E 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2018-0504; FRL-12481-01-OCSPP]

Dicyclohexyl phthalate (DCHP); Draft Risk Evaluation 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 a draft risk evaluation under the Toxic Substances Control Act (TSCA) for Dicyclohexyl phthalate (DCHP) (1,2-benzenedicarboxylic acid, 1,2-dicyclohexyl este*r*) (CASRN 84-61-7). 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, without consideration of costs or other 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 has used the best available science to prepare this draft risk evaluation and to preliminarily determine that DCHP poses unreasonable risk to human health.

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-2018-0504, 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:

Chemical specific information: 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.

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, processing, distribution, use, and disposal of the chemical being evaluated, 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 all chemical substance 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. 15 U.S.C. 2625(h), (i), and (k). See also the implementing procedural regulations at 40 CFR part 702. 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 and seeking public comment on a draft risk evaluation under TSCA for DCHP (CASRN 84-61-7). 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, 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. This draft risk evaluation is consistent with the best available science, based on the weight of scientific evidence, and considers reasonably available information. EPA has preliminarily determined that DCHP poses unreasonable risk to human health.

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 is DCHP?*

DCHP is a common chemical name for the chemical substance 1,2-benzenedicarboxylic acid, 1,2-dicyclohexyl este*r* (CASRN 84-61-7). DCHP is a granular solid at room temperature that is produced by the esterification of phthalic anhydride with cyclohexanols. It is primarily

used as a plasticizer in adhesives and plastic and rubber products and resins for consumer, commercial, and industrial applications.

B. *Why is EPA evaluating this chemical under TSCA?*

In December 2019, EPA announced its designation of DCHP as a high-priority substance for risk evaluation under TSCA (Ref. 1). A draft scope of the DCHP risk evaluation was published in April 2020 (Ref. 2), and after receiving public comment, EPA issued the final scope of the DCHP risk evaluation in September 2020 (Ref. 3).

The Agency has evaluated the health and environmental risks of DCHP under TSCA section 6. Laboratory animal data suggest that developmental toxicity, specifically androgen insufficiency (phthalate syndrome), is the most sensitive and robust non-cancer hazard for DCHP. The Agency included DCHP for cumulative risk assessment along with five other phthalate chemicals that also cause effects on laboratory animals consistent with phthalate syndrome (Ref. 4). Notably, assessments by Health Canada, U.S. CPSC, European Chemicals Agency (ECHA), and the Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS) have reached similar conclusions regarding the effects of DCHP on development and have also conducted cumulative risk assessments of phthalates based on these chemicals' shared ability to cause phthalate syndrome. Further, independent, expert peer reviewers endorsed EPA's proposal to conduct a cumulative risk assessment of phthalates under TSCA during the May 2023 meeting of the Science Advisory Committee on Chemicals (SACC) because doing so represents the best available science. In this draft risk evaluation, EPA has evaluated cumulative exposure to phthalates for the U.S. civilian population using human biomonitoring data. These phthalate exposures to the general U.S. civilian population cannot be attributed to specific conditions of use or other sources. This non-attributable cumulative exposure and risk, representing that of the national population, was taken into consideration by EPA in reaching its preliminary determination of unreasonable risk of injury of human health for DCHP. Had EPA not taken this into consideration, it could have understated the unreasonable

risk of injury to human health for DCHP.

In this draft risk evaluation, EPA has preliminarily determined that DCHP presents an unreasonable risk of injury to human health under the conditions of use (COUs). Of the 24 COUs that EPA evaluated, 9 COUs have risk estimates that raise concerns for workers' exposure to DCHP, and no COUs that raise such concerns for consumers or the general population. In its draft evaluation, EPA's protective, screening-level approaches demonstrated that DCHP does not pose risk to the environment.

After this draft risk evaluation is informed by public comment and independent, expert peer review advice, EPA will issue a final risk evaluation that includes its determination as to whether DCHP presents unreasonable risk to health or the environment under the TSCA COUs. EPA also continues to work on the draft risk evaluations of five additional high-priority chemical substance phthalates.

III. Request for Comment

EPA seeks feedback on the assessment of risk presented in the draft risk evaluation, 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 supports comments, and to the extent permissible, describe any supporting data that is not publicly available.

IV. Next Steps

In its risk evaluation, EPA must determine whether the chemical presents an unreasonable risk to health or the environment under the chemical's conditions of use. These factors include risks to subpopulations who may be at greater exposure or susceptibility than the general population, such as children and workers. TSCA prohibits EPA from considering non-risk factors (e.g., costs/benefits) in making its risk determination.

If EPA determines that a chemical substance presents an unreasonable risk to health or the environment, the chemical substance must immediately move to risk management rulemaking action under TSCA. At the risk management stage, EPA is required to implement, via regulation, regulatory restrictions on the manufacture, processing, distribution, use or disposal so the chemical substance no longer presents an unreasonable risk. EPA is given a range of risk management options under TSCA, including labeling, recordkeeping or notice requirements, actions to reduce human exposure or environmental release, and a ban of the chemical substance or of certain uses. Like the prioritization and risk evaluation processes, there is an opportunity for public comment on any proposed risk management actions.

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).

4. EPA. Cumulative Risk Assessment Under the Toxic Substances Control Act. EPA

website at *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/cumulative-risk-assessment-under-toxic-substances#.*

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

Dated: December 30, 2024.

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

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