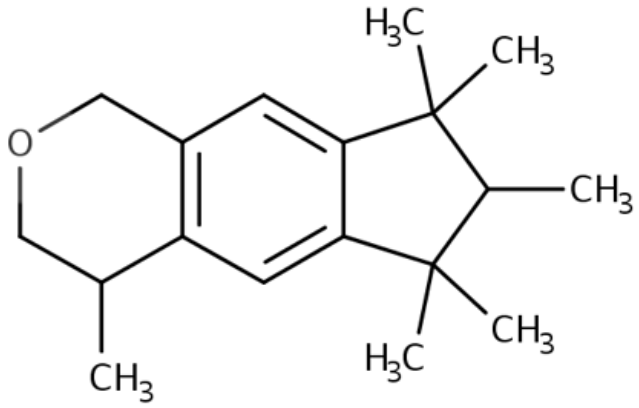
EPA Document# EPA-740-D-20-013
April 2020
Office of Chemical Safety and
Pollution Prevention

United States
Environmental Protection Agency

Draft Scope of the Risk Evaluation for 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-Hexamethylcyclopenta[γ]-2-Benzopyran (HHCB)

CASRN 1222-05-5



April 2020

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ACKNOWLEDGEMENTS

This report was developed by the United States Environmental Protection Agency (U.S. EPA), Office of Chemical Safety and Pollution Prevention (OCSPP), Office of Pollution Prevention and Toxics (OPPT).

Acknowledgements

The OPPT Assessment Team gratefully acknowledges participation or input from Intra-agency reviewers that included multiple offices within EPA, Inter-agency reviewers that included multiple Federal agencies, and assistance from EPA contractors Abt Associates (Contract No. EP-W-16-009), Battelle (Contract No. EP-W-16-017), ERG (Contract No. EP-W-12-006), GDIT (Contract No. HHSN316201200013W), ICF (Contract No. 68HERC19D0003), SRC (Contract No. 68HERH19D0022), and Versar (Contract No. EP-W-17-006).

Docket

Supporting information can be found in public docket: EPA-HQ-OPPT-2018-0430.

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 United States Government.

ABBREVIATIONS AND ACRONYMS

ACGIH	American Conference of Governmental Industrial Hygienists
BP	Boiling point
CAA	Clean Air Act
CASRN	Chemical Abstracts Service Registry Number
CBI	Confidential Business Information
CDR	Chemical Data Reporting
CFR	Code of Federal Regulations
CPCat	EPA Chemical and Product Categories
CWA	Clean Water Act
EC	Engineering Controls
ESD	Emission Scenario Document
EPA	U.S. Environmental Protection Agency
EU	European Union
FR	Federal Register
FYI	For Your Information
HHCB	1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-Hexamethylcyclopenta[γ]-2-Benzopyran
HHE	Health Hazard Evaluation
IMIS	Integrated Information Management System
K_{OC}	Organic carbon-water partition coefficient
K_{OW}	Octanol-water partition coefficient
NIOSH	National Institute for Occupational Safety and Health
NWQMC	National Water Quality Monitoring Council
OECD	Organisation for Economic Co-operation and Development
ONU	Occupational Non-User
OPPT	Office of Pollution Prevention and Toxics
OSHA	Occupational Safety and Health Administration
P-Chem	Physical and chemical
PEL	Permissible exposure limit
PESS	Potentially exposed or susceptible subpopulations
POTW	Publicly owned treatment works
PPE	Personal Protective Equipment
RCRA	Resource Conservation and Recovery Act
SDS	Safety data sheet
SDWA	Safe Drinking Water Act
SMILES	Simplified Molecular-Input Line-Entry System
$t_{1/2}$	Half-life
TBD	To be determined
TIAB	Title and Abstract
TRI	Toxics Release Inventory
TSCA	Toxic Substances Control Act
USGS	United States Geological Survey
VP	Vapor pressure
WWTP	Wastewater treatment plant

EXECUTIVE SUMMARY

In December 2019, EPA designated 1,3,4,6,7,8-hexahydro-4,6,6,7,8,8-hexamethylcyclopenta[γ]-2-benzopyran (HHCB; CASRN 1222-05-5) as a high-priority substance for risk evaluation following the prioritization process required by section 6(b) of the Toxic Substances Control Act (TSCA) and implementing regulations (40 CFR Part 702) (Docket ID: EPA-HQ-OPPT-2018-0430) (U.S. EPA, 2019a). 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 HHCB 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. HHCB is a synthetic polycyclic musk fragrance with a total annual production volume in the United States between > 1 million and 10 million pounds.

Reasonably Available Information. EPA leveraged the data and information sources already described in the document supporting the High-Priority Substance designation for HHCB 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 to date 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 use and inclusion in the risk evaluation. EPA is applying these systematic review methods to collect reasonably available information regarding hazards, exposures, PESS, and conditions of use that will help inform the risk evaluation for HHCB.

Conditions of Use. EPA plans to evaluate manufacturing, including importing; processing; distribution in commerce; industrial, commercial and consumer uses; and disposal of HHCB in the risk evaluation. HHCB is manufactured and imported into the United States. HHCB is processed in several ways: incorporated into formulation, mixture, or reaction products; incorporated into articles; and repackaged. HHCB is used as an odor agent that is used in several industrial sectors (e.g., miscellaneous manufacturing; soap, cleaning compound, and toilet preparation manufacturing; plastics material and resin manufacturing; and all other chemical product and preparation manufacturing). HHCB is used in several commercial and consumer products, such as air care products, cleaning and furnishing care products, laundry and dishwashing products, personal care products, plastic and rubber products, and as aroma chemicals. The consumer uses also include uses in paper products. All personal care products using HHCB are non-TSCA uses.

Conceptual Model. The conceptual models for HHCB 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. EPA plans to focus the risk evaluation for HHCB on the following

exposures, hazards, and receptors with the understanding that updates may be made in the final scope document after consideration of public comments and completion of the systematic review data collection phase.

- *Exposures (Pathways and Routes), Receptors and PESS.* EPA plans to analyze both human and environmental exposures and releases to the environment resulting from the conditions of use of HHCB that EPA plans to consider in the risk evaluation. Exposures for HHCB are discussed in Section 2.3. EPA identified environmental monitoring data reporting the presence of HHCB in soil, air, drinking water, and groundwater. Additional information gathered through systematic review searches will also inform expected exposures.

  In Section 2.6.3, EPA presents the conceptual models describing the identified exposures (pathways and routes), receptors and hazards associated with the conditions of use of HHCB within the scope of the risk evaluation.

  Preliminarily, EPA plans to evaluate the following human and environmental exposure pathways, routes, receptors and PESS in the scope of 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 exposure pathways 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 HHCB (Section 2.3.5).
  - *Consumer and bystander exposure pathways associated with consumer conditions of use:* EPA plans to evaluate the inhalation and dermal exposure to HHCB for consumers and bystanders, and dermal exposure to HHCB for consumers during the handling of automotive care products and plastic and rubber products (Section 2.3.6; Section 2.3.7).
  - *General population pathways:* EPA plans to evaluate exposure to HHCB via drinking water or groundwater, ambient air, fish ingestion for the general population.
  - *Environmental exposure pathways:* EPA plans to evaluate exposure to HHCB for aquatic and terrestrial receptors.
  - *PESS:* EPA plans to include children, women of reproductive age (e.g., pregnant women), workers, ONUs, consumers, and bystanders as PESS in the risk evaluation (Section 2.5).

- *Hazards.* Hazards for HHCB 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 HHCB 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 plans to use systematic review methods to evaluate the epidemiological and toxicological literature for HHCB. 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 the potential human health hazard for HHCB

identified during prioritization. The broad health effect category identified during prioritization is developmental toxicity.

Analysis Plan. The analysis plan for HHCB is presented in Section 2.7. The analysis plan outlines the general science 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 HHCB 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 HHCB, 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 HHCB will be peer reviewed as described in Section 2.8. Peer review will be conducted in accordance with relevant and applicable methods 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 scope of the risk evaluation to be conducted for HHCB under the Frank R. Lautenberg Chemical Safety for the 21st Century Act. The Frank R. Lautenberg Chemical Safety for the 21st Century Act amended TSCA, the Nation's primary chemicals management law, on June 22, 2016. The new law includes statutory requirements and deadlines for actions related to conducting risk evaluations of existing chemicals.

Under TSCA § 6(b), EPA must 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 PESS 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 (Docket ID: EPA-HQ-OPPT-2018-0430), as required by TSCA § 6(b)(2)(B), which initiated the risk evaluation process for those chemical substances. HHCB 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 HHCB. 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. Gray literature, which is defined as the broad category of data/information sources not found in standard, peer-reviewed literature databases;
2. Databases containing publicly available, peer-reviewed literature; and
3. Data and information submitted under TSCA sections 4, 5, 8(e), and 8(d), as well as "for your information" (FYI) submissions.

[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).

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 into useful categories or tags to facilitate the sorting of information through the systematic review process. The search and screening process was 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 HHCB 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 HHCB upon publication of the supplemental documentation of those methods.

2.1.1 Search of Gray Literature

EPA surveyed the gray literature[2] and identified 37 search results relevant to EPA's risk assessment needs for HHCB. Appendix A lists the gray literature sources that yielded 37 discrete data or information sources relevant to HHCB. EPA further categorized the data and information into the various topic areas (or disciplines) supporting the risk evaluation (e.g., physical chemistry, environmental fate, ecological hazard, human health hazard, exposure, engineering) and the breakdown is shown in Figure 2-1. EPA is currently identifying additional reasonably available information (e.g., public comments), and the reported numbers in Figure 2-1 may change.

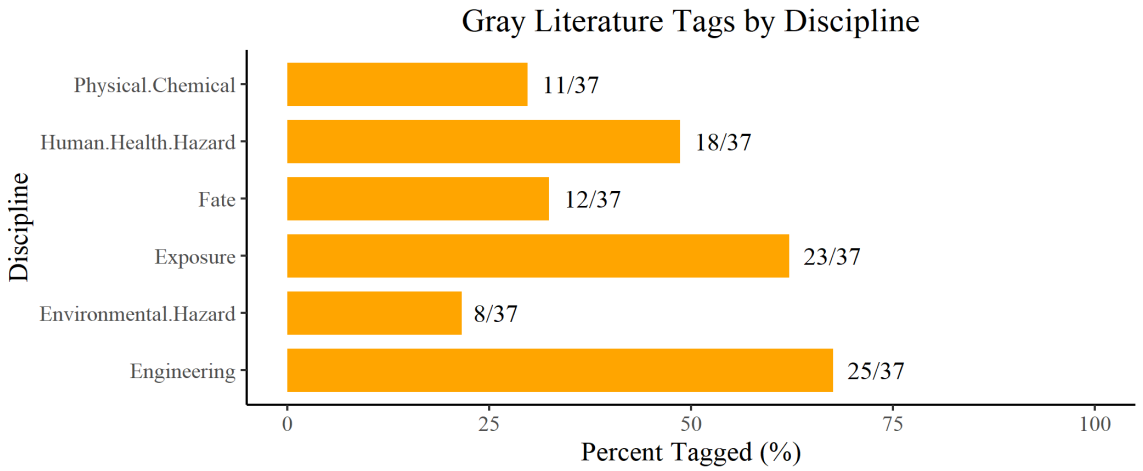

Figure 2-1. Gray Literature Tags by Discipline for HHCB
The percentages across disciplines do not add up to 100%, as each source may provide data or information for various topic areas (or disciplines).

[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 properties, environmental fate and transport, engineering (environmental release and occupational exposure), exposure (environmental, general population and consumer) and environmental and human health hazards of HHCB. 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.

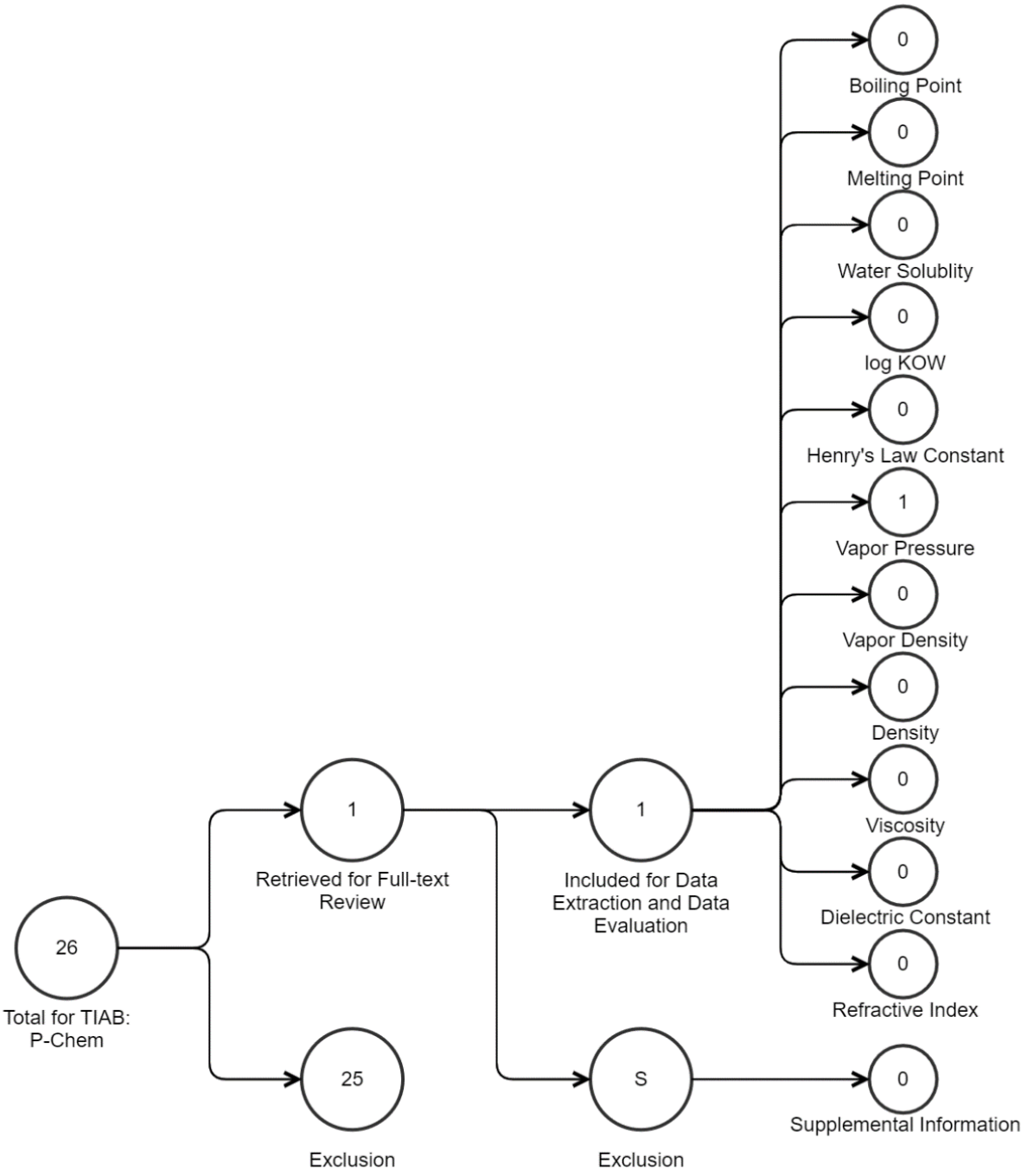

Figure 2-2. Peer-reviewed Literature - Physical-Chemical Properties Search Results for HHCB.

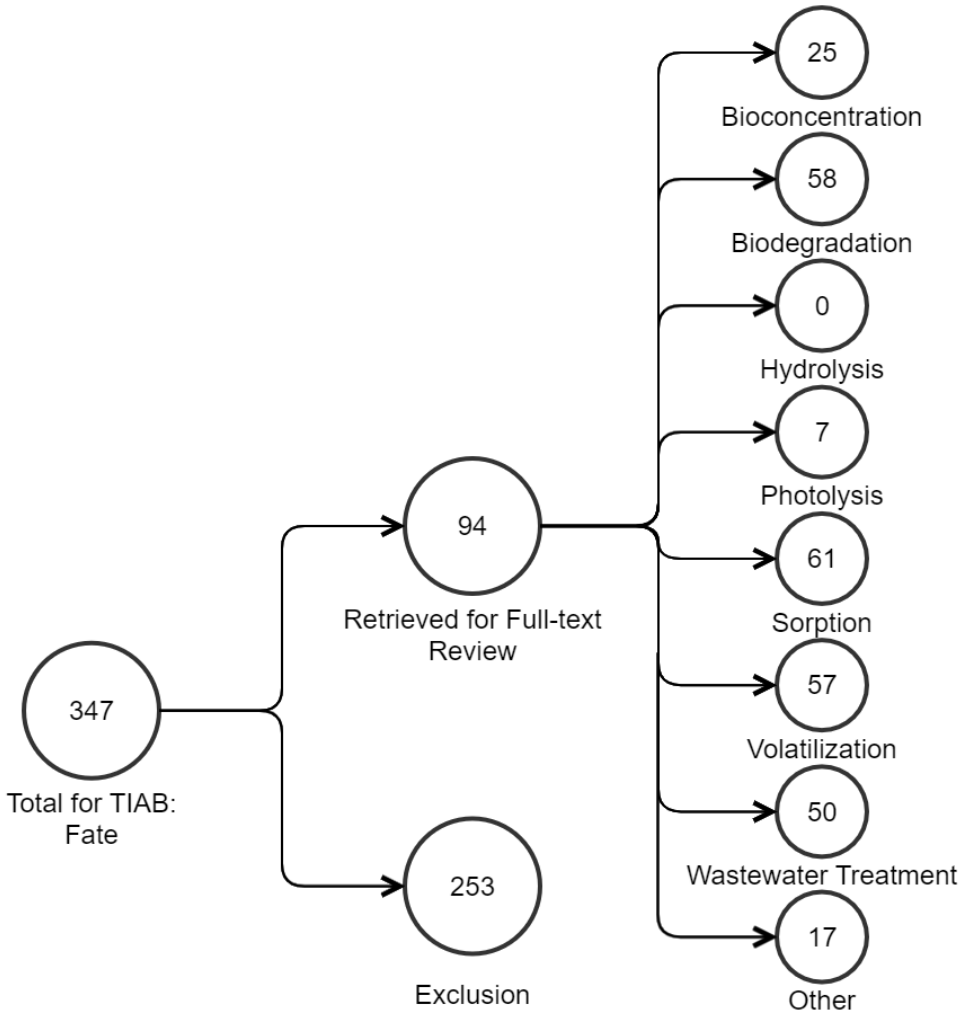

Figure 2-3. Peer-reviewed Literature – Fate and Transport Search Results for HHCB.

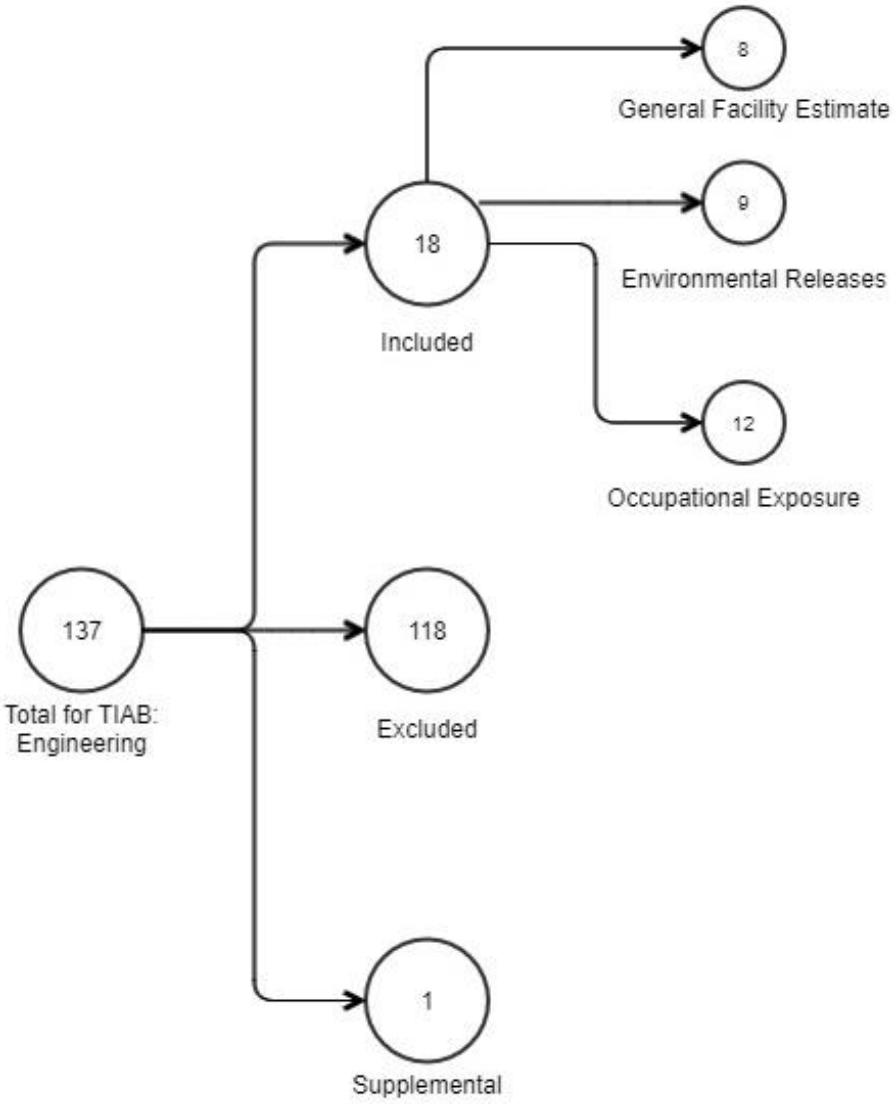

Figure 2-4. Peer-reviewed Literature - Engineering Search Results for HHCB.

Figure 2-5. Peer-reviewed Literature – Exposure Search Results for HHCB.

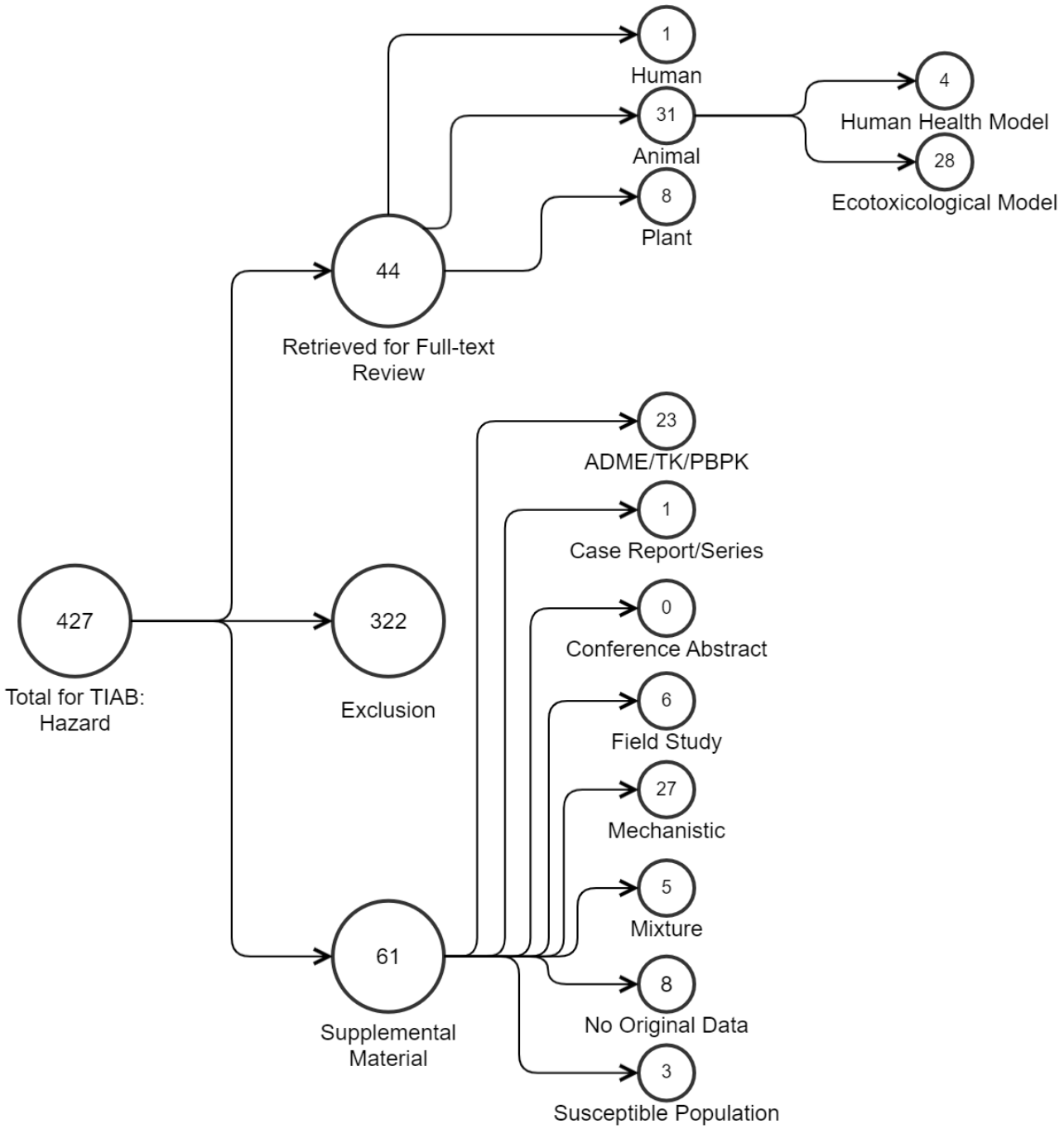

Figure 2-6. Peer-reviewed Literature - Hazard Search Results for HHCB.

2.1.3 Search of TSCA Submissions

Table **2-1** presents the results of screening the titles of data sources and reports submitted to EPA under various sections of TSCA as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act. EPA screened a total of one submission 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 one submission that met the inclusion criteria in these statements and identified zero submissions with supplemental data. EPA excluded zero submissions. 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
Physicochemical Properties	0	0
Environmental Fate and Transport	0	0
Environmental and General Population Exposure	0	0
Occupational Exposure/Release Information	0	0
Environmental Hazard	0	0
Human Health Hazard	1	0

2.2 Conditions of Use

As described in the *Proposed Designation of 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-Hexamethylcyclopenta[γ]-2-Benzopyran (HHCB; CASRN 1222-05-5) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019a), EPA assembled information from the Chemical Data Reporting (CDR) program 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 HHCB, including published literature, company websites, and government and commercial trade databases and publications. To identify formulated products containing HHCB, 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. SDSs were cross-checked with company websites to make sure that each product SDS was current. In addition, EPA incorporated communications with companies, industry groups, and public comments to supplement the condition of use information.

EPA identified and described the categories and subcategories of conditions of use that EPA plans to include 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.

After gathering reasonably available information related to the manufacture, processing, distribution in commerce, use, and disposal of HHCB, EPA identified those activities for HHCB the Agency determined not to be conditions of use or will otherwise be excluded during scoping. These activities are described in Section 2.2.2.

[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.

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 manufacture	Domestic manufacture	CDR U.S. EPA (2019d)
	Import	Import	CDR U.S. EPA (2019d)
Processing	Processing – incorporation into formulation, mixture or reaction product	Odor agent (in all other chemical product and preparation manufacturing; miscellaneous manufacturing; soap, cleaning compound, and toilet preparation manufacturing; other: fragrance mixtures and fragrance raw material)	CDR U.S. EPA (2019d)
	Processing – incorporation into articles	Odor agent (in plastics material and resin manufacturing)	CDR U.S. EPA (2019d)
	Repackaging	Odor agent (in all other chemical product and preparation manufacturing)	CDR U.S. EPA (2019d)
	Recycling	Recycling	CDR U.S. EPA (2019d)
Distribution in commerce	Distribution in commerce	Distribution in commerce	
Commercial Use	Air care products (e.g. aroma chemicals)	Air fresheners for motor vehicles	CDR U.S. EPA (2019d)
		Continuous action air fresheners (e.g. scented candles and solid/gel air fresheners)	CDR U.S. EPA (2019d); EPA-HQ-OPPT-2018-0430-0012 (Fragrance Creators Association , 2019)
		Instant action air fresheners (aerosol and sprays)	CDR U.S. EPA (2019d); EPA-HQ-OPPT-2018-0430-0012 (Fragrance Creators Association , 2019)
	Cleaning and furnishing care products	Cleaning products, including all-purpose liquid cleaner and bathroom cleaners (liquid, aerosol, foam, and spray cleaners)	CDR U.S. EPA (2019d)
	Laundry and dishwashing products	Laundry products, including liquid laundry detergent and fabric softener	CDR U.S. EPA (2019d); EPA-HQ-OPPT-2018-0430-0013 (Earthjustice, 2019)
	Plastic and rubber products not covered elsewhere	Plastic and rubber products	CDR U.S. EPA (2019d)
	Other use	Laboratory chemicals	Sigma-Aldrich (2019)

Consumer use	Air care products (e.g. aroma chemicals)	Air fresheners for motor vehicles	CDR U.S. EPA (2019d)
		Continuous action air fresheners (e.g. scented candles)	CDR U.S. EPA (2019d); EPA-HQ-OPPT-2018-0430-0012 (Fragrance Creators Association , 2019)
		Instant action air fresheners (aerosol and sprays)	CDR U.S. EPA (2019d); EPA-HQ-OPPT-2018-0430-0012 (Fragrance Creators Association , 2019)
	Cleaning and furnishing care products	Cleaning products, including all-purpose liquid cleaner and bathroom cleaners (liquid, aerosol, foam, and spray cleaners)	CDR U.S. EPA (2019d)
	Laundry and dishwashing products	Laundry products, including liquid laundry detergent and fabric softener	CDR U.S. EPA (2019d); EPA-HQ-OPPT-2018-0430-0013 (Earthjustice, 2019)
	Paper products	Paper products	CDR U.S. EPA (2019d)
	Plastic and rubber products not covered elsewhere	Plastic and rubber products	CDR U.S. EPA (2019d)
Disposal	Disposal	Disposal	

- Life Cycle Stage Use Definitions (40 CFR § 711.3)
  - "Industrial use" means use at a site at which one or more chemicals or mixtures are manufactured (including imported) or processed. In the *Proposed Designation of 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-Hexamethylcyclopenta[γ]-2-Benzopyran (HHCB; CASRN 1222-05-5) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019a), there is an industrial use reported for HHCB as surface active agent. After further communication with the industry reporting the use, EPA has concluded that the correct classification of the use of HHCB is "commercial use" and "consumer use" in cleaning and furnishing care products and in laundry and dishwashing products (EPA-HQ-OPPT-2018-0430-0018).
  - "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.

  Although EPA has identified both industrial and commercial uses here for purposes of distinguishing scenarios in this document, the Agency interprets the authority over "any manner or method of commercial use" under TSCA section 6(a)(5) to reach both.
- These categories of conditions of use appear in the Life Cycle Diagram, reflect CDR codes, and broadly represent conditions of use of HHCB in industrial and/or commercial settings.
- These subcategories reflect more specific uses of HHCB.
- The Agency has included information in this draft scope document sourced from the 2012 and 2016 Chemical Data Reporting (CDR) Rule collections. In instances where particular CDR data elements included in this document were claimed as confidential business information (CBI), the Agency reviewed the claims and secured their declassification.

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). TSCA section 3(4) also grants EPA the authority to determine what constitutes a condition of use for a particular chemical substance. EPA does not plan to include in this scope or in the risk evaluation the activities described below that the Agency has concluded do not constitute conditions of use.

HHCB is used in personal care products. After reviewing the public comments received during prioritization and additional outreach to the commenters and consultations with the U.S. Federal Food and Drug Administration, EPA determined that HHCB use in personal care products, including soaps, meets the definition of cosmetic in section 201 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321, and are therefore excluded from the definition of "chemical substance" in TSCA § 3(2)(B)(vi).[4] Activities and releases associated with such personal care products use 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.

2.2.3 Production Volume

As reported to EPA during the 2016 CDR reporting period and described here as a range to protect production volumes that were claimed as confidential business information (CBI), total production volume of HHCB in 2015 was between 1 million and 10 million pounds (U.S. EPA, 2017a). EPA also considered pre-2015 CDR production volume information, as detailed in the *Proposed Designation of 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-Hexamethylcyclopenta[γ]-2-Benzopyran (HHCB; CASRN 1222-05-5) 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 environmental release assessment.

2.2.4 Overview of Conditions of Use and Lifecycle Diagram

This section provides a brief overview of the industrial, commercial, and consumer use categories included in the life cycle diagram (Figure 2-7. HHCB Life Cycle Diagram). The life cycle diagram depicts the conditions of use that EPA plans to consider in the risk evaluation for the various life cycle stages as presented in Section 2.2.1. 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).[5] The production volume of HHCB in 2015 is included in the lifecycle diagram, as reported to EPA during the 2016 CDR reporting period.

[4] *Chemical substance* means any organic or inorganic substance of a particular molecular identity, including any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and any element or uncombined radical. Chemical substance does not include (1) any mixture; (2) any pesticide (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act) when manufactured, processed, or distributed in commerce for use as a pesticide; (3) tobacco or any tobacco product; (4) any source material, special nuclear material, or byproduct material (as such terms are defined in the Atomic Energy Act of 1954 and regulations issued under such Act); (5) any article the sale of which is subject to the tax imposed by section 4181 of the Internal Revenue Code of 1954 (determined without regard to any exemptions from such tax provided by section 4182 or 4221 or any other provision of such Code), and; (6) any food, food additive, drug, cosmetic, or device (as such terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device.

[5] The descriptions are primarily based on the corresponding industrial function category and/or commercial and consumer product category descriptions and can be found in EPA's Instructions for Reporting 2016 TSCA Chemical Data Reporting.

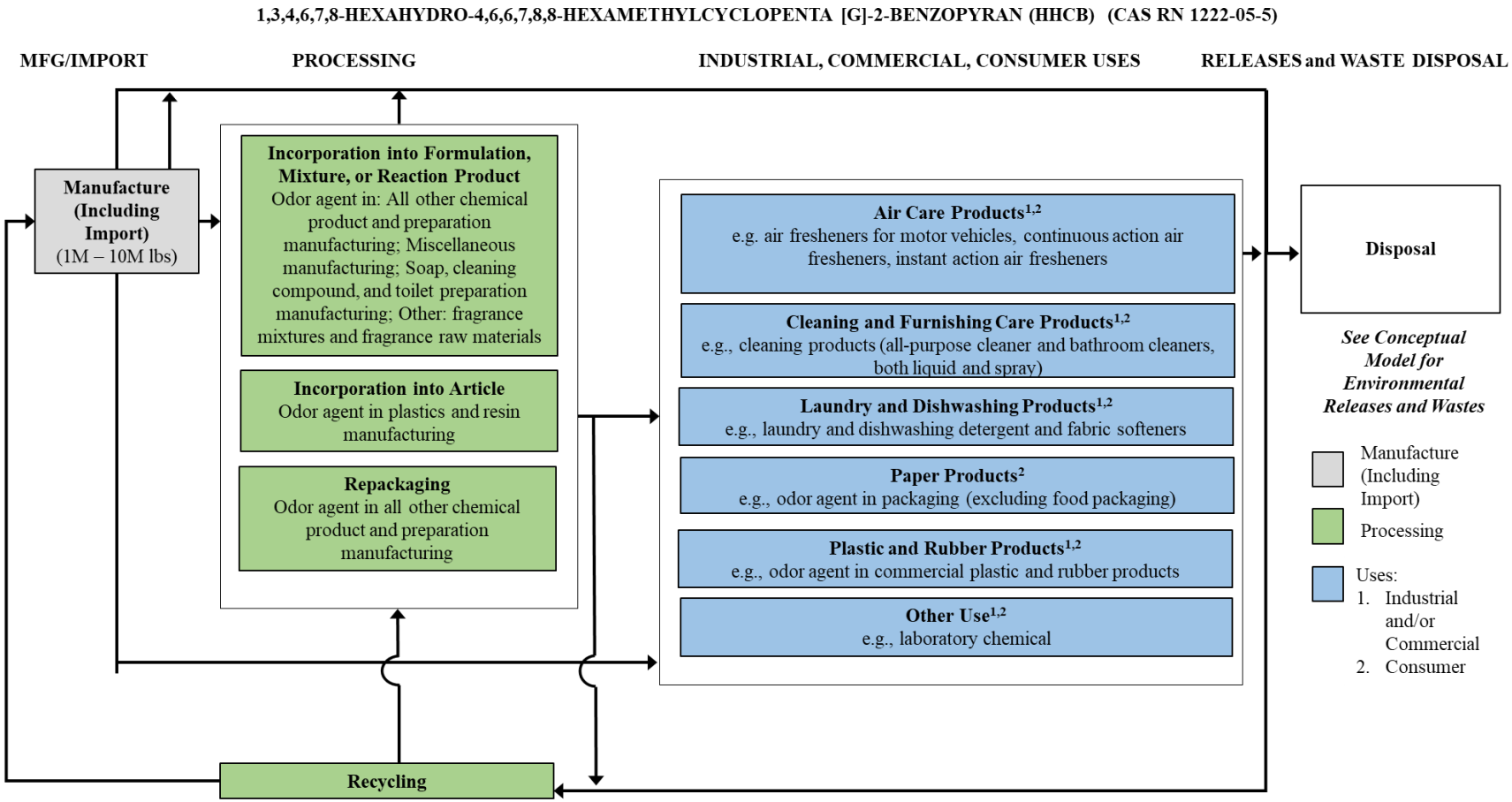

Figure 2-7. HHCB Life Cycle Diagram

Volume is not depicted in the life cycle diagram for processing and industrial, commercial, and consumer uses as specific CDR production volumes are claimed CBI or withheld pursuant to TSCA section § 14. Non-TSCA uses are excluded.

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 of HHCB. 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 plans to consider, where relevant, the duration, intensity (concentration), frequency, and number of exposures in characterizing exposures to HHCB.

2.3.1 Physical and Chemical Properties

Consideration of physical and chemical 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 presented in Appendix B, which are the same as those described in the *Proposed Designation of 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-Hexamethylcyclopenta[γ]-2-Benzopyran (HHCB; CASRN 1222-05-5) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019a), to support the development of the risk evaluation for HHCB. 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 routes and human and environmental receptors that need to be assessed in the risk evaluation for HHCB. EPA plans to use the environmental fate characteristics presented in Appendix C, which are the same as those described in the *Proposed Designation of 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-Hexamethylcyclopenta[γ]-2-Benzopyran (HHCB; CASRN 1222-05-5) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019a), to support the development of the risk evaluation for HHCB. 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 are a component of potential exposure and may be derived from reported data that are obtained through direct measurement, calculations based on empirical data and/or assumptions and models.

For all conditions of use, EPA plans to review gray literature data sources identified in Appendix A during risk evaluation using systematic review evaluation strategies for environmental releases and occupational exposure data sources. EPA includes TRI data in TSCA existing chemical assessments, but HHCB is not a TRI-listed chemical and thus TRI data are not available for it. As systematic review continues for HHCB, published literature will identify potential routes of release of HHCB to the environment. EPA may also reference the Organisation for Economic Co-operation and Development (OECD) Emission Scenario Document (ESD) on the Blending of Fragrance Oils into Commercial and Consumer Products to evaluate releases from applicable conditions of use.

According to the ESD on The Blending of Fragrance Oils into Commercial and Consumer Products, there may be releases of HHCB from industrial sites to wastewater treatment plants (WWTP), surface water, air, incineration, and landfills (OECD, 2010). Additional releases may occur from the commercial and consumer use of products containing HHCB. HHCB use in cleaning products may result in releases to POTWs. The spraying of air fresheners, use of wax melts, scented candles, or solid air fresheners

containing HHCB may release HHCB into indoor air. HHCB formulated into plastic or paper products, may be either incinerated or sent to a landfill.

EPA plans to review these data in conducting the exposure assessment component of the risk evaluation for HHCB.

2.3.4 Environmental Exposures

The manufacturing, processing, distribution, use and disposal of HHCB 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 reasonably available information on environmental exposures in biota to inform the development of the environmental exposure assessment for HHCB.

2.3.5 Occupational Exposures

EPA plans to analyze worker activities where there is a potential for exposure under the 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 expects to consider the effect(s) that engineering controls (EC) and/or personal protective equipment (PPE) have on occupational exposure levels as part of the draft risk evaluation.

Worker activities associated with the conditions of use within the scope of the risk evaluation for HHCB that will be analyzed include, but are not limited to:

- Unloading and transferring HHCB to and from storage containers to process vessels;
- Handling, transporting and disposing of waste containing HHCB;
- Cleaning and maintaining equipment;
- Using HHCB in process equipment (e.g., applicators, process vessels);
- Applying formulations and products containing HHCB onto substrates (e.g., spray applying cleaning and deodorizing products containing HHCB);
- Sampling chemicals, formulations or products containing HHCB for quality control;
- Repackaging chemicals, formulations or products containing HHCB; and
- Performing other work activities in or near areas where HHCB is used.

HHCB is a liquid with a vapor pressure of 5.45×10^{-4} mm Hg at 25ºC. HHCB's vapor pressure and use as a fragrance chemical indicates the potential for inhalation exposure of workers and ONUs to vapors generated by the liquid at ambient room temperature conditions. Additionally, there is the potential for inhalation exposure to mists generated from use in spraying/aerosol products (e.g., liquid spray cleaners).

EPA generally does not evaluate occupational exposures through the oral route because oral exposure is typically incidental in nature. Workers may inadvertently transfer chemicals from their hands to their mouths, ingest inhaled particles that deposit in the upper respiratory tract or consume contaminated food, 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 HHCB.

Based on the conditions of use, EPA plans to evaluate dermal exposures for workers because workers are expected to have skin contact with solids and liquids. ONUs do not directly handle HHCB; therefore, skin contact with liquid HHCB is not expected for ONUs.

2.3.6 Consumer Exposures

EPA plans to be evaluating consumer uses of HHCB in air care products, cleaning and furnishing care products, laundry and dishwashing products, paper products and plastic and rubber products, and other products (e.g. laboratory chemicals).

Consumers using or disposing of these products, and bystanders may be exposed to HHCB in vapors which may lead to inhalation exposure. In addition, consumers using or disposing of air care, cleaning and furnishing products and bystanders may also be exposed to HHCB in mists which may lead to inhalation exposure. Furthermore, consumers using or disposing of cleaning and furnishing products and laundry and dishwashing products. Bystanders may be exposed to HHCB in powders and dusts which may lead to inhalation exposure. Lastly, consumers using or disposing of cleaning and furnishing care products, laundry and dishwashing products, and other products including laboratory chemicals may be exposed to HHCB in liquids which may lead to dermal exposure.

The estimated exposure to HHCB on the skin from the use of a combination of all classes of consumer products on a daily basis was calculated by a European Union (EU) assessment to result in a "worst case situation" of 0.85 mg/kg body weight per day (EU, 2008). The inhalation exposure of consumers to HHCB in household cleaning products and air fresheners was estimated as lower, in total 0.0085 mg/kg body weight per day (EU, 2008). The 2008 EU assessment concluded there was no need for further information and/or testing and no need for risk reduction measures beyond those already being applied for consumers (EU, 2008).

EPA does not expect consumers nor bystanders to receive significant oral exposures to HHCB. In addition, EPA does not expect bystanders to receive a significant amount of dermal exposure to HHCB.

2.3.7 General Population Exposures

Monitoring data were identified in EPA's data search for HHCB 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.

EPA plans to review reasonably available environmental monitoring data for HHCB. The U.S. Geological Survey (USGS) Monitoring Data – National Water Quality Monitoring Council (NWQMC) has identified HHCB in sediment, soil, ground water, and surface water (USGS, 1991a-e). Research suggests moderate-range (regional) atmospheric transport of HHCB may occur, although long-range transport is unlikely (U.S. EPA, 2014). HHCB was identified in filtered and non-filtered drinking water. Measured concentrations within aquatic organisms and birds were also reported (U.S. EPA, 2014).

Releases of HHCB from specific conditions of use, such as consumer and commercial uses, product processing through fragrance compounding, and end-product formulation, disposal, or waste treatment activities may result in general population exposures due to ingestion of contaminated drinking water near industrial processing sites (U.S. EPA, 2014, EU, 2008). Human exposure through ingestion of

water and food including fish, root crops, and mother's milk was noted in a 2014 assessment as the main route of exposure to humans. Exposure via inhalation route to the general population was considered to be negligible, according to the 2014 EPA assessment (U.S. EPA, 2014). Currently, EPA is considering oral exposure in its assessment of HHCB for the general population. However, an EU assessment concluded there was no need for further information and/or testing and no need for risk reduction measures beyond those already applied for the general population exposed via the environment (EU, 2008).

2.4 Hazards (Effects)

2.4.1 Environmental Hazards

As described in the *Proposed Designation of 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-Hexamethylcyclopenta[γ]-2-Benzopyran (HHCB; CASRN 1222-05-5) 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 HHCB. EPA considers all the potential environmental hazards for HHCB 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 HHCB. If necessary, EPA plans to update the list of potential hazards in the final scope document of HHCB. 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 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-Hexamethylcyclopenta[γ]-2-Benzopyran (HHCB; CASRN 1222-05-5) 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 HHCB. The health effect categories screened for during prioritization included acute toxicity, irritation/corrosion, dermal sensitization, respiratory sensitization, genetic toxicity, repeated dose toxicity, reproductive toxicity, developmental toxicity, immunotoxicity, neurotoxicity, carcinogenicity, epidemiological or biomonitoring studies and ADME. EPA plans to evaluate all of the potential human health hazards for HHCB identified during prioritization. The broad health effect category identified during prioritization was developmental toxicity. 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 HHCB 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 of 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 (including those who consume breast milk), women of reproductive age (e.g., pregnant women), workers (including ONUs), and consumers (U.S. EPA 2019d). In addition, preliminary information indicates that HHCB may bioaccumulate in fish (Appendix C); thus, populations with elevated fish ingestion are considered potentially exposed or susceptible. 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, duration or location 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 HHCB. 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 are discussed and depicted the conceptual model shown in Section 2.6.3.

2.6.1 Conceptual Model for Industrial and Commercial Activities and Uses

Figure 2-8. HHCB Conceptual Model for Industrial and Commercial Activities and Uses: Worker and ONU Exposures and Hazards illustrates the conceptual model for the pathways of exposure from industrial and commercial activities and uses of HHCB that EPA plans to include in the risk evaluation. There are exposures to workers and/or ONUs via inhalation routes and/or exposures to workers via dermal routes for all conditions of use identified in this scoping document. The conceptual model includes potential inhalation exposures to HHCB through vapor, mists, and dusts, and dermal exposures through contact with solid and liquid HHCB. In addition to the pathways illustrated in the figure, 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, disposal) rather than a single distribution scenario.

For each condition of use identified in Section 2.2, an initial determination was made as to whether each combination of exposure pathway, route, and receptor will be analyzed in the risk evaluation. The results of that analysis along with the supporting rationale are presented in Appendix F.

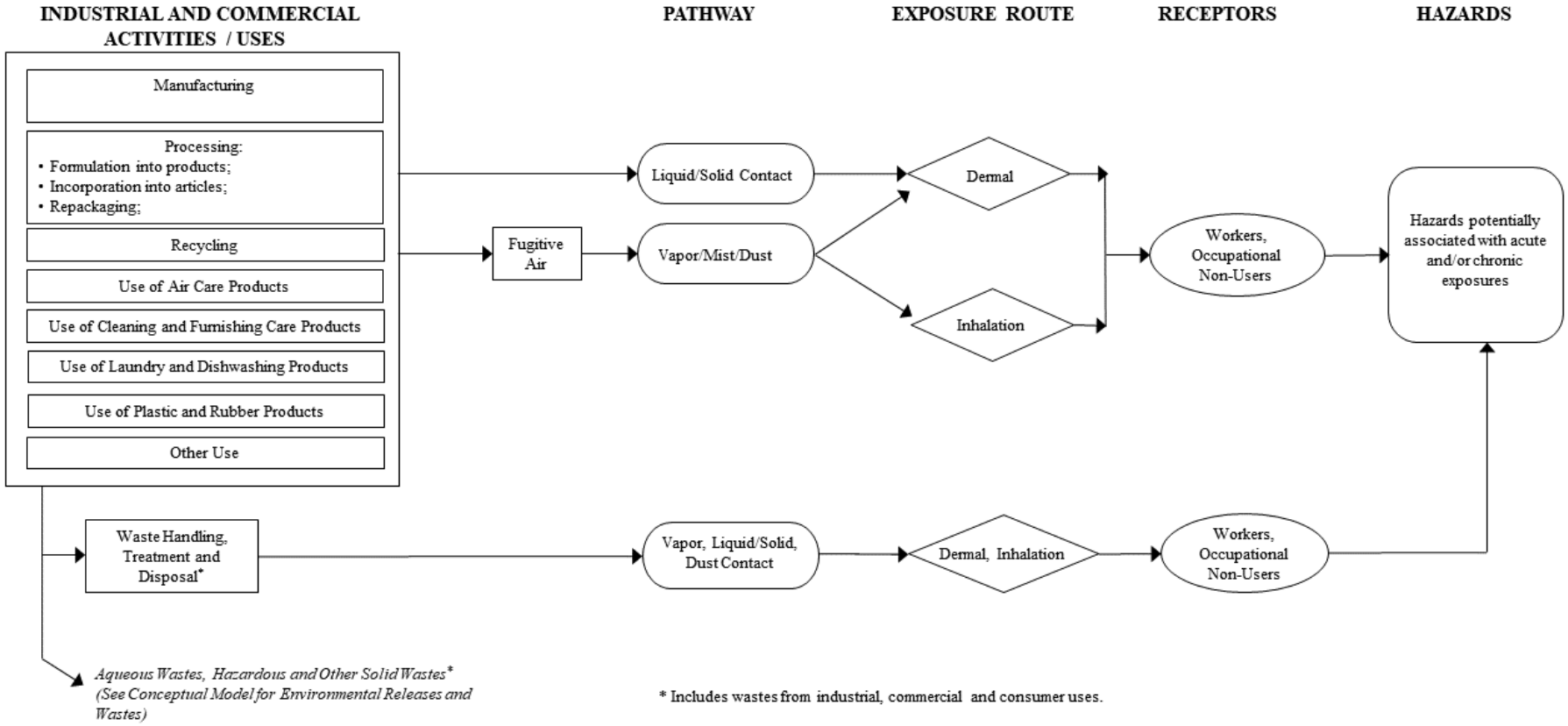

Figure 2-8. HHCB Conceptual Model for Industrial and Commercial Activities and Uses: Worker and ONU Exposures and Hazards

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

[a] Receptors include PESS (see Section 2.5).

[b] When data and information are available to support the analysis, EPA also considers the effect that EC and/or PPE have on occupational exposure level

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 HHCB that EPA plans to include in the risk evaluation. Inhalation is expected to be the primary route of exposure for consumers and plans to evaluate inhalation exposures to HHCB vapors, mists, and dusts for consumers and bystanders. EPA plans to evaluate dermal exposures via mists and direct contact to HHCB during the consumer uses of the product types listed in Figure 2-9. Consumer oral exposures via mists and powders or dust containing HHCB during use is expected to be negligible. As a result, oral ingestion of HHCB will not be evaluated for consumers. In addition, since bystanders are not expected to have significant direct dermal or oral contact to HHCB, these pathways will not be evaluated for bystanders. The supporting rationale for consumer pathways that are in scope for HHCB are included in 2.8Appendix G.

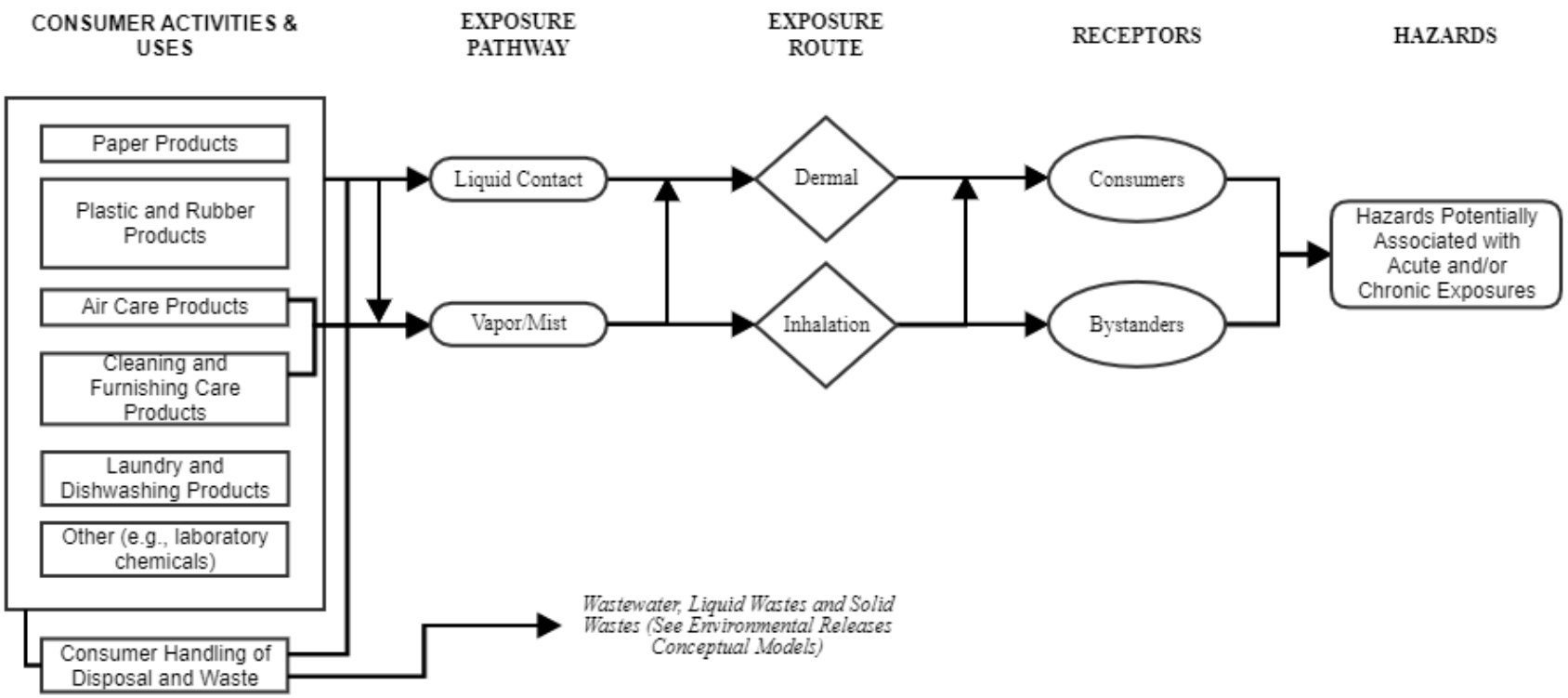

Figure 2-9. HHCB Conceptual Model for Consumer Activities and Uses: Consumer Exposures and Hazards

The conceptual model presents the exposure pathways, exposure routes and hazards to human receptors from consumer activities and uses of HHCB.
[a] Receptors include PESS (see Section 2.5).

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

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 HHCB.

EPA plans to evaluate exposures to receptors (e.g., general population, aquatic, terrestrial species) that may occur from industrial and/or commercial and consumer releases to air, drinking water, ground water, and land, including biosolids and soil. Some aquatic species may be exposed to HHCB by consuming sediments and swimming in water bodies in which HHCB is found. Some terrestrial species may be exposed to HHCB via air and soil found in their natural habitats. Furthermore, the general population may receive oral exposure to HHCB via fish ingestion and drinking water. They may also receive dermal exposure to HHCB through recreational actives such as swimming in surface water bodies. In addition, they may receive inhalation exposures to HHCB through vapor emissions from soil or recycled wastes. The supporting rationale for general population and environmental pathways considered for HHCB are included in 2.8Appendix H.

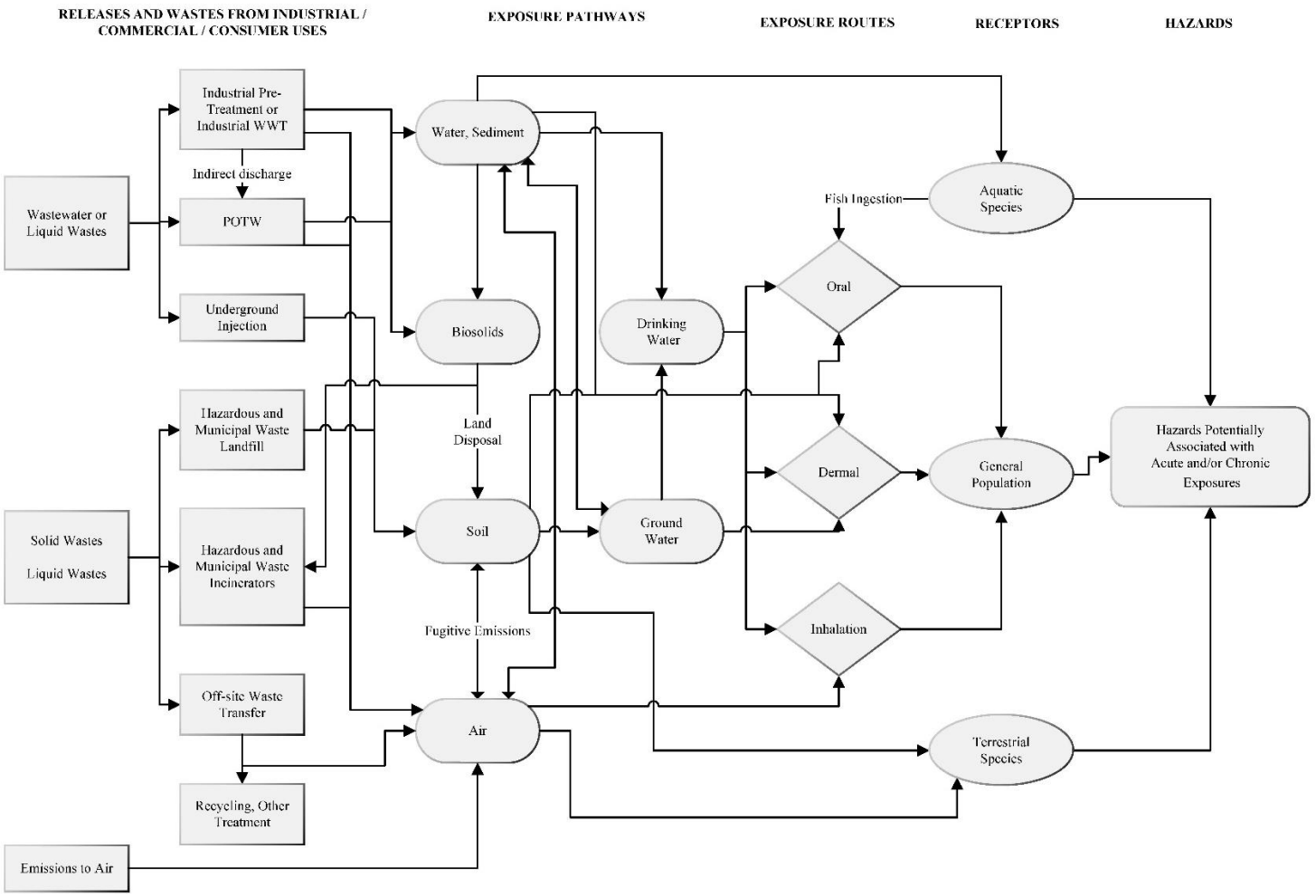

Figure 2-10. HHCB Conceptual Model for Environmental Releases and Wastes: Environmental Exposures and Hazards

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

[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. Groundwater may also be a source of drinking water.

[b] Receptors include PESS (see Section 2.5).

2.7 Analysis Plan

The analysis plan is based on EPA's knowledge of HHCB 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 reasonably 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 p-chem properties and environmental fate and transport of HHCB 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) previously summarized in the *Proposed Designation of 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-Hexamethylcyclopenta[γ]-2-Benzopyran (HHCB; CASRN 1222-05-5) 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.**
   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 HHCB 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 to HHCB via indoor air, ambient air, surface water, groundwater, sediment, and soil for aquatic and terrestrial biota associated with exposure to HHCB. EPA has not yet determined the exposure levels in these media or how they may be used in the risk evaluation. Exposure

scenarios are sources (uses), exposure pathways, and exposed receptors. Draft release/exposure scenarios corresponding to various conditions of use for HHCB are presented in Appendix F. EPA plans to analyze scenario-specific exposures.

Based on their physical-chemical 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 reasonably 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 in Appendix E 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.

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

U.S. EPA Generic Scenarios
OECD Emission Scenario Documents
EU Risk Assessment Reports

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 has reviewed key release data sources as summarized in Section 2.3.3. EPA plans to continue to review relevant data sources during risk evaluation. EPA plans to match identified data to applicable conditions of use and identify data gaps where no data are found for specific 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.**
   Data for similar fragrance chemicals that are used in the same applications may be used as surrogate for HHCB. EPA plans to review literature sources identified and if surrogate data are found, EPA plans to match these data to applicable conditions of use for potentially filling data gaps.

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 steps 2 and 3 above. EPA plans to consider 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 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 2010 ESD on The Blending of Fragrance Oils into Commercial and Consumer Products may be useful as well as the ESD on Plastic Additives and the complementing document on Plastic Additives During the Use of End Products (OECD, 2010) (OECD, 2009a) (OECD, 2019). EPA plans to need 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 plans to perform additional targeted research to understand those conditions of use, which may inform identification of release scenarios. 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.

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 was not able to identify release scenarios corresponding to some conditions of use (e.g. automotive care products, and recycling). EPA plans to perform targeted research to understand those uses, which may inform identification of release scenarios. 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 HHCB and polymer products and formulations containing HHCB, 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 HHCB:

1) **Review reasonably available environmental and biological monitoring data for all media relevant to environmental exposure.**
   For HHCB, environmental media which EPA plans to evaluate are sediment, biosolids, soil, ambient air and surface water. The environmental exposure pathways which have been identified in the literature include aquatic and terrestrial.

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 surface water, sediment, and soil concentrations will be analyzed and considered alongside available surface 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 surface water, sediment, or soil, indirect release into 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) **Review reasonably available biomonitoring data for vegetation, invertebrates, fish, non-fish vertebrates (i.e., amphibians, reptiles, mammals). Consider whether these data could be used to compare with comparable species or taxa-specific toxicological benchmarks.**
   Predatory bird species that consume fish with elevated levels of HHCB will be analyzed. If species-specific biomonitoring data matches toxicity studies, direct comparisons can be made. EPA plans to also consider refining data for other species by using body weight of the birds, fish ingestion rate of birds, and typical fish species consumed.

4) **Determine applicability of existing additional contextualizing information for any monitored data or modeled estimates during risk evaluation.**
   There have been changes to use patterns of HHCB over the last few years. Monitoring data or modeled estimates will be reviewed to determine how representative they are of applicable use patterns.

   Any studies which relate levels of HHCB in the environment or biota with specific sources or groups of sources will be evaluated.

5) **Group each condition(s) of use to the 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 HHCB, 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 related to release into the media of interest, fate and transport, and characteristics of the environment;

- Reasonably available biomonitoring data which 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); and
- Weight of the scientific evidence of environmental occurrence data and modeled estimates.

6) **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 systematic review methods.

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 exposure monitoring data found in published literature (including both personal exposure monitoring data (direct exposures) and area monitoring data (indirect exposures)). EPA has reviewed reasonably available monitoring data collected by the Occupational Safety and Health Administration (OSHA) and National Institute for Occupational Safety and Health (NIOSH) and neither collected data for HHCB exposures. The most recent submissions to CDR for HHCB will be used to identify manufacturing and processing information for HHCB where occupational exposure may occur. CDR may also identify potential uses of HHCB that would indicate occupational exposure. Additionally, systematic review will identify published reports containing worker exposure monitoring data that will inform the occupational exposure assessment of HHCB. EPA plans to continue to review data sources identified in Appendix A for HHCB using systematic review evaluation strategies for environmental releases and occupational exposure data sources.

2) **Review reasonably available exposure data for surrogate chemicals that have uses, volatility and chemical and physical properties similar to HHCB.**
   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. For several conditions of use (e.g., air care products, cleaners, laundry products, and soaps), EPA may consider other similar fragrances that share the same conditions of use as possible surrogates for HHCB.

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 Emission Scenario Documents (ESDs) from the OECD. For example, the ESD on The Blending of Fragrance Oils into Commercial and Consumer Products may be used to estimate occupational exposures as well as the ESD on Plastic Additives and the complementing document on Plastic Additives During the Use of End Products (OECD, 2010) (OECD, 2009a) (OECD, 2019). EPA plans to need to critically review all generic scenarios and ESDs to determine their applicability to the conditions of use assessed. EPA may conduct

industry outreach efforts or perform supplemental, targeted research to understand those conditions of use, which may inform identification of exposure scenarios. EPA plans to consider inhalation exposure to vapor and mist models in the Chemical Screening Tool for Exposure and Environmental Releases (ChemSTEER) Tool that are routinely used for assessing new chemicals. EPA may also need to perform targeted research to identify applicable models that EPA could use to estimate exposures for certain conditions of use (U.S. EPA, 2013).

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).

5) **Consider and incorporate applicable EC and/or PPE into exposure scenarios.**
   EPA plans to review potentially relevant data sources on EC and PPE as identified in Appendix E to determine their applicability and incorporation into exposure scenarios during risk evaluation.

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 as shown in Appendix F. EPA may further refine the mapping/grouping 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 HHCB, the following are noteworthy considerations in constructing consumer exposure scenarios:
   - Conditions of use and type of consumer product

- Duration, frequency and magnitude of exposure
- Weight fraction of chemical in products
- Amount of chemical used

2) **Evaluate the relative potential of indoor exposure pathways based on reasonably available data.**
   Indoor exposure pathways expected to be relatively higher include vapors, mists, and dust inhalation, and liquid dermal contact as a result of indoor use of HHCB consumer products. Indoor exposure pathways expected to be relatively lower include liquid and mist oral ingestion, and dermal contact with HCCB via dust. The data sources associated with these respective pathways have not 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 dust concentrations, or indoor dust surface loadings.**
   Indoor exposure models that estimate emissions from consumer products are available. These models generally consider p-chem properties (e.g., vapor pressure, molecular weight), product specific properties (e.g., weight fraction of the chemical in the product), use patterns (e.g., duration and frequency of use), user environment (e.g., room of use, ventilation rates), and receptor characteristics (e.g., exposure factors, activity patterns). The OPPT's Consumer Exposure Model (CEM) and other similar models can be used to estimate indoor air exposures from consumer products.

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 HHCB 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 HHCB 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 HHCB in specific media (e.g., dust or indoor air).**
   The availability of HHCB 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 and dust 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 systematic review methods.

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 sources and uses, exposure pathways including routes, and exposed populations.**
   For HHCB, the following are noteworthy considerations in constructing exposure scenarios for the general population: routes of exposure, releases to air, water or land resulting from industrial, commercial, and other conditions of use, in addition to:
   - Reviewing reasonably available environmental and biological monitoring data for media to which general population exposures are expected;
   - For exposure pathways where data are not reasonably available, reviewing existing exposure models that may be applicable in estimating exposure levels;
   - Considering and incorporating applicable media-specific regulations into exposure scenarios or modeling;
   - Reviewing 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 reasonably available;
   - Reviewing reasonably available information on releases to determine how modeled estimates of concentrations near industrial point sources compare with reasonably available monitoring data;
   - Reviewing reasonably available population- or subpopulation-specific exposure factors and activity patterns to determine if PESS need be further defined;
   - Evaluating the weight of the scientific evidence of general population exposure data; and
   - Mapping or grouping each condition of use to general population exposure assessment scenario(s).

   EPA plans 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 reasonably available data and approaches. For example, EPA

may consider the co-location of TSCA industrial facilities with reasonably 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 reasonably 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. 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 reasonably available that summarily alters the overall conclusion of a scenario through iterative tiering, EPA can refine its analysis during risk evaluation.

2) **Review reasonably available environmental and biological monitoring data for exposure pathways and media to which general population exposures are expected.**
   General population exposure pathways expected to be relatively higher include ingestion of water and food including fish, root crops, and mother's milk. General population exposure pathways expected to be relatively lower include dermal contact to HHCB via liquids and mists, and inhalation of HHCB via vapors, mists and dusts. The data sources associated with these respective pathways have not been comprehensively evaluated, so quantitative comparisons across exposure pathways or in relation to toxicity thresholds are not yet available.

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

4) **Review reasonably available exposure modeled estimates. For example, existing models developed for a previous HHCB chemical assessment may be applicable to the EPA assessment. In addition, another chemical's assessment may also be applicable if model parameter data are reasonably available.**
   To the extent other organizations have already modeled HHCB general population exposure scenario that is relevant to the OPPT's assessment, EPA plans to evaluate those modeled estimates. In addition, if modeled estimates for other chemicals with similar physical chemical 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.

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

6) **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 HHCB, 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 dust, soil, and diet than adults.

7) **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 systematic review protocols.

2.7.3 Hazards (Effects)

2.7.3.1 Environmental Hazards

EPA plans to conduct an environmental hazard assessment of HHCB 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 HHCB to aquatic and 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 TPP 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, etc.) may be derived

and used to further understand the hazard characteristics of HHCB 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 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 reasonably available monitoring and modeling data, and other available approaches to integrate exposure and hazard assessments.**
EPA plans to consider the aquatic (e.g., water and sediment exposures) and terrestrial pathways in the HHCB conceptual model. These organisms may be exposed to HHCB via several environmental pathways (i.e., surface water, sediment, air, soil, diet).

5) **Conduct an environmental risk characterization of HHCB.**
EPA plans to conduct a risk characterization of HHCB to identify whether there are risks to the aquatic and/or terrestrial environments from the measured and/or predicted concentrations of HHCB found in environmental media (e.g., 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 HHCB.**
EPA plans to consider assessing the persistence, bioaccumulation, and toxic (PBT) potential of HHCB after reviewing relevant physical-chemical properties and exposure pathways. EPA plans to assess the reasonably available studies collected from the systematic review process relating to bioaccumulation and bioconcentration (e.g., BAF/BCF) of HHCB. 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 HHCB 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).**
Human health studies will be evaluated using the systematic review evaluation strategies. 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) **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 HHCB hazard(s). Susceptibility of particular human receptor groups to HHCB will be determined by evaluating information on factors that influence susceptibility.

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

3) **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 systematic review data quality criteria. 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, 2011a, 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 HHCB, 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).

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*. 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 (2011a), 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 systematic review methods.

6) **Consider the route(s) of exposure (oral, inhalation, dermal), available route-to-route extrapolation approaches, reasonably available biomonitoring data and 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 HHCB, which could be important for the worker, consumer, and general population risk analysis. Reasonably available data will be assessed to determine whether a point of departure 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 reasonably 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 the 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 obligations 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 also 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 the 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 HHCB 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 HHCB.

Table_Apx A-1. Gray Literature Sources That Yielded Results for HHCB

Source/ Agency	Source Name	Source Type	Source Category
Aus. Assm.	NICNAS Assessments (human health, Tier I, II or III)	International Resources	Assessment or Related Document
ECHA	European Union Risk Assessment Report (EU, 2008)	International Resources	Assessment or Related Document
ECHA	ECHA Documents (ECHA, 2019)	International Resources	Assessment or Related Document
EPA	Office of Water: STORET and WQX	US EPA Resources	Database
EPA	TSCA Assessments	US EPA Resources	Assessment or Related Document
EPA	TSCA Data Needs Assessments or Problem Formulation	US EPA Resources	Assessment or Related Document
EPA	Other EPA: Misc sources	US EPA Resources	General Search
EPA	EPA: AP-42	US EPA Resources	Regulatory Document or List
EPA	TRI: Envirofacts Toxics Release Inventory 2017 Updated Dataset	US EPA Resources	Database
EPA	Chemical Data Reporting (2012 and 2016 non-CBI CDR database)	US EPA Resources	Database
EPA	Chemical Data Reporting (2012 and 2016 CBI CDR database)	US EPA Resources	Database
EPA	EPA: Generic Scenario	US EPA Resources	Assessment or Related Document
EPA	EPA Discharge Monitoring Report Data	US EPA Resources	Database
EPA	Office of Air: National Emissions Inventory (NEI) - National Emissions Inventory (NEI) Data (2014, 2011, 2008)	US EPA Resources	Database

EPA	Office of Air: CFRs and Dockets	US EPA Resources	Regulatory Document or List
KOECT	Kirk-Othmer Encyclopedia of Chemical Technology Journal Article	Other Resource	Encyclopedia
NLM	National Library of Medicine's PubChem	Other US Agency Resources	Database
OECD	OECD Emission Scenario Documents	International Resources	Assessment or Related Document
OECD	OECD: General Site	International Resources	General Search
OSHA	U.S. OSHA Chemical Exposure Health Data (CEHD) program data [ERG]	Other US Agency Resources	Database
RIVM	RIVM Reports: Risk Assessments	International Resources	Assessment or Related Document

Appendix B PHYSICAL AND CHEMICAL PROPERTIES OF HHCB

This appendix provides p-chem information and data found in preliminary data gathering for HHCB. 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 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-Hexamethylcyclopenta[γ]-2-Benzopyran (HHCB; CASRN 1222-05-5) 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-2018-0430).

Table_Apx B-1. Physical and Chemical Properties of HHCB

Property or Endpoint	Value[a]	Reference	Data Quality Rating
Molecular formula	$C_{18}H_{26}O$	NA	NA
Molecular weight	258.41 g/mol	NA	NA
Physical state	Viscous liquid	NLM, 2018	High
Physical properties	Colorless, strong musk odor	NLM, 2018	High
Melting point	-5°C	U.S. EPA, 2019	High
Boiling point	325°C	U.S. EPA, 2019	High
Density	1.0054 g/cm^3 at 20°C	O'Neil, 2013	High
Vapor pressure	5.45×10^{-4} mm Hg at 25°C	NLM, 2018	High
Vapor density	Not available		
Water solubility	1.75 mg/L at 25°C	NLM, 2018	High
Log Octanol/water partition coefficient (Log Kow)	5.9	U.S. EPA, 2019	High
Henry's Law constant	1.06×10^{-4} atm·m^3/mole at 25°C	U.S. EPA, 2012	
Flash point	Not available		
Auto flammability	Not available		
Viscosity	12,914 cP	NLM, 2018	High
Refractive index	1.5342	O'Neil, 2013	High
Dielectric constant	Not available		

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

Appendix C ENVIRONMENTAL FATE AND TRANSPORT PROPERTIES OF HHCB

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

Table_Apx C-1. Environmental Fate and Transport Properties of HHCB

Property or Endpoint	Value	Reference
Direct Photodegradation	Direct photolysis is not expected to be an important fate process because HHCB does not contain chromophores that absorb at wavelengths >290 nm	NLM, 2018
	Direct photolysis by sunlight and gas-phase reaction with hydroxyl (·OH) radicals are considered to be the major degradation routes for HHCB in the atmosphere	OECD, 2009b
Indirect Photodegradation	Half-life ($t_{1/2}$) = 5 days (based on ·OH reaction rate constant of 2.6×10^{-11} cm^3/molecules·second at an ·OH concentration of 1.5×10^6 ·OH/cm^{-3})	OECD, 2009b
Hydrolysis	Stable; HHCB is not expected to undergo hydrolysis in the environment due to its chemical structure, which lacks functional groups known to undergo hydrolysis under environmental conditions	NLM, 2018; OECD, 2009b
Biodegradation	0%/28 days CO_2 evolution test (OECD test guideline 301 B) (aerobic water)	NLM, 2018; EU, 2008
	18%/200 days activated sludge; byproducts identified were galaxolide lactone and galaxolide hydroxy acid	NLM, 2018 citing Balk and Ford, 1999a
Removal in Wastewater Treatment	92% total removal (0.8% by biodegradation, 91% by sludge and 0.1% by volatilization to air; estimated)[b]	U.S. EPA, 2012c
	91.5% removal activated sludge plant	EU, 2008 citing Simonich, 2000
Bioconcentration Factor	1,584 (whole fish, wet weight) bluegill sunfish (*Lepomis macrochirus*) OECD Test guideline 305E	NLM, 2018 citing Balk and Ford, 1999a
	624 (fresh weight), 33,200 (lipid) zebrafish (*Brachydanio rerio*), OECD Test guideline 305E	EU, 2008 citing Butte and Ewald, 1999
Bioaccumulation Factor	52,370 (crucian carp), 66,030 (common carp), 39,400 (silver carp)	Hu, 2011

Soil Organic Carbon:Water Partition Coefficient (Log K_{OC})	4.87	EU, 2008 citing MacGillivray, 1966
	3.6–3.9	EU, 2008 citing Muller, 2002
	3.8	EU, 2008 citing Artola-Garciana, 2002

[a] Measured unless otherwise noted

[b] EPI Suite™ physical property inputs: Log K_{OW} = 5.90, boiling point = 325 °C, melting point = -5 °C, vapor pressure = 0.000545 mm Hg, water solubility = 1.75 mg/L, biodegradation half-life (in hours) in the primary clarifier of a sewage treatment plant (STP; BioP) = 10,000, biodegradation half-life (in hours) in the aeration vessel of an STP (BioA) = 10,000 and biodegradation half-life (in hours) in the final settling tank of an STP (BioS) = 10,000, Simplified Molecular-Input Line-Entry System (SMILES): O(CC(c(c1cc(c2C(C3C)(C)C)C3(C)C)c2)C)C1

Appendix D REGULATORY HISTORY

HHCB 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 HHCB 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
EPA Regulations		
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.	HHCB is 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 HHCB as high-priority substance constitutes the initiation of the risk evaluation on the chemical.
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.	HHCB manufacturing (including importing), processing and use information is reported under the CDR rule (76 FR 50816, August 16, 2011) (U.S. EPA, 2011b).
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.	HHCB 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) (U.S. EPA, 1995).
TSCA Section 8(e)	Manufacturers (including importers), processors, and distributors must immediately notify EPA if they obtain information that supports the	One risk report was received for HHCB (May 1997) (U.S. EPA,

Statutes/ Regulations	Description of Authority/Regulation	Description of Regulation
	conclusion that a chemical substance or mixture presents a substantial risk of injury to health or the environment.	ChemView. Accessed (March 22, 2019)) (U.S. EPA, 2017a)
Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) - Sections 3 and 6	FIFRA governs the sale, distribution and use of pesticides. Section 3 of FIFRA generally requires that pesticide products be registered by EPA prior to distribution or sale. Pesticides may only be registered if, among other things, they do not cause "unreasonable adverse effects on the environment." Section 6 of FIFRA provides EPA with the authority to cancel pesticide registrations if either (1) the pesticide, labeling, or other material does not comply with FIFRA; or (2) when used in accordance with widespread and commonly recognized practice, the pesticide generally causes unreasonable adverse effects on the environment.	HHCB is an approved nonfood use inert ingredient and as a component of a fragrance. (InertFinder. Accessed (March 22, 2019)) (U.S. EPA, 2019e).

D.2 State Laws and Regulations

Table_Apx D-2. State Laws and Regulations

State Actions	Description of Action
Chemicals of High Concern to Children	Minnesota includes HHCB in the list of chemicals of high concern (Toxic Free Kids Act Minn. Stat. 116.9401 to 116.9407) (MDH, 2019).
Other	California lists HHCB as a designated priority chemical for biomonitoring (California SB 1379). The Oregon Department of Environmental Quality lists HHCB as a priority persistent pollutant (Oregon SB 737).

D.3 International Laws and Regulations

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

Country/ Organization	Requirements and Restrictions
European Union	HHCB is registered for use in the EU. Chemicals Agency (ECHA) database. (ECHA, 2018, Accessed April 2, 2019).

Australia	HHCB was assessed under Human Health Tier II of the Inventory Multi-Tiered Assessment and Prioritisation (IMAP). Use reported include washing and cleaning products; air care products; anti-odour agents; floor and surface treatment products; scented clothes and papers; car care products; photochemicals; leather tanning and textile dyes; coatings and paint thinners; polishes and wax blends; and adsorbents. (NICNAS, 2019, accessed April 4, 2019*).*
Japan	HHCB 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) (NITE, 2019, accessed April 4, 2019).

Appendix E PROCESS, RELEASE AND OCCUPATIONAL EXPOSURE INFORMATION

This appendix provides information and data found in preliminary data gathering for HHCB.

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.

E.1.1 Manufacture (Including Import)

E.1.1.1 Manufacturing

HHCB is manufactured by a three-step reaction (Wiley-VCH, 2002; Zviely, 2002). First, a cycloaddition reaction of .alpha.-methyl styrene and 2-methyl-2-butene (i.e., amylene) is performed under acidic conditions to obtain 1,1,2,3,3-pentamethylindane (1). Second, the pentamethylindane (1) is hydroxyalkylated with propylene oxide in a Friedel-Crafts reaction using aluminum chloride as a catalyst. Third, the ring closure of the resulting 1,1,2,3,3- pentamethyl-5-(-hydroxyisopropyl)indane (2) to 1,3,4,6,7,8-hexahydro-4,6,6,7,8,8- hexamethylcyclopenta-g-benzopyran (HHCB; Galaxolide) is accomplished with paraformaldehyde and a lower aliphatic alcohol via the acetal or with paraformaldehyde and a carboxylic acid anhydride via the acylate (U.S. EPA, 2014).

E.1.1.2 Import

EPA has not identified specific activities related to the import of HHCB at this time. However, EPA anticipates that HHCB is shipped in bulk containers and may be repackaged into smaller containers for resale, such as drums or bottles. The type and size of container will vary depending on customer requirement. In some cases, QC samples may be taken at import and repackaging sites for analyses. Some import facilities may only serve as storage and distribution locations, and repackaging/sampling may not occur at all import facilities.

HHCB may be imported neat or as a component in a formulation. In the 2016 CDR, all eight companies reporting the import of HHCB also reported the maximum concentration of the formulation as over 90 percent HHCB (U.S. EPA, 2019d).

HHCB is imported into the U.S. for processing and distribution. Releases are not expected to result from import activities, but may occur at import sites if HHCB is also diluted and compounded onsite after import, as further discussed below in the processing and distribution section.

E.1.2 Processing and Distribution

E.1.2.1 Incorporation 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. HHCB is incorporated into formulations as an odor agent during the manufacture of chemical products, soaps, cleaning compounds, and fragrance mixtures (U.S. EPA, 2019d). HHCB-specific formulation processes were not identified; however, at least one Emission Scenario Document (ESD) published by the OECD has been identified that provide general process descriptions for these types of products.

E.1.2.2 Incorporation 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 HHCB-containing formulations or reaction products are dependent on the article. HHCB and HHCB formulations or reaction products are incorporated into articles during the manufacturing of plastic material and resins. The ESD on Plastic Additives and the complementing document on Plastic Additives During the Use of End Products will be referenced to provide general process descriptions for the identified articles (OECD, 2009a) (OECD, 2019).

E.1.2.3 Repackaging

EPA has not identified specific information for the repackaging of HHCB. EPA expects repackaging sites receive the chemical in bulk containers and transfer the chemical from the bulk container into another smaller container in preparation for distribution in commerce.

E.1.2.4 Recycling

EPA did not identify HHCB-specific information for recycling.

E.1.3 Uses

Musks are considered important compounds to the fragrance industry because of their unique odor properties, ability to improve the fixation of fragrance compounds, and ability to bind fragrances to fabrics. The function of HHCB in fragrance formulations is as both a fragrance and a fragrance enhancer.

HHCB is used as a fragrance ingredient in cleaning because it is alkali-stable and does not discolor in light. HHCB and other musks provide a unique, dominant scent in products. Because HHCB binds fragrances to fabric and skin, the scent is balanced and longer lasting. HHCB is often used in laundry detergent fragrances because it is one of the few chemicals that can leave a small residual fragrance on cloth after washing and can cover up odors from the detergent itself as well as from dirt in the wash solution. Synthetic musks, including HHCB, also may be used to mask chemical odors and can be found in products labeled “unscented,” but do not seem to be added to products labeled “fragrance free” (U.S. EPA, 2012c).

E.1.3.1 Air Care Products

2012 and 2016 CDR information indicated the use of HHCB in air care products (U.S. EPA, 2019d). Product SDS data and public comments identified HHCB in continuous action air fresheners such as candles, fragrance oils, scented bathroom clips, and air freshener plug-ins (Fragrance Creators Association, 2019) (U.S. EPA 2019f). HHCB is also found in motor vehicle air fresheners and instant action air fresheners such as aerosol sprays, pet deodorizer sprays, and car deodorizer sprays (U.S. EPA 2019f).

Commercial uses of these items may include the use of air care products for professional cleaning, odor reduction near professional drivers, and deodorizing during car detailing.

E.1.3.2 Cleaning and Furnishing Care Products

2012 and 2016 CDR information indicated the use of HHCB in cleaning and furnishing care products (U.S. EPA, 2019d). Specifically, product SDS data indicated HHCB is present in both liquid and spray bathroom cleaners and multi-surface cleaners (U.S. EPA 2019f). Workers who use industrial or bulk cleaners everyday may have occupational exposure to HHCB. Staff in commercial kitchens or bathrooms, hotels, and any professional cleaning business may be included in the affected workers.

E.1.3.3 Laundry and Dishwashing Products

Laundry detergent and fabric softeners were identified as containing HHCB based on product SDS information and public comments (Earthjustice, 2019)(U.S. EPA 2019f). These products may present occupational exposure in commercial laundromats and businesses that provide linen services, such as hotels or resorts.

E.1.3.4 Plastic and Rubber Products Not Covered Elsewhere

EPA identified disposable floor mats and odor eliminating discs containing HHCB (U.S. EPA 2019f). EPA also received a CBI claim regarding other plastic and rubber products containing HHCB.

E.1.3.5 Paper Products

EPA did not identify specific paper products containing HHCB at this time.

E.1.3.6 Other Uses: laboratory Chemical

A Safety Data Sheet for HHCB (<= 100% percent purity) indicates the recommended use as a laboratory chemical. However, specific laboratory use activities are unknown (Sigma-Aldrich, 2019).

E.1.3.7 Disposal

Each of the conditions of use of HHCB may generate waste streams of the chemical that are collected and transported to third-party sites for disposal, treatment, or recycling. Disposal of products and articles containing HHCB will also be considered (e.g., paper products, plastics, etc.). Industrial sites that treat or dispose onsite wastes that they themselves generate will be assessed for each condition of use. Similarly, point source discharges of HHCB to surface water will be assessed for each condition of use (point source discharges are exempt as solid wastes under RCRA). Wastes of HHCB 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: HHCB may be contained in wastewater discharged to POTW or other, non-public treatment works for treatment. Industrial wastewater containing HHCB 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 HHCB will be evaluated for each condition of use.

- Solid Wastes: Because of its properties, HHCB also partitions to solid phases in the wastewater treatment process (sludge), and with further treatment can become concentrated in biosolids. This organic carbon-rich material is disposed of by landfill or incineration or may be utilized for land application to enhance physical soil properties as well as plant yield.

- 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.

HHCB is a not a listed or characterized as a hazardous waste under RCRA; therefore, HHCB is not subject to RCRA subtitle C regulation. Discarded, unused pure and commercial grades of HHCB are collected and disposed of by municipal waste landfills and incinerators.

E.2 Sources Containing Potentially Relevant Data or Information

There are currently no exposure limits for HHCB established by OSHA, NIOSH, or American Conference of Governmental Industrial Hygienists (ACGIH). Because of this, there have been no industrial health studies conducted by any of these organizations for possible worker exposure to HHCB.

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

Table_Apx F-1. Worker and ONU 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/ Import	Domestic Manufacture/ Import	Manufacture of HHCB	Liquid Contact	Dermal	Workers	Yes	HHCB is manufactured as a liquid; therefore, EPA plans to evaluate dermal exposures for workers
				Solid Contact	Dermal	Workers	No	HHCB is manufactured as a liquid; therefore, exposures to solids for workers are not expected
				Vapor	Inhalation	Workers, ONU	Yes	Due to its volatility (VP = 0.000545 mmHg) at room temperature, EPA plans to evaluate inhalation exposure
				Mist	Inhalation/ Dermal	Workers, ONU	No	Mist generation is not expected during Manufacturing
				Dust	Inhalation/ Dermal	Workers, ONU	No	HHCB is manufactured as a liquid; therefore, exposures to dust for workers are not expected
				Liquid/Solid Contact	Dermal	ONU	No	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	The potential for dermal exposure to workers exists during import, but exposure will only occur in the event the imported material is repackaged
				Solid Contact	Dermal	Workers	Yes	HHCB could be imported as a solid; therefore, dermal exposures for workers are expected
				Vapor	Inhalation	Workers, ONU	Yes	Due to its volatility (VP = 0.000545 mmHg) at room temperature, EPA plans to evaluate inhalation pathway
				Mist	Inhalation/ Dermal	Workers, ONU	No	Mist generation is not expected during import or repackaging
				Dust	Inhalation/ Dermal	Workers, ONU	Yes	HHCB could be imported as a solid; therefore, exposures to dust for workers are expected
				Liquid/Solid Contact	Dermal	ONU	No	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
Processing	Repackaging	Odor agent (in all other chemical product and preparation manufacturing)	Repackaging into large and small containers	Liquid Contact	Dermal	Workers	Yes	The potential for dermal exposure to workers exists during import, but exposure will only occur in the event the imported material is repackaged
				Solid Contact	Dermal	Workers	Yes	HHCB could be imported as a solid; therefore, dermal exposures for workers are expected
				Vapor	Inhalation	Workers, ONU	Yes	Due to its volatility (VP = 0.000545 mmHg) at room temperature, EPA plans to evaluate inhalation exposure
				Mist	Inhalation/ Dermal	Workers, ONU	No	Mist generation is not expected during import or repackaging
				Dust	Inhalation/ Dermal	Workers, ONU	Yes	HHCB could be imported as a solid; therefore, exposures to dust for workers are expected
				Liquid/Solid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
	Incorporation into formulation, mixture or reaction product	Odor agent (in all other chemical product and preparation manufacturing; miscellaneous manufacturing; soap, cleaning compound, and toilet preparation manufacturing; other: fragrance mixtures and fragrance raw material)	Formulation of soap, cleaning compound, and toilet preparation manufacturing and fragrance mixtures	Liquid Contact	Dermal	Workers	Yes	The potential for dermal exposure to workers exists during formulation
				Solid Contact	Dermal	Workers	Yes	HHCB may be incorporated into a solid or powder; therefore, exposures to solids for workers are expected
				Vapor	Inhalation	Workers, ONU	Yes	Due to its volatility (VP = 0.000545 mmHg) at room temperature, EPA plans to evaluate inhalation pathway
				Mist	Inhalation/ Dermal	Workers, ONU	No	Mist generation not expected during formulation
				Dust	Inhalation/ Dermal	Workers, ONU	Yes	HHCB may be incorporated into a solid or powder; therefore, exposures to dust for workers are expected
				Liquid/Solid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical
	Incorporation into Article	Odor agent (in plastics material and resin manufacturing)	Plastics material and resin manufacturing	Liquid Contact	Dermal	Workers	Yes	The potential for dermal exposure to workers exists during incorporation into articles
				Solid Contact	Dermal	Workers	Yes	HHCB may be incorporated into a solid or powder; therefore, exposures to solids for workers are expected

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
				Vapor	Inhalation	Workers, ONU	Yes	Due to its volatility (VP = 0.000545 mmHg) at room temperature, EPA plans to evaluate inhalation pathway
				Mist	Inhalation/ Dermal	Workers, ONU	No	Mist generation not expected during incorporation into articles
				Dust	Inhalation/ Dermal	Workers, ONU	Yes	HHCB may be incorporated into a solid or powder; therefore, exposures to dust for workers are expected
				Liquid/Solid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical
	Recycling	Recycling	Recycling of HHCB	Liquid Contact	Dermal	Workers	Yes	HHCB is expected to be recycled as a liquid; therefore, dermal exposures for workers are expected
				Solid Contact	Dermal	Workers	No	HHCB is expected to be recycled as a liquid; therefore, exposures to solids for workers are not expected
				Vapor	Inhalation	Workers, ONU	Yes	Due to its volatility (VP = 0.000545 mmHg) at room temperature, EPA plans to evaluate inhalation pathway
				Mist	Inhalation/ Dermal	Workers, ONU	No	Mist generation is not expected during recycling
				Dust	Inhalation/ Dermal	Workers, ONU	No	HHCB is expected to be recycled as a liquid; therefore, exposures to dust for workers are not expected
				Liquid/Solid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical
Industrial / commercial	Air Care Products	Instant Action Air Fresheners	Aerosol application of scented air freshener	Liquid Contact	Dermal	Workers	Yes	The potential for dermal exposure to workers exists during aerosol air freshener use
				Solid Contact	Dermal	Workers	No	HHCB is used as a liquid in aerosols; therefore, exposures to solids for workers are not expected
				Vapor	Inhalation	Workers, ONU	No	Due to the low volatility (VP = 0.000545 mmHg) of HHCB, inhalation exposures from aerosol applications are expected to be dominated by the aerosol mist, such that exposures to vapors evaporating from the mist droplets does not

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
								contribute significantly to HHCB inhalation exposures for this use
				Mist	Inhalation/ Dermal	Workers, ONU	Yes	Mist generation is expected during aerosol application
				Dust	Inhalation/ Dermal	Workers, ONU	No	HHCB is used as a liquid in aerosols; therefore, exposures to dusts are not expected
				Liquid/Solid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical
		Air fresheners for motor vehicles	Use of solid air freshener	Liquid Contact	Dermal	Workers	Yes	Motor vehicle air fresheners are expected to have liquid residue on a solid, paper substrate
				Solid Contact	Dermal	Workers	No	Although motor vehicle air fresheners are solids, the substrate is a single, continuous solid with liquid fragrance and therefore, exposures to solids for workers are not expected
				Vapor	Inhalation	Workers, ONU	Yes	Due to its volatility (VP = 0.000545 mmHg) at room temperature, EPA plans to evaluate inhalation pathway
				Mist	Inhalation/ Dermal	Workers, ONU	No	Mist generation is not expected during this use
				Dust	Inhalation/ Dermal	Workers, ONU	No	Solid dust exposure is not expected as the product is one single, continuous piece. No powders are expected.
				Liquid/Solid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical
		Continuous Action Air Fresheners Aroma chemicals	Use of solid/gel room air freshener and fragrance oils	Liquid Contact	Dermal	Workers	Yes	HHCB continuous action air fresheners are typically a solid substrate with a liquid fragrance or a thick gel fragrance mixture; therefore, liquid dermal exposures for workers are expected
				Solid Contact	Dermal	Workers	No	Although some continuous air fresheners are solids, the substrate is a single, continuous solid with liquid/gel fragrance and therefore, exposures to solids for workers are not expected

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
				Vapor	Inhalation	Workers, ONU	Yes	Due to its volatility (VP = 0.000545 mmHg) at room temperature, EPA plans to evaluate inhalation pathway
				Mist	Inhalation/ Dermal	Workers, ONU	No	Mist generation is not expected during this use
				Dust	Inhalation/ Dermal	Workers, ONU	No	HHCB continuous action air fresheners do not contain dusts; therefore, exposures to dust for workers are not expected
				Liquid/Solid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical
			Use of scented candles	Liquid Contact	Dermal	Workers	No	Candles are solids, therefore, exposures to liquids for workers is not expected
				Solid Contact	Dermal	Workers	Yes	Candles are solids, therefore, exposures to solids for workers is expected
				Vapor	Inhalation	Workers, ONU	Yes	Due to its volatility (VP = 0.000545 mmHg) at room temperature, EPA plans to evaluate inhalation pathway
				Mist	Inhalation/ Dermal	Workers, ONU	No	Mist generation is not expected during this use
				Dust	Inhalation/ Dermal	Workers, ONU	No	HHCB continuous action air fresheners do not contain dusts; therefore, exposures to dust for workers are not expected
				Liquid/Solid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical
	Cleaning and Furnishing Care Products	Cleaning products, including all-purpose liquid cleaner and bathroom cleaners (liquid,	Spray application of cleaners and deodorizers (such as multi-surface cleaners and	Liquid Contact	Dermal	Workers	Yes	HHCB is used as a liquid in sprays; therefore, dermal exposures for workers are expected
				Solid Contact	Dermal	Workers	No	HHCB is used as a liquid in sprays; therefore, exposures to solids for workers are not expected
				Vapor	Inhalation	Workers, ONU	Yes	Due to its volatility (VP = 0.000545 mmHg) at room temperature, EPA plans to evaluate inhalation pathway

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
		aerosol, foam, spray, and powder cleaners)	bathroom cleaners)	Mist	Inhalation/ Dermal	Workers, ONU	No	Mist generation is not expected during this use
				Dust	Inhalation/ Dermal	Workers, ONU	No	HHCB is used as a liquid in sprays; therefore, exposures to dusts are not expected
				Liquid/Solid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical
			Application of liquid cleaners (such as floor cleaners and hard-surface cleaners)	Liquid Contact	Dermal	Workers	Yes	HHCB is used as a liquid; therefore, dermal exposures for workers are expected
				Solid Contact	Dermal	Workers	No	HHCB is used as a liquid; therefore, exposures to solids for workers are not expected
				Vapor	Inhalation	Workers, ONU	Yes	Due to its volatility (VP = 0.000545 mmHg) at room temperature, EPA plans to evaluate inhalation pathway
				Mist	Inhalation/ Dermal	Workers, ONU	No	Mist generation is not expected during this use
				Dust	Inhalation/ Dermal	Workers, ONU	No	HHCB is used as a liquid; therefore, exposures to dust for workers are not expected
				Liquid/Solid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical
			Application of aerosol cleaning product	Liquid Contact	Dermal	Workers	Yes	The potential for dermal exposure to workers exists during aerosol cleaner use
				Solid Contact	Dermal	Workers	No	HHCB is used as a liquid in aerosols; therefore, exposures to solids for workers are not expected
				Vapor	Inhalation	Workers, ONU	No	Due to the low volatility (VP = 0.000545 mmHg) of HHCB, inhalation exposures from aerosol applications are expected to be dominated by the aerosol mist, such that exposures to vapors evaporating from the mist droplets does not contribute significantly to HHCB inhalation exposures for this use
				Mist	Inhalation/ Dermal	Workers, ONU	Yes	Mist generation is expected during aerosol application
				Dust	Inhalation/ Dermal	Workers, ONU	No	HHCB is used as a liquid in aerosols; therefore, exposures to dusts are not expected

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
				Liquid/Solid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical
			Application of powder cleaners and deodorizers (such as hard surface cleaners and carpet and room deodorizers)	Liquid Contact	Dermal	Workers	No	HHCB cleaning powders are solids; therefore, dermal exposures for workers are not expected
				Solid Contact	Dermal	Workers	Yes	HHCB cleaning powders are solids; therefore, exposures to solids for workers are expected
				Vapor	Inhalation	Workers, ONU	No	EPA plans to evaluate inhalation pathway through dust exposure
				Mist	Inhalation/ Dermal	Workers, ONU	No	Mist generation is not expected during this use
				Dust	Inhalation/ Dermal	Workers, ONU	Yes	Solid dust exposure is expected as the products are powders
				Liquid/Solid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical
	Laundry and Dishwashing Products	Laundry products, including liquid laundry detergent and fabric softener	Application of liquid laundry detergent, fabric softener	Liquid Contact	Dermal	Workers	Yes	HHCB is used as a liquid; therefore, exposures to solids for workers are not expected
				Solid Contact	Dermal	Workers	No	HHCB is used as a liquid; therefore, exposures to solids for workers are not expected
				Vapor	Inhalation	Workers, ONU	Yes	Due to its volatility (VP = 0.000545 mmHg) at room temperature, EPA plans to evaluate inhalation pathway
				Mist	Inhalation/ Dermal	Workers, ONU	No	Mist generation is not expected during this use
				Dust	Inhalation/ Dermal	Workers, ONU	No	HHCB is used as a liquid; therefore, exposures to dust for workers are not expected
				Liquid/Solid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical
			Application of solid laundry detergent	Liquid Contact	Dermal	Workers	No	HHCB washing powders are solids; therefore, dermal exposures for workers are not expected
				Solid Contact	Dermal	Workers	Yes	HHCB washing powders are solids; therefore, exposures to solids for workers are expected

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
				Vapor	Inhalation	Workers, ONU	No	EPA plans to evaluate inhalation pathway through dust exposure
				Mist	Inhalation/ Dermal	Workers, ONU	No	Mist generation is not expected during this use
				Dust	Inhalation/ Dermal	Workers, ONU	Yes	Solid dust exposure is expected as the products are powders
				Liquid/Solid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical
	Plastic and Rubber Products	Plastic and rubber products	Interaction with plastic and rubber packaging	Liquid Contact	Dermal	Workers	No	HHCB plastic and rubber packagings are solids; therefore, dermal exposures for workers are not expected
				Solid Contact	Dermal	Workers	Yes	HHCB plastic and rubber packagings are solids; therefore, exposures to solids for workers are expected
				Vapor	Inhalation	Workers, ONU	No	EPA plans to evaluate inhalation pathway through dust exposure
				Mist	Inhalation/ Dermal	Workers, ONU	No	Mist generation is not expected during this use
				Dust	Inhalation/ Dermal	Workers, ONU	No	No dust exposure is expected as the HHCB in the product will be entrained in the packaging and not handled in a way that will result in dust generation (e.g., it will not be cut or sawed)
				Liquid/Solid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical
	Other Uses	Laboratory Chemicals	Worker handling HHCB	Liquid Contact	Dermal	Workers	Yes	HHCB is used as a liquid; therefore, exposures to solids for workers are not expected
				Solid Contact	Dermal	Workers	No	HHCB is used as a liquid; therefore, exposures to solids for workers are not expected
				Vapor	Inhalation	Workers, ONU	Yes	Due to its volatility (VP = 0.000545 mmHg) at room temperature, EPA plans to evaluate inhalation pathway
				Mist	Inhalation/ Dermal	Workers, ONU	No	Mist generation is not expected during this use

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
				Dust	Inhalation/ Dermal	Workers, ONU	No	HHCB is used as a liquid; therefore, exposures to dust for workers are not expected
				Liquid/Solid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical
Disposal	Waste Handling, Treatment and Disposal	Disposal of HHCB wastes	Worker handling of wastes	Liquid Contact	Dermal	Workers	Yes	The potential for dermal exposure to workers exists during this use as both liquid and solid formulations may be disposed
				Solid Contact	Dermal	Workers	Yes	The potential for dermal exposure to workers exists during this use as both liquid and solid formulations may be disposed
				Vapor	Inhalation	Workers, ONU	Yes	Due to its volatility (VP = 0.000545 mmHg) at room temperature, EPA plans to evaluate inhalation pathway
				Mist	Inhalation/ Dermal	Workers, ONU	No	Mist generation is not expected during this use
				Dust	Inhalation/ Dermal	Workers	Yes	HHCB solid waste may create solid dust during disposal
				Dust	Inhalation/ Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical
				Liquid/Solid Contact	Dermal	ONU	No	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	Paper Products	Paper Products	Direct contact through application or use of products using HHCB-based products	Liquid (HHCB fragrance oil)	Dermal	Consumers	Yes	Dermal exposure to consumers exists during use as a liquid, and is in scope
			Long-term emission/mass-transfer	Vapor	Inhalation	Consumers and Bystanders	Yes	Due to its volatility (VP = 0.000545 mmHg) at room temperature, inhalation pathway is in scope
Consumer Use	Plastic and Rubber Products	Plastic and Rubber Products	Direct contact through application or use of products using HHCB-based products	Liquid (HHCB fragrance oil)	Dermal	Consumers	Yes	Dermal exposure to consumers exists during use as a liquid, and is in scope
			Long-term emission/mass-transfer	Vapor	Inhalation	Consumers and Bystanders	Yes	Due to its volatility (VP = 0.000545 mmHg) at room temperature, inhalation pathway is in scope
Consumer Use	Air Care Products	Air Care Products	Direct contact through application or use of products using HHCB-based products/ Long-term emission/mass-transfer	Vapor/Mist	Inhalation	Consumers and Bystanders	Yes	Vapor, and mist generation is expected during aerosol application. Due to its volatility (VP = 0.000545 mmHg) at room temperature, inhalation of vapor and mist pathway is in scope
					Dermal	Consumers	Yes	Dermal exposure to consumers exists during use as a spray, and is in scope

Life Cycle Stage	Category	Subcategory	Release from Source	Exposure Pathway	Route	Receptor	Plans to Evaluate	Rationale
Consumer Use	Cleaning and Furnishing Care Products	Cleaning and Furnishing Care Products	Direct contact through application or use of products using HHCB-based products	Liquid	Dermal	Consumers	Yes	Dermal exposure to consumers exists during use as a liquid, and is in scope
			Direct contact through application or use of products using HHCB-based products/ Long-term emission/mass-transfer, Direct Transfer to Dust	Vapor/Mist	Inhalation	Consumers and Bystanders	Yes	Vapor, and mist generation is expected during aerosol application. Due to its volatility (VP = 0.000545 mmHg) at room temperature, inhalation of vapor and mist pathway is in scope
					Dermal	Consumers	Yes	Dermal exposure to consumers exists during use as a spray, and is in scope
				Dust	Inhalation	Consumers and Bystanders	Yes	Solid dust exposure pathway is expected as during use of powdered soaps containing HHCB, and is in scope
Consumer Use	Laundry and Dishwashing Products	Laundry and Dishwashing Products	Direct contact through application or use of products using HHCB-based products	Liquid	Dermal	Consumers	Yes	Dermal exposure to consumers exists during use as a liquid, and is in scope
			Direct contact through application or use of products using HHCB-based products/ Long-term emission/mass-transfer, Direct Transfer to Dust	Vapor/Mist	Inhalation	Consumers and Bystanders	Yes	Vapor, and mist generation is expected during aerosol application. Due to its volatility (VP = 0.000545 mmHg) at room temperature, inhalation of vapor and mist pathway is in scope
					Dermal	Consumers	Yes	Dermal exposure to consumers exists during use as a spray, and is in scope

Life Cycle Stage	Category	Subcategory	Release from Source	Exposure Pathway	Route	Receptor	Plans to Evaluate	Rationale
				Dust	Inhalation	Consumers and Bystanders	Yes	Solid dust exposure pathway is expected as during use of powdered soaps containing HHCB, and is in scope
Consumer Use	Other	Laboratory Chemicals	Direct contact through application or use of products using HHCB-based products	Liquid	Dermal	Consumers	Yes	Dermal exposure to consumers exists during use as a liquid, and is in scope
			Direct contact through application or use of products using HHCB-based products/ Long-term emission/mass-transfer	Vapor/Mist	Inhalation	Consumers and Bystanders	Yes	Vapor, and mist generation is expected during aerosol application. Due to its volatility (VP = 0.000545 mmHg) at room temperature, inhalation of vapor and mist pathway is in scope
					Dermal	Consumers	Yes	Dermal exposure to consumers exists during use as a spray, and is in scope

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

Table_Apx H-1. General Population and Environmental Exposure Conceptual Model Supporting Table

Life Cycle Stage	Category	Release	Exposure Pathway / Media	Exposure Routes	Receptor / Population	Plans to Evaluate	Rationale
All	Emissions to Air	Emissions to Air	Near facility ambient air concentrations	Inhalation	General Population	Yes	HHCB deposition to nearby bodies of water and soil are expected exposure pathways, not covered under other EPA regulations, and, therefore in scope.
			Indirect deposition to nearby bodies of water and soil catchments	Oral Dermal	General Population	Yes	
				TBD	Aquatic and Terrestrial Receptors	Yes	
	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	Release of HHCB into surface water and indirect partitioning to sediment exposure pathways to aquatic and terrestrial receptors will be analyzed
				Oral Dermal	General Population	Yes	Release of HHCB into surface water and indirect partitioning to sediment and bioaccumulation exposure pathways to the general population will be analyzed.
			Drinking Water via Surface or Ground Water	Oral Dermal and Inhalation (e.g. showering)	General Population	Yes	Release of HHCB 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 will analyze the pathway from biosolids to the general population and terrestrial species.
				TBD	Terrestrial receptors	Yes	

Life Cycle Stage	Category	Release	Exposure Pathway / Media	Exposure Routes	Receptor / Population	Plans to Evaluate	Rationale
Disposal	Solid and Liquid Wastes	Municipal landfill and other land disposal	Leachate to soil, ground water and/or mitigation to surface water	Oral Dermal	General Population	Yes	EPA will analyze the pathway from municipal landfills and other land disposal to the general population, aquatic and terrestrial receptors.
				TBD	Aquatic and Terrestrial Receptors		