



## ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2018-0430; EPA-HQ-OPPT-2018-0459; FRL-13309-01-OCSPPT]

### **1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta [ $\gamma$ ]-2-benzopyran (HHCB) and Phthalic Anhydride Draft Risk Evaluations under the Toxic Substances Control Act (TSCA); Notice of Availability and Request for Comment**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** The Environmental Protection Agency (EPA or Agency) is announcing the availability of and seeking public comment on draft risk evaluations under the Toxic Substances Control Act (TSCA) for 1,3,4,6,7,8-hexahydro-4,6,6,7,8,8-hexamethylcyclopenta [ $\gamma$ ]-2-benzopyran (HHCB) and phthalic anhydride. The purpose of risk evaluations under TSCA is to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use (COUs), including unreasonable risk to potentially exposed or susceptible subpopulations identified as relevant to the risk evaluation by EPA, and without consideration of costs or non-risk factors. EPA is seeking comment on the draft risk evaluations for HHCB and phthalic anhydride.

**DATES:** Comments must be received on or before [INSERT DATE 60 DAYS FROM DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

#### **ADDRESSES:**

To submit comments on the HHCB draft risk evaluation, submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2018-0430, online at <https://www.regulations.gov> by.

To submit comments on the phthalic anhydride draft risk evaluation, submit your comments, identified by docket ID number EPA-HQ-OPPT-2018-0459, online at <https://www.regulations.gov>.

Follow the online instructions for submitting comments. Do not electronically submit any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Members of the public should also be aware that personal information included in any written comments may be posted on the internet at <https://www.regulations.gov>. Additional information on commenting or visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

#### **FOR FURTHER INFORMATION CONTACT:**

*For technical information on HHCB:* Jeffery Putt, Existing Chemical Risk Management Division (7404M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-3703; email address: [putt.jeffery@epa.gov](mailto:putt.jeffery@epa.gov).

*For technical information on phthalic anhydride:* Wyn Zenni, Existing Chemical Risk Management Division (7404M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-6294; email address: [zenni.wyn@epa.gov](mailto:zenni.wyn@epa.gov).

*For general information:* The TSCA-Hotline, Goodwill of the Finger Lakes, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: [TSCA-Hotline@epa.gov](mailto:TSCA-Hotline@epa.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Executive Summary**

###### *A. Does this action apply to me?*

This action is directed to the public in general and may be of particular interest to those involved in the manufacture (defined under TSCA section 3(9) to include import), processing, distribution, use, and disposal of HHCB and/or phthalic anhydride, related industry trade organizations, non-governmental organizations with an interest in human and environmental

health, State and local governments, Tribal Nations, and/or those interested in the assessment of risks involving chemical substances and mixtures regulated under TSCA. As such, the Agency has not attempted to describe all the specific entities that this action might apply to. If you need help determining applicability, consult the relevant technical contact listed under **FOR**

**FURTHER INFORMATION CONTACT.**

*B. What is the Agency's authority for taking this action?*

The Agency is conducting these risk evaluations under TSCA section 6, (15 U.S.C. 2605) which requires that EPA conduct risk evaluations on chemical substances and identifies the minimum components EPA must include in the risk evaluations. Each risk evaluation must be conducted consistent with the best available science, be based on the weight of the scientific evidence, and consider reasonably available information, and not consider costs or non-risk factors (15 U.S.C. 2625(h), (i), and (k)). See also the implementing procedural regulations at 40 CFR part 702.

*C. What action is the Agency taking?*

EPA is announcing the availability of and seeking public comment on draft risk evaluations under TSCA for HHCB and phthalic anhydride. The purpose of risk evaluations under TSCA is to determine whether a chemical substance presents an unreasonable risk of injury to human health or the environment under the conditions of use, including unreasonable risk to potentially exposed or susceptible subpopulations identified as relevant to the risk evaluation by EPA, and without consideration of costs or non-risk factors. EPA has used the best available science to prepare these draft risk evaluations and, based on the weight of scientific evidence, to preliminarily determine that HHCB does not pose unreasonable risk to human health or the environment and to preliminarily determine that phthalic anhydride does pose unreasonable risk to human health driven primarily by certain COUs analyzed in the draft risk evaluations.

*D. What should I consider as I submit my comments to EPA?*

1. *Submitting CBI.* Do not submit CBI or other sensitive information to EPA through <https://www.regulations.gov> or email. To include information in your comment that you consider to be CBI or otherwise protected, please contact the person listed under **FOR FURTHER INFORMATION CONTACT** to obtain special instructions before submitting that information.

2. *Tips for preparing comments.* When preparing and submitting your comments, see the commenting tips at <https://www.epa.gov/dockets/commenting-epa-dockets>.

## **II. Draft Risk Evaluation for HHCB**

### *A. What is HHCB?*

HHCB is primarily used as a synthetic musk compound found widely in fragrances. HHCB is utilized in household products such as detergents, cleaners, and air fresheners. HHCB is also a key ingredient in non-TSCA uses including perfumes, cosmetics, and personal care products due to its long-lasting scent properties. Workers may be exposed to HHCB through dust, mist, or vapor when making or using these products. Consumers may be exposed to HHCB through dust, mist, or vapor during intended product use (e.g., cleaning a counter, placing an air freshener in a bathroom or small room, or doing laundry). Environmental releases occur primarily when fragrance products are disposed of down the drain, leading to HHCB entering wastewater and, after treatment, being discharged in effluent from Publicly Owned Treatment Works (POTWs). HHCB may also enter wastewater through transfers of manufacturing wastes to POTWs.

### *B. The Risk Evaluation of HHCB*

In December 2019, EPA announced its designation of HHCB (Docket ID: EPA-HQ-OPPT-2018-0430) as a high-priority substance for risk evaluation under TSCA (84 FR 71924 (FRL-10003-15)). In April 2020, EPA published and sought public comment on the draft scope of the HHCB risk evaluation (85 FR 19941 (FRL-10007-11-OCSPP)), and, after considering public comments, issued the final scope on September 4, 2020 (85 FR 55281 (FRL-10013-90-OCSPP)).

### *C. Request for Comment*

EPA seeks feedback on the assessment of risk presented in the draft risk evaluation for HHCB, a copy of which is available in the docket, and encourages all potentially interested parties, including individuals, governmental and non-governmental organizations, non-profit organizations, academic institutions, research institutions, and private sector entities to comment on the draft risk evaluation. To the extent possible, the Agency asks commenters to please cite any public data related to or that support comments provided, and to the extent permissible, describe any supporting data that is not publicly available.

EPA welcomes specific input on each section of the draft risk evaluation, and is particularly interested in:

- Selection and characterization of the bioaccumulation value, implementation of additional modeling refinements, and resulting conclusions;
- Use of screening-level exposure approaches for occupational and consumer assessments;
- Human health hazard conclusions (no acute toxicity and no dermal toxicity at human-relevant doses), and characterization of uncertainties associated with the lack of cancer bioassays, including the application of elements of the Rethinking Carcinogenicity Assessment for Agrochemicals Project.

### *D. Next Steps*

After consideration of comments received from the public on the draft risk evaluation and input from the Scientific Advisory Committee on Chemicals (SACC) peer review, EPA will issue a final risk evaluation for HHCB. Under TSCA section 6, EPA must use the final risk evaluation as a basis to determine, based on the weight of scientific evidence, whether or not the chemical presents an unreasonable risk to human health or the environment under the chemical's COUs. This includes risks to subpopulations who may be at greater risks than the general population, such as children and workers. TSCA prohibits EPA from considering non-risk

factors (e.g., costs/benefits) during risk evaluation.

For more information about the TSCA risk evaluation process for existing chemicals, go to <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca>.

### **III. Draft Risk Evaluation for Phthalic Anhydride**

#### *A. What is Phthalic Anhydride?*

Phthalic anhydride is a white flaky solid primarily used as a chemical intermediate in the manufacture of various products such as plasticizers and resins. Phthalic anhydride is also found as an ingredient in oil-based consumer products such as paints and coatings and as a hardener in adhesives and sealants. Workers may be exposed to phthalic anhydride through dermal contact or inhalation of dusts or mist generated from spray applications when making or using these products. Consumers may be exposed to phthalic anhydride through dermal contact or through mist generated from spray applications during intended product use (e.g., applying spray paint). Phthalic anhydride released to the environment is expected to hydrolyze to ortho (*o*-)phthalic acid upon contact with water or atmospheric moisture. *O*-phthalic acid enters wastewater and, after treatment, is discharged in effluent from POTWs. Phthalic anhydride may also enter wastewater through transfers of manufacturing wastes to POTWs, but will quickly hydrolyze to *o*-phthalic acid. *O*-phthalic acid is also released through stack and fugitive emissions, which can subsequently undergo air-to-soil deposition. However, *o*-phthalic acid is not expected to sorb to soils.

#### *B. The Risk Evaluation of Phthalic Anhydride*

In December 2019, EPA announced its designation of phthalic anhydride (Docket ID: EPA-HQ-OPPT-2018-0459) as a high priority substance for risk evaluation under TSCA (84 FR 71924 (FRL-10003-15)). In April 2020, EPA published and sought public comment on the draft scope of the phthalic anhydride risk evaluation (85 FR 22733 (FRL-10008-05-OCSP)), and, after considering public comments, issued the final scope on September 4, 2020 (85 FR 55281 (FRL-10013-90-OCSP)).

### *C. Request for Comment*

EPA seeks feedback on the assessment of risk presented in the draft risk evaluation for phthalic anhydride, a copy of which is available in the docket, and encourages all potentially interested parties, including individuals, governmental and non-governmental organizations, non-profit organizations, academic institutions, research institutions, and private sector entities to comment on the draft risk evaluation. To the extent possible, the Agency asks commenters to please cite any public data related to or that support comments provided, and to the extent permissible, describe any supporting data that is not publicly available.

EPA welcomes specific input on each section of the draft risk evaluation, particularly input on the following:

- Workplace exposure information including air monitoring data including task-based exposure durations, air monitoring methods (including uncertainties in existing methods such as OSHA 90), engineering controls, personal protective equipment practices and usage;
- EPA's approach to estimate dermal exposures from spray products for consumers and workers;
- EPA's approach to estimate dermal exposure from contact with solids for occupational exposure scenarios using the study by Lansink (1996), including additional studies or information that may inform dermal loading for contact with solids;
- EPA's approach to determine dermal loadings for products using the U.S. EPA (1992b) study wipe experiment, which incorporates wiping off the excess product with a saturated cloth after application as advised in the products' use instructions (e.g., Adhesives and sealants);
- Product-specific phthalic anhydride concentration ranges and use patterns, including updated publicly available Safety Data Sheets related to the use of phthalic anhydride in products considered under COUs in this assessment (e.g., paint and coating products);
- EPA's approach to assess inhalation exposures for acute exposure durations of phthalic anhydride from consumer COUs using an 8-hour time weighted average (TWA);

- EPA's approach to assess inhalation exposures for acute exposure durations of phthalic anhydride using an 8-hour TWA rather than a short-term inhalation value (STEV) based on assumed task durations;
- EPA's derivation of a STEV and occupational exposure values (OEV) and the scientific robustness of deriving OEVs and STEVs based on the dataset and the endpoints (i.e., respiratory sensitization);
- Newly available or recently published hazard/toxicology studies relevant to phthalic anhydride;
- The selection of environmental hazard thresholds based on a relatively small hazard datasets;
- The strengths and uncertainties of the methodology and data used to derive acute and chronic concentration of concern for aquatic thresholds and the strength of the data to support the quantitative aquatic assessment;
- The following weight of evidence conclusions from the human health hazard assessment: 1) phthalic anhydride and *o*-phthalic acid have low systemic toxicity via the oral exposure route; 2) phthalic anhydride is a skin sensitizer; and 3) phthalic anhydride is a respiratory sensitizer;
- The underlying modeling and science used to inform the inhalation toxicokinetics of phthalic anhydride (See Appendix F in the Draft Human Health Hazard Assessment).

#### *D. Next Steps*

After consideration of comments received from the public on the draft risk evaluation and input from the SACC peer review, EPA will issue a final risk evaluation for phthalic anhydride. Under TSCA section 6, EPA must determine in the final risk evaluation, based on the weight of scientific evidence, whether or not the chemical presents an unreasonable risk to human health or the environment under the chemical's conditions of use. This includes consideration of risks to potentially exposed susceptible subpopulations who may be at greater risks than the general

population, such as children and workers. TSCA prohibits EPA from considering non-risk factors (e.g., costs/benefits) during risk evaluation.

For more information about the TSCA risk evaluation process for existing chemicals, go to <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca>.

(Authority: 15 U.S.C. 2601 *et seq.*)

Dated: April 10, 2026.

**Douglas M. Troutman,**

*Assistant Administrator, Office of Chemical Safety and Pollution Prevention*

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