

the technical contact(s) for any TSCA submissions asserting an expiring CBI claim.

In addition to updating company contact information as discussed in this Unit (see 40 CFR 703.5(h)(1)), companies or company contacts with lapsed or inaccessible CDX accounts should reestablish that access by contacting and working with the CDX helpdesk available at [helpdesk@epacdx.net](mailto:helpdesk@epacdx.net) as early as possible. In general, submitters should take care to preserve their CDX passphrases to expedite access to their TSCA submissions.

Companies should also consider whether they submitted information claimed as CBI outside of CDX (e.g., paper TSCA filings pre-dating electronic filing requirements for that submission type, or physical material provided to EPA pursuant to a TSCA subpoena or inspection). Such entities should regularly consult EPA's online notice of CBI filings with expiring claims and submissions with expiring claims to determine if they have submissions eligible for CBI protection extension.

EPA plans to communicate with stakeholders prior to and after the CBI claim extension process begins. EPA anticipates the CBI claim extension process will begin in spring 2026. EPA expects to provide further guidance, to solicit and answer questions, and potentially to host a webinar with information on notices of expiration and instructions for requesting extensions. Entities should monitor the **Federal Register** and EPA websites, listservs, and other communications for further information about expiring TSCA CBI claims and when and how to request CBI protection extensions.

(Authority: 15 U.S.C. 2613.)

Dated: December 30, 2025.

**Mary Elissa Reaves,**

*Director, Office of Pollution Prevention and Toxics.*

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## ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2018-0501, EPA-HQ-OPPT-2018-0503, EPA-HQ-OPPT-2018-0504, EPA-HQ-OPPT-2018-0433, EPA-HQ-OPPT-2018-0434, EPA-HQ-OPPT-2024-0551; FRL-13111-01-OCSPP]

### Butyl Benzyl Phthalate (BBP), Dibutyl Phthalate (DBP), Dicyclohexyl Phthalate (DCHP), Diethylhexyl Phthalate (DEHP), and Diisobutyl Phthalate (DIBP); Risk Evaluation under the Toxic Substances Control Act (TSCA); Notice of Availability

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

**ACTION:** Notice.

**SUMMARY:** The Environmental Protection Agency (EPA or Agency) is announcing the availability of the final risk evaluations under the Toxic Substances Control Act (TSCA) for Butyl Benzyl Phthalate (BBP) (CASRN 85-68-7), Dibutyl Phthalate (DBP) (CASRN 84-74-2), Dicyclohexyl Phthalate (DCHP) (CASRN 84-61-7), Diethylhexyl Phthalate (DEHP) (CASRN 117-81-7), and Diisobutyl Phthalate (DIBP) (CASRN 84-69-5). The purpose of conducting risk evaluations under TSCA is to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or non-risk factors, including unreasonable risk to potentially exposed or susceptible subpopulations identified as relevant to the risk evaluation by EPA, under the conditions of use. EPA used the best available science to prepare these final risk evaluations, and determined, based on the weight of scientific evidence, that BBP, DBP, DCHP, DEHP, and DIBP pose unreasonable risk to human health and/or the environment driven by specific conditions of use. Under TSCA, EPA must initiate risk management actions to address the unreasonable risk.

**ADDRESSES:** The dockets for this action, identified by docket identification (ID) numbers EPA-HQ-OPPT-2018-0501, EPA-HQ-OPPT-2018-0503, EPA-HQ-OPPT-2018-0504, EPA-HQ-OPPT-2018-0433, and EPA-HQ-OPPT-2018-0434 are available online at <https://www.regulations.gov>. Additional information about dockets generally, along with instructions for visiting the docket in-person, is available at <https://www.epa.gov/dockets>.

#### FOR FURTHER INFORMATION CONTACT:

*For technical information on BBP:* Brianne Raccor, 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) 564-0303; email address: [raccor.brianne@epa.gov](mailto:raccor.brianne@epa.gov).

*For technical information on DBP:* Carolyn Mottley, 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) 566-1955; email address: [mottley.carolyn@epa.gov](mailto:mottley.carolyn@epa.gov).

*For technical information on DCHP:* Claire Brisse, 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) 564-9004; email address: [brisse.claire@epa.gov](mailto:brisse.claire@epa.gov).

*For technical information on DEHP:* Dyllan Taylor, 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) 564-2913; email address: [taylor.dyllan@epa.gov](mailto:taylor.dyllan@epa.gov).

*For technical information on DIBP:* Stephen Watkins, 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) 564-3744; email address: [watkins.stephen@epa.gov](mailto:watkins.stephen@epa.gov).

*For general information:* The TSCA-Hotline, Goodwill Vision Enterprises, 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 BBP, DBP, DCHP, DEHP, 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 BBP, DBP, DCHP, DEHP, or DIBP technical contact listed under **FOR FURTHER INFORMATION CONTACT**.

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

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

*C. What action is the Agency taking?*

EPA is announcing the availability of the final risk evaluations under TSCA for BBP, DBP, DCHP, DEHP, 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 and ensured that this action is consistent with Executive Order 14303 "Restoring Gold Standard Science," (May 23, 2025). Based on the weight of scientific evidence, the Agency determined that BBP, DBP, DCHP, DEHP, and DIBP pose unreasonable risk to human health and/or the environment driven by specific conditions of use. EPA will now initiate risk management action as required pursuant to TSCA section 6(a) (15 U.S.C. 2605(a)), to address the unreasonable risk.

## II. Background

*A. What are BBP, DBP, DCHP, DEHP, 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). DBP is a common chemical name for the chemical substance 1,2-

Benzenedicarboxylic acid, 1,2-dibutylester (CASRN 84-74-2). DCHP is a common chemical name for the chemical substance 1,2-benzenedicarboxylic acid, 1,2-dicyclohexyl ester (CASRN 84-61-7). DEHP is a common chemical name for the chemical substance 1,2-Benzenedicarboxylic acid, 1,2-bis(2-ethylhexyl) ester (CASRN 117-81-7). 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, DBP, DCHP, DEHP, and DIBP are manufactured (including imported), processed, distributed, and disposed of as part of industrial, commercial, and consumer conditions of use. These phthalates are used as plasticizers in polyvinyl chloride (PVC) and non-PVC plastics, as well as in adhesives, sealants, paints, coatings, rubbers, and other applications. Between 2016 and 2019, annual production volumes of these phthalates were reported to be between 1 and 20 million pounds (BBP), between 1 and 10 million pounds (DBP), between 500 thousand and 1 million pounds (DCHP), between 10 and 50 million pounds (DEHP), and between 380,000 and 441,000 pounds (DIBP) based on the 2020 TSCA Chemical Data Reporting (CDR) data.

*B. Summary of Activities for the Risk Evaluations of BBP, DBP, DCHP, DEHP, and DIBP*

On December 30, 2019, EPA announced its designation of BBP, DBP, DCHP, DEHP, and DIBP as high-priority substances for risk evaluation under TSCA (84 FR 71924) (FRL-10003-1). On April 23, 2020, EPA sought public comment on the draft scopes of the BBP, DBP, DCHP, DEHP, and DIBP risk evaluations (85 FR 22733) (FRL-10008-05), and, after considering public comments, issued the final scopes on September 4, 2020, (85 FR 55281) (FRL-10013-90). The Science Advisory Committee on Chemicals (SACC) conducted an external peer review of the proposed approach for cumulative risk assessment of these phthalates on May 8, 2023, through May 11, 2023 (88 FR 3974) (FRL-10490-02). On January 7, 2025, EPA sought public comment on the draft risk evaluation of DCHP (90 FR 1125) (FRL-12481-01). On June 5, 2025, EPA sought public comment on the draft risk evaluation of DBP and DEHP (90 FR 23931) (FRL-12808-01-OCSPP). On August 6, 2025, EPA sought public comment on the draft risk evaluation of BBP and DIBP (90 FR 14882) (FRL-12897-01-OCSPP). On August 4, 2025, through August 8, 2025, the SACC conducted an external peer review of

the draft risk evaluations for DBP, DCHP, and DEHP, as well as the hazard assessments for BBP and DIBP (90 FR 24400) (FRL-12418-02-OCSPP). For more information about these SACC meetings, go to the SACC website at <https://www.epa.gov/tsca-peer-review/science-advisory-committee-chemicals-meetings>.

These documents, other supporting documents, and public comments are in the dockets EPA-HQ-OPPT-2018-0501 (BBP), EPA-HQ-OPPT-2018-0503 (DBP), EPA-HQ-OPPT-2018-0504 (DCHP), EPA-HQ-OPPT-2018-0433 (DEHP), EPA-HQ-OPPT-2018-0434 (DIBP), EPA-HQ-OPPT-2022-0918 (SACC 2023), and EPA-HQ-OPPT-2024-0551 (SACC 2025). The following documents are also being released with this notice:

1. A response to public comments document titled, "Response to Public Comments on the Draft Risk Evaluations for Butyl Benzyl Phthalate (BBP); Dibutyl Phthalate (DBP); Dicyclohexyl Phthalate (DCHP); Diethylhexyl Phthalate (DEHP); and Diisobutyl Phthalate (DIBP): EPA-HQ-OPPT-2018-0501; EPA-HQ-OPPT-2018-0503; EPA-HQ-OPPT-2018-0504; EPA-HQ-OPPT-2018-0433; EPA-HQ-OPPT-2018-0434; EPA-HQ-OPPT-2022-0918; and EPA-HQ-OPPT-2024-0551;"
2. A response to peer review comments document titled, "Summary of and Response to External Peer Review on the Risk Evaluations and Technical Support Documents for Di(2-ethylhexyl) Phthalate (DEHP), Dibutyl Phthalate (DBP), Butyl Benzyl Phthalate (BBP), Diisobutyl Phthalate (DIBP), Dicyclohexyl Phthalate (DCHP), and Diisononyl Phthalate (DINP)"
3. A non-technical summary of the final risk evaluation for BBP titled, "Nontechnical Summary of the TSCA Risk Evaluation for Butyl Benzyl Phthalate;"
4. A non-technical summary of the final risk evaluation for DBP titled, "Nontechnical Summary of the TSCA Risk Evaluation for Dibutyl Phthalate;"
5. A non-technical summary of the final risk evaluation for DCHP entitled, "Nontechnical Summary of the TSCA Risk Evaluation for Dicyclohexyl Phthalate;"
6. A non-technical summary of the final risk evaluation for DEHP entitled, "Nontechnical Summary of the TSCA Risk Evaluation for Diethylhexyl Phthalate;"
7. A non-technical summary of the final risk evaluation for DIBP entitled, "Nontechnical Summary of the TSCA Risk Evaluation for Diisobutyl Phthalate;"
8. The final risk evaluation for BBP entitled, "Risk Evaluation for Butyl Benzyl Phthalate;"
9. The final risk evaluation for DBP entitled, "Risk Evaluation for Dibutyl Phthalate;"
10. The final risk evaluation for DCHP entitled, "Risk Evaluation for Dicyclohexyl Phthalate;"
11. The final risk evaluation for DEHP entitled, "Risk Evaluation for Diethylhexyl Phthalate;" and

12. The final risk evaluation for DIBP entitled, "Risk Evaluation for Diisobutyl Phthalate."

### III. Unreasonable Risk Determination

EPA determined that BBP presents an unreasonable risk of injury to human health and the environment driven by 7 of the 38 conditions of use (COUs). EPA has determined that the unreasonable risk to human health presented by BBP is driven by 2 COUs based on non-cancer risks associated with inhalation exposure to workers. The unreasonable risk to the environment is driven by 7 COUs due to chronic exposure of aquatic organisms through surface water. EPA did not identify unreasonable risk of injury to consumers or the general population under any COUs for BBP, nor do cumulative exposures contribute to unreasonable risks.

EPA determined that DBP presents an unreasonable risk of injury to human health and the environment driven by 6 of the 44 COUs. EPA has determined that the unreasonable risk to human health presented by DBP is driven by 5 COUs based on non-cancer risks driven by inhalation and aggregate exposure to workers. The unreasonable risk to the environment is driven by 1 COU due to chronic exposure of aquatic vertebrates, and exposure of aquatic plants and algae, through surface water. EPA did not identify unreasonable risk of injury to consumers or the general population under any COUs for DBP, nor do cumulative exposures contribute to unreasonable risks.

EPA determined that DCHP presents an unreasonable risk of injury to human health driven by 2 of the 24 COUs. EPA has determined that the unreasonable risk to human health presented by DCHP is driven by 2 COUs based on non-cancer risks associated with acute inhalation exposures to workers. EPA did not identify unreasonable risk to the environment under any COUs. EPA did not identify unreasonable risk of injury to consumers or the general population under any COUs for DCHP, nor do cumulative exposures contribute to unreasonable risks.

EPA determined that DEHP presents an unreasonable risk of injury to human health and the environment driven by 20 of the 44 COUs. EPA has determined that the unreasonable risk to human health presented by DEHP is driven by 10 COUs based on non-cancer risks associated with exposure to workers. The unreasonable risk to the environment is driven by 20 COUs due to chronic exposure of aquatic organisms through surface water with a subset of 18 of these COUs also driven

by risk due to chronic exposure of sediment-dwelling organisms through sediment pore water. EPA did not identify unreasonable risk of injury to consumers or the general population under any COUs for DEHP, nor do cumulative exposures contribute to unreasonable risks.

EPA determined that DIBP presents an unreasonable risk of injury to human health and the environment driven by 9 of the 28 COUs. EPA has determined that the unreasonable risk to human health presented by DIBP is driven by 4 COUs based on non-cancer risks associated with inhalation exposure to workers. The unreasonable risk to the environment is driven by 7 COUs due to exposure of algae and chronic exposure of aquatic vertebrates through surface water. EPA did not identify unreasonable risk of injury to consumers or the general population under any COUs for DIBP, nor do cumulative exposures contribute to unreasonable risks.

### IV. Next Step Is Risk Management

Consistent with TSCA section 6(a), EPA will propose risk management regulatory actions to the extent necessary so that BBP, DBP, DCHP, DEHP, and DIBP no longer present an unreasonable risk. EPA expects to focus its risk management actions on the conditions of use that significantly contribute to the unreasonable risks. In proposing rules and selecting among requirements, consistent with TSCA section 6(c)(2), EPA will consider and factor in, to the extent practicable: (i) the effects of BBP, DBP, DCHP, DEHP, and DIBP on health and the environment; (ii) the magnitude of exposure to BBP, DBP, DCHP, DEHP, and DIBP of human beings and the environment; (iii) the benefits of BBP, DBP, DCHP, DEHP, and DIBP for various uses; and (iv) the reasonably ascertainable economic consequences of the rule.

Additional information received may inform the risk management of the phthalates and, like the prioritization and risk evaluation processes, there will be an opportunity for public comment on any proposed risk management actions.

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

Dated: December 31, 2025.

**Nancy B. Beck,**

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket Nos. FDA-2024-E-1294; FDA-2024-E-1295; FDA-2024-E-1296; and FDA-2024-E-1297]

### Determination of Regulatory Review Period for Purposes of Patent Extension; ZURZUVAE

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for ZURZUVAE is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

**DATES:** Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by March 9, 2026. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by July 6, 2026. See "Petitions" in the **SUPPLEMENTARY INFORMATION** section for more information.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 9, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

#### *Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a