



ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2018-0501 and EPA-HQ-OPPT-2018-0434; FRL-12897-01-OCSP]

Butyl Benzyl Phthalate (BBP); Diisobutyl Phthalate (DIBP); 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 the draft risk evaluations under the Toxic Substances Control Act (TSCA) for Butyl Benzyl Phthalate (BBP) (CASRN 85-68-7) and Diisobutyl Phthalate (DIBP) (CASRN 84-69-5). 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, 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 used the best available science to prepare this draft risk evaluation and to preliminarily determine, based on the weight of scientific evidence, that BBP and DIBP pose unreasonable risk to health and the environment driven primarily by certain conditions of use analyzed in the draft risk evaluations.

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

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2018-0501 and EPA-HQ-OPPT-2018-0434, online at <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting and 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 BBP: Brianne Raccor, Existing Chemicals Risk Management Division (7404M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460-0001; telephone number: (202) 564-0303; email address: raccor.brianne@epa.gov.

For technical information on DIBP: Robert Landolfi, Existing Chemicals Risk Management Division (7404M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460-0001; telephone number: (202) 343-9161; email address: landolfi.robert@epa.gov.

For general information: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: 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 BBP and DIBP, 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 technical contact listed under **FOR FURTHER INFORMATION CONTACT**.

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

The Agency is conducting this risk evaluation 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 these draft risk evaluations conducted under TSCA for BBP and DIBP. 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, 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 BBP and DIBP pose unreasonable risk to health and the environment driven primarily by certain conditions of use analyzed in the draft evaluations.

D. What should I consider as I prepare my comments?

1. *Submitting CBI.* Do not submit CBI to EPA through <https://www.regulations.gov> or email. If you wish to include CBI in your comment, please follow the applicable instructions at <https://www.epa.gov/dockets/commenting-epa-dockets#rules> and clearly mark the information that you claim to be CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR parts 2 and 703, as applicable.

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

II. Background

A. What are BBP and DIBP?

BBP is a common chemical name for the chemical substance 1,2-Benzenedicarboxylic acid, 1-butyl 2-(phenylmethyl) ester (CASRN 85-68-7). DIBP is a common chemical name for the chemical substance 1,2-Benzenedicarboxylic acid, 1,2-bis(2-methylpropyl) ester (CASRN 84-69-5). BBP and DIBP are manufactured (including imported), processed, distributed, and disposed as part of industrial, commercial, and consumer conditions of use. BBP and DIBP are used as a plasticizer in polyvinyl chloride (PVC), as well as in adhesives, sealants, paints, coatings, rubbers, non-PVC plastics, and other applications. Between 2016 and 2019, production volume of BBP was reported to be between 1 to 20 million pounds, based on the 2020 TSCA Chemical Data Reporting (CDR) data. Between 2016 and 2020 the production volumes of DIBP reported to CDR were between 380,000 and 441,000 pounds.

B. Summary of Activities for the Risk Evaluations of BBP and DIBP

In December 2019, EPA announced its designation of BBP and DIBP as high priority substances for risk evaluation under TSCA (Ref. 1). In June 2020, EPA sought public comment on the draft scopes of the BBP and DIBP risk evaluations (Ref. 2), and, after considering public comments, issued the final scope in September 2020 (Ref. 3). These documents, other supporting documents, and public comments are in the docket for each chemical at <https://www.regulations.gov>. The human health hazard and environmental hazard technical support documents for BBP and DIBP are being peer reviewed by the Science Advisory Committee on Chemicals (SACC) in August 2025 and are included in the SACC peer review docket (Docket ID No. EPA-HQ-OPPT-2024-0551), along with other materials related to that peer review.

III. Request for Comment

EPA seeks feedback on the assessment of risk presented in the draft risk evaluations for BBP (Docket ID No. EPA-HQ-OPPT-2018-0501) and DIBP (Docket ID No. EPA-HQ-OPPT-

2018-0434), which are available in the chemical specific dockets as identified, 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 evaluations. 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 for each chemical, particularly input on the following:

- whether and how personal protective equipment and engineering controls are used during the manufacture, processing, and use of BBP and DIBP for each condition of use;
- information that could be used to refine upper-bound or screening level assumptions for BBP and DIBP, particularly for the COUs that may significantly contribute to unreasonable risk;
- information on environmental releases of BBP and DIBP, including media of environmental release (i.e., air, land, water, or incineration), facility-specific receiving water bodies, and the use of wastewater treatment;
- information on inhalation occupational exposure to BBP and DIBP under the COUs, including monitoring or personal breathing zone data and exposure to respirable particles (i.e., data on particle formation or size);
- input on the dermal occupational exposure scenarios used to assess BBP and DIBP, including the use of a flux-limited approach to estimate dermal absorption and any supporting data to inform assumptions regarding duration and surface area of exposure;
- information to inform the assessment of dermal and inhalation exposures to BBP and DIBP for occupational non users (ONUs);
- information on the extent to which spray applications of BBP and DIBP are used in industrial and commercial COUs and the volumes of BBP and DIBP that may be used;
- information to inform assumptions of inhalation of dust/particulate matter in the

consumer exposure assessment of BBP;

- approaches used to estimate chemical migration rate for ingestion via mouthing in the BBP and DIBP consumer exposure assessments;
 - selection of human health and environmental hazard endpoints used in the BBP and DIBP risk characterizations;
 - integration of its cumulative risk assessment approach within individual risk evaluations, derivation of relative potency factors (RPFs), and individual BBP and DIBP PODs;
- and
- any other information that may inform the assumptions used for exposure modeling used to assess the COUs for BBP and DIBP.

Two cross-phthalate TSDs were released to the public in May 2025 through the DBP (EPA-HQ-OPPT-2018-0503), DEHP (EPA-HQ-OPPT-2018-0433), and SACC (EPA-HQ-OPPT-2024-0551) dockets: *Draft Cancer Human Health Hazard Assessment for Di(2-ethylhexyl) Phthalate (DEHP), Dibutyl Phthalate (DBP), BBP, DIBP, and DCHP* and *Revised Draft Technical Support Document for the Cumulative Risk Analysis of DEHP, DBP, BBP, DIBP, DCHP, and DINP Under the Toxic Substances Control Act*. These TSDs have been added to the dockets for BBP (EPA-HQ-OPPT-2018-0501), DIBP (EPA-HQ-OPPT-2018-0434), and DCHP (EPA-HQ-OPPT-2018-0504).

IV. Next Steps

After consideration of comments received from the public and the SACC on the draft risk evaluations of BBP, DIBP, revised draft cumulative risk analysis, and other phthalates included in the peer review, EPA will issue final risk evaluations for BBP and DIBP.

Under TSCA section 6, EPA must determine in the final risk evaluations, based on the weight of scientific evidence, whether or not the chemicals present an unreasonable risk to 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.

If EPA determines in its final risk evaluation that a chemical presents an unreasonable risk to health or the environment, the chemical will move to risk management action under TSCA section 6(a) for the relevant conditions of use. EPA would be required to implement, via regulation, regulatory restrictions on the manufacture (including import), processing, distribution, use or disposal of the chemical to the extent necessary to eliminate the identified unreasonable risk. TSCA section 6 includes a range of risk management options that can be applied alone or in combination, including labeling, recordkeeping or notice requirements, actions to reduce human exposure or environmental release, or prohibition of the chemical or of certain uses. Like the prioritization and risk evaluation processes, there would be an opportunity for public comment on any proposed risk management actions.

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

V. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA. High-Priority Substance Designations Under the Toxic Substances Control Act (TSCA) and Initiation of Risk Evaluation on High-Priority Substances; Notice of Availability. *Federal Register*. 84 FR 71924, December 30, 2019 (FRL-10003-15).

2. EPA. Draft Scopes of the Risk Evaluations To Be Conducted for Seven Chemical Substances Under the Toxic Substances Control Act; Notice of Availability. *Federal Register*.

85 FR 22733, April 23, 2020 (FRL-10008-05).

3. EPA. Final Scopes of the Risk Evaluations To Be Conducted for Twenty Chemical Substances Under the Toxic Substances Control Act; Notice of Availability. ***Federal Register***.

85 FR 55281, September 4, 2020 (FRL-10013-90).

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

Dated: August 2, 2025.

Nancy B. Beck,

Principal Deputy Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

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