



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2019-0131; FRL-9991-06]

Initiation of Prioritization under the Toxic Substances Control Act (TSCA)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: As required under the Toxic Substances Control Act (TSCA) and related implementing regulations, EPA is initiating the prioritization process for 20 chemical substances as candidates for designation as High Priority Substances for risk evaluation and 20 chemical substances as candidates for designation as Low Priority Substances for risk evaluation. This document provides the identity of the chemical substances being initiated for prioritization, a general explanation of why the Agency chose these chemical substances and information on the data sources that EPA plans to use to support the designation. EPA is providing a 90-day comment period during which interested persons may submit relevant information on these chemical substances.

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, directing not related to a specific chemical, including comments on Unit V., to docket identification (ID) number EPA-HQ-OPPT-2019-0131; submit information on the 20 candidates for which EPA is initiating the prioritization process before designation as High Priority Substances for risk evaluation to the applicable chemical specific docket ID number identified in Unit III.B.; and submit information on the 20 candidates for which EPA is initiating the prioritization process before designation as

Low Priority Substances for risk evaluation to the applicable chemical specific docket ID number 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 the candidates for high priority contact:* Ana Corado, Chemical Control Division, Office of Pollution Prevention and Toxics, Office of Chemical Safety and Pollution Prevention, Environmental Protection Agency (Mailcode 7408M), 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (202) 564-0140; email address: corado.ana@epa.gov.

For technical information about the candidates for low priority 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.

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. 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, users, non-profit 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 action is the Agency taking?

EPA is initiating the prioritization process under the Toxic Substances Control Act (TSCA), 15 U.S.C. 2601 *et seq.*, for 20 chemical substances as candidates for designation as High Priority Substances for risk evaluation and 20 chemical substances as candidates for designation as Low Priority Substances for risk evaluation. This document includes the identity of the chemical substances entering the prioritization process before designation, and a general explanation of why the Agency chose to initiate prioritization on these chemical substances. In addition, EPA is providing a 90-day comment period during which interested persons may

submit relevant information on these chemical substances. Relevant information might include, but is not limited to, any information that may inform the prioritization screening review conducted pursuant to 40 CFR 702.9(a).

C. Why is the Agency taking this action?

TSCA section 6(b) requires that EPA initiate the prioritization process for chemical substances that may be designated as high priority and low priority for risk evaluation. Per TSCA section 6(b)(2)(B), EPA must designate at least 20 low priority substances and be conducting risk evaluations on at least 20 high priority substances no later than three and one-half years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Pub. L. 114-182). The request for interested persons to submit relevant information on a chemical substance for which EPA has initiated the prioritization process is required by TSCA section 6(b)(1)(C)(i).

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

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

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

This document identifies the 40 chemical substances for which EPA is initiating the prioritization process, provides a general explanation of why the Agency chose to initiate prioritization on these chemical substances, and provides a 90-day comment period for interested persons to submit relevant information. 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 information 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 section 6(b)(1), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Pub. L. 114-182), requires EPA to prioritize chemical substances for risk evaluation and to establish a process for prioritizing chemical substances. As required by TSCA section 6(b) and described in 40 CFR 702.7, EPA is initiating the prioritization process for 20 chemical substances as candidates for High Priority Substances for risk evaluation and 20 chemical substances as candidates for designation as Low Priority Substances.

Under the amended statute (section 6(b)(1)(B)) and implementing regulations (40 CFR 702.3), a High Priority Substance is defined as a chemical substance that EPA determines, 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 potentially exposed or susceptible subpopulations identified as relevant by EPA. A Low Priority Substance is described as a chemical that EPA concludes, based on information sufficient to establish, without

consideration of costs or other non-risk factors, does not meet the statutory criteria for designation as a High Priority Substance.

Initiation of prioritization for substances as High Priority candidates is not a finding of risk. Rather, when prioritization is complete, for those chemicals designated as high, the Agency will have evidence that this substance 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. Final designation of a high priority substance initiates the risk evaluation process (40 CFR 702.17), which culminates in a finding of whether or not the chemical substance presents an unreasonable risk under the conditions of use. A final designation of a Low Priority substance does not require a finding of low or no risk; rather, it is sufficient to show that the chemical does not meet the statutory criteria for a High Priority substance and that risk evaluation is not warranted at this time (40 CFR 702.15).

This document is intended to fulfill the TSCA section 6(b)(1)(C)(i) requirement that the Administrator request interested persons to submit relevant information on chemical substances that the Administrator has identified as candidates for designation as High Priority and Low Priority Substances for risk evaluation. As described in 40 CFR 702.7, this document also initiates the prioritization process, and provides 90 days during which interested persons may submit relevant information.

As described in 40 CFR 702.9(b) *Information sources*, in conducting the screening review during the prioritization process, EPA will consider 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), including, as appropriate, sources for hazard and exposure data listed in Appendices A and

B of the TSCA Work Plan Chemicals: Methods Document (February 2012).

Consistent with the approach in our *A Working Approach for Identifying Potential Candidate Chemicals for Prioritization* (September 27, 2018) and prioritization process (40 CFR 702.7), EPA consulted with other federal agencies and intends to continue to collaborate with them to identify information that is useful throughout the prioritization process.

III. High Priority Candidate Chemical Substances for which EPA is Initiating Prioritization

A. Candidates for which EPA is initiating prioritization for designation as High Priority Substances for risk evaluation.

EPA's working approach to selecting candidates for designation as High Priority Substances for risk evaluation is outlined in the document, *A Working Approach for Identifying Potential Candidate Chemicals for Prioritization*, released to the public on September 27, 2018 (https://www.epa.gov/sites/production/files/2018-09/documents/preprioritization_white_paper_9272018.pdf). To identify candidates for designation as High Priority Substances the Agency primarily looked to the TSCA Work Plan for Chemical Assessments: 2014 Update (2014 TSCA Work Plan). EPA surveyed the information and checked quality data elements in a step-wise approach that ensured responsible and timely completion of the process according to TSCA timelines. Additionally, EPA opened dockets for each of the 2014 TSCA Work Plan chemicals, and an additional docket for non-2014 TSCA Work Plan chemicals, to allow for public comment on the prioritization of these chemicals.

The sources of information, as described in the document *A Working Approach for Identifying Potential Candidate Chemicals for Prioritization*, included:

1. Type 1 sources: Existing databases (and dashboards) that allow the user to sift through

information using a graphical user-interface, a direct query such as Structured Query Language (SQL), or webservice Application Programming Interface (APIs). EPA's National Center for Computational Toxicology's Chemistry Dashboard (Chemistry Dashboard) (<https://comptox.epa.gov/dashboard>) is one of the several examples of a Type 1 source.

2. Type 2 sources: Additional details from existing information from public and non-public (i.e., confidential business information) sources that are maintained by competent authorities – this includes supporting information from other EPA program offices, state and federal agencies including assessments or evaluations from various US and international organizations (e.g., including but not limited to EPA's Integrated Risk Information System (IRIS) Assessments, EPA's Office of Water, EPA's Office of Air and Radiation, EPA's High Production Volume Challenge Program, International Agency for Research on Cancer (IARC), National Toxicology Program (NTP), National Institute for Occupational Safety and Health (NIOSH), Organisation for Economic Co-operation and Development (OECD), Agency for Toxic Substances and Disease Registry (ATSDR), and California Environmental Protection Agency (Cal EPA)).

3. Type 3 sources: Initial searches of additional sources of information within the public and gray literature domains that are not available from Type 1 and 2 sources (e.g., searches in PubMed, ToxNet, other US government and international websites).

After identifying evidence of information from reasonably available sources, the information was evaluated across several data elements including hazard, exposure, uses, and physicochemical, fate and transport properties.

After reviewing the three types of data, as explained previously, the chemical substances were reviewed for data availability across all data elements (e.g., hazard, exposure, uses, and

physicochemical, fate and transport properties). Considerations were given for chemical similarity, similar identified functions (e.g., solvents, phthalates, flame retardants), existing OPPT work (e.g., experience gained from the first ten chemicals to undergo risk evaluation) and other information as identified in available risk assessments (e.g., IRIS, ECHA), and public literature.

In the absence of measured data on chemicals being evaluated, EPA may use alternative means or new approach methods (NAMs) to obtain relevant data. These NAMs can reduce vertebrate testing, consistent with TSCA section 4(h)(1)(A). EPA intends to use this approach to the extent practicable and scientifically justified.

To identify chemical substances, EPA considered information such as the 2016 CDR reported uses and products as a surrogate for complexity of information to inform prioritization and risk evaluation. EPA considered the release and use information for these chemicals and screened them according to the types of industrial uses and types of products where the chemicals were used, as reported in the 2016 CDR. EPA considers a chemical with fewer unique uses as a lower work load and a chemical with multiple uses reported as a higher work load.

EPA intends to update and refine its initial review based on data sources identified by the public during the comment period (see EPA's request for data in Unit V.) and, where permitted by TSCA section 14 and subject to EPA confidentiality regulations at 40 CFR part 2, subpart B, intends to make this information publicly available for the 20 initiated chemicals when we publish the proposed priority designation.

B. Chemicals Initiated

EPA is initiating the prioritization process for the following twenty chemicals as candidates for designation as High Priority Substance candidates.

1. *1,3-Butadiene, CAS RN 106-99-0, Docket number: EPA-HQ-OPPT-2018-0451.* This chemical was listed in the 2014 Work Plan Chemicals with a hazard score of 3; an exposure score of 3; and a persistence and bioaccumulation score of 1. Data regarding the use of this chemical was reported to EPA in 2016. EPA also receives information annually on this chemical through the Toxics Release Inventory. Information is available from assessments by another federal agency and by other countries.

2. *Butyl benzyl phthalate (BBP) (1,2-Benzenedicarboxylic acid, 1-butyl 2-(phenylmethyl) ester), CAS RN 85-68-7, Docket number: EPA-HQ-OPPT-2018-0501.* This phthalate ester was listed in the 2014 Work Plan Chemicals with a hazard score of 3; an exposure score of 3; and a persistence and bioaccumulation score of 1. Data regarding the use of this chemical was reported to EPA in 2016. EPA also receives information annually on this chemical through the Toxics Release Inventory. Information is available from assessments by other countries.

3. *Dibutyl phthalate (DBP) (1,2-Benzenedicarboxylic acid, 1,2-dibutyl ester), CAS RN 84-74-2, Docket number: EPA-HQ-OPPT-2018-0503.* This phthalate ester was listed in the 2014 Work Plan Chemicals with a hazard score of 3; an exposure score of 3; and a persistence and bioaccumulation score of 1. Data regarding the use of this chemical was reported to EPA in 2016. EPA also receives information annually on this chemical through the Toxics Release Inventory. Information is available from assessments by another federal agency and by other countries.

4. *1,1-Dichloroethane, CAS RN 75-34-3, Docket number: EPA-HQ-OPPT-2018-0426.* This chlorinated solvent was listed in the 2014 Work Plan Chemicals with a hazard score of 2; an exposure score of 3; and a persistence and bioaccumulation score of 2. Data regarding the use of this chemical was reported to EPA in 2016. EPA also receives information on this chemical

through the Toxics Release Inventory. Information is available from assessments by another federal agency.

5. *1,2-Dichloroethane, CAS RN 107-06-2, Docket number: EPA-HQ-OPPT-2018-0427.*

This chlorinated solvent was listed in the 2014 Work Plan Chemicals with a hazard score of 3; an exposure score of 3; and a persistence and bioaccumulation score of 2. Data regarding the use of this chemical was reported to EPA in 2016. EPA also receives information annually on this chemical through the Toxics Release Inventory. Information is available from assessments conducted by another federal agency and another country.

6. *1,2-Dichloropropane, CAS RN 78-87-5, Docket number: EPA-HQ-OPPT-2018-0428.*

This chlorinated solvent was listed in the 2014 Work Plan Chemicals with a hazard score of 2; an exposure score of 3; and a persistence and bioaccumulation score of 2. Data regarding the use of this chemical was reported to EPA in 2016. EPA also receives information annually on this chemical through the Toxics Release Inventory. This chemical is also subject to other EPA regulations. In addition, information is available from assessments by another federal agency.

7. *Dicyclohexyl phthalate (1,2-Benzenedicarboxylic acid, 1,2-dicyclohexyl ester), CAS RN 84-61-7, Docket number: EPA-HQ-OPPT-2018-0504.* This phthalate ester was listed in the 2014 Work Plan Chemicals with a hazard score of 3 (based solely on environmental toxicity); an exposure score of 3; and a persistence and bioaccumulation score of 1. Data regarding the use of this chemical was reported to EPA in 2016. Information is available from assessment by another country.

8. *Di-ethylhexyl phthalate (DEHP) (1,2-Benzenedicarboxylic acid, 1,2-bis(2-ethylhexyl ester), CAS RN 117-81-7, Docket number: EPA-HQ-OPPT-2018-0433.* This phthalate ester was listed in the 2014 Work Plan Chemicals with a hazard score of 3; an exposure score of 3; and a

persistence and bioaccumulation score of 1. Data regarding the use of this chemical was reported to EPA in 2016. EPA also receives information annually on this chemical through the Toxics Release Inventory. Information is available from assessments by another federal agency and by other countries.

9. *Di-isobutyl phthalate (DIBP) (1,2-Benzenedicarboxylic acid, 1,2-bis(2-methylpropyl) ester)*, CAS RN 84-69-5, Docket number: EPA-HQ-OPPT-2018-0434. This phthalate ester was listed in the 2014 Work Plan Chemicals with a hazard score of 1; an exposure score of 2; and a persistence and bioaccumulation score of 1. Data regarding the use of this chemical was reported to EPA in 2016. Information is available from assessments by other countries.

10. *Ethylene dibromide (Ethane, 1,2-dibromo-)*, CAS RN 106-93-4, Docket number: EPA-HQ-OPPT-2018-0488. This chemical was listed in the 2014 Work Plan Chemicals with a hazard score of 3; an exposure score of 2; and a persistence and bioaccumulation score of 2. Data regarding the use of this chemical was reported to EPA in 2016. EPA also receives information annually on this chemical through the Toxics Release Inventory. EPA released a screening-level hazard characterization in 2009. In addition, information is available from assessments by another federal agency.

11. *Formaldehyde*, CAS RN 50-00-0, Docket number: EPA-HQ-OPPT-2018-0438. This chemical was listed in the 2014 Work Plan Chemicals with a hazard score of 3; an exposure score of 3; and a persistence and bioaccumulation score of 1. Data regarding the use of this chemical was reported to EPA in 2016. EPA also receives information on this chemical annually through the Toxics Release Inventory. EPA published the Formaldehyde Emission Standards for Composite Wood Products final rule in 2016. Information is available from assessments by another federal agency and other countries.

12. *1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta [g]-2-benzopyran (HHCB)*, CAS RN 1222-05-5, *Docket number: EPA-HQ-OPPT-2018-0430*. This chemical was listed in the 2014 Work Plan Chemicals with a hazard score of 2; an exposure score of 3; and a persistence and bioaccumulation score of 2. Data regarding the use of this chemical was reported to EPA in 2016. This chemical is also subject to other EPA regulations. EPA completed a risk assessment of the ecological risks from HHCB as fragrance ingredient in commercial and consumer products in 2014. EPA released a screening-level hazard characterization in 2008. In addition, information is available from assessment by another country.

13. *4,4'-(1-Methylethylidene)bis[2, 6-dibromophenol] (TBBPA)* , CAS RN 79-94-7, *Docket number: EPA-HQ-OPPT-2018-0462*. This halogenated flame retardant was listed in the 2014 Work Plan Chemicals with a hazard score of 2 (based solely on environmental toxicity); an exposure score of 3; and a persistence and bioaccumulation score of 2. Data regarding the use of this chemical was reported to EPA in 2016. EPA also receives information annually on this chemical through the Toxics Release Inventory. EPA released a problem formulation for TBBPA in 2015. Information is available from assessment by another country.

14. *o-Dichlorobenzene (Benzene, 1,2-dichloro-)*, CAS RN 95-50-1, *Docket number: EPA-HQ-OPPT-2018-0444*. This chlorinated solvent was listed in the 2014 Work Plan Chemicals with a hazard score of 2; an exposure score of 3; and a persistence and bioaccumulation score of 2. Data regarding the use of this chemical was reported to EPA in 2016. EPA also receives information on this chemical through the Toxics Release Inventory. EPA completed a screening-level hazard characterization of this chemical in 2009. Information is available from assessments by another federal agency and other countries.

15. *p-Dichlorobenzene (Benzene, 1,4-dichloro-)*, CAS RN 106-46-7, *Docket number:*

EPA-HQ-OPPT-2018-0446. This chlorinated solvent was listed in the 2014 Work Plan Chemicals with a hazard score of 3; an exposure score of 3; and a persistence and bioaccumulation score of 2. Data regarding the use of this chemical was reported to EPA in 2016. EPA also receives information annually on this chemical through the Toxics Release Inventory. EPA identified information available from assessments by another federal agency and other countries.

16. *Phosphoric acid, triphenyl ester (TPP), CAS RN 115-86-6, Docket number: EPA-HQ-OPPT-2018-0458*. This halogenated flame retardant was listed in the 2014 Work Plan Chemicals with a hazard score of 3 (based solely on environmental toxicity); an exposure score of 3; and a persistence and bioaccumulation score of 2. Data regarding the use of this chemical was reported to EPA in 2016.

17. *Phthalic anhydride (1,3-Isobenzofurandione), CAS RN 85-44-9, Docket number: EPA-HQ-OPPT-2018-0459*. This chemical was listed in the 2014 Work Plan Chemicals with a hazard score of 3; an exposure score of 3; and a persistence and bioaccumulation score of 1. Data regarding the use of this chemical was reported to EPA in 2016. EPA also received receives information on this chemical annually through the Toxics Release Inventory.

18. *trans-1,2- Dichloroethylene (Ethene, 1,2-dichloro-, (1E)-), CAS RN 156-60-5, Docket number: EPA-HQ-OPPT-2018-0465*. This chlorinated solvent was listed in the 2014 Work Plan Chemicals with a hazard score of 2; an exposure score of 3; and a persistence and bioaccumulation score of 2. Data regarding the use of this chemical was reported to EPA in 2016. EPA completed a screening-level hazard characterization of this chemical in 2015.

19. *1,1,2-Trichloroethane, CAS RN 79-00-5, Docket number: EPA-HQ-OPPT-2018-0421*. This chlorinated solvent was listed in the 2014 Work Plan Chemicals with a hazard score

of 3; an exposure score of 2; and a persistence and bioaccumulation score of 2. Data regarding the use of this chemical was reported to EPA in 2016. EPA also receives information annually on this chemical through the Toxics Release Inventory. Information is available from assessments by another federal agency.

20. *Tris(2-chloroethyl) phosphate (TCEP) (Ethanol, 2-chloro-, 1,1',1''-phosphate)*, CAS RN 115-96-8, Docket number: EPA-HQ-OPPT-2018-0476. This halogenated flame retardant was listed in the 2014 Work Plan Chemicals with a hazard score of 2; an exposure score of 2; and a persistence and bioaccumulation score of 2. Data regarding the use of this chemical was reported to EPA in 2016. EPA released a problem formulation for TCEP in 2015. Information is available from assessment by another country.

IV. Low Priority Candidate Chemical Substances for which EPA is Initiating Prioritization

A. Candidates for which EPA is initiating prioritization for designation as Low Priority Substances for risk evaluation.

1. EPA's working approach to selecting candidates for designation as Low Priority Substances for risk evaluation is outlined in the document, *A Working Approach for Identifying Potential Candidate Chemicals for Prioritization*, released to the public on September 27, 2018 (https://www.epa.gov/sites/production/files/2018-09/documents/preprioritization_white_paper_9272018.pdf). As elaborated in this unit, EPA has taken steps to implement the approach outlined in the working approach document.

Starting with over 30,000 chemicals from the April 2018 interim update of the TSCA active inventory, EPA applied a series of filtering steps to identify potential Low Priority Substance candidates. EPA's goal was to select chemicals that are among the best-suited for possible Low Priority Substance designation. EPA identified potential Low Priority Substance

candidates based on low-hazard, across a range of endpoints, as the initial criterion since EPA knew the data on hazard would be the most readily available.

EPA first narrowed the candidate pool to chemicals that had been evaluated by a government body like the US EPA or an OECD member nation. EPA's Safer Chemicals Ingredients List (SCIL) and Chemical Assessment Management Program (ChAMP), as well as the OECD Screening Information Data Sets, served as sources of government-evaluated chemicals. The SCIL (<https://www.epa.gov/saferchoice/safer-ingredients>) is a continuously updated list of chemicals that meet low-concern Safer Choice criteria (<https://www.epa.gov/saferchoice/standard>) for both human health and ecological endpoints. Based on assessments used to support their listing on the SCIL, EPA has found these chemicals to be relatively rich in data on hazard. Under ChAMP, EPA scientists performed interim evaluations of hazard, use, and exposure of high- and medium-production volume chemicals. These screening-level risk characterizations were interim evaluations that constituted neither a final Agency determination on risk nor a determination as to whether sufficient data were available to characterize risk. Screening Information Dataset (SIDS) Initial Assessment Reports (SIARs) (<https://hpcvchemicals.oecd.org/ui/Default.aspx>), prepared by OECD member nations, represent a systematic investigation of the potential risks to human health and the environment, and are most often associated with high-production-volume (HPV) chemicals. SIARs include a base set of hazard information, known as the SIDS elements, for each chemical substance and incorporate available information on use patterns and exposure to put hazard(s) into context (<http://www.oecd.org/chemicalsafety/risk-assessment/1947541.pdf>). Through public meetings and comments, EPA stakeholders indicated support for use of SCIL, ChAMP evaluations on chemicals of low concern, and relevant SIDS assessments as a starting point for identifying Low

Priority Substance candidates.

2. As a next filtering step and to increase confidence in the information on hazard, conditions of use and exposure, EPA filtered the pool of approximately 1,600 chemicals to approximately 200 substances having discretely defined structures. Data on chemicals with discrete structures, as opposed to those with variable structures, are more reliable and easily compared because of the certainty a definitive molecular structure provides in assessing hazard, conditions of use, and exposure. EPA further filtered the chemicals with discrete structures and selected those with the most available data, narrowing the pool to about 75 chemicals with low-hazard status among an internationally accepted set of endpoints. EPA applied a final screen by conducting a literature search to update and verify candidate information for reliability, completeness and consistency. With a set of high-quality data relevant to a potential designation as a Low Priority Substance, EPA reduced the candidate pool to the 20 chemical substances being initiated today. EPA will make transparent literature search documentation available at the proposal phase for the 20 Low Priority Substance candidates. EPA intends to update and refine its initial review based on data sources identified by the public during the comment period (see EPA's request for data in Unit V.) and, where permitted by TSCA section 14 and subject to EPA confidentiality regulations at 40 CFR part 2, subpart B, intends to make this information publicly available for the 20 initiated chemicals at proposal. This unit contains information on the data sources EPA is using to obtain reasonably available information for evaluating candidate Low Priority Substances consistent with TSCA section 6(b)(1)(B) and implementing regulations. EPA encourages submission of additional information relevant to Low Priority Substance designation that stakeholders believe may not be found in the sources listed.

a. *Data sources.* EPA intends to search for and review literature from primary literature

databases and gray literature and additional search strategies.

b. *NAMs and Analogous chemical data.* In the absence of measured data on chemicals being evaluated, EPA may use alternative means or new approach methods (NAMs) to obtain relevant data. These NAMs can reduce vertebrate testing, consistent with TSCA section 4(h)(1)(A). EPA intends to use this approach to the extent practicable and scientifically justified.

EPA will consider closely related, analogous chemicals, or analogs, and use data from these chemicals to demonstrate the suitability of a chemical for proposal as a Low Priority Substance where appropriate. The use of appropriate analogs in chemical assessment is a scientifically valid, widely adopted practice. Governments worldwide use analogs to fill data gaps in both regulatory and prioritization contexts. Examples can be found in the OECD screening information dataset (SIDS), the EU Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), the Canadian Chemicals Management Plan (CMP), and the Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS).

Suitable analogs will be chosen based on chemical biological similarities (e.g., chemical structure, metabolic breakdown or likely mechanistic/mode of action considerations). Information on the value of analogs and guidance for identifying suitable analogs can be found in OECD Series on Testing and Assessment No. 194 Guidance on Grouping of Chemicals, Second Edition (2014). EPA will use expert judgment to determine if the analog or model used is appropriate for the attribute being evaluated. EPA will consider each case separately, make the analog we have selected and the data we are using from it transparent, and accept public comment on alternative approaches.

EPA will also consider modeled data from sources such as ECOSAR, Oncologic, EPI Suite, and other models when determined to be within the domain of applicability or supported

by analog data.

B. Chemicals Initiated

EPA is initiating the prioritization process for the following twenty chemicals as candidates for designation as Low Priority Substance candidates.

1. *1-Butanol, 3-methoxy-, 1-acetate (CAS RN 4435-53-4), Docket ID number: EPA-HQ-OPPT-2019-0106.* EPA has selected 1-butanol, 3-methoxy-, 1-acetate for initiation as a candidate for potential designation as a low priority substance because it has a comprehensive data set demonstrating lower hazard, based on an internationally accepted set of low-concern thresholds for a broad range of endpoints, and in view of its known, intended and reasonably foreseen uses. Given the low-hazard profile, EPA does not expect estimated exposures to alter the assessment supporting its initiation as a candidate for potential designation as a low priority substance.

2. *D-gluco-Heptonic acid, sodium salt (1:1), (2.xi)- (CAS RN 31138-65-5), Docket ID number: EPA-HQ-OPPT-2019-0107.* EPA has selected d-gluco-heptonic acid, sodium salt (1:1), (2.xi)- for initiation as a candidate for potential designation as a low priority substance because it has a comprehensive data set demonstrating lower hazard, based on an internationally accepted set of low-concern thresholds for a broad range of endpoints, and in view of its known, intended and reasonably foreseen uses. Given the low-hazard profile, EPA does not expect estimated exposures to alter the assessment supporting its initiation as a candidate for potential designation as a low priority substance.

3. *D-Gluconic acid (CAS RN 526-95-4), Docket ID number: EPA-HQ-OPPT-2019-0108.* EPA has selected d-gluconic acid for initiation as a candidate for potential designation as a low priority substance because it has a comprehensive data set demonstrating lower hazard, based on

an internationally accepted set of low-concern thresholds for a broad range of endpoints, and in view of its known, intended and reasonably foreseen uses. Given the low-hazard profile, EPA does not expect estimated exposures to alter the assessment supporting its initiation as a candidate for potential designation as a low priority substance. While EPA will present an independent review if this chemical is proposed as a Low Priority Substance, EPA notes that this chemical has been evaluated and determined to be “low priority for further work” for human health and the environment in the OECD SIDS Initial Assessment Report (April 2004).

4. *D-Gluconic acid, calcium salt (2:1) (CAS RN 299-28-5), Docket ID number: EPA-HQ-OPPT-2019-0109.* EPA has selected d-gluconic acid, calcium salt (2:1) for initiation as a candidate for potential designation as a low priority substance because it has a comprehensive data set demonstrating lower hazard, based on an internationally accepted set of low-concern thresholds for a broad range of endpoints, and in view of its known, intended and reasonably foreseen uses. Given the low-hazard profile, EPA does not expect estimated exposures to alter the assessment supporting its initiation as a candidate for potential designation as a low priority substance. While EPA will present an independent review if this chemical is proposed as a Low Priority Substance, EPA notes that this chemical has been evaluated and determined to be “low priority for further work” for human health and the environment in the OECD SIDS Initial Assessment Report (April 2004).

5. *D-Gluconic acid, .delta.-lactone (CAS RN 90-80-2), Docket ID number: EPA-HQ-OPPT-2019-0110.* EPA has selected d-gluconic acid, .delta.-lactone for initiation as a candidate for potential designation as a low-priority substance because it has a comprehensive data set demonstrating lower hazard, based on an internationally accepted set of low-concern thresholds for a broad range of endpoints, and in view of its known, intended and reasonably foreseen uses.

Given the low-hazard profile, EPA does not expect estimated exposures to alter the assessment supporting its initiation as a candidate for potential designation as a low priority substance.

While EPA will present an independent review if this chemical is proposed as a Low Priority Substance, EPA notes that this chemical has been evaluated and determined to be “low priority for further work” for human health and the environment in the OECD SIDS Initial Assessment Report (April 2004).

6. *D-Gluconic acid, potassium salt (1:1) (CAS RN 299-27-4), Docket ID number: EPA-HQ-OPPT-2019-0111.* EPA has selected d-gluconic acid, potassium salt (1:1) for initiation as a candidate for potential designation as a low priority substance because it has a comprehensive data set demonstrating lower hazard, based on an internationally accepted set of low-concern thresholds for a broad range of endpoints, and in view of its known, intended and reasonably foreseen uses. Given the low-hazard profile, EPA does not expect estimated exposures to alter the assessment supporting its initiation as a candidate for potential designation as a low priority substance. While EPA will present an independent review if this chemical is proposed as a Low Priority Substance, EPA notes that this chemical has been evaluated and determined to be “low priority for further work” for human health and the environment in the OECD SIDS Initial Assessment Report (April 2004).

7. *D-Gluconic acid, sodium salt (1:1) (CAS RN 527-07-1), Docket ID number: EPA-HQ-OPPT-2019-0112.* EPA has selected d-gluconic acid, sodium salt (1:1) for initiation as a candidate for potential designation as a low priority substance because it has a comprehensive data set demonstrating lower hazard, based on an internationally accepted set of low-concern thresholds for a broad range of endpoints, and in view of its known, intended and reasonably foreseen uses. Given the low-hazard profile, EPA does not expect estimated exposures to alter

the assessment supporting its initiation as a candidate for potential designation as a low priority substance. While EPA will present an independent review if this chemical is proposed as a Low Priority Substance, EPA notes that this chemical has been evaluated and determined to be “low priority for further work” for human health and the environment in the OECD SIDS Initial Assessment Report (April 2004).

8. *Decanedioic acid, 1,10-dibutyl ester (CAS RN 109-43-3), Docket ID number: EPA-HQ-OPPT-2019-0113.* EPA has selected decanedioic acid, 1,10-dibutyl ester for initiation as a candidate for potential designation as a low priority substance because it has a comprehensive data set demonstrating lower hazard, based on an internationally accepted set of concern thresholds for a broad range of endpoints, and in view of its known, intended and reasonably foreseen uses. Given the low-hazard profile, EPA does not expect estimated exposures to alter the assessment supporting its initiation as a candidate for potential designation as a low priority substance.

9. *1-Docosanol (CAS RN 661-19-8), Docket ID number: EPA-HQ-OPPT-2019-0114.* EPA has selected 1-docosanol for initiation as a candidate for potential designation as a low-priority substance because it has a comprehensive data set demonstrating lower hazard, based on an internationally accepted set of low-concern thresholds for a broad range of endpoints, and in view of its known, intended and reasonably foreseen uses. Given the low-hazard profile, EPA does not expect estimated exposures to alter the assessment supporting its initiation as a candidate for potential designation as a low priority substance. While EPA will present an independent review if this chemical is proposed as a Low Priority Substance, EPA notes that this chemical has been evaluated and determined to be “low priority for further work” for human health and the environment in the OECD SIDS Initial Assessment Report (April 2006). 1-

docosanol was also evaluated by EPA's ChAMP program.

10. *1-Eicosanol (CAS RN 629-96-9), Docket ID number: EPA-HQ-OPPT-2019-0115.*

EPA has selected 1-eicosanol for initiation as a candidate for potential designation as a low priority substance because it has a comprehensive data set demonstrating lower hazard, based on an internationally accepted set of low-concern thresholds for a broad range of endpoints, and in view of its known, intended and reasonably foreseen uses. Given the low-hazard profile, EPA does not expect estimated exposures to alter the assessment supporting its initiation as a candidate for potential designation as a low priority substance. While EPA will present an independent review if this chemical is proposed as a Low Priority Substance, EPA notes that this chemical has been evaluated and determined to be "low priority for further work" for human health and the environment in the OECD SIDS Initial Assessment Report (April 2006). 1-eicosanol was also evaluated by EPA's ChAMP program.

11. *1,2-Hexanediol (CAS RN 6920-22-5), Docket ID number: EPA-HQ-OPPT-2019-0116.* EPA has selected 1,2-hexanediol for initiation as a candidate for potential designation as a low priority substance because it has a comprehensive data set demonstrating lower hazard, based on an internationally accepted set of low-concern thresholds for a broad range of endpoints, and in view of its known, intended and reasonably foreseen uses. Given the low-hazard profile, EPA does not expect estimated exposures to alter the assessment supporting its initiation as a candidate for potential designation as a low priority substance.

12. *1-Octadecanol (CAS RN 112-92-5), Docket ID number: EPA-HQ-OPPT-2019-0117.* EPA has selected 1-octadecanol for initiation as a candidate for potential designation as a low priority substance because it has a comprehensive data set demonstrating lower hazard, based on an internationally accepted set of low-concern thresholds for a broad range of endpoints, and in

view of its known, intended and reasonably foreseen uses. Given the low-hazard profile, EPA does not expect estimated exposures to alter the assessment supporting its initiation as a candidate for potential designation as a low priority substance. While an OECD SIDS Initial Assessment Report (August 2002) indicated a need to examine anaerobic biodegradability and potential long-term fish toxicity, the follow-on SIDS Initial Assessment Report (April 2006) concludes, based on new information, that fatty acids with chain lengths greater than 16, like 1-octadecanol, have low solubility (and hence low bioavailability), limiting potential chronic toxicity as well as limiting the need for further research.

13. *Propanol, [2-(2-butoxymethylethoxy)methylethoxy]- (CAS RN 55934-93-5), Docket ID number: EPA-HQ-OPPT-2019-0118.* EPA has selected propanol, [2-(2-butoxymethylethoxy)methylethoxy]- for initiation as a candidate for potential designation as a low priority substance because it has a comprehensive data set demonstrating lower hazard, based on an internationally accepted set of low-concern thresholds for a broad range of endpoints, and in view of its known, intended and reasonably foreseen uses. Given the low-hazard profile, EPA does not expect estimated exposures to alter the assessment supporting its initiation as a candidate for potential designation as a low priority substance.

14. *Propanedioic acid, 1,3-diethyl ester (CAS RN 105-53-3), Docket ID number: EPA-HQ-OPPT-2019-0119.* EPA has selected propanedioic acid, 1,3-diethyl ester for initiation as a candidate for potential designation as a low priority substance because it has a comprehensive data set demonstrating lower hazard, based on an internationally accepted set of low-concern thresholds for a broad range of endpoints, and in view of its known, intended and reasonably foreseen uses. Given the low-hazard profile, EPA does not expect estimated exposures to alter the assessment supporting its initiation as a candidate for potential designation as a low priority

substance. While EPA will present an independent review if this chemical is proposed as a Low Priority Substance, EPA notes that this chemical has been evaluated and determined to be “low priority for further work” for human health and the environment in the OECD SIDS Initial Assessment Report (April 2005).

15. *Propanedioic acid, 1,3-dimethyl ester (CAS RN 108-59-8), Docket ID number: EPA-HQ-OPPT-2019-0120.* EPA has selected propanedioic acid, 1,3-dimethyl ester for initiation as a candidate for potential designation as a low priority substance because it has a comprehensive data set demonstrating lower hazard, based on an internationally accepted set of low-concern thresholds for a broad range of endpoints, and in view of its known, intended and reasonably foreseen uses. Given the low-hazard profile, EPA does not expect estimated exposures to alter the assessment supporting its initiation as a candidate for potential designation as a low priority substance. While EPA will present an independent review if this chemical is proposed as a Low Priority Substance, EPA notes that this chemical has been evaluated and determined to be “low priority for further work” for human health and the environment in the OECD SIDS Initial Assessment Report (April 2005).

16. *Propanol, 1(or 2)-(2-methoxymethylethoxy)-, acetate (CAS RN 88917-22-0), Docket ID number: EPA-HQ-OPPT-2019-0121.* EPA has selected propanol, 1(or 2)-(2-methoxymethylethoxy)-, acetate for initiation as a candidate for potential designation as a low priority substance because it has a comprehensive data set demonstrating lower hazard, based on an internationally accepted set of low-concern thresholds for a broad range of endpoints, and in view of its known, intended and reasonably foreseen uses. Given the low-hazard profile, EPA does not expect estimated exposures to alter the assessment supporting its initiation as a candidate for potential designation as a low priority substance. While EPA will present an

independent review if this chemical is proposed as a Low Priority Substance, EPA notes that this chemical has been evaluated and determined to be “low priority for further work” for human health and the environment in the OECD SIDS Initial Assessment Report (November 2003).

17. *Propanol, [(1-methyl-1,2-ethanediyl)bis(oxy)]bis-* (CAS RN 24800-44-0), *Docket ID number: EPA-HQ-OPPT-2019-0122*. EPA has selected propanol, [(1-methyl-1,2-ethanediyl)bis(oxy)]bis- for initiation as a candidate for potential designation as a low priority substance because it has a comprehensive data set demonstrating lower hazard, based on an internationally accepted set of low-concern thresholds for a broad range of endpoints and in view of its known, intended and reasonably foreseen uses. Given the low-hazard profile, EPA does not expect estimated exposures to alter the assessment supporting its initiation as a candidate for potential designation as a low priority substance. While EPA will present an independent review if this chemical is proposed as a Low Priority Substance, EPA notes that this chemical has been evaluated and determined to be “low potential risk and low priority for further work” in the OECD SIDS Initial Assessment Report (July 1994).

18. *2-Propanol, 1,1'-oxybis-* (CAS RN 110-98-5), *Docket ID number: EPA-HQ-OPPT-2019-0123*. EPA has selected 2-propanol, 1,1'-oxybis- for initiation as a candidate for potential designation as a low priority substance because it has a comprehensive data set demonstrating lower hazard, based on an internationally accepted set of low-concern thresholds for a broad range of endpoints and in view of its known, intended and reasonably foreseen uses. Given the low-hazard profile, EPA does not expect estimated exposures to alter the assessment supporting its initiation as a candidate for potential designation as a low priority substance. While EPA will present an independent review if this chemical is proposed as a Low Priority Substance, EPA notes that this chemical has been evaluated and determined to be “low priority for further work”

in the OECD SIDS Initial Assessment Report (January 2001).

19. *Propanol, oxybis-* (CAS RN 25265-71-8), *Docket ID number: EPA-HQ-OPPT-2019-0124*. EPA has selected propanol, oxybis- for initiation as a candidate for potential designation as a low priority substance because it has a comprehensive data set demonstrating lower hazard, based on an internationally accepted set of low-concern thresholds for a broad range of endpoints and in view of its known, intended and reasonably foreseen uses. Given the low-hazard profile, EPA does not expect estimated exposures to alter the assessment supporting its initiation as a candidate for potential designation as a low priority substance. While EPA will present an independent review if this chemical is proposed as a Low Priority Substance, EPA notes that this chemical has been evaluated and determined to be “low priority for further work” in the OECD SIDS Initial Assessment Report (January 2001).

20. *Tetracosane, 2,6,10,15,19,23-hexamethyl-* (CAS RN 111-01-3), *Docket ID number: EPA-HQ-OPPT-2019-0125*. EPA has selected tetracosane, 2,6,10,15,19,23-hexamethyl- for initiation as a candidate for potential designation as a low priority substance because it has a comprehensive data set demonstrating lower hazard, based on an internationally accepted set of low-concern thresholds for a broad range of endpoints and in view of its known, intended and reasonably foreseen uses. Given the low-hazard profile, EPA does not expect estimated exposures to alter the assessment supporting its initiation as a candidate for potential designation as a low priority substance.

V. Relevant Information

Through this initiation of prioritization for a chemical substance, EPA is providing a 90-day comment period as required by the statute (TSCA section 6(b)(1)(C)(i)) and implementing regulations (40 CFR 702.7(d)), and requests that interested persons voluntarily submit relevant

information. Relevant information might include, but is not limited to, information that may inform the screening review conducted pursuant to 40 CFR 702.9(a) and consistent with the scientific standard of TSCA section 26(h), as follows:

- The chemical substance's hazard and exposure potential;
- The chemical substance's persistence and bioaccumulation;
- Potentially exposed or susceptible subpopulations which the submitter believes are relevant to the prioritization;
- Whether there is any storage of the chemical substance near significant sources of drinking water, including the storage facility location and the nearby drinking water source(s);
- The chemical substance's conditions of use or significant changes in conditions of use, including information regarding trade names;
- The chemical substance's production volume or significant changes in production volume; and
- Any other information relevant to the potential risks of the chemical substance that might be relevant to the designation of the chemical substance's priority for risk evaluation.

If the information is publicly available, citations are sufficient (including, but not limited to: title, author, date of publication, publication source), and the submission does not need to include copies of the information.

A person seeking to protect from disclosure as "confidential business information" any information that person submits under TSCA must assert and substantiate a claim for protection from disclosure concurrent with submission of the information in accordance with the requirements of TSCA section 14. While EPA may consider confidential business information when conducting its review under 40 CFR 702.9(a), the Agency encourages submitters to

minimize claims for protection from disclosure wherever possible to maximize transparency in EPA's screening review. More information on asserting and substantiating confidential business information claims under TSCA can be found at <https://www.epa.gov/tsca-cbi>.

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

Dated: March 18, 2019.

Andrew R. Wheeler,

Administrator.

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