



## ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2018-0436; FRL-8806-02-OCSPP]

### **Di-isononyl phthalate (DINP); Draft Risk Evaluation Under the Toxic Substances Control Act (TSCA); Notice of Availability, Webinar 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 di-isononyl phthalate (DINP) (1,2-Benzene- dicarboxylic acid, 1,2-diisononyl ester) (CASRN 28553-12-0). 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 (COU). EPA has used the best available science to prepare this draft risk evaluation and to preliminarily determine that DINP poses unreasonable risk to human health.

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

*Webinar on:* September 26, 2024, 2-3 p.m. EST.

*Register by:* September 8, 2024, 12 p.m. EST, to receive the webcast meeting link and audio teleconference information before the meeting.

*Request special accommodation by:* September 8, 2024, 5 p.m. EST, to allow EPA time to process the request before the meeting.

**Special accommodations:** In addition, To allow EPA time to process your request, please submit your request to EPA by 5 p.m. EST on September 8, 2024, 5 p.m.

**ADDRESSES:** *Registration:* Register online at <https://usepa.zoomgov.com/meeting/register/vJisc-mprzguHuiILu5jNuwk-Q84wPrRr8>.

*Special accommodation requests:* Submit your request to the webinar contact person listed under **FOR FURTHER INFORMATION CONTACT**.

*Written comments:* Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2018-0436, 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:** *Webinar information:* Sarah Soliman, Project Management and Operations Division (7407M), Office of Chemical Safety and Pollution Prevention, Environmental Protection Agency, 1201 Constitution Ave. NW, Washington, DC 20004; telephone number: (202) 564-8820; email address: [soliman.sarah@epa.gov](mailto:soliman.sarah@epa.gov).

*Chemical specific information:* Todd Coleman, 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) 564-1208; email address: [coleman.todd@epa.gov](mailto:coleman.todd@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](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, 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.

*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 DINP (CASRN 28553-12-0). 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 COU. 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 DINP 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 DINP?*

DINP is a common chemical name for the category of chemical substances that includes the following substances: 1,2-benzenedicarboxylic acid, 1,2-isononyl ester (CASRN 28553-12-0) and 1,2-benzenedicarboxylic acid, di-C9-11-branched alkyl esters, C9-rich (CASRN 68515-48-0). Both CASRNs contain mainly C9 dialkyl phthalate esters. Both DINP, and another phthalate also undergoing TSCA risk evaluation, DIDP (1,2-Benzene- dicarboxylic acid, 1,2-diisodecyl ester, CASRN 26761-40-0 and 68515-49-1), are primarily used as plasticizers in polyvinyl chloride (PVC) in consumer, commercial, and industrial applications. DIDP and DINP are both structurally similar phthalates, and therefore many aspects of physical-chemical (p-chem) properties and exposure (to humans and ecological species) are similar, as described further in the draft physical chemical and fate assessments for both chemical substances.

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

On May 24, 2019, EPA received requests to conduct risk evaluations for both DINP and DIDP from ExxonMobil Chemical Company, Evonik Corporation, and Teknor Apex, through the American Chemistry Council's High Phthalates Panel (ACC HPP). In December 2019, EPA notified ACC HPP that the Agency had granted their manufacturer requested risk evaluations. See [insert cite to the FRN that announced this]. On May 17, 2024, EPA released for public comment and peer review draft technical support documents on DINP's physical chemical

properties, fate and transport in the environment, environmental hazard for terrestrial and aquatic species, human health non-cancer hazards, and human health cancer hazards. See 89 FR 43847, May 20, 2024 (FRL-11760-02-OCSP). The draft documents and public comments are in docket ID number EPA-HQ-OPPT-2024-0073.

Given the similar exposure and physical chemical properties of DIDP and DINP, EPA is developing these individual risk evaluations in parallel, and similarly the external peer review of the methods and novel analyses for the draft risk evaluations are occurring concurrently. Due to these similarities, EPA sought external peer review of technical portions of the DINP draft physical chemical properties, the fate and transport in the environment, environmental hazard for terrestrial and aquatic species, human health non-cancer hazards, and human health cancer hazards technical support documents, along with the DIDP draft risk evaluation. Thus, the focus of this public comment period is to solicit feedback regarding DINP-specific exposure analyses and the integration of these analyses with previously peer reviewed data.

DINP exhibits extremely low water solubility and will be preferentially sorbed into sediments, soils, and suspended solids in surface water and wastewater. It is expected to be persistent in anaerobic environments. Under indoor settings, DINP is expected to partition to airborne particles and is expected to have extended lifetime compared to outdoor settings. Liver and developmental toxicity are indicated as the most sensitive and robust non-cancer hazards for DINP. Developmental toxicity results in androgen insufficiency (phthalate syndrome), and effects on the liver include cancer.

The Agency has evaluated the health and environmental risks of DINP under TSCA section 6. In its draft risk evaluation, EPA's protective, screening-level approaches demonstrated that DINP does not pose risk to the environment or the general population. Of the 45 COUs that EPA evaluated, two COUs have risk estimates that raise concerns for workers' exposure and one COU has risk estimates that raise concerns for consumers. Based on these concerns, EPA preliminarily finds that DINP presents an unreasonable risk of injury to human

health.

After this draft risk evaluation is informed by public comment, EPA will issue a final risk evaluation that includes its determination as to whether DINP presents unreasonable risk to health or the environment under its COUs. EPA also continues to work on the draft risk evaluations of five additional high-priority chemical substance phthalates, in addition to a draft cumulative risk assessment (CRA) for DINP and the other five 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.

Because many of the DINP technical support documents have undergone public comment and are currently undergoing external peer review, input on the following is of particular interest to the EPA:

- Sections 3, 4 and 5 of the Draft Risk Evaluation for DINP;
- Draft Environmental Release and Occupational Exposure Assessment for DINP;
- Draft Consumer and Indoor Exposure Assessment for DINP;
- Draft Environmental Media and General Population Screening for DINP;
- Draft Environmental Exposure Assessment for DINP;
- Whether high-pressure spray applications of DINP-containing adhesives and sealants

and paints and coatings are currently in use in industrial settings, or may be used in the future due to changing industrial practices.

### **IV. Next Steps**

At the conclusion of the risk evaluation phase, EPA must use the risk evaluation as a basis to determine whether the chemical presents an unreasonable risk to health or the environment under the chemical's COUs. TSCA prohibits EPA from considering non-risk factors (e.g., costs/benefits) during risk evaluation. This includes risks to subpopulations who may be at greater risks than the general population, such as children and workers.

If at the end of the risk evaluation process, 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 of the chemical substance to eliminate the 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.

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: August 28, 2024.

**Michal Freedhoff,**

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

[FR Doc. 2024-19698 Filed: 8/30/2024 8:45 am; Publication Date: 9/3/2024]