



ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2018-0436; FRL-10017-15]

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

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is announcing the availability of and soliciting public comment on the draft scope document for the risk evaluation to be conducted for di-isononyl phthalate (DINP) (1,2-benzene-dicarboxylic acid, 1,2-diisononyl ester, and 1,2-benzenedicarboxylic acid, di-C8-10-branched alkyl esters, C9-rich; Chemical Abstracts Service Registry Number (CASRN) 28553-12-0 and CASRN 68515-48-0) a category of chemical substances for which EPA received a manufacturer request for risk evaluation. The draft scope document for this category of chemical substances includes the conditions of use, hazards, exposures, and the potentially exposed or susceptible subpopulations EPA plans to consider in conducting the risk evaluation for this category of chemical substances. EPA is also asking the public to provide additional data or information that could be useful to the Agency in finalizing the scope of the risk evaluations; comments may be submitted to this docket.

DATES: Comments must be received on or before **[INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2018-0436, through the Federal eRulemaking Portal at <http://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. To make special arrangements for hand delivery or

delivery of boxed information, please follow the instructions at

<http://www.epa.gov/dockets/contacts.html>.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Collin Beachum, Existing Chemical Risk Assessment Division (Mailcode E205-02), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 109 T.W. Alexander Drive, RTP, NC 27711; telephone number: (919) 541-7554; email address: beachum.collin@epa.gov.

For general information contact: 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. General Information

A. Does this action apply to me?

This action is directed to the public in general and may be of interest to entities that manufacture (including import) a chemical substance regulated under TSCA (*e.g.*, entities identified under North American Industrial Classification System (NAICS) codes 325 and 324110). The action may also be of interest to chemical processors, distributors in commerce, and users; non-governmental organizations in the environmental and public health sectors; state and local government agencies; and members of the public. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities and corresponding NAICS codes for entities that may be interested in or affected by this action.

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

The draft scope document is issued pursuant to TSCA section 6(b) and EPA's

implementing regulations at 40 CFR 702.41(c)(7).

C. What action is the Agency taking?

EPA is publishing the draft scope of the risk evaluation for DINP under TSCA. Through the risk evaluation process, EPA will determine whether the category of chemical substances presents an unreasonable risk of injury to health or the environment under the conditions of use, as determined by the Administrator, in accordance with TSCA section 6(b)(4).

II. Background

TSCA allows chemical manufacturers to request an EPA-conducted risk evaluation of a chemical under 40 CFR 702.37. On May 24, 2019, EPA received a manufacturer request for a risk evaluation of DINP (Ref. 1). On December 20, 2019, the Agency granted the request, and subsequently initiated the scoping process for the risk evaluation for this category of chemical substances. The purpose of a risk evaluation is to determine whether a chemical substance, or group of chemical substances, presents an unreasonable risk to health or the environment, under the conditions of use, including an unreasonable risk to a relevant potentially exposed or susceptible subpopulation (15 U.S.C. 2605(b)(4)(A)). As part of this process, EPA must evaluate both hazards and exposures for the conditions of use; describe whether aggregate or sentinel exposures were considered and the basis for consideration; not consider costs or other nonrisk factors; take into account where relevant, likely duration, intensity, frequency, and number of exposures; and describe the weight of the scientific evidence for hazards and exposures (15 U.S.C. 2605(b)(4)(F)). This process will culminate in a determination of whether or not the category of chemical substances presents an unreasonable risk of injury to health or the environment under the conditions of use (15 U.S.C. 2605(b)(4)(A); 40 CFR 702.47).

III. Draft Scope of the Risk Evaluation for Di-isononyl phthalate (DINP)

The category of chemical substances for which EPA is publishing the draft scope of the risk evaluation includes the following chemical substances: 1,2-benzene-dicarboxylic acid, 1,2-diisononyl ester (CASRN 28553-12-0), and 1,2-benzenedicarboxylic acid, di-C8-10-branched

alkyl esters, C9-rich; (CASRN 68515-48-0). The draft scope of the risk evaluation for this category of chemical substances includes the conditions of use, hazards, exposures, and the potentially exposed or susceptible subpopulations EPA plans to consider in the risk evaluation (15 U.S.C. 2605(b)(4)(D)). Development of the scope is the first step of a risk evaluation. The draft scope of the risk evaluation will include the following components (40 CFR 702.41(c)):

- The conditions of use, as determined by the Administrator, that EPA plans to consider in the risk evaluation.
- The potentially exposed populations that EPA plans to evaluate; the ecological receptors that EPA plans to evaluate; and the hazards to health and the environment that EPA plans to evaluate.
- A description of the reasonably available information and the science approaches that the Agency plans to use.
- A conceptual model that will describe the actual or predicted relationships between the chemical substance, the conditions of use within the scope of the evaluation and the receptors, either human or environmental, with consideration of the life cycle of the chemical substance -- from manufacturing, processing, distribution in commerce, use, to release or disposal – and identification of human and ecological health hazards EPA plans to evaluate for the exposure scenarios EPA plans to evaluate.
- An analysis plan, which will identify the approaches and methods EPA plans to use to assess exposure, hazards, and risk, including associated uncertainty and variability, as well as a strategy for using reasonably available information and best available science approaches.
- A plan for peer review.

EPA encourages commenters to provide information they believe might be missing or may further inform the risk evaluation. EPA will publish a notice in the *Federal Register* announcing the availability of the final scope within three months of publishing the draft scope.

IV. References

The following is a listing of the documents that are specifically referenced in this *Federal Register* notice. The docket for this action includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket. For assistance in locating these referenced documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA. Di-isononyl Phthalate (DINP) (1,2-Benzene- dicarboxylic acid, 1,2- diisononyl ester); Manufacturer Request for Risk Evaluation Under the Toxic Substances Control Act (TSCA); Notice of Availability and Request for Comments. *Federal Register*. (84 FR 42912, August 19, 2019) (FRL-9998-25).

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

Andrew Wheeler,

Administrator.

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