



BILLING CODE 6560-50-P

## ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2019-0450; FRL-9997-63]

### **Proposed Low-Priority Substance Designation under the Toxic Substances Control Act (TSCA); Notice of Availability and Request for Comment**

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

**ACTION:** Notice.

**SUMMARY:** As required under section 6(b) of the Toxic Substances Control Act (TSCA) and implementing regulations, EPA is proposing to designate 20 chemical substances as Low-Priority Substances for which risk evaluation is not warranted at this time. This document provides a summary of the approach used by EPA to support the proposed designations, the proposed designation for each of the chemical substances, and instructions on how to access the chemical-specific information, analysis and basis used by EPA to make the proposed designation for each chemical substance. EPA is providing a 90-day comment period during which interested persons may provide comments on the proposed designations.

**DATES:** Comments must be received on or before [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE *Federal Register*].

**ADDRESSES:** Use one of the following methods to submit comments: For comments not related to a specific chemical substance, including comments on EPA's Approach Document for Screening Hazard Information for Low-Priority Substances Under TSCA (July 2019), direct your comments to docket identification (ID) number EPA-HQ-OPPT-2019-0450. For comments on one or more of the 20 chemical substances, use the applicable chemical specific docket ID number(s) identified in Unit IV.B.

• *Federal eRulemaking Portal: <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.

• *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001.

• *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** *For technical information about Low-Priority Substances contact:* Lauren Sweet, Chemistry, Economics and Sustainable Strategies Division, Office of Pollution Prevention and Toxics, Office of Chemical Safety and Pollution Prevention, Environmental Protection Agency (Mailcode 7406M), 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (202) 564-0376; email address: [sweet.lauren@epa.gov](mailto:sweet.lauren@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](mailto:TSCA-Hotline@epa.gov).

## **I. Executive Summary**

### *A. Does this action apply to me?*

This action is directed to the public in general and may be of interest to entities that

currently or may 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-profit organizations in the environmental and public health sectors; state and local government agencies; and members of the public. Because interest in this notice may be broad, 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 action is the Agency taking?*

EPA is proposing to designate 20 chemical substances as Low-Priority Substances pursuant to section 6(b) of the Toxic Substances Control Act (TSCA), 15 U.S.C. 2605(b). This document includes a summary of the approach used by EPA to support the proposed designations, the proposed designation for each of the chemical substances, and instructions on how to access the chemical-specific information, analysis and basis used by EPA to make the proposed designation for each chemical substance. EPA is providing a 90-day comment period during which interested persons may submit comments on the proposed designation.

*C. Why is the Agency taking this action?*

EPA is proposing to designate as Low-Priority Substances 20 chemical substances for which EPA initiated the prioritization process required by TSCA section 6(b) on March 21, 2019 (Ref. 1). EPA is providing a 90-day comment period during which the public may submit comments on EPA's proposed designations of Low-Priority Substances, as required by TSCA section 6(b)(1)(C)(ii).

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

This document is issued pursuant to TSCA section 6(b)(1).

E. *What are the estimated incremental impacts of this action?*

This document identifies 20 chemical substances for proposed designation as Low-Priority Substances. This document does not establish any requirements on persons or entities outside of the Agency. No incremental impacts are therefore anticipated, and consequently EPA did not estimate potential incremental impacts for this action.

F. *What should I consider as I prepare my comments for EPA?*

1. *Submitting Confidential Business Information (CBI).* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <http://www.epa.gov/dockets/comments.html>.

## **II. Background**

TSCA, as amended in 2016 by the Frank R. Lautenberg Chemical Safety for the 21<sup>st</sup> Century Act (Pub. L. 114-182), at section 6(b)(1), requires EPA to prioritize chemical substances for designation. As required by TSCA section 6(b) and described in 40 CFR 702.7, on March 21, 2019 (Ref. 1), EPA initiated the prioritization process for 20 chemical substances identified as candidates for Low-Priority Substance designation.

Under TSCA section 6(b)(1)(B) and implementing regulations (40 CFR 702.3), a Low-

Priority Substance is defined as a chemical substance that the Administrator concludes, based on information sufficient to establish, without consideration of costs or other non-risk factors, does not meet the standard for a High-Priority Substance. A High-Priority Substance is defined as a chemical substance that the Administrator concludes, without consideration of costs or other non-risk factors, may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator. A chemical substance designated as Low-Priority indicates a risk evaluation is not warranted at that time.

This document is intended to fulfill the requirement in TSCA section 6(b)(1)(C)(ii) and 40 CFR 702.9 that the Administrator propose the designation of 20 chemical substances as Low-Priority Substances for risk evaluation after conducting a screening review, as required by TSCA section 6(b)(1)(A) and 40 CFR 702.9(a). EPA generally used reasonably available information to screen the candidate chemical substances against the following criteria and considerations (40 CFR 702.9(a)):

- the chemical substance's hazard and exposure potential;
  - the chemical substance's persistence and bioaccumulation;
  - potentially exposed or susceptible subpopulations;
  - storage of the chemical substance near significant sources of drinking water;
  - the chemical substance's conditions of use or significant changes in conditions of use;
  - the chemical substance's production volume or significant changes in production volume; and
- other risk-based criteria that EPA determines to be relevant to the designation of the

chemical substance's priority for risk evaluation.

As described in 40 CFR 702.9(b), in conducting the screening review during the prioritization process, EPA considered sources of information relevant to the screening-review criteria as outlined in the statute (TSCA section 6(b)(1)(A)) and implementing regulations (40 CFR 702.9(a)) and consistent with the scientific standards of TSCA section 26(h). All hazard and fate information for these proposed low-priority substances was collected and evaluated in accordance with the methodology laid out in the Approach Document for Screening Hazard Information for Low-Priority Substances Under TSCA (July 2019) (Ref. 2). Information gathered according to this approach document was included in each chemical substance's screening review, which are provided in Unit IV.B. In addition, as required by 40 CFR 702.9, EPA considered the hazard and exposure potential of the chemical substances and did not consider cost or other non-risk factors in making a proposed priority designation.

### **III. Information and Comments Received**

The initiation of the prioritization process (docket EPA-HQ-OPPT-2019-0131) included a 90-day comment period during which interested persons were able to submit relevant information on those chemical substances identified as candidates for Low-Priority Substance designation. With the exception of comments providing information for specific chemical substances being proposed as Low-Priority Substances, EPA will respond to comments received in an upcoming notice.

During the 90-day comment period, commenters submitted information on four chemical substances proposed for Low-Priority designation:

- *Propanol, [(1-methyl-1,2-ethanediyl)bis(oxy)]bis-* (CAS RN 24800-44-0)
- *Propanol, 1(or 2)-(2-methoxymethylethoxy)-, acetate* (CAS RN 88917-22-0)

- *Propanol, [2-(2-butoxymethylethoxy)methylethoxy]- (CAS RN 55934-93-5)*
- *Propanol, oxybis- (CAS RN 25265-71-8)*

The submitted information is addressed in the respective dossiers (see Unit IV.B.).

#### **IV. Chemical Substances for which EPA is Proposing a Low-Priority Substance**

##### **Designation for Prioritization**

*A. Approach for gathering information, conducting analysis and forming the basis to support the proposed Low-Priority Substance designation.*

EPA used reasonably available information, including public comments received on specific chemical substances during the 90-day comment period following initiation of the prioritization process for Low-Priority Substances, to screen the candidate chemical substances against the criteria and considerations in TSCA section 6(b)(1)(A) and 40 CFR 702.9 (see Unit III.).

EPA developed a document to identify the information, analysis and basis used to support the proposed designations as a Low-Priority Substance for each chemical substance. These documents are available in the docket of each of the chemical substances with a proposed designation as a Low-Priority Substance. The proposed designations are presented in Unit IV.B., along with the docket references.

Each chemical-specific document for the chemical substances proposed for designation as a Low-Priority Substance includes the information, analysis and basis for the proposed designation. In the absence of experimental data for a given endpoint, EPA integrated information using New Approach Methodologies (NAMs). Each of the screening reviews includes an overview of the considerations in TSCA section 6(b)(1)(A) and the regulatory section addressing the criteria and considerations at 40 CFR 702.9:

1. *Hazard potential.* EPA considered reasonably available information to screen potential hazards for each chemical substance. EPA surveyed the reasonably available information for potential human health and environmental hazards for a range of toxicological endpoints. EPA benchmarked these data against low-concern thresholds. These low-concern endpoints and thresholds are based on EPA OPPT's New Chemicals Program, the Globally Harmonized System of Classification and Labelling of Chemicals classifications, OPPT's criteria for high production volume chemical categorization, EPA's Office of Pesticide Programs categories, and the International Agency for Research on Cancer's classifications.

2. *Exposure potential.* EPA gathered reasonably available information on physical-chemical properties, production volumes, and uses to determine potential routes of exposure. Using this information, and adhering to methodologies outlined in each chemical-specific dossier, EPA screened for potential environmental, general population, and potentially exposed or susceptible subpopulations exposure for each chemical substance:

- For environmental exposures, EPA considered the conditions of use and fate properties of each chemical substance to anticipate its presence in different environmental media.

- For general population exposure, EPA considered releases from certain conditions of use, such as manufacturing, that may result in general population exposures via drinking water ingestion and/or inhalation from air releases.

- For exposures to potentially exposed or susceptible subpopulations, EPA identified subpopulations such as workers, consumers, pregnant women, and children using Chemical Data Reporting (CDR) information and other reasonably available information specified in each chemical substance's screening review. The CDR rule requires manufacturers to report information on the chemical substances they produce domestically or import into the U.S. CDR

includes information on the manufacturing, processing, and use of chemical substances. For worker or occupational exposure, EPA identified the conditions of use that are likely to result in workers exposures, such as manufacturing, processing, industrial use, and commercial use. For consumer and children's exposures, EPA identified certain conditions of use that may result in the chemical substance's exposure to consumers and children.

3. *Persistence and bioaccumulation.* EPA considered reasonably available information on the chemical substance and interpreted persistence and bioaccumulation potential based on best available science. In the screening reviews, EPA presents a summary of the environmental fate characteristics of each chemical substance.

4. *Potentially exposed or susceptible subpopulations.* In the screening reviews, EPA considered reasonably available information to identify potentially exposed or susceptible subpopulations. At this stage, EPA analyzed information regarding children, infants, pregnant women, consumers, and workers:

- For children and infants, EPA evaluated the chemical substance's use in products and articles regulated under TSCA and intended for children using CDR information and other reasonably available information on uses. In the screening reviews, EPA presents information regarding those commercial and consumer uses where the chemical substance was used in products intended, known, or reasonably foreseen for use by children and infants.

- For pregnant women, EPA examined reasonably available information and considered whether the chemical substance could potentially pose reproductive or developmental adverse effects.

- For workers, EPA identified the potential for occupational exposures to workers based on the conditions of use of each chemical substance, using CDR information and other

reasonably available information.

- For consumers, EPA identified the consumer uses of the chemical substance and the potential for consumer exposure under those conditions of use, using CDR information and other reasonably available information.

5. *Storage near significant sources of drinking water.* EPA evaluated elements of risk associated with the chemical substance's storage near surface and underground sources of drinking water. EPA considered possible adverse effects that could result from an accidental one-time-high-volume release of a substance, and from a slower release over time. For its analysis, EPA relied in large part on the chemical substance's potential human health hazards, including to potentially exposed or susceptible subpopulations, and environmental fate properties as they relate to the potential for the chemical substance to enter a hypothetical drinking water source. Among the reasons that EPA chose this approach for analysis is that data on storage of the chemicals being proposed as Low-Priority Substances are not tracked under TSCA and are not generally available. EPA also investigated whether the chemical substance was monitored for and detected in a range of environmental media under other federal statutes and regulations. EPA assumed that if a chemical substance is regulated under the National Primary Drinking Water Regulations or the Clean Water Act, or if its release is subject to reporting requirements under the Emergency Planning and Community Right-to-Know Act (ECPRA), the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) or the Clean Air Act (CAA), there is a potential human health hazard from a potential release near a significant source of drinking water.

6. *Conditions of use or significant changes in conditions of use.* EPA evaluated conditions of use or significant changes in conditions of use of the chemical substance by

reviewing CDR data and supplementing that data from a broad range of other sources, including information from other governments, and information from publicly available internet sources to develop a comprehensive list of intended, known, and reasonably foreseen conditions of use within the TSCA regulatory scope. To analyze the potential for concern based on the possibility of change in known uses, EPA relied in large part on the chemical substance's potential human health and environmental hazards.

7. *Production volume or significant changes in production volume.* EPA considered current volume or significant changes in volume of the chemical substance using manufacturers' (including importers') reported information under the CDR rule under TSCA section 8(a). EPA assembled information from 1986 through 2016 on the production volume reported under the Inventory Update Rule (IUR) and CDR.

8. *Other risk-based criteria that EPA determined to be relevant to the designation of the chemical substance's priority.* EPA did not find other risk-based criteria relevant to the proposed designations of the candidate chemical substances as Low-Priority Substances.

#### *B. Proposed Designation as Low- Priority Substances for Risk Evaluation*

EPA is proposing to designate the following 20 chemical substances as Low-Priority Substances for which risk evaluation is not warranted at this time. The proposed designations are based on the conclusion that the chemical substance satisfies the definition of Low-Priority Substance. Under TSCA section 6(b)(1)(B) and implementing regulations (40 CFR 702.3), a Low-Priority Substance is described as a chemical substance that the Administrator concludes does not meet the standard for designation as a high-priority substance, based on information sufficient to establish that conclusion, without consideration of costs or other non-risk factors (Section 6(b)(1)(B)).

1. *1-Butanol, 3-methoxy-, 1-acetate, CAS RN 4435-53-4, Docket number: EPA-HQ-OPPT-2019-0106.* The information, analysis and basis used to support the proposed designation as Low-Priority Substance are in the docket for this chemical substance.

2. *D-gluco-Heptonic acid, sodium salt (1:1), (2.xi.)-, CAS RN 31138-65-5, Docket number: EPA-HQ-OPPT-2019-0107.* The information, analysis and basis used to support the proposed designation as Low-Priority Substance are in the docket for this chemical substance.

3. *D-Gluconic acid, CAS RN 526-95-4, Docket number: EPA-HQ-OPPT-2019-0108.* The information, analysis and basis used to support the proposed designation as Low-Priority Substance are in the docket for this chemical substance.

4. *D-Gluconic acid, calcium salt (2:1), CAS RN 299-28-5, Docket number: EPA-HQ-OPPT-2019-0109.* The information, analysis and basis used to support the proposed designation as Low-Priority Substance are in the docket for this chemical substance.

5. *D-Gluconic acid, .delta.-lactone, CAS RN 90-80-2, Docket number: EPA-HQ-OPPT-2019-0110.* The information, analysis and basis used to support the proposed designation as Low-Priority Substance are in the docket for this chemical substance.

6. *D-Gluconic acid, potassium salt (1:1), CAS RN 299-27-4, Docket number: EPA-HQ-OPPT-2019-0111.* The information, analysis and basis used to support the proposed designation as Low-Priority Substance are in the docket for this chemical substance.

7. *D-Gluconic acid, sodium salt (1:1), CAS RN 527-07-1, Docket number: EPA-HQ-OPPT-2019-0112.* The information, analysis and basis used to support the proposed designation as Low-Priority Substance are in the docket for this chemical substance.

8. *Decanedioic acid, 1,10-dibutyl ester, CAS RN 109-43-3, Docket number: EPA-HQ-OPPT-2019-0113.* The information, analysis and basis used to support the proposed designation

as Low-Priority Substance are in the docket for this chemical substance.

9. *1-Docosanol, CAS RN 661-19-8, Docket number: EPA-HQ-OPPT-2019-0114.* The information, analysis and basis used to support the proposed designation as Low-Priority Substance are in the docket for this chemical substance.

10. *1-Eicosanol, CAS RN 629-96-9, Docket number: EPA-HQ-OPPT-2019-0115.* The information, analysis and basis used to support the proposed designation as Low-Priority Substance are in the docket for this chemical substance.

11. *1,2-Hexanediol, CAS RN 6920-22-5, Docket number: EPA-HQ-OPPT-2019-0116.* The information, analysis and basis used to support the proposed designation as Low-Priority Substance are in the docket for this chemical substance.

12. *1-Octadecanol, CAS RN 112-92-5, Docket number: EPA-HQ-OPPT-2019-0117.* The information, analysis and basis used to support the proposed designation as Low-Priority Substance are in the docket for this chemical substance.

13. *Propanol, [2-(2-butoxymethylethoxy)methylethoxy]-, CAS RN 55934-93-5, Docket number: EPA-HQ-OPPT-2019-0118.* The information, analysis and basis used to support the proposed designation as Low-Priority Substance are in the docket for this chemical substance.

14. *Propanedioic acid, 1,3-diethyl ester, CAS RN 105-53-3, Docket number: EPA-HQ-OPPT-2019-0119.* The information, analysis and basis used to support the proposed designation as Low-Priority Substance are in the docket for this chemical substance.

15. *Propanedioic acid, 1,3-dimethyl ester, CAS RN 108-59-8, Docket number: EPA-HQ-OPPT-2019-0120.* The information, analysis and basis used to support the proposed designation as Low-Priority Substance are in the docket for this chemical substance.

16. *Propanol, 1(or 2)-(2-methoxymethylethoxy)-, acetate, CAS RN 88917-22-0, Docket*

*number: EPA-HQ-OPPT-2019-0121.* The information, analysis and basis used to support the proposed designation as Low-Priority Substance are in the docket for this chemical substance.

17. *Propanol, [(1-methyl-1,2-ethanediyl)bis(oxy)]bis-, CAS RN 24800-44-0, Docket number: EPA-HQ-OPPT-2019-0122.* The information, analysis and basis used to support the proposed designation as Low-Priority Substance are in the docket for this chemical substance.

18. *2-Propanol, 1,1'-oxybis-, CAS RN 110-98-5, Docket number: EPA-HQ-OPPT-2019-0123.* The information, analysis and basis used to support the proposed designation as Low-Priority Substance are in the docket for this chemical substance.

19. *Propanol, oxybis-, CAS RN 25265-71-8, Docket number: EPA-HQ-OPPT-2019-0124.* The information, analysis and basis used to support the proposed designation as Low-Priority Substance are in the docket for this chemical substance.

20. *Tetracosane, 2,6,10,15,19,23-hexamethyl-, CAS RN 111-01-3, Docket number: EPA-HQ-OPPT-2019-0125.* The information, analysis and basis used to support the proposed designation as Low-Priority Substance are in the docket for this chemical substance.

## **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 technical person listed under **FOR FURTHER INFORMATION CONTACT.**

1. EPA. Initiation of Prioritization Under the Toxic Substances Control Act (TSCA). Notice. *Federal Register*. (84 FR 10491, March 21, 2019) (FRL-9991-06).

2. EPA. Approach Document for Screening Hazard Information for Low-Priority Substances Under TSCA. August 2019. EPA Document ID No. 740B19008. Office of Pollution Prevention and Toxics. Washington, DC.

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

Dated: August 9, 2019.

**Andrew R. Wheeler,**

*Administrator.*

[FR Doc. 2019-17558 Filed: 8/14/2019 8:45 am; Publication Date: 8/15/2019]