



## **ENVIRONMENTAL PROTECTION AGENCY**

**[EPA-HQ-OPPT-2018-0436; FRL-8806-04-OCSP]**

**Diisononyl Phthalate (DINP); Risk Evaluation under the Toxic Substances Control Act;**

**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 evaluation under the Toxic Substances Control Act (TSCA) for diisononyl 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 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 final risk evaluation and determined, based on the weight of scientific evidence, that DINP poses unreasonable risk to human health. Under TSCA, EPA must initiate risk management actions to address the unreasonable risk.

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2018-0436, is 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:* 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*.

*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 DINP, 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 conducted 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 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 evaluation under TSCA for DINP.

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 this final risk evaluation and, based on the weight of scientific evidence, determined that DINP poses unreasonable risk to human health. Upon a determination of unreasonable risk, EPA must 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 is DINP?*

DINP is a common chemical name for the category of chemical substances that includes the following substances: Di-isononyl phthalate (DINP) (1,2-Benzene- dicarboxylic acid, 1,2-diisononyl ester) (CASRN 28553-12-0 and 68515-48-0). Both CASRNs contain mainly C9 dialkyl phthalate esters. DINP is manufactured (including imported), processed, distributed, and disposed as part of industrial, commercial, and consumer conditions of use. DINP is used primarily as a plasticizer to make flexible polyvinyl chloride (PVC). It is also used to make building and construction materials; automotive articles; and other commercial and consumer products including adhesives and sealants, paints and coatings, and electrical and electronic products. DINP production volumes are available through the TSCA Chemical Data Reporting (CDR) rule under two associated CAS Registry Numbers (CASRNs): 1) The production volume for CASRN 28553-12-0 in 2015 was between 100 to 250 million pounds (lb.) and decreased to 50 to 100 million lb. in 2019 based on the latest 2020 CDR data; and 2) The production volume for CASRN 68515-48-0 in 2015 ranged between 100 to 250 million lb. and changed to between 100 million and 1 billion lb. in 2019 based on the latest 2020 CDR data.

### *B. Summary of Activities for the Risk Evaluation of DINP*

In May 2019, EPA received a request to conduct a risk evaluation for DINP 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 the manufacturer requested risk evaluation (Ref. 1). In November 2020, EPA released the draft scope of the DINP risk evaluation (Ref. 2), and, after receiving public comments, issued the problem formulation in August 2021 (Ref. 3). In May 2024, the Environmental Hazard and Human Health Hazard technical support documents for DINP were released for public comment and peer review by the Science Advisory Committee on Chemicals (SACC) (Ref. 4). In September 2024, EPA released a full draft risk evaluation for public comment (Ref. 5). The draft documents and public comments are in docket ID number EPA-HQ-OPPT-2024-0436.

The docket also includes a response to comments document (Ref. 6), a non-technical summary of the final risk evaluation (Ref. 7), and the final risk evaluation (Ref. 8).

### **III. Unreasonable Risk Determination**

EPA has determined that DINP presents an unreasonable risk of injury to human health under the COUs. EPA did not identify risk of injury to the environment that would contribute to the unreasonable risk determination for DINP. EPA has determined that the unreasonable risk to human health presented by DINP is due to the following: 1) Non-cancer effects (developmental toxicity) in female workers of reproductive age from acute inhalation exposures; 2) Non-cancer effects (liver effects) in female workers of reproductive age from chronic aggregate exposures; and 3) Non-cancer effects (liver effects) in workers from chronic and aggregate exposures. This unreasonable risk determination is based on the information in the risk evaluation, the appendices, and technical support documents of the risk evaluation in accordance with TSCA section 6(b). It is also based on TSCA's best available science (TSCA section 26(h)), weight of scientific evidence standards (TSCA section 26(i)), and relevant implementing regulations in 40 CFR part 702.

The COUs that EPA identified as significantly contributing to the unreasonable risk from

DINP include those that lead to exposures to average adult workers, including female workers of reproductive age, in scenarios in which unprotected workers used spray adhesives and sealants or paints and coatings that contain DINP, because doing so could create high concentrations of DINP in mist that an unprotected worker could inhale.

Between release of the draft risk evaluation and finalization of the DINP risk evaluation, EPA updated the risk determination to find that four conditions of use (COUs) significantly contribute to the unreasonable risk of DINP. These updates were based on new information identified by EPA, information provided by public commenters, and recommendations of the Science Advisory Committee on Chemicals (SACC). These changes stem from consideration of 1) multiple factors impacting occupational exposure during spray application; and 2) determination that the liver effects associated with chronic exposure are relevant to adult workers, adult consumers, and adult members of the general population, but not infants and children.

#### **IV. Next Step is Risk Management**

Consistent with TSCA section 6(a), EPA will propose a risk management regulatory action to the extent necessary so that DINP no longer presents an unreasonable risk. EPA expects to focus its risk management action on the COUs that significantly contribute to the unreasonable risk. However, it should be noted that, under TSCA section 6(a), EPA is not limited to regulating the specific activities found to drive unreasonable risk and may select from among a suite of risk management requirements in TSCA section 6(a) related to manufacture (including import), processing, distribution in commerce, commercial use, and disposal as part of its regulatory options to address the unreasonable risk. As a general example, EPA may regulate upstream activities (*e.g.*, processing, distribution in commerce) to address downstream activities (*e.g.*, consumer uses) driving unreasonable risk, even if the upstream activities do not drive the unreasonable risk. 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. Di-isononyl Phthalate (DINP); Manufacturer Request for Risk Evaluation Under the Toxic Substances Control Act (TSCA). *Federal Register*. 84 FR 42912, August 19, 2019 (FRL-9998-25-OCSPP).

2. EPA. Di-isononyl Phthalate (DINP); Draft Scope of the Risk Evaluation To Be Conducted Under the Toxic Substances Control Act (TSCA); Notice of Availability and Request for Comments. *Federal Register*. 85 FR 76072, November 27, 2020 (FRL-10017-15-OSCPP).

3. EPA. Di-isononyl Phthalate (DINP); Final Scope of the Risk Evaluation To Be Conducted Under the Toxic Substances Control Act (TSCA); Notice of Availability. *Federal Register*. 86 FR 48693, August 31, 2021 (FRL- 8806-01-OSCPP).

4. EPA. Di-isodecyl Phthalate (DIDP) and Di-isononyl Phthalate (DINP); Science Advisory Committee on Chemicals (SACC) Peer Review of Draft Documents; Notice of SACC Meeting; Availability; and Request for Comment. *Federal Register*. 89 FR 43847, May 20, 2024 (FRL-11760-02-OCSPP).

5. EPA. Di-isononyl phthalate (DINP); Draft Risk Evaluation Under the Toxic Substances Control Act (TSCA); Notice of Availability, Webinar and Request for Comment. *Federal Register*. 89 FR 71270, September 3, 2024 (FRL-8806-02-OCSPP).

6. EPA. Comment Summary and Responses for Di-isodecyl Phthalate (DIDP) and Diisononyl Phthalate (DINP). December 2024.

7. EPA. Nontechnical Summary of the TSCA Risk Evaluation for Di-isononyl Phthalate (DINP). December 2024. (EPA Publication ID No. EPA-740-S-25-001).

8. EPA. TSCA Risk Evaluation for Di-isononyl Phthalate (DINP). December 2024. (EPA Publication ID No. EPA-740-R-25-001).

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

Dated: January 7, 2025.

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