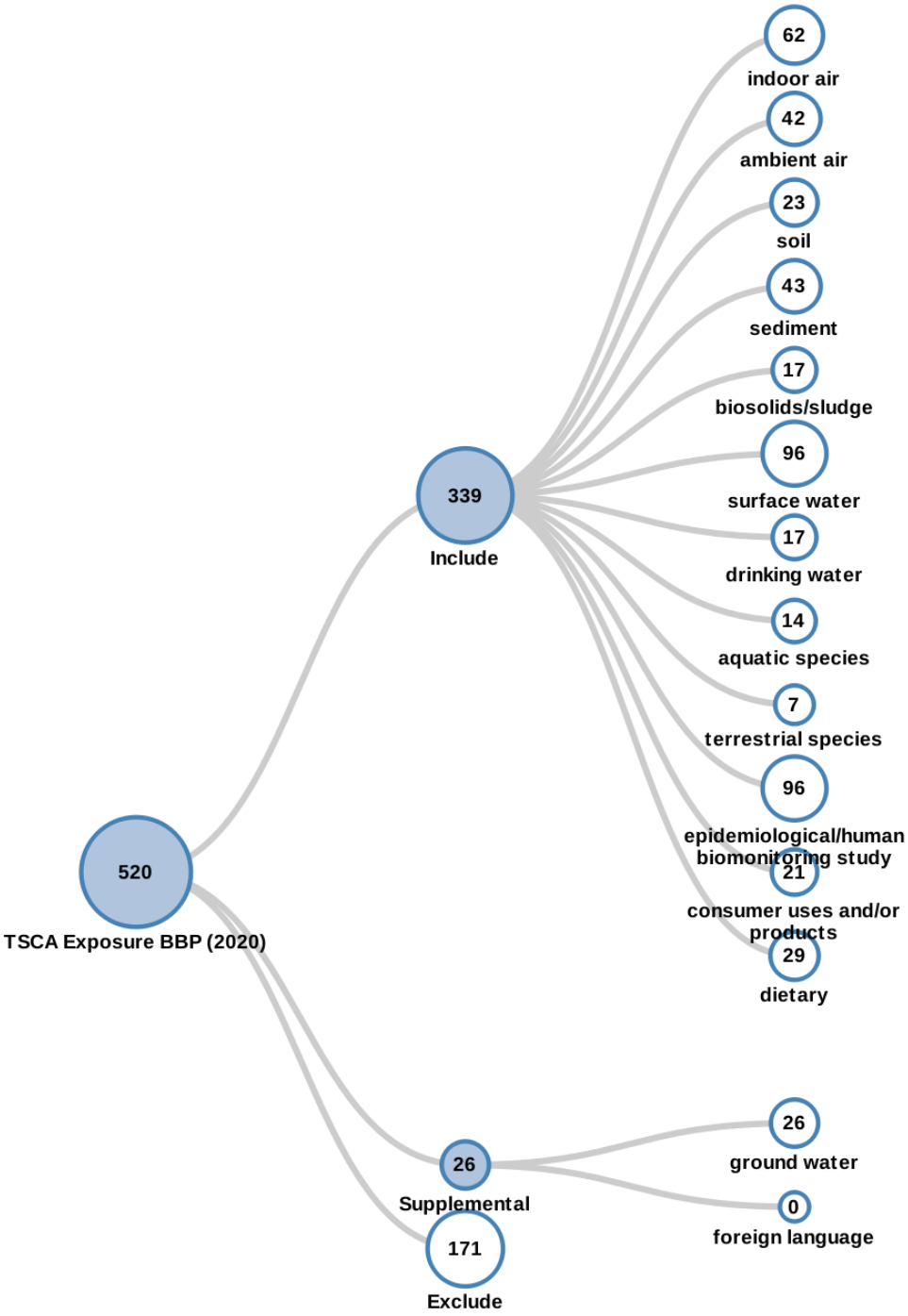

Figure 2-5 Peer-reviewed Literature - Exposure Search Results for Butyl Benzyl Phthalate
Click here for interactive HAWC diagram.

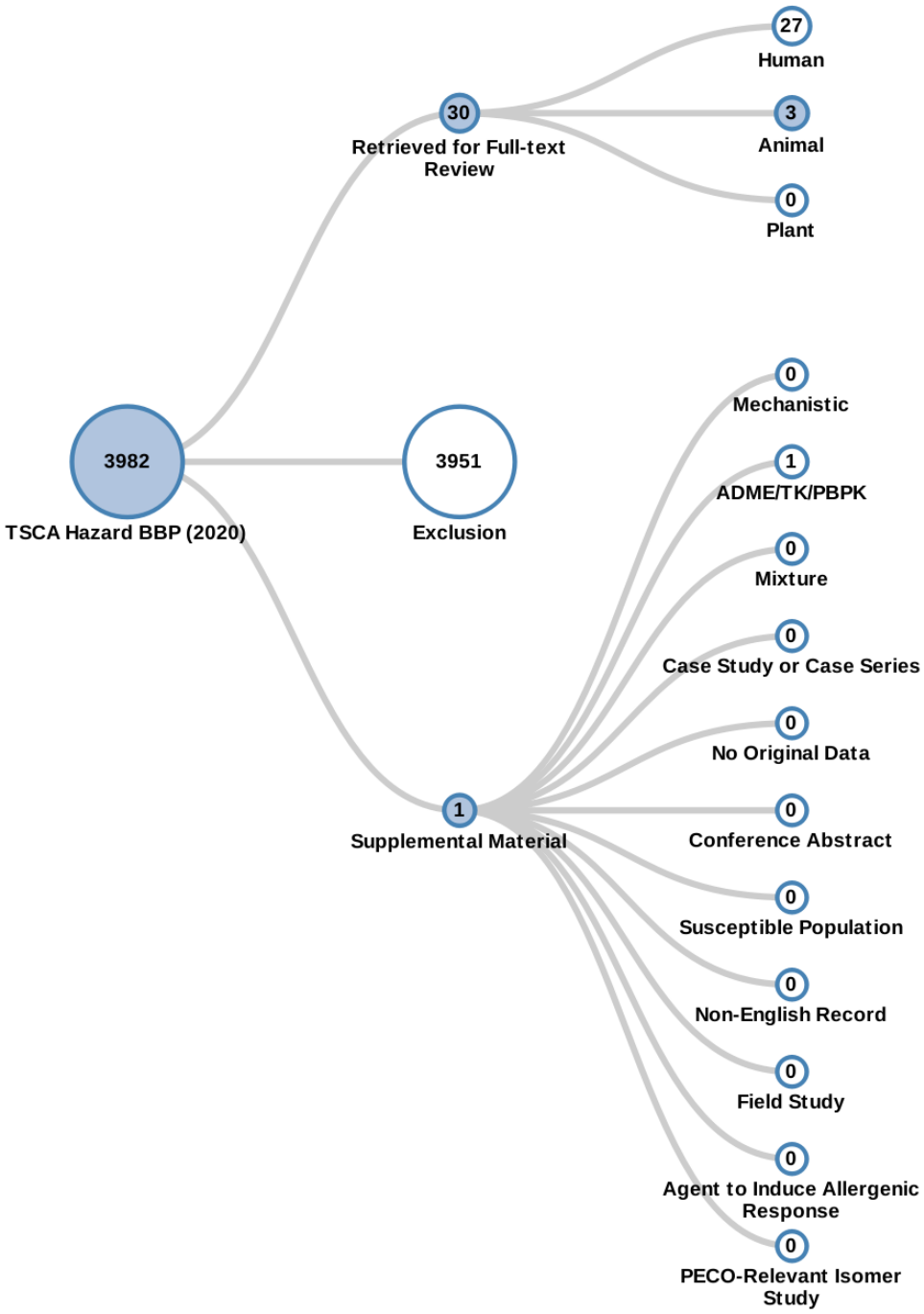

Figure 2-6 Peer-reviewed Literature - Hazard Search Results for Butyl Benzyl Phthalate
Click here for interactive HAWC diagram.

2.1.3 Search of TSCA Submissions

Table 2-1presents the results of screening the titles of data sources and reports submitted to EPA under various sections of the TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act. EPA screened a total of 185 submissions using inclusion/ exclusion criteria specific to individual disciplines (see Table 2-1 for the list of disciplines). The details about the criteria are not part of this document but will be provided in a supplemental document that EPA anticipates releasing prior

to the finalization of the scope document. EPA identified 160 submissions that met the inclusion criteria in these statements and identified 15 submissions with supplemental data. EPA excluded 10 submissions because the reports were identified as one of the following:

- Abstract or full prepublication copy of a manuscript that was later published and that would be identified via other peer or gray literature searches
- Record of telephone communication
- Study of toxicity to bacteria
- Notice of withdrawal of test rule by EPA
- Letter with no data
- Submission on a different chemical
- Comparison of studies containing no primary data
- Letter with correction to previous letter

EPA plans to conduct additional deduplication at later stages of the systematic review process (e.g., full text screening), when more information regarding the reports is available.

Table 2-1 Results of Title Screening of Submissions to EPA under Various Sections of TSCA

Discipline	Included	Supplemental
P-Chem Properties	11	0
Environmental Fate and Transport	30	0
Environmental and General Population Exposure	29	1
Occupational Exposure/Release Information	10	0
Environmental Hazard	62	2
Human Health Hazard	35	12

2.2 Conditions of Use

As described in the *Proposed Designation of Butyl Benzyl Phthalate (CASRN 85-68-7) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019a), EPA assembled information from the CDR and TRI programs to determine conditions of use[3] or significant changes in conditions of use of the chemical substance. EPA also consulted a variety of other sources to identify uses of butyl benzyl phthalate, including published literature, company websites, and government and commercial trade databases and publications. To identify formulated products containing butyl benzyl phthalate, EPA searched for safety data sheets (SDS) using internet searches, EPA Chemical and Product Categories (CPCat) data, and other resources in which SDSs could be found. In addition, EPA incorporated communications with companies, industry groups, environmental organizations, and public comments to supplement the use information.

EPA identified and described the categories and subcategories of conditions of use that will be included in the scope of the risk evaluation (Section 2.2.1;
Table 2-2). The conditions of use included in the scope are those reflected in the life cycle diagrams and conceptual models.

[3] *Conditions of use* means the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of (15 U.S.C. § 2602(4)).

After gathering the conditions of use, EPA identified those categories or subcategories of use activities for butyl benzyl phthalate the Agency determined not to be conditions of use or will otherwise be excluded during scoping. These categories and subcategories are described in Section 2.2.2.

2.2.1 Categories and Subcategories of Conditions of Use Included in the Scope of the Risk Evaluation

Table **2-2** lists the conditions of use that are included in the scope of the risk evaluation.

Table 2-2 Categories and Subcategories of Conditions of Use Included in the Scope of the Risk Evaluation

Life-Cycle Stage	Category	Subcategory	Reference
Manufacture	Domestic manufacturing	Domestic manufacturing	U.S. EPA (2019b)
	Import	Import	U.S. EPA (2019b)
Processing	Incorporating into formulation, mixture or reaction product	Fillers in: – Custom compounding of purchased resin	U.S. EPA (2019b)
		Plasticizers in: – Adhesive manufacturing – All Other Basic Inorganic Chemical Manufacturing – Dental product manufacturing – Paints and coatings manufacturing – Personal care products – Printing ink manufacturing	U.S. EPA (2019b); GoodGuide (2011); SPIN (2019); Ash et al. (2009)
		Processing aid in: – Petroleum production	Orem et al. (2007)
		Laboratory chemical manufacturing	EPA-HQ-OPPT-2018-0504-0019
		Biocide carrier manufacturing	EPA-HQ-OPPT-2018-0501-0015
	Incorporating into articles	Plasticizers in: – Asphalt paving, roofing, and coating materials manufacturing – Fabric, textile, and leather products not covered elsewhere manufacturing – Floor coverings manufacturing – Food contact surfaces manufacturing – Plastics product manufacturing – Rubber product manufacturing – Textiles, apparel, and leather manufacturing – Transportation equipment manufacturing	U.S. EPA (2019b); FDA (2018); EPA-HQ-OPPT-2019-0131-0022; Ash et al. (2009)

Life-Cycle Stage	Category	Subcategory	Reference
	Repackaging	Repackaging	EPA-HQ-OPPT-2018-0504-0019
	Recycling	Recycling	
Distribution in commerce	Distribution in commerce		
Industrial use	Adhesives and sealants	Adhesives and sealants	U.S. EPA (2019b)
	Automotive, Fuel, Agriculture, Outdoor Use Products	Automotive care products	ACC (2019); NLM (2015)
	Castings	Castings	BJB Enterprises Inc. (2018)
	Construction, Paint, Electrical, and Metal Products	Building/construction materials not covered elsewhere	DeLima Associates (2011)
	Floor coverings	Floor coverings	U.S. EPA (2019b)
	Furnishing, Cleaning, Treatment/Care Products	Fabric, textile, and leather products not covered elsewhere	U.S. EPA (2019b)
	Paints and coatings	Paints and coatings	U.S. EPA (2019b)
	Plastic and rubber products not covered elsewhere	Plastic and rubber products not covered elsewhere in: - Transportation equipment manufacturing	EPA-HQ-OPPT-2019-0131-0022
	Processing aid, specific to petroleum production	Hydraulic fracturing	Orem et al. (2007)
	Other uses	Chemical intermediate	NLM (2015); SPIN (2019); Ash et al. (2009)
		Laboratory Chemicals	Sigma-Aldrich (2019)
		Plastic and rubber products not covered elsewhere - Component of compound (resin) used to cast models	NASA (2020)
Commercial uses	Adhesives and sealants	Adhesives and sealants	U.S. EPA (2019b)
	Automotive, Fuel, Agriculture, Outdoor Use Products	Automotive care products	ACC (2019); NLM (2015)

Life-Cycle Stage	Category	Subcategory	Reference
	Castings	Castings	BJB Enterprises Inc. (2018)
	Construction, Paint, Electrical, and Metal Products	Building/construction materials not covered elsewhere	DeLima Associates (2011)
	Floor coverings	Floor coverings	U.S. EPA (2019b)
	Furnishing, Cleaning, Treatment/Care Products	Fabric, textile, and leather products not covered elsewhere	U.S. EPA (2019b)
	Paints and coatings	Paints and coatings	U.S. EPA (2019b)
	Plastic and rubber products not covered elsewhere	Plastic and rubber products not covered elsewhere in: - Transportation equipment manufacturing	EPA-HQ-OPPT-2019-0131-0022
	Processing aid, specific to petroleum production	Hydraulic fracturing	Orem et al. (2007)
	Other uses	Chemical intermediate	NLM (2015); SPIN (2019); Ash et al (2009)
		Laboratory Chemicals	Sigma-Aldrich (2019)
		Plastic and rubber products not covered elsewhere - Component of compound (resin) used to cast models	NASA (2020)
Consumer uses	Adhesives and sealants	Adhesives and sealants	U.S. EPA (2019b)
	Automotive, Fuel, Agriculture, Outdoor Use Products	Automotive care products	ACC (2019); NLM (2015)
	Construction, Paint, Electrical, and Metal Products	Building/construction materials not covered elsewhere	DeLima Associates (2011)
	Floor coverings	Floor coverings	U.S. EPA (2019b)
	Furnishing, Cleaning, Treatment/Care Products	Fabric, textile, and leather products not covered elsewhere	U.S. EPA (2019b)
	Packaging, Paper, Plastic, Hobby Products	- Arts, crafts, and hobby materials - Toys, playground, and sporting equipment - Ink, toner, and colorant products	U.S. EPA (2019b)

Life-Cycle Stage	Category	Subcategory	Reference
	Paints and coatings	Paints and coatings	U.S. EPA (2019b)
	Plastic and rubber products not covered elsewhere	Plastic and rubber products not covered elsewhere in: - Transportation equipment manufacturing	NLM (2015)
Disposal	Disposal	Disposal	

Notes:

- Life Cycle Stage Use Definitions
  - "Industrial use" means use at a site at which one or more chemicals or mixtures are manufactured (including imported) or processed.
  - "Commercial use" means the use of a chemical or a mixture containing a chemical (including as part of an article) in a commercial enterprise providing saleable goods or services.
  - "Consumer use" means the use of a chemical or a mixture containing a chemical (including as part of an article, such as furniture or clothing) when sold to or made available to consumers for their use.

2.2.2 Activities Excluded from the Scope of the Risk Evaluation

As explained in the final rule, *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act*, TSCA Section 6(b)(4)(D) requires EPA to identify the hazards, exposures, conditions of use, and the PESS the Administrator expects to consider in a risk evaluation, suggesting that EPA may exclude certain activities that it determines to be conditions of use on a case-by-case basis (82 FR 33726, 33729; July 20, 2017). As a result, EPA will not include in this scope or in the risk evaluation the activities described below that the Agency has concluded do not constitute conditions of use.

EPA has determined that the following uses of butyl benzyl phthalate are non-TSCA uses:

- EPA determined that butyl benzyl phthalate is used in dental sealants and nail polish which meets the definition of cosmetics under Section 201 of the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 321, and are therefore excluded from the definition of "chemical substance" in TSCA § 3(2)(B)(vi). Activities and releases associated with such cosmetics are therefore not "conditions of use" (defined as circumstances associated with "a chemical substance," TSCA § 3(4)) and will not be evaluated during risk evaluation. However, manufacturing, processing, and industrial uses of these products are covered by TSCA and will be considered a condition of use.

- EPA recognizes that the Food and Drug Administration lists butyl benzyl phthalate as an optional substance to be used in food packaging materials. Food packaging materials meet the definition for a "food additive" described in Section 201 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. § 321. Therefore, the consumer uses are excluded from the definition of "chemical substance" in TSCA § 3(2)(B)(vi) and are not included in Table 2-2. However, manufacturing, processing, and industrial uses of these products are covered by TSCA and will be considered a condition of use.

2.2.3 Production Volume

Production volume of butyl benzyl phthalate in 2015, as reported to EPA during the 2016 CDR reporting period, was between 10 million and 50 million pounds (U.S. EPA, 2017). EPA also uses pre-2015 CDR production volume information, as detailed in the *Proposed Designation of Butyl Benzyl Phthalate (CASRN 85-68-7) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019a) and

will include future production volume information as it becomes available to support the exposure assessment.

2.2.4 Overview of Conditions of Use and Lifecycle Diagram

The life cycle diagram provided in Figure 2-7 depicts the conditions of use that are considered within the scope of the risk evaluation for the various life cycle stages as presented in Section 2.2.1. Section 2.2.1 provides a brief overview of the industrial, commercial and consumer use categories included in the life cycle diagram. The activities that EPA determined are out of scope are not included in the life cycle diagram. Appendix E contains more detailed descriptions (e.g., process descriptions, worker activities, process flow diagrams) for each manufacture, processing, distribution in commerce, use and disposal category.

The information in the life cycle diagram is grouped according to the CDR processing codes and use categories (including functional use codes for industrial uses and product categories for industrial, commercial and consumer uses).

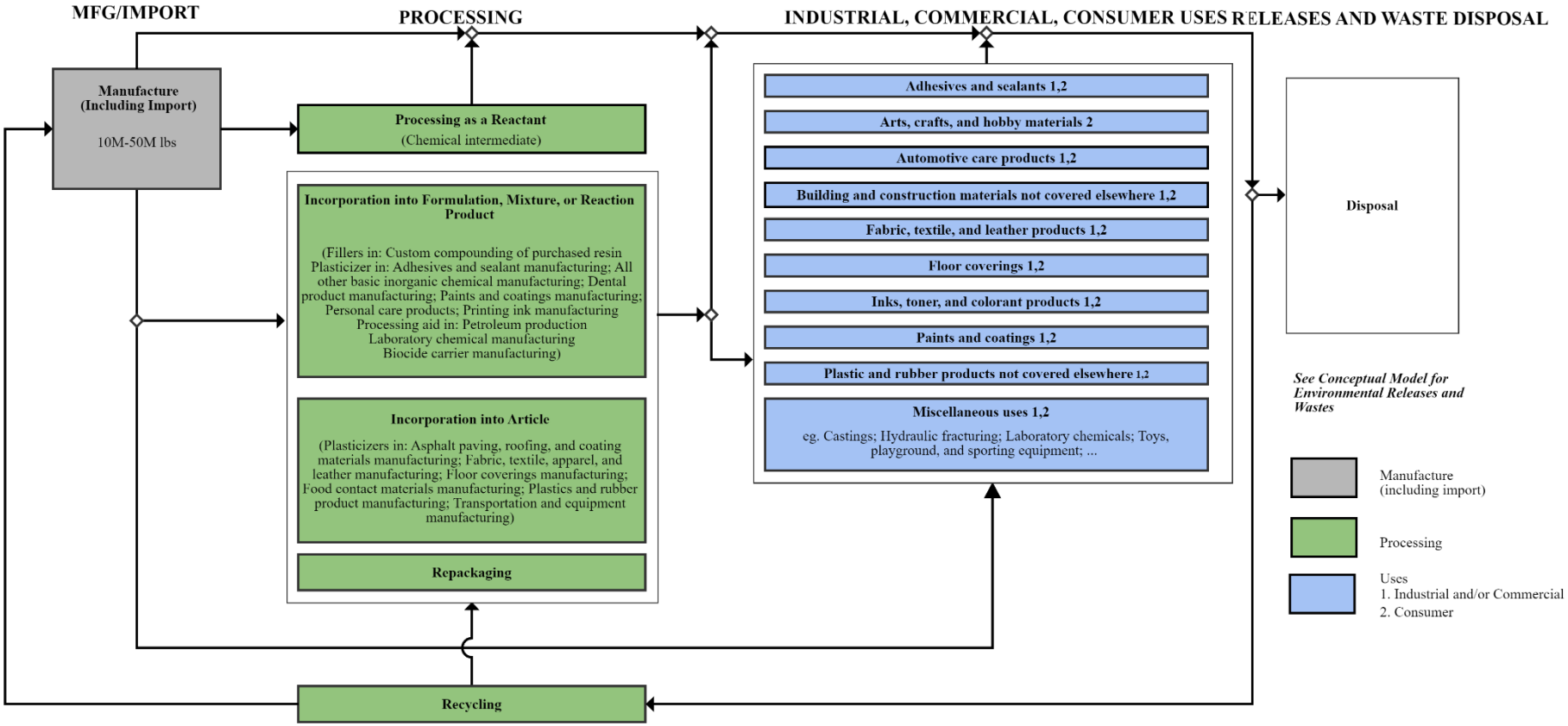

Figure 2-7 Butyl Benzyl Phthalate Life Cycle Diagram

Volume is not depicted in the life cycle diagram for processing and industrial, commercial, and consumer uses as specific production volume is claimed confidential business information (CBI) or withheld pursuant to TSCA Section § 14.

2.3 Exposures

For TSCA exposure assessments, EPA plans to analyze exposures and releases to the environment resulting from the conditions of use within the scope of the risk evaluation for butyl benzyl phthalate. Release pathways and routes will be described to characterize the relationship or connection between the conditions of use of the chemical and the exposure to human receptors, including PESS, and environmental receptors. EPA will consider, where relevant, the duration, intensity (concentration), frequency and number of exposures in characterizing exposures to butyl benzyl phthalate.

2.3.1 Physical and Chemical Properties

Consideration of p-chem properties is essential for a thorough understanding or prediction of environmental fate (i.e., transport and transformation) and the eventual environmental concentrations. They can also inform the hazard assessment. EPA plans to use the physical and chemical properties described in Appendix B of the *Proposed Designation of Butyl Benzyl Phthalate (CASRN 85-68-7) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019a) to support the development of the risk evaluation for butyl benzyl phthalate. The values for the physical and chemical properties (Appendix B) may be updated as EPA collects additional information through systematic review methods.

2.3.2 Environmental Fate and Transport

Understanding of environmental fate and transport processes assists in the determination of the specific exposure pathways and potential human and environmental receptors that need to be assessed in the risk evaluation for butyl benzyl phthalate. EPA plans to use the environmental fate characteristics described in Appendix C of the *Proposed Designation of Butyl Benzyl Phthalate (CASRN 85-68-7) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019a) to support the development of the risk evaluation for butyl benzyl phthalate. The values for the environmental fate properties (Appendix C) may be updated as EPA collects additional information through systematic review methods.

2.3.3 Releases to the Environment

Releases to the environment from conditions of use (e.g., manufacturing. industrial, and commercial processes, commercial or consumer uses resulting in down-the-drain releases) are a component of potential exposure and may be derived from reported data that are obtained through direct measurement, calculations based on empirical data or assumptions and models.

Butyl benzyl phthalate was covered under the Toxics Release Inventory (TRI) program until 1993, at which time it was removed from the TRI list of chemicals. Since 1993, butyl benzyl phthalate has not been a TRI-listed chemical; therefore, release data from TRI are not available for butyl benzyl phthalate for 1993 to present. There may be releases of butyl benzyl phthalate from industrial sites to wastewater treatment plants (WWTP), surface water, air and landfill. Articles that contain butyl benzyl phthalate may release butyl benzyl phthalate to the environment during use or through recycling and disposal.

2.3.4 Environmental Exposures

The manufacturing, processing, distribution, use and disposal of butyl benzyl phthalate can result in releases to the environment and exposure to aquatic and terrestrial receptors (biota). Environmental exposures to biota are informed by releases into the environment, overall persistence, degradation, and bioaccumulation, and partitioning across different media. Concentrations of chemical substances in biota provide evidence of exposure. EPA plans to review available environmental exposure data in biota to inform development of the environmental exposure assessment for butyl benzyl phthalate.

Monitoring data were identified in the EPA's data search for butyl benzyl phthalate and can be used in the exposure assessment. Relevant and reliable monitoring studies provide information that can be used in an exposure assessment. Monitoring studies that measure environmental concentrations or concentrations of chemical substances in biota provide evidence of exposure. Monitoring data shows that butyl benzyl phthalate has been identified in various environmental compartments including air, water, sediment, and soil samples (U.S. EPA, 2019a). A review of the available literature has also identified that there is environmental aquatic, non-mammalian biomonitoring data available (U.S. EPA, 2019a). EPA plans to review available environmental monitoring data in the risk evaluation.

2.3.5 Occupational Exposures

EPA plans to analyze worker activities where there is a potential for exposure under the various conditions of use described in Section 2.2.1. In addition, EPA plans to analyze exposure to ONUs (i.e., workers, who do not directly handle the chemical but perform work in an area where the chemical is present). EPA also plans to consider the effect(s) that engineering controls (ECs) and/or personal protective equipment (PPE) have on occupational exposure levels as part of the draft risk evaluation.

Worker activities associated with conditions of use within the scope of the risk evaluation will be analyzed, including, but not limited to:

- Unloading and transferring butyl benzyl phthalate to and from storage containers to process vessels;
- Handling, transporting and disposing of waste containing butyl benzyl phthalate;
- Cleaning and maintaining equipment;
- Sampling chemicals, formulations or products containing butyl benzyl phthalate for quality control;
- Repackaging chemicals, formulations or products containing butyl benzyl phthalate;

Butyl benzyl phthalate is liquid at room temperature and has a vapor pressure of 8.25×10^{-6} mm Hg at 25ºC/77°F (NLM, 2015) and inhalation exposure to vapor is expected to be low when working with the material at room temperature. However, EPA plans to analyze inhalation exposure in occupational scenarios where butyl benzyl phthalate is applied via spray or roll application methods or is handled as a dry powder or at elevated temperatures. Occupational exposure limits for butyl benzyl phthalate have not been established by the Occupational Safety and Health Administration (OSHA), the National Institute for Occupational Safety (NIOSH), or the American Conference of Governmental Industrial Hygienists (ACGIH).

Based on the conditions of use, EPA also plans to analyze worker exposure to liquids and/or solids via the dermal route. EPA does not expect to analyze dermal exposure for ONUs that do not directly handle butyl benzyl phthalate.

EPA generally does not evaluate occupational exposures through the oral route. Workers may inadvertently transfer chemicals from their hands to their mouths or ingest inhaled particles that deposit in the upper respiratory tract. The frequency and significance of this exposure route are dependent on several factors including the p-chem properties of the substance during expected worker activities, workers' awareness of the chemical hazards, the visibility of the chemicals on the hands while working, workplace practices, and personal hygiene that is difficult to predict (Cherrie et al., 2006). However, EPA will consider oral exposure on a case-by-case basis for certain COUs and worker activities where there is information and data on incidental ingestion of inhaled dust. EPA will consider ingestion of inhaled dust as an inhalation exposure for butyl benzyl phthalate.

2.3.6 Consumer Exposures

Based on CDR reporting and conversations with industry, butyl benzyl phthalate appears to be widely used in consumer products and articles specifically adhesives and sealants, automotive care products, arts, crafts, and hobby materials, cleaning and furnishing care products, fabric, textile, and leather products, floor coverings, paints and coatings, plastic and rubber products, toys, playground and sporting equipment, and ink, toner, and colorant products (See Section 2.6.2 and Figure 2-9). These uses can result in exposures to consumers and bystanders. In addition, consumer handling of the disposal on butyl benzyl phthalate containing materials can lead to consumer and bystander exposures.

Based on reasonably available known consumer conditions of use, inhalation of butyl benzyl phthalate is possible through either inhalation of vapor/mist during product usage or indoor air/dust. Oral exposure of butyl benzyl phthalate is possible through either ingestion through product use via transfer from hand to mouth or via through mouthing of articles containing butyl benzyl phthalate. Dermal exposure may occur via contact with vapor or mist deposition onto the skin, via direct liquid contact during use, or direct dermal contact of articles containing butyl benzyl phthalate. Based on these potential sources and pathways of exposure, EPA plans to analyze oral, dermal and inhalation exposures to consumers and inhalation exposures to bystanders that may result from the conditions of use of butyl benzyl phthalate.

2.3.7 General Population Exposures

Releases of butyl benzyl phthalate from certain conditions of use, such as manufacturing, processing, or disposal activities, may result in general population exposures. The general population is primarily exposed via ingestion (NTP 2003, IARC 1999, CPSC 2010). Monitoring data shows that butyl benzyl phthalate has been identified in various environmental compartments including air, water, sediment, and soil samples (U.S. EPA, 2019a). EPA plans to review the reasonably available information for the presence of butyl benzyl phthalate in environmental media relevant to general population exposure. EPA also plans to review any reasonably available human biomonitoring data in the risk evaluation for butyl benzyl phthalate.

2.4 Hazards (Effects)

2.4.1 Environmental Hazards

As described in the *Proposed Designation of Butyl Benzyl Phthalate (CASRN 85-68-7) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019a), EPA considered reasonably available information from peer-reviewed assessments and databases to identify potential environmental hazards for butyl benzyl phthalate. EPA considers all the potential environmental hazards for butyl benzyl phthalate identified during prioritization (U.S. EPA, 2019a) to be relevant for the risk evaluation and thus they remain within the scope of the evaluation. EPA is in the process of identifying additional reasonably available information through systematic review methods and public comments, which may update the list of potential environmental hazards associated with butyl benzyl phthalate. If necessary, EPA plans to update the list of potential hazards in the final scope document of butyl benzyl phthalate. Based on information identified during prioritization, environmental hazard effects were identified for aquatic and terrestrial organisms.

2.4.2 Human Health Hazards

As described in the *Proposed Designation of Butyl Benzyl Phthalate (CASRN 85-68-7) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019a), EPA considered reasonably available information from peer-reviewed assessments and databases to identify potential human health hazards for butyl benzyl phthalate. The health effect categories screened during prioritization included acute toxicity, repeat dose toxicity, irritation/corrosion, dermal sensitization, respiratory sensitization, genetic toxicity, reproductive toxicity, developmental toxicity, immunotoxicity, neurotoxicity, carcinogenicity, epidemiology or biomonitoring findings and absorption, distribution, metabolism, and excretion (ADME).

The broad health effect categories included for further evaluation from designation are developmental and reproductive effects. EPA is in the process of identifying additional reasonably available information through systematic review methods and public input, which may update the list of potential human health hazards under the scope of the risk evaluation. If necessary, EPA plans to update the list of potential hazards in the final scope document of the butyl benzyl phthalate risk evaluation.

2.5 Potentially Exposed or Susceptible Subpopulations

TSCA §6(b)(4) requires EPA to determine whether a chemical substance presents an unreasonable risk to "a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation." TSCA §3(12) states that "the term 'potentially exposed or susceptible subpopulation' means a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population for adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly." General population is "the total of individuals inhabiting an area or making up a whole group" and refers here to the U.S. general population (U.S. EPA, 2011a).

During the Prioritization process, EPA identified the following PESS based on CDR information and studies reporting developmental and reproductive effects: children, women of reproductive age (including, but not limited to, pregnant women), workers and consumers (U.S. EPA, 2019a). EPA plans to evaluate these PESS in the risk evaluation.

In developing exposure scenarios, EPA plans to analyze reasonably available information to ascertain whether some human receptor groups may be exposed via exposure pathways that may be distinct to a

particular subpopulation or life stage (e.g., children's crawling, mouthing or hand-to-mouth behaviors) and whether some human receptor groups may have higher exposure via identified pathways of exposure due to unique characteristics (e.g., activities that would lead to elevated fish ingestion or otherwise lead to increased duration or level of exposure) when compared with the general population (U.S. EPA, 2006a). Likewise, EPA plans to evaluate available human health hazard information to ascertain whether some human receptor groups may have greater susceptibility than the general population to the chemical's hazard(s).

2.6 Conceptual Models

In this section, EPA presents the conceptual models describing the identified exposures (pathways and routes), receptors and hazards associated with the conditions of use of butyl benzyl phthalate. Pathways and routes of exposure associated with workers and ONUs are described in Section 2.6.1, and pathways and routes of exposure associated with consumers are described in Section 2.6.2. Pathways and routes of exposure associated with environmental releases and wastes, including those pathways that may be addressed pursuant to other Federal laws are discussed and depicted the conceptual model shown in Section 2.6.3. Pathways and routes of exposure associated with environmental releases and wastes, excluding those pathways that may be addressed pursuant to other Federal laws, are presented in the conceptual model shown in Section 2.6.4.

2.6.1 Conceptual Model for Industrial and Commercial Activities and Uses

Figure 2-8 illustrates the conceptual model for the pathways of exposure from industrial and commercial activities and uses of butyl benzyl phthalate that EPA plans to include in the risk evaluation. There is potential for exposures to workers and/or ONUs via inhalation routes and exposures to workers via dermal routes. EPA plans to evaluate activities resulting in exposures associated with distribution in commerce (e.g., loading, unloading) throughout the various lifecycle stages and conditions of use (e.g., manufacturing, processing, industrial use, commercial use, and disposal) rather than a single distribution scenario. For each condition of use identified in
Table 2-2, an initial determination was made as to whether or not EPA plans to analyze each combination of exposure pathway, route, and receptor in the risk evaluation. The results of that analysis along with the supporting rationale are presented in Appendix F.

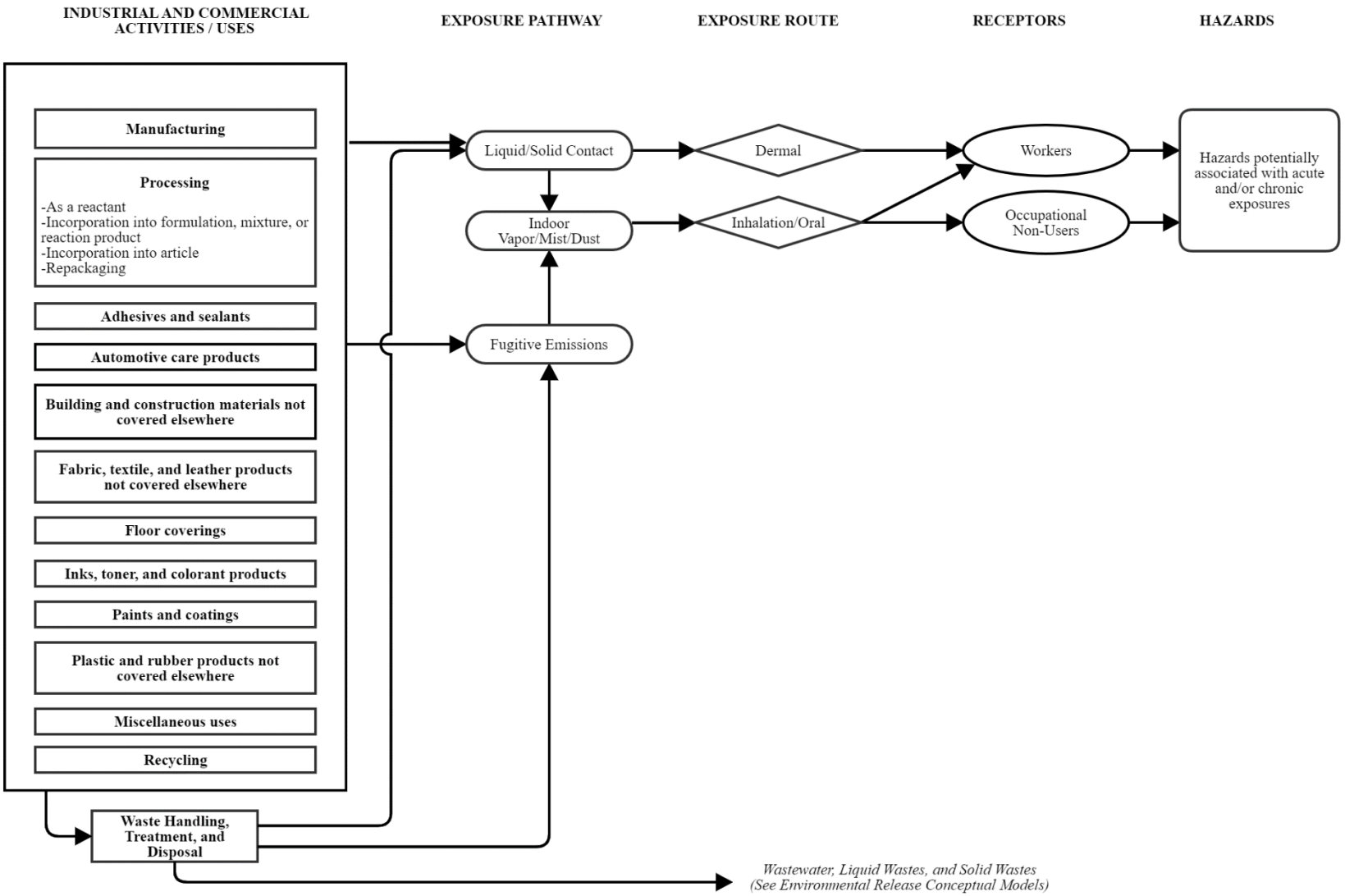

Figure 2-8 Butyl Benzyl Phthalate Conceptual Model for Industrial and Commercial Activities and Uses: Worker and Occupational Non-User Exposures and Hazards

The conceptual model presents the exposure pathways, exposure routes, and hazards to human receptors from industrial and commercial activities and uses of butyl benzyl phthalate.

2.6.2 Conceptual Model for Consumer Activities and Uses

The conceptual model in Figure 2-9 presents the exposure pathways, exposure routes and hazards to human receptors from consumer activities and uses of butyl benzyl phthalate. EPA expects that consumers may be exposed through use of products or articles containing butyl benzyl phthalate through oral, dermal, and inhalation routes. During use of articles, EPA expects that consumers may also be exposed via direct dermal contact or mouthing. Bystanders are expected to be exposed through product use via inhalation. It should be noted that some consumers may purchase and use products primarily intended for commercial use. EPA plans to analyze pathways and routes of exposure that may occur during the varied identified consumer activities and uses. The supporting rationale are presented in Appendix G. The conceptual model in Figure 2-9 presents the exposure pathways, exposure routes and hazards to human receptors from consumer activities and uses of butyl benzyl phthalate. EPA expects that consumers may be exposed through product use or articles containing butyl benzyl phthalate through oral, dermal, and inhalation routes. Bystanders are expected to be exposed through product use via inhalation.

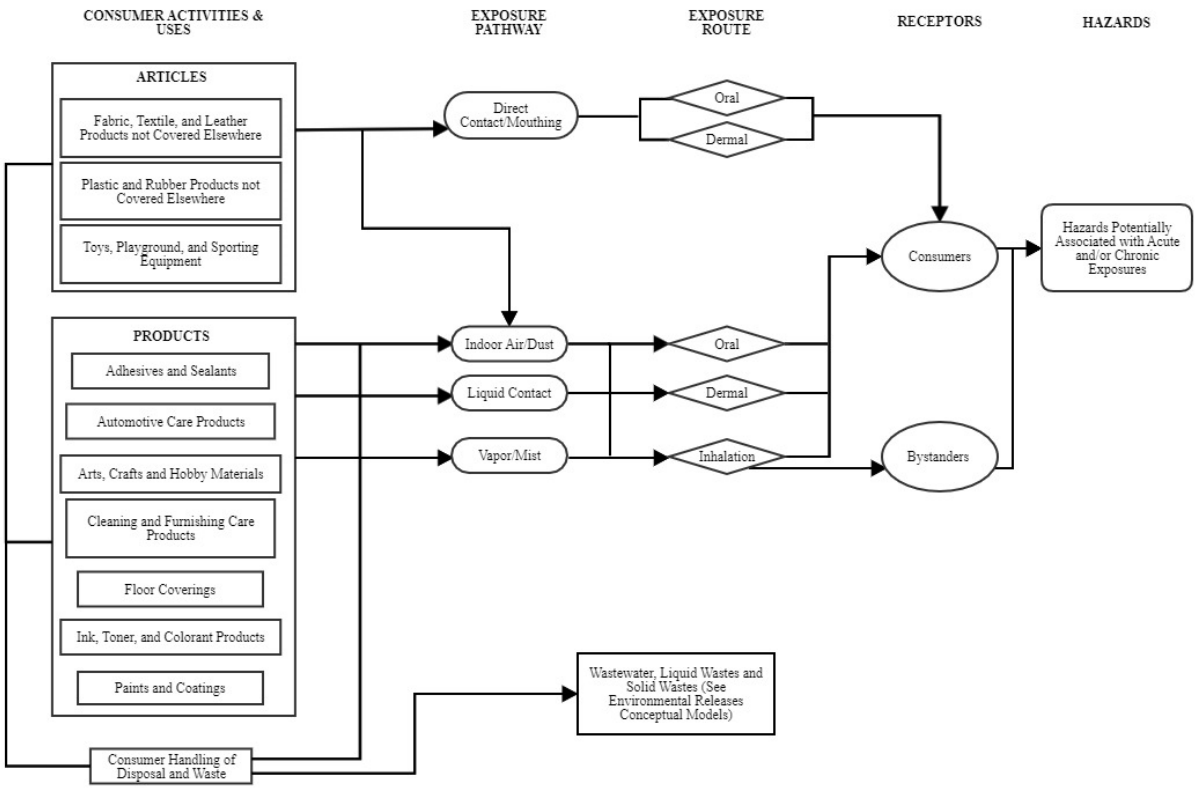

Figure 2-9 Butyl Benzyl Phthalate Conceptual Model for Consumer Activities and Uses: Consumer Exposures and Hazards
The conceptual model presents the exposure pathways, exposure routes, and hazards to human receptors from consumer activities and uses of butyl benzyl phthalate.

2.6.3 Conceptual Model for Environmental Releases and Wastes: Potential Exposures and Hazards (Regulatory Overlay)

In this section, EPA presents the conceptual models describing the identified exposures (pathways and routes), receptors and hazards associated with the conditions of use of butyl benzyl phthalate within the scope of the risk evaluation. It also discusses those pathways that may be addressed pursuant to other Federal laws.

In complying with TSCA, EPA plans to efficiently use Agency resources, avoid duplicating efforts taken pursuant to other Agency programs, maximize scientific and analytical efforts, and meet the statutory deadline for completing risk evaluations. OPPT is working closely with the offices within EPA that administer and implement the Clean Air Act (CAA), the Safe Drinking Water Act (SDWA), the Clean Water Act (CWA) and the Resource Conservation and Recovery Act (RCRA), to identify how those statutes and any associated regulatory programs address the presence of butyl benzyl phthalate in exposure pathways falling under the jurisdiction of these EPA statutes.

The conceptual model in Figure 2-10 presents the potential exposure pathways, exposure routes and hazards to human and environmental receptors from releases and waste streams associated with industrial, commercial, and consumer uses of butyl benzyl phthalate. This figure includes overlays, labeled and shaded to depict the regulatory programs (e.g., CAA, SDWA, CWA, RCRA) and associated pathways that EPA considered in developing this conceptual model for the draft scope document. The pathways are further described in Section 2.6.3.1 through Section 2.6.3.2.

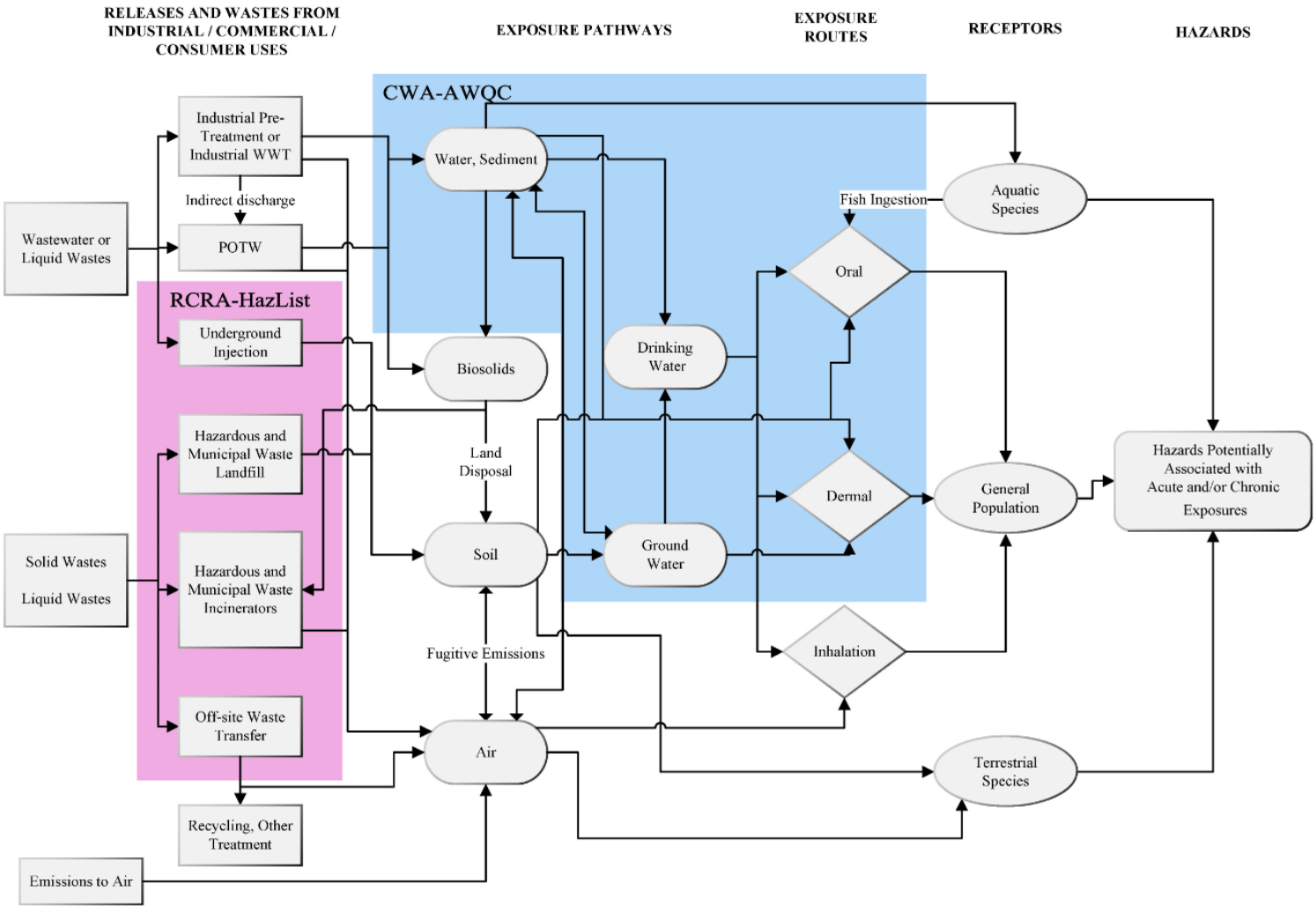

Figure 2-10 Butyl Benzyl Phthalate Conceptual Model for Environmental Releases and Wastes: Environmental and General Population Exposures and Hazards (Regulatory Overlay)

The conceptual model presents the exposure pathways, exposure routes and hazards to human and environmental receptors from releases and wastes from industrial and commercial, and consumer uses of butyl benzyl phthalate Including the environmental statutes covering those pathways. Notes:

a) Industrial wastewater or liquid wastes may be treated on-site and then released to surface water (direct discharge), or pre-treated and released to Publicly Owned Treatment Works (POTW) (indirect discharge). For consumer uses, such wastes may be released directly to POTW. Drinking water will undergo further treatment in drinking water treatment plant. Ground water may also be a source of drinking water. Inhalation from drinking water may occur via showering.

b) Receptors include potentially exposed or susceptible subpopulations (see Section 2.5).

c) For regulation of hazardous and municipal waste incinerators and municipal waste landfills CAA and RCRA may have shared regulatory authority.

2.6.3.1 Ambient Water Pathway

EPA develops recommended water quality criteria under Section 304(a) of the CWA for pollutants in surface water that are protective of aquatic life or human health designated uses. EPA has developed recommended water quality criteria for protection of human health for butyl benzyl phthalate which are available for possible adoption into state water quality standards and are available for possible use by NPDES permitting authorities in deriving effluent limits to meet state narrative criteria. As such, EPA does not plan to include this pathway in the risk evaluation under TSCA. EPA's OW and OPPT will continue to work together providing understanding and analysis of the CWA water quality criteria development process and to exchange information related to toxicity of chemicals undergoing risk evaluation under TSCA.

EPA has developed CWA Section 304(a) recommended human health criteria for 122 chemicals and aquatic life criteria for 47 chemicals. A subset of these chemicals is identified as "priority pollutants" (103 human health and 27 aquatic life), including butyl benzyl phthalate. The CWA requires that states adopt numeric criteria for priority pollutants for which EPA has published recommended criteria under Section 304(a), the discharge or presence of which in the affected waters could reasonably be expected to interfere with designated uses adopted by the state.

For pollutants with recommended human health criteria, EPA regulations require that state criteria contain sufficient parameters and constituents to protect designated uses. Once states adopt criteria as water quality standards, the CWA requires that National Pollutant Discharge Elimination System (NPDES) discharge permits include effluent limits as stringent as necessary to meet standards CWA Section 301(b)(1)(C). This permit issuance process accounts for risk in accordance with the applicable ambient water exposure pathway (human health or aquatic life as applicable) for the designated water use.

EPA has not developed CWA Section 304(a) recommended water quality criteria for the protection of aquatic life for butyl benzyl phthalate, so there are no national recommended criteria for this use available for adoption into state water quality standards and available for use in NPDES permits. EPA may issue CWA Section 304(a) aquatic life criteria for butyl benzyl phthalate in the future if it is identified as a priority under the CWA.

2.6.3.2 Disposal and Soil Pathways

Butyl benzyl phthalate is included on the list of hazardous wastes pursuant to RCRA 3001 (40 CFR §§ 261.33) as a hazardous constituent. The general standard in Section RCRA 3004(a) for the technical criteria that govern the management (treatment, storage, and disposal) of hazardous waste are those "necessary to protect human health and the environment," RCRA 3004(a). The regulatory criteria for identifying "characteristic" hazardous wastes and for "listing" a waste as hazardous also relate solely to the potential risks to human health or the environment (40 CFR §§ 261.11, 261.21-261.24). RCRA statutory criteria for identifying hazardous wastes require EPA to "tak[e] 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." Subtitle C controls cover not only hazardous wastes that are landfilled, but also hazardous wastes that are incinerated (subject to joint control under RCRA Subtitle C and the Clean Air Act (CAA) hazardous waste combustion Maximum Achievable Control Technology (MACT)) or injected into Underground Injection Control (UIC) Class I hazardous waste wells (subject to joint control under Subtitle C and the Safe Drinking Water Act (SDWA)).

EPA has not identified TRI releases since 1993. If butyl benzyl phthalate is present in commercial and consumer products it may be disposed of in landfills, such as Municipal Solid Waste landfills. Design standards for Subtitle C landfills require double liner, double leachate collection and removal systems, leak detection system, run on, runoff, and wind dispersal controls, and a construction quality assurance program. They are also subject to closure and post-closure care requirements including installing and maintaining a final cover, continuing operation of the leachate collection and removal system until leachate is no longer detected, maintaining and monitoring the leak detection and groundwater monitoring system. Bulk liquids may not be disposed in Subtitle C landfills. Subtitle C landfill operators are required to implement an analysis and testing program to ensure adequate knowledge of waste being managed, and to train personnel on routine and emergency operations at the facility. Hazardous waste being disposed in Subtitle C landfills must also meet RCRA waste treatment standards before disposal. Given these controls, general population exposure in groundwater from Subtitle C landfill leachate is not expected to be a significant pathway.

Butyl benzyl phthalate is present in commercial and consumer products that may be disposed of in Municipal Solid Waste (MSW) landfills. However, TRI releases have not been identified since 1993. While permitted and managed by the individual states, municipal solid waste (MSW) landfills are required by federal regulations to implement some of the same requirements as Subtitle C landfills. MSW landfills generally must have a liner system with leachate collection and conduct groundwater monitoring and corrective action when releases are detected. MSW landfills are also subject to closure and post-closure care requirements and must have financial assurance for funding of any needed corrective actions. MSW landfills have also been designed to allow for the small amounts of hazardous waste generated by households and very small quantity waste generators (less than 220 lb per month). Bulk liquids, such as free solvent, may not be disposed of at MSW landfills.

On-site releases to land from industrial non-hazardous and construction/demolition waste landfills may occur for butyl benzyl phthalate. Industrial non-hazardous and construction/demolition waste landfills are primarily regulated under authorized state regulatory programs. States must also implement limited federal regulatory requirements for siting, groundwater monitoring, and corrective action, and a prohibition on open dumping and disposal of bulk liquids. States may also establish additional requirements such as for liners, post-closure and financial assurance, but are not required to do so.

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

As described in Section 2.6.3, some pathways in the conceptual models are covered under the jurisdiction of other environmental statutes administered by EPA. The conceptual model depicted in Figure 2-11 presents the exposure pathways, exposure routes and hazards to human and environmental receptors from releases and wastes from industrial, commercial, and consumer uses of butyl benzyl phthalate that EPA plans to consider in the risk evaluation. The exposure pathways, exposure routes and hazards presented in this conceptual model are subject to change in the final scope, in light of comments received on this draft scope and other reasonably available information. EPA continues to consider whether and how other EPA-administered statutes and any associated regulatory programs address the presence of butyl benzyl phthalate in exposure pathways falling under the jurisdiction of these EPA statutes.

The diagram shown in Figure 2-11 includes releases from industrial, commercial and/or consumer uses to water/sediment; biosolids and soil, via direct and indirect discharges to water and emissions to air that may lead to exposure to aquatic and terrestrial receptors, and to the general population via drinking

water and emissions to ambient air. The supporting basis for environmental pathways considered for butyl benzyl phthalate are included in Appendix H.

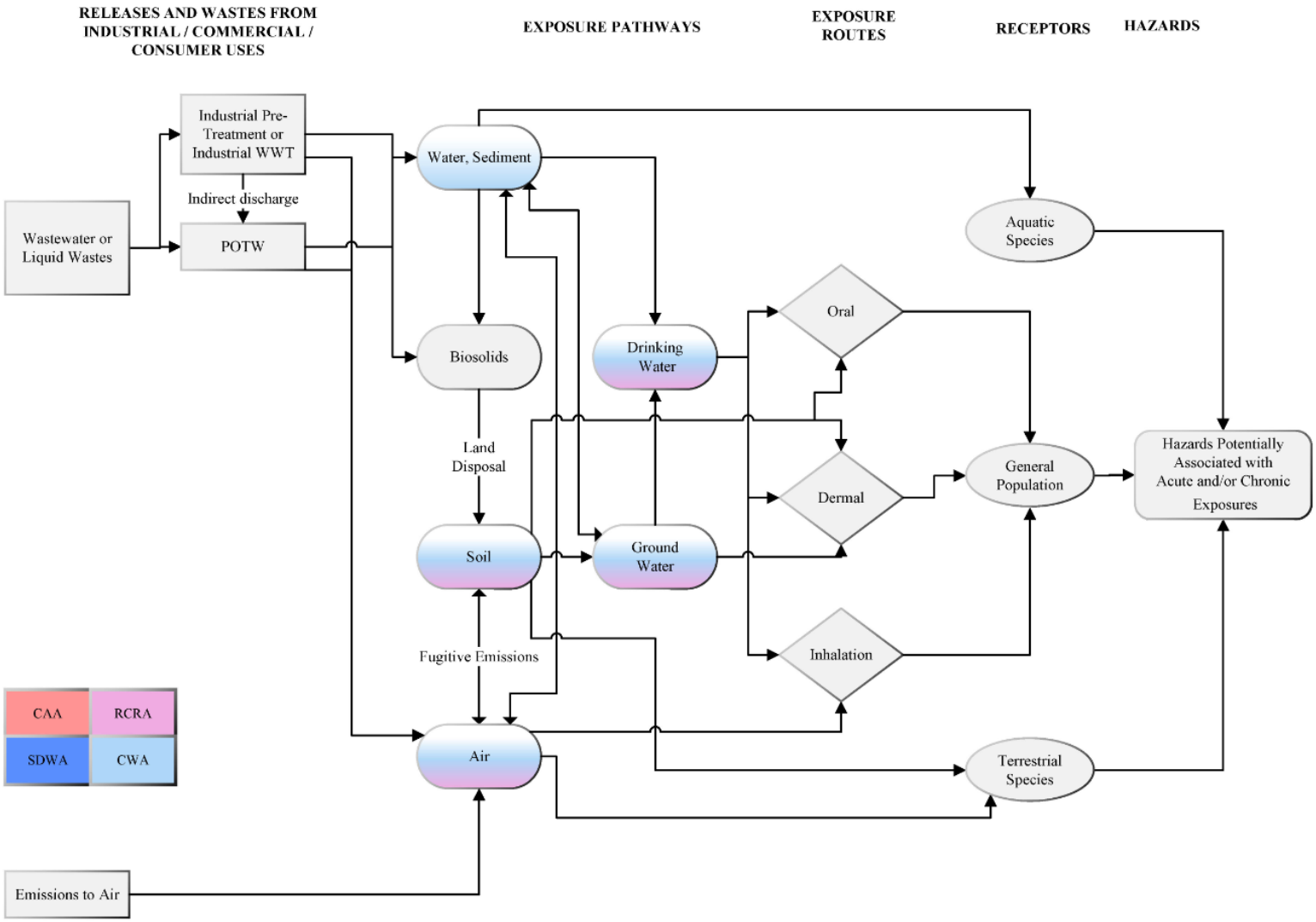

Figure 2-11 Butyl Benzyl Phthalate Conceptual Model for Environmental Releases and Wastes: Environmental and General Population Exposures and Hazards

The conceptual model presents the exposure pathways, exposure routes and hazards to human and environmental receptors from releases and wastes from industrial, commercial and consumer uses of butyl benzyl phthalate that EPA plans to consider in the risk evaluation. Notes:

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

b) Receptors include potentially exposed or susceptible subpopulations (see Section 2.5).

2.7 Analysis Plan

The analysis plan is based on EPA's knowledge of butyl benzyl phthalate to date which includes a partial, but not complete, review of reasonably available information as described in Section 2.1. EPA encourages submission of additional data, such as full study reports or workplace monitoring from industry sources, that may be relevant for EPA's evaluation of conditions of use, exposures, hazards and PESS during risk evaluation. Further, EPA may consider any relevant CBI in a manner that protects the confidentiality of the information from public disclosure. EPA plans to continue to consider new information submitted by the public. Should additional data or approaches become available, EPA may update its analysis plan in the final scope document.

2.7.1 Physical and Chemical Properties and Environmental Fate

EPA plans to analyze the physical and chemical (p-chem) properties and environmental fate and transport of butyl benzyl phthalate as follows:

1) **Review reasonably available measured or estimated p-chem and environmental fate endpoint data collected using systematic review procedures and, where available, environmental assessments conducted by other regulatory agencies.**
   EPA plans to review data and information collected through the systematic review methods and public comments about the p-chem properties (Appendix B) and fate endpoints (Appendix C), some of which appeared in the *Proposed Designation of Butyl Benzyl Phthalate (CASRN 85-68-7) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019a). All sources cited in EPA's analysis will be evaluated according to the procedures described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document. Where the systematic review process fails to identify experimentally measured chemical property values of sufficiently high quality, these values will be estimated using chemical parameter estimation models as appropriate. Model-estimated fate properties will be reviewed for applicability and quality.

2) **Using measured data and/or modeling, determine the influence of p-chem properties and environmental fate endpoints (e.g., persistence, bioaccumulation, partitioning, transport) on exposure pathways and routes of exposure to human and environmental receptors.**
   EPA plans to use measured data and, where necessary, model predictions of p-chem properties and environmental fate endpoints will be used to characterize the persistence and movement of butyl benzyl phthalate within and across environmental media. The fate endpoints of interest include volatilization, sorption to organic matter in soil and sediments, water solubility, aqueous and atmospheric photolysis rates, aerobic and anaerobic biodegradation rates, and potential bioconcentration and bioaccumulation. These endpoints will be used in exposure calculations.

3) **Conduct a weight-of-evidence evaluation of p-chem and environmental fate data, including qualitative and quantitative sources of information.**
   During risk evaluation, EPA plans to evaluate and integrate the p-chem and environmental fate evidence identified in the literature inventory using the methods described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document.

2.7.2 Exposure

EPA plans to analyze exposure levels for indoor air, ambient air, surface water, groundwater, sediment, soil, aquatic biota, and terrestrial biota associated to exposure to butyl benzyl phthalate. EPA has not yet determined the exposure levels in these media or how they may be used in the risk evaluation. Exposure

scenarios are combinations of sources (uses), exposure pathways, and exposed receptors. EPA plans to analyze scenario-specific exposures.

Based on their p-chem properties, expected sources, and transport and transformation within the outdoor and indoor environment, chemical substances are more likely to be present in some media and less likely to be present in others. Exposure level(s) can be characterized through a combination of available monitoring data and modeling approaches.

2.7.2.1 Environmental Releases

EPA plans to analyze releases to environmental media as follows:

1) **Review reasonably available published literature and other reasonably available information on processes and activities associated with the conditions of use to analyze the types of releases and wastes generated.**
   EPA has reviewed some key data sources containing information on processes and activities resulting in releases, and the information found is described in Appendix E. EPA plans to continue to review data sources identified during risk evaluation using the evaluation strategy in the systematic review documentation that EPA plans to publish prior to finalizing the scope document. Potential sources of environmental release data are summarized in Table 2-3 below:

   Table 2-3 Potential Categories and Sources of Environmental Release Data

U.S. EPA Generic Scenarios
OECD Emission Scenario Documents
EU Risk Assessment Reports
Discharge Monitoring Report (DMR) surface water discharge data from NPDES-permitted facilities

2) **Review reasonably available chemical-specific release data, including measured or estimated release data (e.g., data from risk assessments by other environmental agencies).**
   EPA plans to match identified data to applicable conditions of use and identify data gaps where no data are found for particular conditions of use. EPA plans to attempt to address data gaps identified as described in steps 3 and 4 below by considering potential surrogate data and models.

   Additionally, for conditions of use where no measured data on releases are available, EPA may use a variety of methods including release estimation approaches and assumptions in the Chemical Screening Tool for Occupational Exposures and Releases (ChemSTEER) (U.S. EPA, 2013).

3) **Review reasonably available measured or estimated release data for surrogate chemicals that have similar uses and physical properties.**
   If surrogate data are identified, these data will be matched with applicable conditions of use for potentially filling data gaps. Measured or estimated release data for other phthalate esters may be considered as surrogates for butyl benzyl phthalate.

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

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

5) **Review and determine applicability of OECD Emission Scenario Documents (ESDs) and EPA Generic Scenarios to estimation of environmental releases.**
EPA has identified potentially relevant OECD Emission Scenario Documents (ESDs) and EPA Generic Scenarios (GS) that correspond to some conditions of use; for example, the 2009 ESD on Adhesive Formulation, the 2011 ESD on Coating Application via Spray-Painting in the Automotive Refinishing Industry, the 2011 ESD on Chemical Industry, the 2011 ESD on Radiation Curable Coating, Inks and Adhesives, the 2015 ESD on the Use of Adhesives, and the 2019 ESD on Plastic Additives may be useful to assess potential releases. EPA intends to critically review these generic scenarios and ESDs to determine their applicability to the conditions of use assessed.

   EPA Generic Scenarios are available at the following: https://www.epa.gov/tsca-screening-tools/using-predictive-methods-assess-exposure-and-fate-under-tsca#fate.

   OECD Emission Scenario Documents are available at the following: http://www.oecd.org/chemicalsafety/risk-assessment/emissionscenariodocuments.htm

   EPA may also need to perform targeted research for applicable models and associated parameters that EPA may use to estimate releases for certain conditions of use. If ESDs and GSs are not available, other methods may be considered. Additionally, for conditions of use where no measured data on releases are available, EPA may use a variety of methods including the application of default assumptions such as standard loss fractions associated with drum cleaning (3%) or single process vessel cleanout (1%).

6) **Map or group each condition of use to a release assessment scenario(s).**
EPA has identified release scenarios and mapped (i.e., grouped) them to relevant conditions of use as shown in Appendix F. EPA may further refine the mapping of release scenarios based on factors (e.g., process equipment and handling, magnitude of production volume used, and release sources and usage rates of butyl benzyl phthalate and polymer products and formulations containing butyl benzyl phthalate, or professional judgment) corresponding to conditions of use as additional information is identified during risk evaluation.

7) **Evaluate the weight of the scientific evidence of environmental release data.**
During risk evaluation, EPA plans to evaluate and integrate the exposure evidence identified in the literature inventory using the methods described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document. The data integration strategy will be designed to be fit-for-purpose in which EPA plans to use systematic review methods to assemble the relevant data, evaluate the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence.

2.7.2.2 Environmental Exposures

EPA plans to analyze the following in developing its environmental exposure assessment of butyl benzyl phthalate:

1) **Review available environmental and biological monitoring data for all media relevant to environmental exposure.**
   For butyl benzyl phthalate, environmental media which will be analyzed are sediment, soil, air, groundwater, and surface water.

2) **Review reasonably available information on releases to determine how modeled estimates of concentrations near industrial point sources compare with available monitoring data.**
   Reasonably available environmental exposure models that meet the TSCA Section 26(h) and (i) Science Standards and that estimate water, sediment, and soil concentrations will be analyzed and considered alongside reasonably available water, sediment, and soil monitoring data to characterize environmental exposures. Modeling approaches to estimate surface water concentrations, sediment concentrations and soil concentrations generally consider the following inputs: direct release into air, groundwater, surface water, sediment, or soil, indirect release into air, groundwater, surface water, sediment, or soil (i.e., air deposition), fate and transport (partitioning within media) and characteristics of the environment (e.g., river flow, volume of lake, meteorological data).

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

4) **Group each condition(s) of use to environmental assessment scenario(s).**
   EPA plans to refine and finalize exposure scenarios for environmental receptors by considering combinations of sources (use descriptors), exposure pathways including routes, and populations exposed. For butyl benzyl phthalate, the following are noteworthy considerations in constructing exposure scenarios for environmental receptors:
   - Estimates of surface water concentrations, sediment concentrations and soil concentrations near industrial point sources based on available monitoring data.
   - Modeling inputs for release into the media of interest, fate and transport and characteristics of the environment.
   - Reasonably available biomonitoring data. Monitoring data could be used to compare with species or taxa-specific toxicological benchmarks.
   - Applicability of existing additional contextualizing information for any monitored data or modeled estimates during risk evaluation. Review and characterize the spatial and temporal variability, to the extent that data are available, and characterize exposed aquatic and terrestrial populations.
   - Weight of the scientific evidence of environmental occurrence data and modeled estimates.

5) **Evaluate the weight of the scientific evidence of environmental occurrence data and modeled estimates.**
   During risk evaluation, EPA plans to evaluate and integrate the exposure evidence identified in the literature inventory using the methods described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document.

2.7.2.3 Occupational Exposures

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

1) **Review reasonably available exposure monitoring data for specific condition(s) of use.**
EPA plans to review available butyl benzyl phthalate exposure monitoring data for specific conditions of use. Example exposure data include workplace monitoring data collected by government agencies such as OSHA and NIOSH, and monitoring data in published literature. The data may include both personal exposure monitoring measurements and area monitoring measurements.

2) **Review reasonably available exposure data for surrogate chemicals that have uses, volatility and chemical and physical properties similar to butyl benzyl phthalate.**
EPA plans to review literature sources identified and if surrogate data are found, these data will be matched to applicable conditions of use for potentially filling data gaps. EPA believes other phthalate esters utilized in similar ways to butyl benzyl phthalate may serve as surrogates for butyl benzyl phthalate.

3) **For conditions of use where data are limited or not available, review existing exposure models that may be applicable in estimating exposure levels.**
EPA has identified potentially relevant OECD ESDs and EPA GS corresponding to some conditions of use. For example, the 2015 ESD on the Use of Adhesives and the 2009 ESD on Plastic Additives are some of the ESDs and GS's that EPA may use to estimate occupational exposures. EPA will need to critically review these generic scenarios and ESDs to determine their applicability to the conditions of use assessed. EPA plans to perform additional targeted research to understand those conditions of use where ESDs or GS's were not identified, which may inform the exposure scenarios. EPA may also need to perform targeted research to identify applicable models that EPA may use to estimate exposures for certain conditions of use.

4) **Review reasonably available data that may be used in developing, adapting or applying exposure models to a particular risk evaluation scenario.**
This step will be performed after Steps #2 and #3 are completed. Based on information developed from Steps #2 and #3, EPA plans to evaluate relevant data to determine whether the data can be used to develop, adapt, or apply models for specific conditions of use (and corresponding exposure scenarios). EPA may utilize existing, peer-reviewed exposure models developed by EPA/OPPT, other government agencies, or available in the scientific literature, or EPA may elect to develop additional models to assess specific condition(s) of use. Inhalation exposure models may be simple box models or two-zone (near-field/far-field) models. In two-zone models, the near-field exposure represents potential inhalation exposures to workers, and the far-field exposure represents potential inhalation exposures to ONUs.

5) **Consider and incorporate applicable ECs and/or PPE into exposure scenarios.**
EPA plans to review potentially relevant data sources on ECs and PPE to determine their applicability and incorporation into exposure scenarios during risk evaluation. EPA plans to assess worker exposure pre- and post-implementation of ECs, using reasonably available information on available control technologies and control effectiveness. For example, EPA may assess worker exposure in industrial use scenarios before and after implementation of local exhaust ventilation.

6) **Map or group each condition of use to occupational exposure assessment scenario(s).**
EPA has identified occupational exposure scenarios and mapped them to relevant conditions of use (see Appendix F). As presented in the fourth column in Table_Apx F-1, EPA has grouped the scenarios into representative release/exposure scenarios. EPA was not able to identify

occupational scenarios corresponding to some conditions of use. EPA plans to perform targeted research to understand those uses which may inform identification of occupational exposure scenarios. EPA may further refine the mapping of occupational exposure scenarios based on factors (e.g., process equipment and handling, magnitude of production volume used, and exposure/release sources) corresponding to conditions of use as additional information is identified during risk evaluation.

7) **Evaluate the weight of the scientific evidence of occupational exposure data, which may include qualitative and quantitative sources of information.**
During risk evaluation, EPA plans to evaluate and integrate the exposure evidence identified in the literature inventory using the methods described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document. EPA plans to rely on the weight of the scientific evidence when evaluating and integrating occupational data. The data integration strategy will be designed to be fit-for-purpose in which EPA plans to use systematic review methods to assemble the relevant data, evaluate the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence.

2.7.2.4 Consumer Exposures

EPA plans to analyze both consumers using a consumer product and bystanders associated with the consumer using the product as follows:

1) **Group each condition of use to consumer exposure assessment scenario(s).**
Refine and finalize exposure scenarios for consumers by considering combinations of sources (ongoing consumer uses), exposure pathways including routes, and exposed populations.

   For butyl benzyl phthalate, the following are noteworthy considerations in constructing consumer exposure scenarios:
   - Conditions of use
   - Duration of exposure
   - Weight fraction of chemical in products
   - Amount of chemical used

2) **Evaluate the relative potential of indoor exposure pathways based on available data.**
Indoor exposure pathways expected to be relatively higher include inhalation of vapors from indoor air during butyl benzyl phthalate use and disposal. Indoor exposure pathways expected to be relatively lower include dermal contact to liquid. The data sources associated with these respective pathways have not yet been comprehensively evaluated, so quantitative comparisons across exposure pathways or in relation to toxicity thresholds are not yet available.

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

4) **Review reasonably available empirical data that may be used in developing, adapting or applying exposure models to a particular risk evaluation scenario. For example, existing models developed for a chemical assessment may be applicable to another chemical assessment if model parameter data are available.**
   To the extent other organizations have already modeled a butyl benzyl phthalate consumer exposure scenario that is relevant to the OPPT's assessment, EPA plans to evaluate those modeled estimates. In addition, if other chemicals similar to butyl benzyl phthalate have been modeled for similar uses, those modeled estimates will also be evaluated. The underlying parameters and assumptions of the models will also be evaluated.

5) **Review reasonably available consumer product-specific sources to determine how those exposure estimates compare with each other and with indoor monitoring data reporting butyl benzyl phthalate in specific media (e.g., indoor air).**
   The availability of butyl benzyl phthalate concentration for various ongoing uses will be evaluated. This data provides the source term for any subsequent indoor modeling. Source attribution between overall indoor air levels and various indoor sources will be analyzed.

6) **Review reasonably available population- or subpopulation-specific exposure factors and activity patterns to determine if PESS need to be further refined.**
   During risk evaluation, EPA plans to evaluate and integrate the exposure evidence identified in the literature inventory using the methods described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document.

7) **Evaluate the weight of the scientific evidence of consumer exposure estimates based on different approaches.**
   EPA plans to rely on the weight of the scientific evidence when evaluating and integrating data related to consumer exposure. The weight of the scientific evidence may include qualitative and quantitative sources of information. The data integration strategy will be designed to be fit-for-purpose in which EPA plans to use systematic review methods to assemble the relevant data, evaluate the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence.

2.7.2.5 General Population

EPA plans to analyze general population exposures as follows:

1) **Refine and finalize exposure scenarios for general population by considering combinations of sources and uses, exposure pathways including routes, and exposed populations.**
   For butyl benzyl phthalate, the following are noteworthy considerations in constructing exposure scenarios for the general population:
   - Review reasonably available environmental and biological monitoring data for media to which general population exposures are expected.
   - For exposure pathways where data are not available, review existing exposure models that may be applicable in estimating exposure levels.
   - Consider and incorporate applicable media-specific regulations into exposure scenarios or modeling.
   - Review reasonably available data that may be used in developing, adapting or applying exposure models to the particular risk evaluation. For example, existing models developed for a chemical assessment may be applicable to another chemical assessment if model parameter data are available.

- Review reasonably available information on releases to determine how modeled estimates of concentrations near industrial point sources compare with available monitoring data.
- Review reasonably available population- or subpopulation-specific exposure factors and activity patterns to determine if PESS need be further defined.
- Evaluate the weight of the scientific evidence of general population exposure data.
- Map or group each condition of use to general population exposure assessment scenario(s).
- Environmental Exposure pathways regulated by non-TSCA EPA laws and regulations will be excluded from analysis

EPA intends to evaluate a variety of data types to determine which types are most appropriate when quantifying exposure scenarios. Environmental monitoring data, biomonitoring data, modeled estimates, experimental data, epidemiological data, and survey-based data can all be used to quantify exposure scenarios. In an effort to associate exposure estimates with sources of exposure and/or conditions of use, EPA plans to consider source apportionment across exposure scenarios during risk evaluation. EPA anticipates that there will be a wide range in the relative exposure potential of the exposure scenarios identified in Appendix G. Source apportionment characterizes the relative contribution of any of the following: a use/source toward a total media concentration, a media concentration toward a total exposure route, or an exposure route toward a total external or internal dose. This consideration may be qualitative, semi-quantitative, or quantitative, and is dependent upon available data and approaches. For example, EPA may consider the co-location of TSCA industrial facilities with available monitoring data or modeled estimates. EPA may compare modeled estimates for discrete outdoor and indoor sources/uses that apply to unique receptor groups.

After refining and finalizing exposure scenarios, EPA plans to quantify concentrations and/or doses for these scenarios. The number of scenarios will depend on how combinations of uses, exposure pathways, and receptors are characterized. The number of scenarios is also dependent upon the available data and approaches to quantify scenarios. When quantifying exposure scenarios, EPA plans to use a tiered approach. First-tier analysis is based on data that is readily available without a significant number of additional inputs or assumptions, and may be qualitative, semi-quantitative, or quantitative. First-tier analyses were conducted during problem formulation and are expected to continue during risk evaluation. The results of first tier analyses inform whether scenarios require more refined analysis. Refined analyses will be iterative and require careful consideration of variability and uncertainty. Should data become available that summarily alters the overall conclusion of a scenario through iterative tiering, EPA can refine its analysis during risk evaluation.

2) **For exposure pathways where empirical data is not available, review existing exposure models that may be applicable in estimating exposure levels.**
For butyl benzyl phthalate, media where exposure models will be considered for general population exposure include models that estimate, surface water concentrations, sediment concentrations, soil concentrations, and uptake from aquatic and terrestrial environments into edible aquatic and terrestrial organisms.

3) **Review available exposure modeled estimates. For example, existing models developed for a previous butyl benzyl phthalate chemical assessment may be applicable to EPA's**

assessment. In addition, another chemical's assessment may also be applicable if model parameter data are available.
To the extent other organizations have already modeled butyl benzyl phthalate general population exposure scenario that is relevant to this assessment, EPA plans to evaluate those modeled estimates. In addition, if modeled estimates for other chemicals with similar p-chem properties and similar uses are available, those modeled estimates will also be evaluated. The underlying parameters and assumptions of the models will also be evaluated.

4) **Review reasonably available information on releases to determine how modeled estimates of concentrations near industrial point sources compare with available monitoring data.**
The expected releases from industrial facilities may change over time. Any modeled concentrations based on recent release estimates will be carefully compared with available monitoring data to determine representativeness.

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

6) **Evaluate the weight of the scientific evidence of general population exposure estimates based on different approaches.**
During risk evaluation, EPA plans to evaluate and integrate the exposure evidence identified in the literature inventory using the methods described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document.

2.7.3 Hazards (Effects)

2.7.3.1 Environmental Hazards

EPA plans to conduct an environmental hazard assessment of butyl benzyl phthalate as follows:

1) **Review reasonably available environmental hazard data, including data from alternative test methods (e.g., computational toxicology and bioinformatics; high-throughput screening methods; data on categories and read-across; in vitro studies).**
EPA plans to analyze the hazards of butyl benzyl phthalate to aquatic and/or terrestrial organisms, including plants, invertebrates (e.g., insects, arachnids, mollusks, crustaceans), and vertebrates (e.g., mammals, birds, amphibians, fish, reptiles) across exposure durations and conditions if potential environmental hazards are identified through systematic review results and public comments. Additional types of environmental hazard information will also be considered (e.g., analogue and read-across data) when characterizing the potential hazards of butyl benzyl phthalate to aquatic and/or terrestrial organisms.

   Environmental hazard data will be evaluated using the environmental toxicity data quality criteria outlined in the systematic review documentation that EPA plans to publish prior to finalizing the scope document. The study evaluation results will be documented in the risk evaluation phase and data from suitable studies will be extracted and integrated in the risk evaluation process.

Hazard endpoints (e.g., mortality, growth, immobility, reproduction) will be evaluated, while considering data availability, relevance, and quality.

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

3) **Evaluate the weight of the scientific evidence of environmental hazard data.**
During risk evaluation, EPA plans to evaluate and integrate the environmental hazard evidence identified in the literature inventory using the methods described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document.

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

5) **Conduct an environmental risk characterization of butyl benzyl phthalate.**
EPA plans to conduct a risk characterization of butyl benzyl phthalate to identify if there are risks to the aquatic and/or terrestrial environments from the measured and/or predicted concentrations of butyl benzyl phthalate in environmental media (i.e., water, sediment, soil). Risk quotients (RQs) may be derived by the application of hazard and exposure benchmarks to characterize environmental risk (U.S. EPA, 1998; Barnthouse et al., 1982).

6) **Consider a Persistent, Bioaccumulative, and Toxic (PBT) Assessment of butyl benzyl phthalate.**
EPA plans to consider the persistence, bioaccumulation, and toxic (PBT) potential of butyl benzyl phthalate after reviewing relevant p-chem properties and exposure pathways. EPA plans to assess the available studies collected from the systematic review process relating to bioaccumulation and bioconcentration (e.g., BAF, BCF) of butyl benzyl phthalate. In addition, EPA plans to integrate traditional environmental hazard endpoint values (e.g., LC_{50}, LOEC) and exposure concentrations (e.g., surface water concentrations, tissue concentrations) for butyl benzyl phthalate with the fate parameters (e.g., BAF, BCF, BMF, TMF).

2.7.3.2 Human Health Hazards

EPA plans to analyze human health hazards as follows:

1) **Review reasonably available human health hazard data, including data from alternative test methods (e.g., computational toxicology and bioinformatics; high-throughput screening methods; data on categories and read-across; *in vitro* studies; systems biology).**

EPA plans to use systematic review methods to evaluate the epidemiological and toxicological literature for butyl benzyl phthalate. EPA plans to publish the systematic review documentation prior to finalizing the scope document.

Relevant mechanistic evidence will also be considered, if reasonably available, to inform the interpretation of findings related to potential human health effects and the dose-repose assessment. Mechanistic data may include analyses of alternative test data such as novel *in vitro* test methods and high throughput screening. The association between acute and chronic exposure scenarios to the agent and each health outcome will also be integrated. Study results will be extracted and presented in evidence tables or another appropriate format by organ/system.

2) **Conduct hazard identification (the qualitative process of identifying non-cancer and cancer endpoints) and dose-response assessment (the quantitative relationship between hazard and exposure) for identified human health hazard endpoints.**
Human health hazards from acute and chronic exposures will be identified by evaluating the human and animal data that meet the systematic review data quality criteria described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document. Hazards identified by studies meeting data quality criteria will be grouped by routes of exposure relevant to humans (e.g., oral, dermal, inhalation) and by cancer and noncancer endpoints.

   Dose-response assessment will be performed in accordance with EPA guidance (U.S. EPA, 2012a, 2011b, 1994). Dose-response analyses may be used if the data meet data quality criteria and if additional information on the identified hazard endpoints are not available or would not alter the analysis.

   The cancer mode of action (MOA) determines how cancer risks can be quantitatively evaluated. If cancer hazard is determined to be applicable to butyl benzyl phthalate, EPA plans to evaluate information on genotoxicity and the mode of action for all cancer endpoints to determine the appropriate approach for quantitative cancer assessment in accordance with the U.S. EPA Guidelines for Carcinogen Risk Assessment (U.S. EPA, 2005).

3) **In evaluating reasonably available data, determine whether particular human receptor groups may have greater susceptibility to the chemical's hazard(s) than the general population.**
Reasonably available human health hazard data will be evaluated to ascertain whether some human receptor groups may have greater susceptibility than the general population to butyl benzyl phthalate hazard(s). Susceptibility of particular human receptor groups to butyl benzyl phthalate will be determined by evaluating information on factors that influence susceptibility.

   EPA has reviewed some sources containing hazard information associated with PESS and lifestages such as pregnant women and infants. Pregnancy (i.e., gestation) and childhood are potential susceptible lifestages for butyl benzyl phthalate exposure. EPA plans to review the current state of the literature in order to potentially quantify these differences for risk evaluation purposes.

4) **Derive points of departure (PODs) where appropriate; conduct benchmark dose modeling depending on the reasonably available data. Adjust the PODs as appropriate to conform (e.g., adjust for duration of exposure) to the specific exposure scenarios evaluated.**
Hazard data will be evaluated to determine the type of dose-response modeling that is applicable. Where modeling is feasible, a set of dose-response models that are consistent with a variety of potentially underlying biological processes will be applied to empirically model the dose-

response relationships in the range of the observed data consistent with EPA's *Benchmark Dose Technical Guidance Document* (U.S. EPA, 2012a). Where dose-response modeling is not feasible, NOAELs or LOAELs will be identified. Non-quantitative data will also be evaluated for contribution to weight of the scientific evidence or for evaluation of qualitative endpoints that are not appropriate for dose-response assessment.

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

5) **Evaluate the weight of the scientific evidence of human health hazard data.**
During risk evaluation, EPA plans to evaluate and integrate the human health hazard evidence identified in the literature inventory under acute and chronic exposure conditions using the methods described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document.

6) **Consider the route(s) of exposure (oral, inhalation, dermal), reasonably available route-to-route extrapolation approaches, reasonably available biomonitoring data and reasonably available approaches to correlate internal and external exposures to integrate exposure and hazard assessment.**
At this stage of review, EPA believes there will be sufficient data to conduct a dose-response analysis and/or benchmark dose modeling for the oral route of exposure. EPA plans to also evaluate any potential human health hazards following dermal and inhalation exposure to butyl benzyl phthalate, which could be important for worker, consumer, and general population risk analyses. Reasonably available data will be assessed to determine whether or not a POD can be identified for the dermal and inhalation routes. This may include using route-to-route extrapolation methods, where appropriate and depending on the nature of available data.

If sufficient toxicity studies are not identified in the literature search to assess risks from dermal and inhalation exposures, then a route-to-route extrapolation from oral toxicity studies would be needed to assess systemic risks from dermal or inhalation exposures. Without an adequate PBPK model, the approaches described in EPA guidance document *Risk Assessment Guidance for Superfund Volume I: Human Health Evaluation Manual (Part E, Supplemental Guidance for Dermal Risk Assessment)* (U.S. EPA, 2004) could be applied to extrapolate from oral to dermal exposure. These approaches may be able to further inform the relative importance of dermal exposures compared with other routes of exposure. Similar methodology may also be used for assessing inhalation exposures.

2.7.4 Summary of Risk Approaches for Characterization

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

limitations of the assessment, and a description of how others have assessed the risk into an integrated picture.

The level of information contained in each risk characterization varies according to the type of assessment for which the characterization is written. Regardless of the level of complexity or information, the risk characterization for TSCA risk evaluations will be prepared in a manner that is transparent, clear, consistent, and reasonable (U.S. EPA, 2000) and consistent with the requirements of the *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act* (82 FR 33726). For instance, in the risk characterization summary, EPA plans to further carry out the requirements under TSCA Section 26; for example, by identifying and assessing uncertainty and variability in each step of the risk evaluation, discussing considerations of data quality such as the reliability, relevance and whether the methods utilized were reasonable and consistent, explaining any assumptions used, and discussing information generated from independent peer review.

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

2.8 Peer Review

Peer review will be conducted in accordance with EPA's regulatory procedures for chemical risk evaluations, including using EPA's Peer Review Handbook and other methods consistent with Section 26 of TSCA (See 40 CFR 702.45). As explained in the preamble to Risk Evaluation Rule, the purpose of peer review is for the independent review of the science underlying the risk assessment (See 82 Fed. Reg. 33726, 33744 (July 12, 2017)). Peer review will therefore address aspects of the underlying science as outlined in the charge to the peer review panel such as hazard assessment, assessment of dose-response, exposure assessment, and risk characterization. The draft risk evaluation for butyl benzyl phthalate will be peer reviewed.

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APPENDICES

Appendix A LIST OF GRAY LITERATURE SOURCES

Table_Apx A-1 provides a list of gray literature sources that yielded results for butyl benzyl phthalate.

Table_Apx A-1 Gray Literature Sources that Yielded Results for Butyl Benzyl Phthalate

Source/Agency	Source Name	Source Type	Source Category
Australian Government Department of Health	NICNAS Assessments (eco)	International Resources	Assessment or Related Document
Australian Government Department of Health	NICNAS Assessments (human health, Tier I, II or III)	International Resources	Assessment or Related Document
CAL EPA	Technical Support Documents for regulations: Proposition 65, Cancer	Other U. S. Agency Resources	Assessment or Related Document
CAL EPA	Technical Support Documents for regulations: Proposition 65, Reproductive Toxicity	Other U.S. Agency Resources	Assessment or Related Document
CPSC	Chronic Hazard Advisory Panel Reports	Other U.S. Agency Resources	Assessment or Related Document
CPSC	Technical Reports: Exposure/Risk Assessment	Other U.S. Agency Resources	Assessment or Related Document
CPSC	Technical Reports: Toxicity Review	Other U.S. Agency Resources	Assessment or Related Document
ECHA	European Union Risk Assessment Report	International Resources	Assessment or Related Document
ECHA	ECHA Documents	International Resources	Assessment or Related Document
ECHA	Annex XVII Restriction Reports	International Resources	Assessment or Related Document
ECHA	Annex XVII To REACH - Conditions of Use	International Resources	Assessment or Related Document

Source/Agency	Source Name	Source Type	Source Category
Env Canada	Priority Substances List Assessment Report; State of Science Report, Environment Canada Assessment	International Resources	Assessment or Related Document
Env Canada	Canada Substance Grouping Pages	International Resources	Assessment or Related Document
Env Canada	Guidelines, Risk Management, Regulations	International Resources	Assessment or Related Document
EPA	Office of Water: STORET and WQX	U.S. EPA Resources	Database
EPA	EPA Office of Water: Ambient Water Quality Criteria documents	U.S. EPA Resources	Assessment or Related Document
EPA	TSCA Hazard Characterizations	U.S. EPA Resources	Assessment or Related Document
EPA	Included in 2011 NATA	U.S. EPA Resources	Assessment or Related Document
EPA	Office of Air: National Emissions Inventory (NEI) - National Emissions Inventory (NEI) Data (2014, 2011, 2008)	U.S. EPA Resources	Database
EPA	Other EPA: Misc sources	U.S. EPA Resources	General Search
EPA	EPA: AP-42	U.S. EPA Resources	Regulatory Document or List
EPA	TRI: Envirofacts Toxics Release Inventory 2017 Updated Dataset	U.S. EPA Resources	Database
EPA	Chemical Data Reporting (2012 and 2016 non-CBI CDR database)	U.S. EPA Resources	Database
EPA	Chemical Data Reporting (2012 and 2016 CBI CDR database)	U.S. EPA Resources	Database
EPA	EPA: Generic Scenario	U.S. EPA Resources	Assessment or Related Document
EPA	EPA Discharge Monitoring Report Data	U.S. EPA Resources	Database
EPA	Office of Water: CFRs	U.S. EPA Resources	Regulatory Document or List

Source/Agency	Source Name	Source Type	Source Category
EPA	Office of Air: CFRs and Dockets	U.S. EPA Resources	Regulatory Document or List
IARC	IARC Monograph	International Resources	Assessment or Related Document
Japan	Japanese Ministry of the Environment Assessments - Environmental Risk Assessments (Class I Designated Chemical Substances Summary Table)	International Resources	Regulatory Document or List
KOECT	Kirk-Othmer Encyclopedia of Chemical Technology Journal Article	Other Resource	Encyclopedia
NIOSH	CDC NIOSH - Health Hazard Evaluations (HHEs)	Other U. S. Agency Resources	Assessment or Related Document
NIOSH	CDC NIOSH - Workplace Survey Reports	Other U.S. Agency Resources	Assessment or Related Document
NIOSH	CDC NIOSH - Publications and Products	Other U.S. Agency Resources	Assessment or Related Document
NLM	National Library of Medicine’s PubChem	Other U.S. Agency Resources	Database
NTP	OHAT Monographs	Other U.S. Agency Resources	Assessment or Related Document
NTP	Technical Reports	Other U.S. Agency Resources	Assessment or Related Document
OECD	OECD Substitution and Alternatives Assessment	International Resources	Assessment or Related Document
OECD	OECD Emission Scenario Documents	International Resources	Assessment or Related Document
OECD	OECD: General Site	International Resources	General Search

Source/Agency	Source Name	Source Type	Source Category
OSHA	OSHA Chemical Exposure Health Data	Other U.S. Agency Resources	Database
OSHA	U.S. OSHA Chemical Exposure Health Data (CEHD) program data [ERG]	Other U.S. Agency Resources	Database
RIVM	RIVM Reports: Risk Assessments	International Resources	Assessment or Related Document
TERA	Toxicology Excellence for Risk Assessment	Other Resources	Assessment or Related Document
UNEP	Risk Profile / Stockholm Convention	International Resources	Assessment or Related Document

Appendix B PHYSICAL AND CHEMICAL PROPERTIES

This appendix provides p-chem information and data found in preliminary data gathering for butyl benzyl phthalate. Table_Apx B-1 summarizes the p-chem property values preliminarily selected for use in the risk evaluation from among the range of reported values collected as of March 2020. This table differs from that presented in the *Proposed Designation of Butyl Benzyl Phthalate (CASRN 85-68-7) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019a) and may be updated as EPA collects additional information through systematic review methods. All p-chem property values that were extracted and evaluated as of March 2020 are presented in the supplemental file *Data Extraction and Data Evaluation Tables for Physical Chemical Property Studies* (EPA-HQ-OPPT-2018-0501).

Table_Apx B-1 Physical and Chemical Properties of Butyl Benzyl Phthalate

Property or Endpoint	Value[a]	Reference	Data Quality Rating
Molecular formula	$C_{19}H_{20}O_4$	NA	NA
Molecular weight	312.37 g/mol	NA	NA
Physical state	Liquid	NLM, 2015	High
Physical properties	Clear oil, liquid; slight odor	NLM, 2015	High
Melting point	-35°C	NLM, 2015	High
Boiling point	370°C	NLM, 2015	High
Density	1.119 g/cm^3 at 25°C	Haynes, 2014	High
Vapor pressure	8.25×10^{-6} mm Hg at 25°C	NLM, 2015	High
Vapor density	10.8 (air = 1)	NLM, 2015	High
Water solubility	2.69 mg/L at 25°C	NLM, 2015	High
Log Octanol/water partition coefficient (Log Kow)	4.73	NLM, 2015	High
Henry's Law constant	7.61×10^{-7} atm·m^3/mol	Elsevier, 2019	High
Flash point	110-113°C	RSC, 2019	Medium
Auto flammability	NA		

Property or Endpoint	Value[a]	Reference	Data Quality Rating
Viscosity	55 cP at 20°C	Elsevier, 2019	High
Refractive index	1.5356	Elsevier, 2019	High
Dielectric constant	NA		

[a] Measured unless otherwise noted.
NA = Not applicable

Appendix C ENVIRONMENTAL FATE AND TRANSPORT PROPERTIES

Table_Apx C-1 provides the environmental fate characteristics that EPA identified and considered in developing the scope for butyl benzyl phthalate.

Table_Apx C-1 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 ℃ based on ·OH rate constant of 1.1 × 10^{-11} cm^3/molecule second and 1.5 × 10^6 ·OH/cm_3; estimated)[b]	U.S. EPA (2012b)
Hydrolysis	$t_{1/2}$ >100 days	ECHA (2018) citing Gledhill et al. (1980)
Biodegradation (Aerobic)	74−79%/10−50 days at 25 ºC (activated sludge)	NLM, 2015 citing Desai (1992)
	$t_{1/2}$ = 5 days (lake water/sediment microcosm)	NLM, 2015 citing Carson et al. (1990)
	81%/2 weeks based on BOD (MITI test)	NLM, 2015 citing NITE (2015)
Biodegradation (Anaerobic)	$t_{1/2}$ = 107 hours (sewage sludge)	NLM, 2015 citing Ziogou et al. (1989)
	98.3%/120 days at 35 ºC	NLM, 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]	U.S. EPA (2012b)
Bioconcentration Factor	663 and 772 (*Lepomis macrochirus*)	NLM, 2015 citing Carr et al. (1992)
	0.13 to 45 (*Ipomoea aquatica)*	NLM, 2015 citing Cai et al. (2006)

Property or Endpoint	Value[a]	Reference
Soil Organic Carbon:Water Partition Coefficient (Log K_{OC})	3.3 at pH 4.8	NLM, 2015 citing Zurmuehl et al. (1991)
	3.21	NLM, 2015 citing Sabljic et al. (1995)

Notes: [a]Measured unless otherwise noted. [b]EPI Suite™ physical property inputs: Log Kow = 4.73, BP = 370 ºC, MP = -40.5 ºC, VP = 8.25 × 10^{-6} mm Hg, WS= 2.69 mg/L BioP = 4, BioA = 1 and BioS = 1 SMILES O=C(OCc(cccc1)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

Appendix D REGULATORY HISTORY

The chemical substance, butyl benzyl phthalate, is subject to federal and state laws and regulations in the United States (Table_Apx D-1 and Table_Apx D-2). Regulatory actions by other governments, tribes and international agreements applicable to butyl benzyl phthalate are listed in Table_Apx D-3.

D.1 Federal Laws and Regulations

Table_Apx D-1 Federal Laws and Regulations

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
Toxic Substances Control Act (TSCA) – Section 6(b)	EPA is directed to identify high-priority chemical substances for risk evaluation; and conduct risk evaluations on at least 20 high priority substances no later than three and one-half years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.	Butyl benzyl phthalate s one of the 20 chemicals EPA designated as a High-Priority Substance for risk evaluation under TSCA (84 FR 71924, December 30, 2019). Designation of butyl benzyl phthalate as a high-priority substance constitutes the initiation of the risk evaluation on the chemical.
Toxic Substances Control Act (TSCA) – Section 8(a)	The TSCA Section 8(a) CDR Rule requires manufacturers (including importers) to give EPA basic exposure-related information on the types, quantities, and uses of chemical substances produced domestically and imported into the United States.	Butyl benzyl phthalate manufacturing (including importing), processing, and use information is reported under the CDR rule (76 FR 50816, August 16, 2011).
Toxic Substances Control Act (TSCA) – Section 8(b)	EPA must compile, keep current, and publish a list (the TSCA Inventory) of each chemical substance manufactured (including imported) or processed in the United States.	Butyl benzyl phthalate was on the initial TSCA Inventory and therefore was not subject to EPA's new chemicals review process under TSCA Section 5 (60 FR 16309, March 29, 1995).
Toxic Substances Control Act (TSCA) – Section 8(e)	Manufacturers (including importers), processors, and distributors must immediately notify EPA if they obtain information that supports the conclusion that a chemical substance or mixture presents a substantial risk of injury to health or the environment.	Eleven risk reports received for butyl benzyl phthalate (Received: 1992-2009). One worker exposure submission was received in 2007. U.S. EPA, ChemView. (Accessed April 9, 2019).
Toxic Substances Control Act (TSCA) – Section 4	Provides EPA with authority to issue rules, enforceable consent agreements and orders requiring manufacturers (including importers) and processors to test chemical substances and mixtures.	Ten chemical data submissions from test rules received for butyl benzyl phthalate one acute aquatic plant toxicity studies, five acute toxicity studies, two chronic aquatic toxicity studies, one bioaccumulation potential report, one persistence report. (U.S.

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
		EPA, ChemView. Accessed April 9, 2019).
Emergency Planning and Community Right-To-Know Act (EPCRA) – Section 313	Requires annual reporting from facilities in specific industry sectors that employ 10 or more full-time equivalent employees and that manufacture, process or otherwise use a TRI-listed chemical in quantities above threshold levels. A facility that meets reporting requirements must submit a reporting form for each chemical for which it triggered reporting, providing data across a variety of categories, including activities and uses of the chemical, releases and other waste management (e.g., quantities recycled, treated, combusted) and pollution prevention activities (under Section 6607 of the Pollution Prevention Act). These data include on- and off-site data as well as multimedia data (i.e., air, land and water).	Butyl benzyl phthalate was on the original TRI chemical list in 1987 and it was delisted from the list in calendar year 1994 (40 CFR Part 372). The last reporting year was 1993.
Clean Water Act (CWA) - Section 304(a)(1)	Requires EPA to develop and publish ambient water quality criteria (AWQC) reflecting the latest scientific knowledge on the effects on human health that may be expected from the presence of pollutants in any body of water.	In 2015, EPA published updated AWQC for butyl benzyl phthalate, including a recommendation of 0.1 µg/L for "Human Health for the consumption of Water + Organism" and 0.1 µg/L for "Human Health for the consumption of Organism Only" for states and authorized tribes to consider when adopting criteria into their water quality standards. (Docket ID: EPA-HQ-OW-2014-0135-0213)
Clean Water Act (CWA) – Section 301, 304, 306, 307 and 402	Clean Water Act Section 307(a) establishes a list of toxic pollutants or combination of pollutants under the CWA. The statute specifies a list of families of toxic pollutants also listed in the Code of Federal Regulations at 40 CFR Part 401.15. The "priority pollutants" specified by those families are listed in 40 CFR Part 423 Appendix A. These are pollutants for which best available technology effluent limitations must be established on either a national basis through rules (Sections 301(b),	Phthalate esters are designated as a toxic pollutant under Section 307(a)(1) of the CWA and as such is subject to effluent limitations. Butyl benzyl phthalate is listed as a "priority pollutant" in Appendix A to CFR 40 Part 423 – 126 Priority Pollutants. Under CWA Section 304, butyl benzyl phthalate is included in the list of total toxic organics (TTO) (40 CFR 413.02(i)).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	304(b), 307(b), 306) or on a case-by-case best professional judgement basis in NPDES permits, see Section 402(a)(1)(B). EPA identifies the best available technology that is economically achievable for that industry after considering statutorily prescribed factors and sets regulatory requirements based on the performance of that technology.	
Resource Conservation and Recovery Act (RCRA) – Section 3001	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.	Butyl benzyl phthalate is listed as a hazardous constituent in Appendix VIII of Part 261 – Hazardous Constituents RCRA (40 CFR 261).
Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) – Sections 102(a) and 103	Authorizes EPA to promulgate regulations designating as hazardous substances those substances which, when released into the environment, may present substantial danger to the public health or welfare or the environment. EPA must also promulgate regulations establishing the quantity of any hazardous substance the release of which must be reported under Section 103. Section 103 requires persons in charge of vessels or facilities to report to the National Response Center if they have knowledge of a release of a hazardous substance above the reportable quantity threshold.	Butyl benzyl phthalate is a hazardous substance under CERCLA. Releases of butyl benzyl phthalate in excess of 100 pounds must be reported (40 CFR 302.4).
Superfund Amendments and Reauthorization Act (SARA) –	Requires the Agency to revise the hazardous ranking system and update the National Priorities List of hazardous waste sites, increases state and citizen involvement in the superfund program	Butyl benzyl phthalate is listed on SARA, an amendment to CERCLA and the CERCLA Priority List of Hazardous Substances. This list includes substances most commonly found at facilities on the CERCLA National Priorities List (NPL)

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	and provides new enforcement authorities and settlement tools.	that have been deemed to pose the greatest threat to public health.
Other Federal Regulations		
Consumer Product Safety Improvement Act of 2008 (CPSIA)	Under Section 108 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), CPSC prohibits the manufacture for sale, offer for sale, distribution in commerce or importation of eight phthalates in toys and child care articles at concentrations greater than 0.1 percent.	The use of butyl benzyl phthalate at concentrations greater than 0.1 percent is banned in toys and child care articles (16 CFR part 1307).
Federal Hazardous Materials Transportation Act (HMTA)	Section 5103 of the Act directs the Secretary of Transportation to: • Designate material (including an explosive, radioactive material, infectious substance, flammable or combustible liquid, solid or gas, toxic, oxidizing or corrosive material, and compressed gas) as hazardous when the Secretary determines that transporting the material in commerce may pose an unreasonable risk to health and safety or property. • Issue regulations for the safe transportation, including security, of hazardous material in intrastate, interstate and foreign commerce.	Butyl benzyl phthalate is listed as a hazardous material with regard to transportation and is subject to regulations prescribing requirements applicable to the shipment and transportation of listed hazardous materials. Its reportable quantity is 100 lbs (49 CFR 172.1, Appendix A, Table 1)

D.2 State Laws and Regulations

Table_Apx D-2 State Laws and Regulations

State Actions	Description of Action
State Air Regulations	Allowable Ambient Levels Rhode Island (Air Pollution Regulation No. 22) 700 µg/m3 in 24 hours
State Drinking Water Standards and Guidelines	Florida (Fla. Admin. Code R. Chap. 62-550), Michigan (Mich. Admin. Code r.299.44 and r.299.49, 2017)

State Actions	Description of Action
State Right-to-Know Acts	Massachusetts (105 Code Mass. Regs. § 670.000 Appendix A), New Jersey (8:59 N.J. Admin. Code § 9.1) and Pennsylvania (P.L. 734, No. 159 and 34 Pa. Code § 323).
Chemicals of High Concern to Children	Several states have adopted reporting laws for chemicals in children's products containing butyl benzyl phthalate, including Maine (38 MRSA Chapter 16-D), Minnesota (Toxic Free Kids Act Minn. Stat. 116.9401 to 116.9407), Oregon (Toxic-Free Kids Act, Senate Bill 478, 2015), Vermont (18 V.S.A § 1776) and Washington State (Wash. Admin. Code 173-334-130).
Other	California listed butyl benzyl phthalate on Proposition 65 on December 2, 2005 due to developmental toxicity. (Cal Code Regs. Title 27, § 27001). Butyl benzyl phthalate is listed as a Candidate Chemical under California's Safer Consumer Products Program (Health and Safety Code § 25252 and 25253). California issued a Health Hazard Alert for butyl benzyl phthalate (Hazard Evaluation System and Information Service, 2016). Butyl benzyl phthalate is on the MA Toxic Use Reduction Act (TURA) list of 2019 (300 CMR 41.00).

D.3 International Laws and Regulations

Table_Apx D-3 Regulatory Actions by other Governments, Tribes, and International Agreements

Country/Tribe/ Organization	Requirements and Restrictions
Canada	Butyl benzyl phthalate is on Canada's National Pollutant Release Inventory (NPRI). Reportable to NPRI if manufactured, processed or otherwise used at quantities greater than 10 tons.
European Union	In February 2011, butyl benzyl phthalate was added to Annex XIV of REACH (Authorisation List) with a sunset date of February 2015. (European Chemicals Agency (ECHA) database. Accessed April 16, 2019).
Australia	Butyl benzyl phthalate is subject to secondary notifications when importing or manufacturing the chemical in Australia. Butyl benzyl phthalate was assessed under Human Health Tier II of the Inventory Multi-Tiered Assessment and Prioritisation (IMAP) as part of the C4-6 side chain transitional phthalates. Uses reported include as a plasticiser for polyvinyl chloride consumer products (including gumboots, toys – secondary

Country/Tribe/ Organization	Requirements and Restrictions
	plasticizer, play and exercise balls), in adhesives, textile printing inks, automotive refinish, road-marking paints, light industrial, wood coatings and building products (NICNAS, 2016, Human Health Tier II assessment for C4-6 side chain transitional phthalates). In addition, butyl benzyl phthalate was assessed under Environment Tier II of IMAP as part of the phthalate esters. In 2015, butyl benzyl phthalate was also assessed as a Priority Existing Chemical (Assessment Report No. 40) (National Industrial Chemicals Notification and Assessment Scheme (NICNAS). Chemical inventory. Database accessed April 3, 2019).
Japan	Butyl benzyl phthalate is regulated in Japan under the following legislation: •Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Chemical Substances Control Law; CSCL) •Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof •Air Pollution Control Act (National Institute of Technology and Evaluation [NITE] Chemical Risk Information Platform [CHRIP]. Accessed April 11, 2019]).
Austria, Denmark, Germany, New Zealand, Poland, Sweden, United Kingdom	Occupational exposure limits for butyl benzyl phthalate (GESTIS International limit values for chemical agents (Occupational exposure limits, OELs) database. [Accessed April 03, 2019]).

Appendix E PROCESS, RELEASE AND OCCUPATIONAL EXPOSURE INFORMATION

This appendix provides information and data found in preliminary data gathering for butyl benzyl phthalate.

E.1 Process Information

Process-related information potentially relevant to the risk evaluation may include process diagrams, descriptions and equipment. Such information may inform potential release sources and worker exposure activities. EPA plans to consider this information in combination with available monitoring data and estimation methods and models, as appropriate, to quantify occupational exposure and releases for the various conditions of use in the risk evaluation.

E.1.1 Manufacturing (Including Import)

The 2016 CDR reports three facilities that submitted activity data for 2015. Two of these facilities stated that they imported butyl benzyl phthalate in 2015 and the remaining facility's 2015 manufacture or import activity is claimed as CBI (U.S. EPA, 2019b). According to 2016 public CDR data, butyl benzyl phthalate is imported into the United States in liquid and wet solid form (U.S. EPA, 2019b).

E.1.1.1 Domestic Manufacturing

Butyl benzyl phthalate is manufactured through reaction of the monobutyl ester of phthalic acid with benzyl chloride in solution (PubChem, 2010). The monobutyl ester can be produced through reaction of phthalic anhydride with n-butyl alcohol, before reaction with benzyl chloride to produce butyl benzyl phthalate (PubChem, 2010).

E.1.1.2 Import

In general, chemicals may be imported into the United States in bulk via water, air, land, and intermodal shipments (Tomer and Kane, 2015). These shipments take the form of oceangoing chemical tankers, railcars, tank trucks, and intermodal tank containers. Butyl benzyl phthalate is shipped in liquid and wet solid form according to 2016 CDR. Of the two facilities in 2016 CDR that imported butyl benzyl phthalate in 2015 (excluding the facility for which the importation/manufacturing activity was withheld or claimed CBI), EPA has identified one site that imported butyl benzyl phthalate directly to other sites for processing or use (the importing site does not directly handle or store the imported butyl benzyl phthalate) (U.S. EPA, 2019b). The remaining importation site claimed this activity as CBI.

E.1.2 Processing and Distribution

E.1.2.1 Reactant or Intermediate

Processing as a reactant or intermediate is the use of butyl benzyl phthalate as a feedstock in the production of another chemical via a chemical reaction in which butyl benzyl phthalate is consumed to form the product. None of the three sites that reported to 2016 CDR indicated that butyl benzyl phthalate was processed as a reactant. However, EPA identified that butyl benzyl phthalate is used as an intermediate to produce organic chemicals in the Use Report (SPIN, 2019; NLM, 2015; Synapse, 2009).

Exact operations for the use of butyl benzyl phthalate as a reactant to produce other chemicals are not known at this time. For using a chemical as a reactant, operations would typically involve unloading the chemical from transport containers and feeding the chemical into a reaction vessel(s), where the chemical would react either fully or to a lesser extent. Following completion of the reaction, the

produced substance may be purified further, thus removing unreacted butyl benzyl phthalate (if any exists).

E.1.2.2 Incorporated into a Formulation, Mixture or Reaction Product

Incorporation into a formulation, mixture or reaction product refers to the process of mixing or blending of several raw materials to obtain a single product or preparation. Exact process operations involved in the incorporation of butyl benzyl phthalate into a chemical formulation, mixture, or reaction product are dependent on the specific manufacturing process or processes involved. In the 2016 CDR, one company reported use of butyl benzyl phthalate in the custom compounding of purchased resins (U.S. EPA, 2019b). Butyl benzyl phthalate is also used in the formulation of adhesives and sealants, paints and coatings, ink, toner, and colorant products, among other formulations (U.S. EPA, 2019a; U.S. EPA, 2019b; SPIN, 2019; GoodGuide, 2011; Synapse, 2009). The exact processes used to formulate products containing butyl benzyl phthalate are not known at this time; however, several ESDs published by the OECD and Generic Scenarios published by EPA have been identified that provide general process descriptions for these types of products. EPA plans to further investigate processing uses of butyl benzyl phthalate during risk evaluation.

E.1.2.3 Incorporated into an Article

Incorporation into an article typically refers to a process in which a chemical becomes an integral component of an article (as defined at 40 CFR 704.3) for distribution in commerce. Exact process operations involved in the incorporation of butyl benzyl phthalate-containing formulations or reaction products are dependent on the article. Butyl benzyl phthalate may be incorporated into asphalt paving, roofing, and coating materials; fabric, textile, and leather products; floor coverings; food contact surfaces; plastic products; rubber products; and transportation equipment (U.S. EPA, 2019a; U.S. EPA, 2019b; FDA, 2018; Auto Alliance, 2019; Synapse, 2009). EPA plans to further investigate processing uses of butyl benzyl phthalate during risk evaluation.

E.1.2.4 Repackaging

Repackaging refers to preparation of a chemical substance for distribution into commerce in a different form, state, or quantity than originally received/stored, where such activities include transferring a chemical substance form a bulk storage container into smaller containers.

E.1.2.5 Recycling

In 2016 CDR, three facilities reported that butyl benzyl phthalate was not recycled (U.S. EPA, 2019b). EPA plans to further investigate the potential for recycling of butyl benzyl phthalate during risk evaluation.

E.1.3 Uses

E.1.3.1 Adhesives, Sealants, Paints, and Coatings

Butyl benzyl phthalate is used in a variety of adhesive, sealant, paint, and coating products. Specifically, butyl benzyl phthalate is used in adhesives used in floor sealing and coverings, adhesives and sealants used in transportation equipment manufacturing, automotive paints and adhesives, lacquers, and varnishes (U.S. EPA, 2019ab; U.S. EPA, 2019b; American Chemistry Council, 2019; NLM, 2015). The application procedure depends on the type of adhesive, sealant, paint, or coating formulation and the type of substrate. The formulation is loaded into the application reservoir or apparatus and applied to the substrate via brush, spray, roll, dip, curtain, or syringe or bead application. Application may be manual or automated. After application, the adhesive, sealant, paint, or coating is allowed to dry or cure (OECD,

2015). The drying/curing process may be promoted through the use of heat or radiation (radiation can include ultraviolet (UV) and electron beam radiation (OECD, 2010).

E.1.3.2 Automotive Products

Butyl benzyl phthalate is used in automotive care products, such as cleaning formulations, paints and varnishes, car brake adhesives, and power steering fluid (ACC, 2019; NLM, 2015). EPA plans to further investigate these uses of butyl benzyl phthalate during risk evaluation.

E.1.3.3 Building/Construction Materials Not Covered Elsewhere

Butyl benzyl phthalate is used in building and construction materials not covered elsewhere, including in caulk, ceramics, and bricklaying (ACC, 2019; NLM, 2015; DeLima Associates, 2011). EPA did not find additional information on these products. EPA plans to further investigate these uses of butyl benzyl phthalate during risk evaluation.

E.1.3.4 Ink, Toner, and Colorant Products

Butyl benzyl phthalate is used in coloring agents, dyes, and pigments (NLM, 2015). Butyl benzyl phthalate is also used in printing ink and toner and was identified in one handstamp product (U.S. EPA, 2019a; U.S. EPA, 2019b; SPIN, 2019; GoodGuide, 2011; Synapse, 2009). Printing inks consist of colorants (e.g., pigments, dyes and toners) dispersed in a formulation to form a paste, liquid or solid, which can be applied to a substrate's surface and dried (U.S. EPA, 2010). Industrial printing processes can be categorized as lithographic, flexographic, gravure, letterpress, screen printing or digital printing. Commercial printing may involve lithographic, flexographic, gravure and letterpress printing - all of which involve the transfer of images from printing plates to a substrate. Screen printing requires a mesh screen to transfer the ink to a substrate, whereas digital printing allows for the transfer of a digital image directly onto a substrate. Inkjet printing is the most common form of digital printing. It involves the application of small drops of ink onto a substrate, with direct contact between the ink nozzle and the substrate (U.S. EPA, 2010).

E.1.3.5 Plastic and Rubber Products

As described in Section E.1.2.3, butyl benzyl phthalate is used to increase the flexibility of plastic and rubber products, which may be used industrially, commercially, and by consumers. These products are used in a variety of products, including floor coverings (such as vinyl floor tiles), vinyl wallpaper, shower curtains, dental impression materials and equipment, toys, and products used in transportation equipment manufacturing (U.S. EPA, 2019a; U.S. EPA, 2019b; DeLima Associates, 2011; NLM, 2015; Auto Alliance, 2019; NASA, 2020). Butyl benzyl phthalate is likely entrained in the products; however, butyl benzyl phthalate may be available for exposure depending on the application of the end use products, such as if flooring materials are cut prior to installation. EPA plans to further investigate these uses of butyl benzyl phthalate during risk evaluation.

E.1.3.6 Other Uses

Butyl benzyl phthalate is also used in castings (BJB Enterprises Inc., 2018), hydraulic fracturing (Orem et al, 2007), and laboratory chemicals (Sigma-Aldrich, 2019; EPA-HQ-OPPT-2018-0504-0019). Laboratory procedures are generally done within a fume hood, on a bench with local exhaust ventilation or under general ventilation. EPA plans to further investigate the uses of butyl benzyl phthalate during risk evaluation.

E.1.4 Disposal

Each of the conditions of use of butyl benzyl phthalate may generate waste streams of the chemical that are collected and transported to third-party sites for disposal, treatment, or recycling. Industrial sites that

treat or dispose onsite wastes that they themselves generate are assessed in each condition of use assessment. Similarly, point source discharges of butyl benzyl phthalate to surface water are assessed in each condition of use assessment (point source discharges are exempt as solid wastes under RCRA). Wastes of butyl benzyl phthalate that are generated during a condition of use and sent to a third-party site for treatment, disposal, or recycling may include the following:

- Wastewater: Butyl benzyl phthalate may be contained in wastewater discharged to POTW or other, non-public treatment works for treatment. Industrial wastewater containing butyl benzyl phthalate discharged to a POTW may be subject to EPA or authorized NPDES state pretreatment programs. The assessment of wastewater discharges to POTWs and non-public treatment works of butyl benzyl phthalate is included in each of the condition of use assessments.

- Solid Wastes: Solid wastes are defined under RCRA as any material that is discarded by being: abandoned; inherently waste-like; a discarded military munition; or recycled in certain ways (certain instances of the generation and legitimate reclamation of secondary materials are exempted as solid wastes under RCRA). Solid wastes may subsequently meet RCRA's definition of hazardous waste by either being listed as a waste at 40 CFR §§ 261.30 to 261.35 or by meeting waste-like characteristics as defined at 40 CFR §§ 261.20 to 261.24. Solid wastes that are hazardous wastes are regulated under the more stringent requirements of Subtitle C of RCRA, whereas non-hazardous solid wastes are regulated under the less stringent requirements of Subtitle D of RCRA.

  Butyl benzyl phthalate is listed as a hazardous constituent in Appendix VIII of Part 261 waste under RCRA.

- Wastes Exempted as Solid Wastes under RCRA: Certain conditions of use of butyl benzyl phthalate may generate wastes of butyl benzyl phthalate that are exempted as solid wastes under 40 CFR § 261.4(a). For example, the generation and legitimate reclamation of hazardous secondary materials of butyl benzyl phthalate may be exempt as a solid waste.

E.2 Preliminary Occupational Exposure Data

NIOSH HHEs have not been conducted with a focus on butyl benzyl phthalate monitoring and/or workplace exposure to date. Butyl benzyl phthalate does not have an OSHA IMIS code. As such, OSHA has not collected monitoring data for this chemical.

Appendix F SUPPORTING INFORMATION - CONCEPTUAL MODEL FOR INDUSTRIAL AND COMMERCIAL ACTIVITIES AND USES

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

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
Manufacture	Domestic Manufacture	Domestic Manufacture	Manufacture and Packaging	Liquid Contact	Dermal	Workers	Yes	2016 CDR references manufacture in liquid form. Thus, the potential for exposures to workers exists during manufacturing.
				Solid Contact	Dermal	Workers	No	2016 CDR does not reference manufacture in solid form.
				Vapor	Inhalation	Workers, ONU	No	Due to PA's vapor pressure (VP) (VP = 8.25 × 10-6 mm Hg) at room temperature, potential for vapor generation is low.
				Mist	Inhalation/Dermal	Workers, ONU	No	Mist generation is not expected during manufacturing.
				Dust	Inhalation/Dermal	Workers, ONU	No	2016 CDR does not reference manufacture in solid form.
				Liquid/Solid Contact	Dermal	ONU	No	Exposure is expected to be primarily restricted to workers who are directly involved in working with the chemical. Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
	Import	Import	Repackaging of import containers	Liquid Contact	Dermal	Workers	Yes	2016 CDR references import in liquid form. The potential for exposures to workers exists during import, but exposure will only occur in the event the imported material is repackaged.
				Solid Contact	Dermal	Workers	Yes	2016 CDR references import in wet solid form. The potential for exposures to workers exists during import, but exposure will only occur in the event the imported material is repackaged.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
				Vapor	Inhalation	Workers, ONU	No	Due to PA's vapor pressure (VP) (VP = 8.25 × 10-6 mm Hg) at room temperature, potential for vapor generation is low.
				Mist	Inhalation/Dermal	Workers, ONU	No	Mist generation is not expected during repackaging of import containers.
				Dust	Inhalation/Dermal	Workers, ONU	Yes	2016 CDR references wet solid form, which may create dust depending on the moisture content. The potential for dust exposures to workers and ONUs exists during import, but exposure will only occur in the event the imported material is repackaged.
				Liquid/Solid Contact	Dermal	ONU	No	Exposure is expected to be primarily restricted to workers who are directly involved in working with the chemical. Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
Processing	Incorporated into formulation, mixture or reaction product	Filler in: Custom of purchased resin compounding Plasticizer in: adhesive manufacturing; all other basic inorganic chemical manufacturing; dental product manufacturing; paints and coatings manufacturing; personal care	Processing into formulations, mixtures, or reaction product	Liquid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during processing (incorporation into formulation, mixture, or reaction product), as butyl benzyl phthalate may be in liquid form.
				Solid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during processing (incorporation into formulation, mixture, or reaction product), as butyl benzyl phthalate may be in wet solid form.
				Vapor	Inhalation	Workers, ONU	Yes	Due to butyl benzyl phthalate's vapor pressure (VP) (VP = 8.25 × 10-6 mm Hg) at room temperature, potential for vapor generation is low. However, some of these operations may occur at elevated

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
		products; printing ink manufacturing Processing aid in: petroleum production Laboratory chemical manufacturing Biocide carrier manufacturing						temperatures, which increase the potential for vapor generation.
				Mist	Inhalation/Dermal	Workers, ONU	No	Mist generation is not expected during processing (incorporation into formulation, mixture, or reaction product).
				Dust	Inhalation/Dermal	Workers, ONU	Yes	The potential for dust exposures to workers and ONUs exists during processing as butyl benzyl phthalate may be in wet solid form, which may create dust depending on the moisture content.
				Liquid/Solid Contact	Dermal	ONU	No	Exposure is expected to be primarily restricted to workers who are directly involved in working with the chemical. Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
	Incorporated into articles	Plasticizers in: asphalt paving, roofing, and coating materials manufacturing; fabric, textile, and leather products not covered elsewhere manufacturing; floor coverings manufacturing; food contact surfaces manufacturing; plastics product manufacturing; rubber product manufacturing; textiles, apparel,	Plastics and Rubber product manufacturing (Plastic Converting) Other article manufacturing	Liquid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during incorporation into articles, as butyl benzyl phthalate may be in liquid form.
				Solid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during processing (incorporation into articles), as butyl benzyl phthalate may be in solid form, such as for resins.
				Vapor	Inhalation	Workers, ONU	Yes	Due to butyl benzyl phthalate's vapor pressure (VP) (VP = 8.25 × 10-6 mm Hg) at room temperature, potential for vapor generation is low. However, some of these operations may occur at elevated temperatures, which increase the potential for vapor generation.
				Mist	Inhalation/Dermal	Workers, ONU	No	Mist generation is not expected during incorporation into article.
				Dust	Inhalation/Dermal	Workers, ONU	Yes	The potential for exposures to workers exists during processing

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
		and leather manufacturing; Transportation equipment manufacturing						(incorporation into articles), as butyl benzyl phthalate may be in solid form, such as for resins.
				Liquid/Solid Contact	Dermal	ONU	No	Exposure is expected to be primarily restricted to workers who are directly involved in working with the chemical. Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
	Repackaging	Repackaging	Repackaging into large and small containers	Liquid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during repackaging, as butyl benzyl phthalate may be in liquid form.
				Solid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during repackaging, as butyl benzyl phthalate may be incorporated into products in solid form.
				Vapor	Inhalation	Workers, ONU	No	Due to butyl benzyl phthalate's vapor pressure (VP) (VP = 8.25 × 10-6 mm Hg) at room temperature, potential for vapor generation is low.
				Mist	Inhalation/Dermal	Workers, ONU	No	Mist generation is not expected during repackaging.
				Dust	Inhalation/Dermal	Workers, ONU	Yes	The potential for dust exposures to workers and ONUs exists during processing (repackaging), as butyl benzyl phthalate may be incorporated into products in solid form.
				Liquid/Solid Contact	Dermal	ONU	No	Exposure is expected to be primarily restricted to workers who are directly involved in working with the chemical. Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
	Recycling	Recycling	Recycling of butyl benzyl phthalate and products containing butyl benzyl phthalate	Liquid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during this use as liquid formulations may be recycled.
				Solid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during this use as solid formulations may be recycled.
				Vapor	Inhalation	Workers, ONU	No	Due to butyl benzyl phthalate's vapor pressure (VP) (VP = 8.25 × 10-6 mm Hg) at room temperature, potential for vapor generation is low.
				Mist	Inhalation/Dermal	Workers, ONU	No	Mist generation is not expected during recycling of liquid wastes.
				Dust	Inhalation/Dermal	Workers, ONU	Yes	Dust generation is possible during recycling of solid wastes.
				Liquid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during this use as liquid formulations may be recycled.
Industrial/ Commercial Use	Adhesives and sealants; furnishing cleaning and care products; paints and coatings	Adhesives and sealants; furnishing cleaning and care products; paints and coatings	Spray, brush, roll, dip, and other forms of application	Liquid Contact	Dermal	Workers	Yes	These products are in liquid form; therefore, exposures to workers exists for butyl benzyl phthalate used in these products.
				Solid Contact	Dermal	Workers	No	The potential for exposures to solid butyl benzyl phthalate is not expected during the use of these products because they are in liquid form.
				Vapor	Inhalation	Workers, ONU	No	Due to butyl benzyl phthalate's vapor pressure (VP) (VP = 8.25 × 10-6 mm Hg) at room temperature, potential for vapor generation is low.
				Mist	Inhalation/Dermal	Workers, ONU	Yes	Mist generation is possible during application of these products.
				Dust	Inhalation/Dermal	Workers, ONU	No	The potential for exposures to solid butyl benzyl phthalate does not exist during the use of these products because they are in liquid form.
				Liquid/Solid Contact	Dermal	ONU	No	Exposure is expected to be primarily restricted to workers who are directly involved in working with

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
								the chemical. Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
	Automotive care products; hydraulic fracturing; chemical intermediate; laboratory use	Automotive care products; hydraulic fracturing; chemical intermediate; laboratory use	Use of automotive care products Use in hydraulic fracturing Use as chemical intermediate Use in laboratories	Liquid Contact	Dermal	Workers	Yes	These products are in liquid form; therefore, exposures to workers exists for butyl benzyl phthalate used in these products.
				Solid Contact	Dermal	Workers	No	The potential for exposures to solid butyl benzyl phthalate is not expected during the use of these products because they are in liquid form.
				Vapor	Inhalation	Workers, ONU	No	Due to butyl benzyl phthalate's vapor pressure (VP) (VP = 8.25 × 10-6 mm Hg) at room temperature, potential for vapor generation is low.
				Mist	Inhalation/Dermal	Workers, ONU	No	Mist generation is not expected during use of these products.
				Dust	Inhalation/Dermal	Workers, ONU	No	The potential for exposures to solid butyl benzyl phthalate does not exist during the use of these products because they are in liquid form.
				Liquid/Solid Contact	Dermal	ONU	No	Exposure is expected to be primarily restricted to workers who are directly involved in working with the chemical. Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
	Castings; building/ construction materials not covered elsewhere; floor coverings;	Castings; building/ construction materials not covered elsewhere; floor coverings; plastic and rubber	Use of articles made using butyl benzyl phthalate	Liquid Contact	Dermal	Workers	No	The potential for exposures to liquid butyl benzyl phthalate is not expected during the use of these products because they are solid articles.
				Solid Contact	Dermal	Workers	Yes	These products may include solid articles in which butyl benzyl phthalate is entrained; therefore,

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
	plastic and rubber products not covered elsewhere (transportation equipment manufacturing, cast models)	products not covered elsewhere (transportation equipment manufacturing, cast models)						butyl benzyl phthalate exposures to workers is unlikely but may occur if cutting /sawing / other machining operations occur.
				Vapor	Inhalation	Workers, ONU	No	Due to butyl benzyl phthalate's vapor pressure (VP) (VP = 8.25 × 10-6 mm Hg) at room temperature, potential for vapor generation is low.
				Mist	Inhalation/Dermal	Workers, ONU	No	Mist generation is not expected during use of these products.
				Dust	Inhalation/Dermal	Workers, ONU	Yes	These products may include solid articles in which butyl benzyl phthalate is entrained; therefore, butyl benzyl phthalate exposures to workers and ONUs is unlikely but may occur if cutting /sawing / other machining operations occur.
				Liquid/Solid Contact	Dermal	ONU	No	Exposure is expected to be primarily restricted to workers who are directly involved in working with the chemical. Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
Disposal	Disposal	Disposal of butyl benzyl phthalate wastes	Worker handling of wastes	Liquid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during this use as liquid formulations may be disposed.
				Solid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during this use as solid formulations may be disposed
				Vapor	Inhalation	Workers, ONU	No	Due to butyl benzyl phthalate's vapor pressure (VP) (VP = 8.25 × 10-6 mm Hg) at room temperature, potential for vapor generation is low.
				Mist	Inhalation/Dermal	Workers, ONU	No	Mist generation is not expected during disposal of liquid wastes.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
				Dust	Inhalation/Dermal	Workers, ONU	Yes	Dust generation is possible during disposal of solid wastes.
				Liquid/Solid Contact	Dermal	ONU	No	Exposure is expected to be primarily restricted to workers who are directly involved in working with the chemical. Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.

Appendix G SUPPORTING INFORMATION -– CONCEPTUAL MODEL FOR CONSUMER ACTIVITIES AND USES

Table_Apx G-1 Consumer Exposure Conceptual Model Supporting Table

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

Life Cycle Stage	Category	Subcategory	Release from source	Exposure Pathway	Route	Receptor	Plans to Evaluate	Rationale
			Long-term emission/mass-transfer, Abrasion, Transfer to Dust	Dust	Dermal, Inhalation, Oral	Consumers, Bystanders	Yes	Dermal, oral and inhalation exposure from this condition of use may occur. EPA plans to evaluate exposure.
Consumer Use	Packaging, Paper, Plastic, Hobby Products	Toys, Playground, and Sporting Equipment (Article)	Direct contact through handling of articles containing chemical	Direct Contact	Dermal	Consumers	Yes	Dermal exposure may occur for this condition of use. EPA plans to evaluate exposure.
			Direct contact through mouthing of articles containing chemical	Mouthing	Oral	Consumers	Yes	Oral exposure may occur for this condition of use. EPA plans to evaluate exposure.
			Long-term emission/mass-transfer, Abrasion, Transfer to Dust	Dust	Dermal, Inhalation, Oral	Consumers, Bystanders	Yes	Dermal, oral and inhalation exposure from this condition of use may occur. EPA plans to evaluate exposure.
Consumer Use	Construction, Paint, Electrical, and Metal Products	Adhesives and Sealants (Product)	Long-term emission/mass-transfer, Abrasion, Transfer to Dust	Dust	Dermal, Inhalation, Oral	Consumers, Bystanders	Yes	Dermal, oral and inhalation exposure from this condition of use may occur. EPA plans to evaluate exposure.
			Direct contact through application or use of products	Liquid Contact	Dermal	Consumers	Yes	Exposure is expected to be primarily restricted to consumers who are directly involved in using the chemical.
			Long-term emission/mass-transfer through application or use of products	Vapor	Inhalation	Consumers and Bystanders	Yes	Inhalation is possible; EPA plans to evaluate exposure.

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

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

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

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

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

Table_Apx H-1 Environmental Exposure Conceptual Model Supporting Table

Life Cycle Stage	Category	Release	Exposure Pathway / Media	Exposure Routes	Receptor / Population	Plans to Evaluate[4]	Rationale
All	Emissions to Air	Emissions to Air	Near facility ambient air concentrations	Inhalation	General Population	Yes	Butyl benzyl phthalate air and deposition to nearby bodies of water and soil are expected exposure pathways, not under the jurisdiction of other EPA regulations.
			Indirect deposition to nearby bodies of water and soil catchments	Oral Dermal	General Population	Yes	
				TBD	Aquatic and Terrestrial Receptors	Yes	
		Hazardous and Municipal Waste Incinerator	Near facility ambient air concentrations/ Indirect deposition to nearby bodies of water and soil catchments	Inhalation	General Population	No	EPA does not have release information about this pathway, however, butyl benzyl phthalate is considered a hazardous constituent.
				TBD	Aquatic and Terrestrial Species		
	Wastewater or Liquid Wastes	Industrial pre-treatment and wastewater treatment, or POTW	Direct release into surface water and indirect partitioning to sediment	TBD	Aquatic and Terrestrial Receptors	Yes	EPA has developed Ambient Water Quality Criteria for protection of human health for butyl benzyl phthalate.
				Oral Dermal	General Population	No	

[4] The exposure pathways, exposure routes and hazards EPA plans to consider are subject to change in the final scope, in light of comments received on this draft scope and other reasonably available information. EPA continues to consider whether and how other EPA-administered statutes and any associated regulatory programs address the presence of butyl benzyl phthalate in exposure pathways falling under the jurisdiction of these EPA statutes.

Life Cycle Stage	Category	Release	Exposure Pathway / Media	Exposure Routes	Receptor / Population	Plans to Evaluate[4]	Rationale
			Drinking Water via Surface or Ground Water	Oral Dermal and Inhalation (e.g. showering)	General Population	Yes	Release of butyl benzyl phthalate into surface water and indirect partitioning to drinking water is an expected exposure pathway.
			Biosolids: application to soil and/or migration to groundwater and/or surface water	Oral (e.g. ingestion of soil) Inhalation	General Population	Yes	EPA plans to analyze the pathway from biosolids to the general population and terrestrial species.
				TBD	Aquatic and Terrestrial receptors	Yes	
		Underground injection	Migration to groundwater, potential surface/drinking water	Oral Dermal Inhalation	General Population	No	EPA does not have butyl benzyl phthalate release information for this pathway since 1992. Butyl benzyl phthalate is a hazardous constituent and underground injection to hazardous waste wells is under the jurisdiction of SDWA and RCRA.
					Aquatic and Terrestrial Species		
				TBD			
Disposal	Solid and Liquid Wastes	Hazardous, Municipal landfill and other land disposal	Leachate to soil, ground water and/or mitigation to surface water	Oral Dermal	General Population	No	EPA does not have release information about this pathway, however, butyl benzyl phthalate is considered a hazardous constituent.