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ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2019-0450; FRL-10004-82]

Final Designation of Low-Priority Substances under the Toxic Substances Control Act (TSCA); Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: As required by the Frank R. Lautenberg Chemical Safety for the 21st Century Act amendments to the Toxic Substances Control Act (TSCA) and implementing regulations, EPA is designating 20 chemical substances as Low-Priority Substances for which risk evaluation is not warranted at this time. This document provides the final 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 final designation for each chemical substance.

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 (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.

Additional instructions on visiting the docket, along with more information about dockets

generally, is available at <http://www.epa.gov/dockets>.

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, 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 designating 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 the final 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 final designation for each chemical substance.

C. Why is the Agency taking this action?

As required by TSCA section 6(b)(2)(B), EPA is designating 20 chemical substances as Low-Priority Substances. EPA initiated the prioritization process required by TSCA section 6(b) on March 21, 2019 (Ref. 1) and published screening reviews supporting their proposed designation as Low-Priority Substances on August 15, 2019 (Ref. 2).

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

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

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

This document identifies 20 chemical substances 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.

II. Background

TSCA section 6(b), as amended in 2016 by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Pub. L. 114-182), requires EPA to prioritize chemical substances for designation as a High-Priority Substance or a Low-Priority Substance. In accordance with TSCA section 6(b) and 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 and sought public comment on the identified candidates. On August 15, 2019 (Ref. 2), EPA proposed 20 chemical substances as Low-Priority Substances and sought additional public comment on these proposals.

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. Designation of a chemical substance as a Low-Priority Substance indicates a risk evaluation is not warranted at that time (TSCA Section 6(b)(1)(A) and 40 CFR 702.15).

This document is intended to fulfill the requirement in TSCA section 6(b)(2)(B) that the Administrator finalize the designation of 20 chemical substances as Low-Priority Substances. The prioritization rule states at 40 CFR 702.11 that EPA will publish such designations in the Federal Register.

As described in the proposal notice (Ref. 2), EPA used reasonably available information to screen each candidate chemical substance against the following criteria and considerations (40 CFR 702.9(a)) and thereby inform the proposed designation:

- 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.

For the final priority designation, EPA considered comments and information submitted by the public during two public comment periods (after initiation and after proposed designation) and incorporated them as appropriate in finalizing the 20 chemical substances designated as Low-Priority Substances, as outlined in the statute (TSCA section 6(b)(1)(A)) and implementing

regulations (40 CFR 702.11(a)) and consistent with the scientific standards of TSCA section 26(h) and (i). In addition, as required by TSCA section 6(b)(1)(B)(ii) and 40 CFR 702.11(b), EPA did not consider cost or other non-risk factors in making a priority designation.

III. Information and Comments Received

A. Initiation

The initiation of the prioritization process (Ref. 1) 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.

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

- *Propanol, [(1-methyl-1,2-ethanediyl)bis(oxy)]bis-* (CAS RN 24800-44-0) (Ref. 3)
- *Propanol, 1(or 2)-(2-methoxymethylethoxy)-, acetate* (CAS RN 88917-22-0) (Ref. 4)
- *Propanol, [2-(2-butoxymethylethoxy)methylethoxy]-* (CAS RN 55934-93-5) (Ref. 5)
- *Propanol, oxybis-* (CAS RN 25265-71-8) (Ref. 6)

EPA incorporated the chemical-specific information submitted during the initiation public comment period in the screening reviews published at proposal.

EPA also received general prioritization comments during the initiation public comment period, as summarized below. A high-level synopsis of comments received during the initiation stage, and Agency responses to those comments, follows. Additional information is included in the Agency's full response to general comments document (Ref. 7) and in its full response to chemical-specific comments document (Ref. 8).

The following provides an overview of public comments received during initiation and EPA's responses.

1. Agency Approach and Rationale

Comment: Several commenters requested that EPA clearly explain its approach to applying the statutory considerations and criteria of TSCA section 6(b)(1)(A) during the screening review of the candidate chemical substances, as well as its rationale for proposed priority designations. Specific concerns included how EPA would address instances where new data for some Work Plan chemicals identified as high- or low-priority chemicals might not satisfy the Section 6 statutory criteria for prioritization, and that “EPA should establish a risk-based screening process and criteria” and “should not decouple the hazard and exposure elements from the risk equation and transform them into independent considerations.”

Response: As required by Congress and codified in the regulations from the “Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act” Rule (Ref. 9), there are two comment opportunities during the prioritization process, in accordance with applicable statutory and regulatory requirements. EPA considered the information submitted as part of its proposed and final designations.

For prioritization, EPA considered sources of information consistent with the scientific standards in TSCA section 26(h), including the sources listed in EPA’s “Approach Document for Screening Hazard Information for Low-Priority Substances under TSCA” (Ref. 10) (also referred to as “Approach Document”).

In response to commenter’s specific concerns regarding implementation of the statutory considerations and criteria of TSCA section 6(b)(1)(A), EPA notes that the Agency developed a screening review document for each candidate chemical substance at proposal to identify the information, analysis and basis used to support the proposed designation as a low-priority substance. These documents are available in the respective dockets of each chemical substance

with a proposed designation as a Low-Priority Substance (Ref. 2). Each document includes an overview of the requirements in TSCA section 6(b)(1)(A) and in the regulation addressing the “screening review criteria” and considerations for proposed priority designations (40 CFR 702.9). Those documents describe how EPA considered each of the applicable statutory and regulatory requirements and criteria, including those related to hazard, exposure, the “conditions of use or significant changes in conditions of use,” and “potentially exposed or susceptible subpopulations,” to support the proposed designation.

TSCA section 6(b)(1)(A) requires EPA to determine whether a chemical may present unreasonable risk “because of a potential hazard and a potential route of exposure,” indicating that hazard and exposure potential are considerations for the risk-based priority designations.

2. Potentially Exposed or Susceptible Subpopulations

Comment: One commenter urged EPA to identify relevant potentially exposed or susceptible subpopulations (PESS), including infants, children, pregnant women, workers, the elderly, and “people living in proximity to sources of contamination,” as well as to consider environmental justice concerns in the prioritization process.

Response: EPA explained in the response to comments on the prioritization rule (Ref. 11) that EPA has, in practice, evaluated risks across populations, with particular attention to workers, pregnant women, children, infants and the elderly, among others. The Agency will continue to use and refine its processes for prioritization to determine risks to potentially exposed or susceptible subpopulations.

In the screening reviews conducted for prioritization, EPA considered reasonably available information to identify the relevant potentially exposed or susceptible subpopulations, such as children, workers or consumers. EPA used human health hazard information, the

conditions of use, and exposure potential to identify potentially exposed or susceptible subpopulations. These data provide an indication about whether children or other susceptible subpopulations may be potentially exposed to the reported chemical.

3. Future Prioritization Efforts

Comment: Some commenters offered thoughts on future prioritization efforts, including urging EPA to allow data to drive the priority designation and to not predetermine an outcome for the candidates as High- or Low-Priority Substances.

Response: EPA agrees that priority designation should be driven by data as explained in the Approach Document (Ref. 10). Similar to the process to designate the first 20 Low-Priority Substances, in the future, EPA intends to use reasonably available information in proposed designation documents to explain why it chose to initiate the process for the particular chemical substance (e.g., whether EPA viewed this as a potential candidate for high- or low-priority) (“Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act” rule (Ref. 9 at 33759)). In addition, the two 90-day comment periods provided an opportunity for any interested person to submit additional information before EPA finalized a designation for a candidate chemical substance.

4. Stakeholder Engagement and Transparency

Comment: Several commenters supported stakeholder engagement and transparency during the prioritization process, including maintaining an open and transparent process that “encourages submission of the most relevant information,” providing “greater transparency and clarity” and “more information to ascertain what information [EPA] already has and what information is needed,” and stating that “transparency and information exchange is critical to the success of future prioritization efforts.” Other commenters indicated shortcomings with the

transparency of the process and/or provided recommendations for improvements, including placing all the “reasonably available information” in the dockets for public review, increasing transparency about the information received during the initiation of public comment period and indicating if EPA used that information to screen the chemical against the criteria for proposing a priority designation, so that members of the public can comment on such information during the proposed designation comment period.

Response: EPA appreciates the feedback regarding engaging with stakeholders and transparency. Regarding the process and criteria used, as described in Unit III.A of the Initiation of Prioritization Under the Toxic Substances Control Act (Ref. 1), EPA used the Safer Chemical Ingredients List (SCIL) as a starting point for narrowing down potential candidates for Low-Priority Substances, but performed an independent review of the reasonably available information to screen each candidate chemical substance against all of the statutory criteria and considerations under TSCA section 6(b)(1)(A) and 40 CFR 702.9. This information was included in the screening reviews for each chemical substance. In addition, the two 90-day comment periods provided an opportunity for any interested person to submit additional information before EPA finalized a designation for a candidate chemical substance.

Leading up to the nine- to twelve-month statutory window for prioritization, EPA worked diligently to gather stakeholder input on the process for identifying candidates for initiation of prioritization. On December 11, 2017, EPA held a public meeting to discuss possible approaches for identifying potential candidate chemicals for EPA’s prioritization process under TSCA (82 FR 51415). EPA described and took comment on a number of possible approaches that could guide the Agency in identification of potential candidate chemicals for prioritization. EPA considered that input and on October 5, 2018, published notice of its release of “A Working

Approach for Identifying Potential Candidate Chemicals for Prioritization” and opened a docket for comment (83 FR 50366). When prioritization was actually initiated under the statutory timeline, EPA provided an opportunity for the public to provide information for the chemical substances by publishing the notice initiating the prioritization process (Ref. 1). In the notice with the proposed priority designation (Ref. 2), EPA developed a screening review document for each candidate chemical substance to identify the information, analysis and basis used to support the proposed Low-Priority Substance designation. These documents include linked citations to the Health and Environmental Research Online (HERO) database (Ref. 12) for all references used in the literature review for each of these chemical substances. Those references are accessible to the public via links provided in the HERO database.

5. Designation Terminology

Comment: One commenter called for greater clarity in the definitions of High- and Low-Priority Substances, beyond the statutory definitions.

Response: In a previous response to public comment, the Agency articulated its rationale for not elaborating on or modifying statutory standards for High-Priority and Low-Priority Substances: “EPA did not establish the standard for a High-Priority designation; Congress did in the definitions of High- (and Low-) Priority Substances ... The statutory standard for High-Priority designations – that the chemical ‘may present an unreasonable risk’ based on a ‘potential hazard and a potential route of exposure’ – is the only place where such a standard appears in TSCA.” (Ref. 11). EPA believes it is appropriate to rely on the statutory standards for designating High-Priority and Low-Priority Substances, without introducing new binding language. Yet to help explain the context, purpose, and timing of this effort, EPA wishes to offer some of the Agency’s views from its experience in this initial round of prioritization.

Every chemical substance may present risks of one sort or another. A spill of fresh water into a marine environment may present risks to aquatic life, and excessive consumption of water may present a risk of water intoxication to humans. People encounter chemicals in their daily lives that may present some risk. Notably, EPA's role in prioritization and risk evaluation under section 6 of TSCA is to scrutinize chemical substances for *unreasonable* risks. It would be inappropriate for every potential risk – even those from water – to be considered an unreasonable risk and even more inappropriate to think that the statutory text contemplates that the presence of potential risks forecloses a designation as a Low-Priority Substance. Rather, the statutory use of the term 'unreasonable' necessarily leaves some ambiguity for the Agency to resolve in exercising its technical and policy discretion in each decision it makes under the prioritization process. A determination of whether or not a chemical may present unreasonable risk is made on a case-by-case, chemical-specific basis.

In the final prioritization and risk evaluation rules, EPA retained its discretion by not promulgating a definition of unreasonable risk (82 FR 33726; Ref. 9). Indeed, in the risk evaluation rule's preamble, EPA discussed a non-exhaustive list of factors that the Agency may weigh in considering unreasonable risk: "To account for the number of different risk characterization approaches and for changing science, EPA will not include any specific definition in this final rule. To make a risk determination, EPA may weigh a variety of factors in determining unreasonable risk. The Administrator will consider relevant factors including, but not limited to: The effects of the chemical substance on health and human exposure to such substance under the conditions of use (including cancer and non-cancer risks); the effects of the chemical substance on the environment and environmental exposure under the conditions of use; the population exposed (including any susceptible populations), the severity of hazard (the nature

of the hazard, the irreversibility of hazard), and uncertainties” (82 FR 33726 at 33735). In recently issued draft risk evaluations, EPA further elaborated: “EPA also takes into consideration the Agency’s confidence in the data used in the risk estimate. This includes an evaluation of the strengths, limitations and uncertainties associated with the information used to inform the risk estimate and the risk characterization.”

The statute tasks the Agency with first teasing apart and designating High-Priority Substances for risk evaluation from Low-Priority Substances that will not proceed to risk evaluation – at least not at the current time based upon EPA’s review of reasonably available information. For High-Priority Substances, EPA must proceed to risk evaluation and, upon any determination of unreasonable risk, to risk management.

The statutory framework is thus clear that prioritization is not meant to be a risk evaluation. Nor can it be with the timeline provided under TSCA. The statute required that EPA designate 20 High-Priority Substances and 20 Low-Priority Substances within three and a half years of enactment (TSCA section 6(b)(2)(B)). Yet EPA first had to undertake a notice-and-comment rulemaking to lay out the process for this prioritization process (TSCA section 6(b)(1)(A)). The statute further specified the prioritization timeline: It must include multiple stages (initiation plus opportunity for public comment, with opportunity for extension; proposal plus opportunity for public comment; and final designation), and it must last no longer than one year but no shorter than nine months (TSCA section 6(b)(1)(C)). Between the statutory window of no more than one year for the entire prioritization process, the statutory requirement for EPA to designate 20 Low-Priority Substances by December 2019, and the plain statutory text explaining that EPA is to use a “screening process” to designate “low-priority” substances “for which risk evaluations are not warranted at the time,” the statute is clear that EPA need not

perform nearly as exhaustive a review of a chemical substance as a risk evaluation before designating the chemical substance as a Low-Priority Substance.

Moreover, Congress chose not to define “screening process” in the statute, leaving EPA the discretion to create a risk-based screening process according to the considerations expressed in section 6(b)(1)(A). EPA created a transparent literature review method for the purposes of prioritization and screening review under this section. The Approach Document (Ref. 10) includes a description of elements for weight of the scientific evidence and explains how these can be applied in a manner appropriate to screening-level review and Low-Priority Substance designations. The Approach Document (Ref. 10) explains the methods used to ensure comprehensive, objective, transparent and consistent review of reasonably available information.

EPA included exposure and potential changes in exposure through considerations such as conditions of use (including all known, intended or reasonably foreseen uses), significant changes in the conditions of use, production volume, and significant changes in the production volume. The selection of chemical substances with consistently low-hazard characteristics means that an increase in the frequency or magnitude of exposure would not significantly change the outcome of a screening-level review. In compliance with section 26, EPA considered the reasonably available information, including studies and data, on each proposed Low-Priority Substance relevant to the screening criteria and used such information in a manner consistent with best available science. EPA notes the following text from the Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act: “The screening review is not a risk evaluation, but rather a review of reasonably available information on the chemical substance that relates to the screening criteria. EPA expects to review all sources of relevant information, consistent with the scientific standards in 15 U.S.C. 2625(h), while

conducting the screening review” (Ref. 9 at 33759).

EPA also kept in mind the nine- to twelve-month deadline to complete the prioritization process, while accommodating and incorporating the statutorily-required cumulative six months of public comment. Congress recognized the important of public input and EPA has considered and incorporated, as appropriate, the comments that were received. The statutory provisions at TSCA sections 6(b)(1)(A) and 6(b)(1)(B)(ii) direct EPA to undertake a limited screening process and to render priority determinations based on sufficient supporting information.

Congress’s requirement for EPA to designate twenty chemical substances as Low-Priority Substances within three and a half years after the Lautenberg amendments to TSCA, within the nine- to twelve-month process prescribed by the statute, and only after first proposing and then promulgating a rule to lay out the process for prioritization, indicates that Congress expected the identification of such chemical substances to be a manageable exercise for the Agency. Low-priority designations are not determinations that these chemical substances do not present any risks, rather that EPA, through the prioritization process, has determined that sufficient information supports the determination that these chemical substances do not meet the standard provided in TSCA section 6(b)(1)(B)(i) to designate these chemical substances as High-Priority Substances.

Still, the final, yet not permanent, nature of the Low-Priority Substance designation gives EPA the authority to revisit a Low-Priority Substance designation given the ever-changing reality of scientific discovery. EPA notes the following text from the Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act: “Designation of a chemical substance as a Low-Priority Substance under §702.11 means that a risk evaluation of the chemical substance is not warranted at the time, but does not preclude EPA

from later revising the designation pursuant to §702.13, if warranted” (40 CFR 702.15; Ref. 9). EPA further notes the following text from Senate Report 114-67 – Frank R. Lautenberg Chemical Safety for the 21st Century Act: “By including these mandatory criteria in the statute, it is the Committee’s intent to require EPA to ensure that important, broad science-based considerations, classifications and designations drive the prioritization screening process, without locking EPA into specific designations based upon ever-changing science” (Ref. 12). EPA’s prioritization rule expressly recognizes that EPA may revise a Low-Priority Substance designation based on reasonably available information (40 CFR 702.13).

6. Timeframe for Providing Chemical Substance Information

Comment: Commenters described the challenges to collecting, identifying, assessing, and submitting chemical-specific data in the 90-day comment period following the initiation of the prioritization process, including challenges gathering information that resides with international downstream suppliers, limitations of available data gathering tools, and time and resource requirements, including a call for additional time during the comment period.

Response: EPA understands such challenges and has been committed to giving the public and interested stakeholders as many opportunities as possible, under the timing requirements of the statute, to provide relevant chemical substance information and comment on key aspects of the prioritization process in general, as well as for each chemical substance. The prioritization process was designed, by law, to take no fewer than nine months, and no more than twelve months – a timeframe set by Congress to allow interested stakeholders to provide the Agency with relevant, necessary information. EPA does not have the discretion to adjust the timeframe set by Congress. Within the nine- to twelve-month timeframe, there are two three-month comment periods (following initiation and proposed designation for the substances), for a total of

six months for public comment during the prioritization process.

Comment: A commenter stated that EPA “could use its authority under TSCA 4(a)(1)(A)(i) [to require the development of new information before initiating prioritization] and that it could also use its authority under 4(a)(1)(A)(ii) for chemicals that meet the statutory criteria of being produced and potentially released in substantial quantities or if there is potentially significant exposure,” while noting the “difficulty in making a may present unreasonable risk finding as required under 4(a)(1)(A)(i) was among the motivations for amending TSCA, and this difficulty would still need to be overcome.” The commenter then stated that “timing requirements might indeed be difficult to meet in some cases, [but] such difficulty does not remove the clear requirement under 4(a)(2)(B)(i) to make a priority designation within 90 days of receipt of any information requested.”

Response: EPA appreciates the comment regarding the Agency’s data collection authority. EPA identified sufficient information to complete the prioritization screening review and make final priority designations.

7. Confidential Business Information

Comment: One commenter urged EPA to implement the requirements of TSCA section 14 when prioritizing chemical substances, urging adherence to the requirements for disclosure of certain information by the Agency and the timing for confidentiality claims and substantiations.

Response: EPA generally makes the information it uses for decision making publicly available, consistent with the requirements of TSCA section 14. EPA considered all reasonably available information, including CBI, to perform the screening review for Low-Priority Substances. All reasonably available information used in the screening review was publicly available for the 20 Low-Priority Substances designated at this time.

8. Low-Priority Substance Designations

Comment: One commenter raised concerns that “EPA must be in possession of data for all relevant health and ecological endpoints developed using adequate test methodologies” to support a Low-Priority Substance designation. The commenter encouraged EPA to provide a description of “endpoints and related testing methodologies on which it will rely in the upcoming Federal Register notice proposing specific substances for low-priority listing.”

Response: Each chemical substance’s screening review provides the endpoints and methodology used to screen the chemical substance. The data quality criteria used to screen reasonably available hazard information is provided in the Approach Document (Ref. 10). As previously explained, EPA based its selection of candidate chemicals on the best available science, consistent with TSCA section 26(h), and selected candidates with robust data sets for consideration of hazard and exposure potential. Before initiating the prioritization process, EPA reviewed the reasonably available hazard and exposure-related information and determined whether there was sufficient information to complete the prioritization process within the statutory deadlines.

Comment: One commenter urged EPA to “provide a focused and robust message on low priority designations which clearly identify low priority chemicals as such, so that they do not occupy a place of uncertainty and are not associated with statements of implied risk” and “to continue to make low priority designations.”

Response: In the preamble of the prioritization rule (Ref. 9), EPA clarified the messaging associated with Low-Priority Substance designations by stating “final designation of a chemical substance as a Low-Priority Substance is a final agency action that means that a risk evaluation of the chemical substance is not warranted at the time.” In regard to continuing to make Low-

Priority Substance designations, EPA appreciates the commenter's viewpoint. Each chemical's screening review contains the reasonably available information sufficient to make the final designation of the chemical substance as a Low-Priority Substance, which is a final agency action that means that a risk evaluation of the chemical substance is not warranted at this time.

B. Screening Review and Proposed Priority Designation

The proposed designation stage of the prioritization process (Ref. 2) included a 90-day comment period during which interested persons were able to submit relevant information on those chemical substances proposed for Low-Priority Substance designation. 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 (Ref. 10). Information gathered according to this Approach Document was included in each chemical substance's screening review. EPA considered the information submitted during the screening review and the proposed priority designation public comment period for specific chemical substances, as appropriate, in finalizing the Low-Priority Substance designation. During the public comment period for the proposed designation stage, EPA received 11 submissions from eight different entities, including environmental and health advocacy groups, a trade association, an academic institution, and anonymous commenters. A high-level synopsis of comments received during the proposed designation stage, and Agency responses to those comments, follows. Additional information is included in the Agency's full response to general comments document (Ref. 7) and in its full response to chemical-specific comments document (Ref. 8).

The following provides an overview of public comments received during the proposal and EPA's responses.

1. Overall Strategy for Data Search, Screening, and Evaluation

Comment: Several commenters stated EPA failed to exercise its information collection authorities to gather all reasonably available information when designating chemicals as Low-Priority Substances. Some commenters wrote that EPA failed to develop test data to fill gaps in the existing data, despite having testing authority to do so. These commenters stated that because TSCA section 6(b)(2)(B) requires that EPA designate 20 High-Priority Substances and 20 Low-Priority Substances within three and a half years of enactment, testing that could have taken up to those three and a half years should or could be reasonably available information. Other commenters stated that EPA's strategies for data search, screening relevance, and evaluating data quality were sound and appropriate to ensure the relevance and quality of sufficient, reasonably available information to support designation of Low-Priority Substances.

Response: EPA found it had sufficient information to support the Low-Priority Substance designations and did not need to exercise its information gathering authorities. As explained further in section 1(a) of the full response to general comments document (Ref. 7), the timeframe for initiation, proposal, and public comment, did not allow for requiring, conducting, and documenting toxicological studies. More information on the Agency's rationale and response can be found in the full response to general comments document (Ref. 7).

Comment: A few commenters generally stated that EPA changed the "weight of the scientific evidence" definition to a new definition that is inconsistent with the definition in EPA's risk evaluation regulations and currently accepted scientific standards. These commenters also disagreed with EPA's use of weight of evidence to make a low-concern finding for specific endpoints. Other commenters supported EPA's strategies for evaluating data and stated they were sound, relevant, and sufficient to support designation of Low-Priority Substances.

Response: The risk evaluation definition of "weight of the scientific evidence" is beyond

the scope of prioritization. EPA ensured elements of weight of scientific evidence appropriate to screening-level review and Low-Priority Substance designation were incorporated in the screening-level reviews. The document “A Working Approach for Identifying Potential Candidate Chemicals for Prioritization” (Ref. 13) explains the methods used to ensure comprehensive, objective, transparent and consistent review of all reasonably available information for the Low-Priority Substances.

Comment: Several commenters suggested that the range of studies considered by EPA should have been more inclusive. In particular, one commenter recommended additional sources of information within U.S. government agencies and programs, and a few commenters stated that EPA’s review should not have excluded foreign language studies.

Response: EPA considered all reasonably available information and relied on the data quality criteria outlined in the Approach Document (Ref. 10) to ensure sufficient information to support a Low-Priority Substance designation.

Comment: One commenter pointed out a lack of clarity in the way EPA cited sources obtained from the European Chemicals Agency (ECHA) database. The commenter further stated that EPA needs to review and consider the full study reports corresponding to the summaries obtained from the ECHA database.

Response: EPA has updated the citations in the screening reviews to “Reported to the ECHA database” to reflect that ECHA is not the author of these studies. EPA found that the information in study summaries provided sufficient information to determine whether it met EPA’s data quality metrics (Ref. 10). Where summaries provided insufficient information, EPA did not use that study.

2. Additional Endpoints EPA Should Have Considered

Comment: Several commenters suggested additional endpoints that EPA should have considered during the prioritization process: physical hazards, immunotoxicity, respiratory sensitization, endocrine effects, and developmental neurotoxicity.

One commenter recommended that EPA should consider physical hazards, such as flammability, self-ignition, and explosive properties, when determining whether a substance meets the requirements for low-priority designation. The commenter wrote that TSCA does not define “hazard,” so the ordinary meaning of “a danger or risk” should be applied. The commenter pointed to the dossier for 3-methoxybutyl acetate as an example of EPA not considering or analyzing that substance’s moderate flammability.

Response: EPA considered all reasonably available information, which included the additional endpoints recommended by the commenters, in the screening review of the Low-Priority Substances. For example, EPA considered potential acute physical hazards, like flammability and explosive and self-ignition properties, for the Low-Priority Substances and found that the 20 Low-Priority Substances do not exhibit explosive, flammable, or self-ignition properties near ambient temperatures. As a result, EPA did not include acute physical hazard endpoints in its published screening review because the physical-chemical properties of the Low-Priority Substances indicate that these chemicals do not meet the standard for a High-Priority Substance for risk evaluation.

Comment: Two commenters stated that EPA failed to consider immunotoxicity and respiratory sensitization for all 20 Low-Priority Substances, and that EPA needs to consider these endpoints to fulfill its mandate under TSCA. In particular, commenters pointed out that immunotoxicity is relevant to vulnerable populations, including women, children, and the elderly, who may be more susceptible to immune system damage from chemical exposure, and

respiratory sensitization is particularly relevant to children's health issues due to increasing childhood asthma and other illnesses.

Response: EPA has added discussion of immunotoxicity and respiratory sensitization to each Low-Priority Substance's screening review. Inclusion of these endpoints helps to clarify that the Agency has addressed potential concerns for populations that could be exposed or susceptible to immunological toxicants.

Comment: A few commenters stated that EPA's mandate under TSCA requires a consideration of potential adverse endocrine effects and developmental neurotoxicity for the Low-Priority Substances.

Response: In considering the reasonably available information, EPA reviewed repeated dose, reproductive and developmental studies for documented changes in developmental neurotoxicity, such as behavioral, functional, or structural changes related to neurological outcomes in mammalian offspring. The Agency also reviewed information from high-throughput ToxCast assays and found no evidence of endocrine activity. Therefore, EPA believes it has sufficient information to designate these chemical substances as Low-Priority Substances.

3. Sufficient Information to Support a Low-Priority Substance Designation

Comment: Several commenters generally stated that EPA did not have sufficient information to support a low-priority designation for these 20 substances. Commenters also contended that EPA's methods disregarded, without sufficient justification, pieces of evidence suggesting the substances may have adverse effects. One commenter stated that more robust and complete data are needed for low-priority designations than for high-priority designations, and that EPA should not risk an erroneous designation of a substance as low priority.

Response: Congress chose not to define "screening process" in the statute, leaving EPA

the discretion to create a risk-based screening process according to the considerations expressed in section 6(b)(1)(A). EPA created a transparent literature review method for the purposes of prioritization and screening review under this section. The Approach Document (Ref. 10) includes a description of elements for weight of scientific evidence and explains how these can be applied in a manner appropriate to screening-level review and Low-Priority Substance designations. In compliance with section 26, EPA considered the reasonably available information, including studies and data, on each Low-Priority Substance relevant to the screening criteria and used such information in a manner consistent with best available science. EPA notes the following text from the Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act: “The screening review is not a risk evaluation, but rather a review of reasonably available information on the chemical substance that relates to the screening criteria. EPA expects to review all sources of relevant information, consistent with the scientific standards in 15 U.S.C. 2625(h), while conducting the screening review” (Ref. 9 at 33759). EPA also kept in mind the nine- to twelve-month deadline to complete the prioritization process, while accommodating and incorporating the statutorily-required cumulative six months of public comment. Congress recognized the importance of public input and EPA has considered and incorporated, as appropriate, the comments that were received.

Low-Priority Substance designations are not determinations that these chemical substances do not present any risks, rather that EPA, through the prioritization process, has determined that sufficient information supports the determination that these chemical substances do not meet the standard provided in TSCA section 6(b)(1)(B)(i) to designate these chemical substances as High-Priority Substances.

Comment: Two commenters raised concerns about the adequacy of EPA’s Low-Concern

Criteria and their application to the 20 Low-Priority Substances. For example, commenters stated that the Low-Concern Criteria were not sufficiently rigorous to determine whether a substance had an insignificant toxicological hazard, and pointed out flaws in the Criteria including missing endpoints and insufficient consideration of expected exposure. Another commenter recommended that EPA use transparent and scientifically accepted methods when evaluating studies for consideration in the prioritization process.

Response: In developing an approach for evaluating Low-Priority Substances, EPA assembled protective, pragmatic benchmarks and methodologies informed by precedent, routinely used by the Agency, and familiar to the regulated community and the public. The Approach Document (Ref. 10) explains the methods used to ensure comprehensive, objective, transparent and consistent review of all reasonably available information for the Low-Priority Substances, while remaining grounded in the view that what is required is sufficient information for designation.

Comment: One commenter generally supported EPA's approach to considering conditions of use, but recommended that EPA apply a quality review to all sources of information used when assessing conditions of use. The commenter suggested that this quality review process be addressed in the Approach Document (Ref. 10). The commenter also stated that EPA's considerations of changes in conditions of use and changes in volume were pragmatic.

Response: EPA included all known, intended, or reasonably foreseen uses in the Low-Priority Substance screening reviews to be as inclusive as possible and to account for reasonably foreseeable uses.

Comment: One commenter supported EPA's pragmatic approach to considering storage

near drinking water and recommended that EPA approach this criterion in the longer term using improved exposure models that can better predict fate and environmental partitioning into water sources. Another commenter stated that EPA's Low-Priority Substance dossiers did not adequately analyze storage near significant sources of drinking water. The commenter stated that EPA should have obtained data on the substances' actual storage near drinking water sources.

Response: EPA has sufficient information to establish that the Low-Priority Substances do not meet the definition for a High-Priority Substance based on their low-hazard profiles, biodegradation potential, wastewater treatment plant removal (greater than 80% for all 20 chemicals) and related characteristics. The Agency therefore did not use its information gathering authorities to obtain data on storage of the Low-Priority Substances. Additionally, similar to longer-term testing that is unavailable within the prioritization timeframe, EPA did not find information on the storage location of the Low-Priority Substances that was reasonably available.

Comment: One commenter stated that EPA dismissed, or did not seek, information regarding certain subpopulations' heightened susceptibility to adverse effects from chemical exposure. The commenter stated that EPA made unjustified assumptions that subpopulations such as children face the same level of risk as does the general public.

Response: EPA did consider potentially exposed or susceptible subpopulations (PESS) in its Low-Priority Substance designations, per TSCA section 6(b)(1). EPA found that a change in the conditions of use for the Low-Priority Substances could result in an increase in exposures to certain populations, but that the consistently low-hazard profiles associated with these chemicals are sufficient information to demonstrate that there are no groups with heightened susceptibility. Based on the weight of scientific evidence, EPA has sufficient information to support the Low-

Priority Substance designation of these chemical substances as they do not meet the standard for a High-Priority Substance for risk evaluation, including consideration of PESS.

Comment: Commenters stated that EPA dismissed the importance of exposure by making unsubstantiated assumptions of low exposure, and also failed to consider data on inhalation and dermal routes of exposure, both of which preclude definitive low-priority designations. One commenter further stated that EPA must establish the absence of adverse effects or potential exposure to support a low-priority designation. Another commenter generally supported EPA's approach to addressing exposure potential, but suggested that EPA could improve public understanding of its risk-based screening approach by adding information to the Approach Document (Ref. 10) explaining its approach to identifying, screening, evaluating, and integrating relevant information about potential exposure. The commenter also suggested that EPA consider formalizing risk-based screening by presenting margins of exposure.

Response: EPA developed a fit-for-purpose screening process appropriate for the designation of Low-Priority Substances. This approach focused on identifying chemicals that consistently exhibit low-hazard characteristics across the spectrum of endpoints. The hazard data included experimental data on the chemicals themselves and close analogs, data from New Approach Methodologies (NAMs), and data extrapolated across routes of exposure. For a small number of chemicals, EPA performed route-to-route extrapolations from available data to predict toxicity values from inhalation and/or dermal exposures. EPA included a qualitative review of exposure potential as requiring margin of exposure estimates or other elements of a risk evaluation are beyond the scope of a screening-level review for prioritization. EPA included potential changes in exposure, conditions of use and production volume, and determined that changes in conditions of use or production volume would be unlikely to change the Agency's

Low-Priority Substance designations.

Comment: Several commenters expressed that EPA did not sufficiently address specific human health hazard endpoints. Generally, commenters stated that for multiple endpoints, EPA relied on insufficient data, made unsupported assumptions of low risk, dismissed data, and failed to make appropriate use of metrics and criteria for assessing these endpoints. For several endpoints, one commenter stated that EPA had appropriately used available tools and information to designate substances without requiring the development of new information, consistent with the goals of the amended TSCA. Comments were received on the following human health hazard endpoints: inhalation and dermal toxicity; adsorption, distribution, metabolism, and excretion (ADME); acute mammalian toxicity; reproductive toxicity; mutagenicity/genotoxicity; carcinogenicity; neurotoxicity; and eye irritation.

Response: In developing an approach for evaluating Low-Priority Substances, EPA assembled protective, pragmatic criteria and methodologies informed by precedent, routinely used by the Agency, and familiar to the regulated community and the public. EPA's approach was thorough in searching for and compiling data and information on individual chemicals and toxicological endpoints. At the same time, the approach was grounded in the view that what is required is sufficient information for prioritization, which would consider a chemical substance's overall hazard profile, application of assessment methods with reasonably available data, the weight of toxicological evidence, and the requisite definition for a Low-Priority Substance (namely, a chemical that at the time of its designation would not meet the standard for a High-Priority Substance). More detailed responses can be found in the full response to general comments document (Ref. 7).

Comment: Similarly, multiple commenters stated that EPA did not sufficiently address

environmental hazard endpoints, including chronic aquatic toxicity, bioaccumulation, persistence, and biodegradation. One commenter stated that EPA's system for environmental hazard classification was incomplete or not in alignment with established systems. Generally, commenters stated that for multiple endpoints, EPA relied on insufficient data or relied only on model predictions, dismissed possible concerns, or made unjustified assumptions. For some endpoints, two commenters stated that EPA designated the Low-Priority Substances using tools and information that were sufficient for prioritization purposes.

Response: While the Low-Priority Substances may not have experimental data for every endpoint, new approach methods, including QSARs and modeling, such as ECOSAR and EPISuite, are widely accepted methodologies for estimating environmental hazard endpoints. More detailed responses can be found in the full response to general comments document (Ref. 7).

4. Discrepancies with Other Governing Bodies

Comment: Several commenters noted discrepancies between EPA's approach to reviewing and designating low-priority candidates and Globally Harmonized System of Classification and Labelling of Chemicals (GHS) criteria, other EPA criteria and guidance, and other organizations' findings on specific chemicals. Several commenters called out discrepancies for specific human health and environmental endpoints, including acute mammalian toxicity, reproductive and developmental toxicity, carcinogenicity, neurotoxicity, immunotoxicity, respiratory sensitization, and acute and chronic aquatic toxicity.

Response: EPA developed a fit-for-purpose screening process appropriate for the designation of Low-Priority Substances. The risk evaluation guidelines suggested by the commenters are not appropriate for the purposes of prioritization. In developing an approach for

evaluating Low-Priority Substances, EPA assembled protective, pragmatic benchmarks and methodologies informed by precedent, routinely used by the Agency, and familiar to the regulated community and the public. As part of its thorough search for information on the Low-Priority Substances, EPA considered the hazard findings of other countries as noted in each chemical's screening review. It is not unusual for data interpretations and findings to differ among countries because every country assesses chemicals and makes decisions based on its own governing statutes. EPA made Low-Priority Substance designations according to TSCA's risk-based statutory requirements. Based on its low-concern benchmarks, reasonably available information, and data screening approach, EPA finds it has sufficient information to designate the 20 chemical substances as Low-Priority Substances and that the chemical substances do not meet the standard for a High-Priority Substance for risk evaluation.

5. Analog Selection and Use

Comment: Multiple commenters raised concerns about the rigor and transparency of EPA's analog selection method and stated that EPA did not sufficiently justify its analog selections. Another commenter stated that EPA appropriately used the available tools and information, as well as its own expert judgement, to designate these substances without requiring the development of new information, consistent with the goals of the amended TSCA.

Response: EPA provides more information in the full response to general comments document (Ref. 7) on its selection of analogs based on the publicly available Analog Identification Methodology (AIM) software, the availability of relevant data on potential analogs, and EPA's best professional judgement.

6. Additional Comments

Comment: One commenter noted technical corrections related to the descriptions of

dipropylene glycol and tripropylene glycol in Section 2 of the respective supporting documents.

Response: EPA updated Section 2 of both supporting documents to reflect these corrections.

Comment: Several commenters provided broader comments on how EPA should have improved the prioritization process or how EPA could improve the process for future prioritization efforts. For example, one commenter stated that EPA underestimated the costs of prioritization in the TSCA fee rule, and as a result did not devote the resources necessary to compile sufficiently robust low priority dossiers. The commenter recommended that EPA incorporate additional prioritization costs in the TSCA fee rule.

Response: EPA appreciates commenters' concern for Agency resources. The screening reviews for each Low-Priority Substance contain the statutorily required elements needed to support designation. Using its current resource base, the Agency has compiled and analyzed sufficient reasonably available information to support candidate identification, screening review, and Low-Priority Substance designation for each chemical substance. Comments on the TSCA fee rule are outside of this action's scope.

Comment: Several commenters argued there is missing or incomplete information in EPA's Approach Document (Ref. 10). Commenters recommended that information be added or improved around several topics including statutory and regulatory screening criteria, EPA's approach to data integration, and EPA's approach to evaluating data quality. Commenters also stated that some criteria presented in the Approach Document (Ref. 10) were not supported by EPA precedent or by the broader scientific community. Commenters stated that EPA's criteria for reviewing and integrating studies was inconsistent with previous EPA criteria and with currently accepted approaches, and also stated that EPA used a new "weight of the scientific

evidence” definition that is inconsistent with EPA’s risk evaluation regulations and currently accepted scientific standards. One commenter expressed support for EPA’s development and application of the Approach Document (Ref. 10).

Response: The goal of the Approach Document (Ref. 10) was to establish a transparent process for review of the reasonably available hazard information presented in the Low-Priority Substance supporting documents. The Approach Document is not intended to address all elements of a systematic review or risk evaluation, which are beyond the scope of a screening review. The individual screening reviews provide further details regarding EPA’s approach and the statutory criteria for designating Low-Priority Substances. EPA will consider updating its Approach Document (Ref. 10) in the future to elaborate on its data integration methodology.

Comment: One commenter stated that the presence of a substance on the Safer Chemical Ingredients List (SCIL) is not sufficient for designating the substance as low-priority. The commenter stated that EPA should also consider, among other things, whether sufficient information exists on all conditions of use and hazard endpoints, what vulnerable subpopulations may be exposed, and whether there are potential environmental releases.

Response: EPA did not base its Low-Priority Substance designations on a chemical’s presence on SCIL. Instead, SCIL offered a pool of chemicals and a starting point in the Agency’s search for suitable Low-Priority Substance candidates. EPA reviewed the Low-Priority Substances by gathering and analyzing the reasonably available information to assess these chemicals and determined with sufficient information that these chemicals do not meet the statutory standard to be considered a High-Priority Substance.

Comment: One commenter commended EPA for taking care in its prioritization procedures rule, in its working approach document, in its Approach Document, and in its notices

initiating prioritization and proposing chemicals as low-priority to make clear what a designation of a chemical as a High-Priority Substance or as a Low-Priority Substance means.

Response: EPA appreciates the commenter's viewpoint.

Comment: One commenter provided recommendations for EPA's longer-term approaches to substance prioritization. The commenter recommended that EPA examine the applicability of using advanced approaches for evaluating exposure and bioactivity/toxicity as parallel evidence for use at the screening review step of the prioritization process. The commenter also recommended that EPA consider recent developments to tools for assessing persistence and bioaccumulation, and generally recommended that EPA should rely increasingly on use of New Approach Methodologies (NAMs) and other 21st century tools and sources of information to identify and propose chemicals as low priority.

Response: EPA appreciates the commenter's points and will consider them going forward.

IV. Chemical Substances which EPA is Designating as a Low-Priority Substance for Prioritization

A. Approach for Gathering Information, Conducting Analysis and Forming the Basis to Support the Final Low-Priority Substance Designation

EPA used reasonably available information, including public comments received on specific chemical substances during the 90-day comment periods following initiation of the prioritization process and proposal of the designations 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.).

Each supporting document for the chemical substances designated as a Low-Priority

Substance includes the information, analysis and basis for the final designation. In the absence of experimental data for a given endpoint, EPA integrated information using New Approach Methodologies (NAMs), discussed further in the respective supporting documents. These documents are available in the docket of each of the chemical substances with a final designation as a Low-Priority Substance. The final designations are presented in Unit IV.B., along with the docket references.

B. Final Priority Designation as Low-Priority Substances

EPA is publishing the final designation for the following 20 chemical substances as Low-Priority Substances for which risk evaluation is not warranted at this time. Using the approach described in Unit IV.A., and including information provided by commentators during comment periods in the designation process, as appropriate, the final 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. The chemical substances designated as Low-Priority Substances are listed below:

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 final designation as a 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 final designation as a 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 final designation as a 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 final designation as a 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 final designation as a 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 final designation as a 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 final designation as a 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 final designation as a 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 final designation as a 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 final designation as a 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 final designation as a 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 final designation as a 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 final designation as a 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 final designation as a 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 final designation as a 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 final designation as a 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 final designation as a 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 final designation as a 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 final designation as a 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 final designation as a 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. Proposed Low-Priority Substance Designation Under the Toxic Substances Control Act (TSCA). Notice. *Federal Register*. (84 FR 41712, August 15, 2019) (FRL-9997-63).

3. EPA. Information Relevant to Prioritization for Propanol, [(1-methyl-1,2-ethanediyl)bis(oxy)]bis-. Docket ID: EPA-HQ-OPPT-2019-0122. Available at <https://www.regulations.gov>.

4. EPA. Information Relevant to Prioritization for Propanol, 1(or 2)-(2-

methoxymethylethoxy)-, acetate. Docket ID: EPA-HQ-OPPT-2019-0121. Available at <https://www.regulations.gov>.

5. EPA. Information Relevant to Prioritization for Propanol, [2-(2-butoxymethylethoxy)methylethoxy]-. Docket ID: EPA-HQ-OPPT-2019-0118. Available at <https://www.regulations.gov>.

6. EPA. Information Relevant to Prioritization for Propanol, oxybis-. Docket ID: EPA-HQ-OPPT-2019-0124. Available at <https://www.regulations.gov>.

7. EPA. Summary of General Public Comments and Responses on the Proposed Designation of Low-Priority Substances under the Toxic Substances Control Act (TSCA). January 16, 2020.

8. EPA. Summary of Chemical-Specific Public Comments and Responses on the Proposed Designation of Low-Priority Substances under the Toxic Substances Control Act (TSCA). January 16, 2020.

9. EPA. Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act. Notice. *Federal Register*. (82 FR 33753, September 18, 2017) (FRL-9964-24).

10. 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. Available at <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0450-0002>.

11. EPA. *Procedures for Prioritization of Chemicals for Risk Evaluation under TSCA: Response to Public Comments*; SAN 5943; RIN 2070-AK23; EPA-HQ-OPPT-2016-0636. 2017. EPA. Health and Environmental Research Online: a Database of Scientific Studies and

References. Available at <https://hero.epa.gov/hero/>.

12. *S. Rep. No. 114-67*, 114th Cong., 1st Sess. 2015. Available at <https://www.congress.gov/114/crpt/srpt67/CRPT-114srpt67.pdf>.

13. EPA. “A Working Approach for Identifying Potential Candidate Chemicals for Prioritization.” (https://www.epa.gov/sites/production/files/2018-09/documents/preprioritization_white_paper_9272018.pdf). September 26, 2018.

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

Dated: February 19, 2020.

Andrew R. Wheeler,

Administrator.

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