equipment or pollution prevention process modifications;" section 8.26, "Civil or criminal penalties for failure to comply;" section 8.27, "Special facility-wide permit provisions;" and section 8.28, "Delay of testing;" as described in section II of this preamble. The EPA has made, and will continue to make, these materials generally available through www.regulations.gov and at the EPA Region 2 Office (please contact the person identified in the FOR FURTHER INFORMATION CONTACT section of this preamble for more information).

VI. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely proposes to approve State law as meeting Federal requirements and does not impose additional requirements beyond those imposed by State law. For that reason, this proposed action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 14094 (88 FR 21879, April 11, 2023);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999).
- Is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it approves a state program;
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001); and
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act.

In addition, this proposed SIP will not apply on any Indian reservation land or

in any other area where EPA or an Indian Tribe has demonstrated that a Tribe has jurisdiction. In those areas of Indian country, the rules do not have Tribal implications and will not impose substantial direct costs on Tribal governments or preempt Tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

Executive Order 12898 (Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations, 59 FR 7629, Feb. 16, 1994) directs Federal agencies to identify and address "disproportionately high and adverse human health or environmental effects" of their actions on communities with EI concerns to the greatest extent practicable and permitted by law. Executive Order 14096 (Revitalizing Our Nation's Commitment to Environmental Justice for All, 88 FR 25251, April 26, 2023) builds on and supplements E.O. 12898 and defines EJ as, among other things, the just treatment and meaningful involvement of all people, regardless of income, race, color, national origin, or Tribal affiliation, or disability in agency decision-making and other Federal activities that affect human health and the environment.

The NJDEP considered EJ as part of its SIP submittal given that the CAA and applicable implementing regulations neither prohibit nor require an evaluation. The EPA's review of the NJDEP's EJ considerations is described above in the section titled, "Environmental Justice Considerations." The consideration was done for the purpose of providing additional context and information about this rulemaking to the public, not as a basis of the action. The EPA is taking action under the CAA on bases independent of the consideration of EJ. Due to the nature of the action being taken here, this action is expected to have a neutral to positive impact on the air quality of the affected area. In addition, there is no information in the record upon which this decision is based that is inconsistent with the stated goal of E.O. 12898/14096 of achieving EJ for communities with EJ concerns.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Ammonia, Incorporation by reference, Intergovernmental relations, Nitrogen oxides, Particulate matter, Reporting and recordkeeping requirements, Sulfur dioxide, Volatile organic compounds.

Authority: 42 U.S.C. 7401 et seq.

Lisa Garcia,

Regional Administrator, Region 2. [FR Doc. 2024–29525 Filed 12–16–24; 8:45 am] BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[EPA-HQ-OPPT-2024-0079; FRL-12386-01-OCSPP]

RIN 2070-AB27

Significant New Use Rules on Certain Chemical Substances (24–3.5e)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing significant new use rules (SNURs) under the Toxic Substances Control Act (TSCA) for certain chemical substances that were the subject of premanufacture notices (PMNs) and are also subject to an Order issued by EPA pursuant to TSCA. The SNURs require persons who intend to manufacture (defined by statute to include import) or process any of these chemical substances for an activity that is proposed as a significant new use by this rulemaking to notify EPA at least 90 days before commencing that activity. The required notification initiates EPA's evaluation of the conditions of that use for that chemical substance. In addition, the manufacture or processing for the significant new use may not commence until EPA has conducted a review of the required notification, made an appropriate determination regarding that notification, and taken such actions as required by that determination.

DATES: Comments must be received on or before January 16, 2025.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2024-0079, at https://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. Additional instructions on commenting and visiting the docket, along with more information about dockets generally, is available at https://www.epa.gov/dockets.

FOR FURTHER INFORMATION CONTACT:

For technical information: Jordan Garbin, New Chemicals Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–4156; email address:

garbin.jordan@epa.gov.

For general information on SNURs: William Wysong, New Chemicals Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–4163; email address: wysong.william@epa.gov.

For general information on TSCA: 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. What is the Agency's authority for taking this action?

TSCA section 5(a)(2) (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a "significant new use." EPA must make this determination by rule after considering all relevant factors, including the factors in TSCA section 5(a)(2) (see also the discussion in Unit II.).

B. What action is the Agency taking?

EPA is proposing SNURs for the chemical substances discussed in Unit III. These SNURs, if finalized as proposed, would require persons who intend to manufacture or process any of these chemical substances for an activity that is designated as a significant new use to notify EPA at least 90 days before commencing that activity.

C. Does this action apply to me?

1. General Applicability

This action applies to you if you manufacture, process, or use the chemical substances contained in this proposed rule. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Manufacturers or processors of one or more subject chemical substances (NAICS codes 325 and 324110), e.g., chemical manufacturing and petroleum refineries.
- 2. Applicability to Importers and Exporters

This action may also apply to certain entities through pre-existing import

certification and export notification requirements under TSCA (https:// www.epa.gov/tsca-import-exportrequirements).

Chemical importers are subject to TSCA section 13 (15 U.S.C. 2612), the requirements in 19 CFR 12.118 through 12.127, 19 CFR 127.28, and the EPA policy in support of import certification at 40 CFR part 707, subpart B. Chemical importers must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA, including regulations issued under TSCA sections 5, 6, 7 and Title IV.

Pursuant to 40 CFR 721.20, any persons who export or intend to export a chemical substance that is the subject of this proposed rule on or after January 16, 2025 are subject to TSCA section 12(b) (15 U.S.C. 2611(b)) and must comply with the export notification requirements in 40 CFR part 707, subpart D.

D. What are the incremental economic impacts of this action?

EPA has evaluated the potential costs of establishing SNUN reporting requirements for potential manufacturers (including importers) and processors of the chemical substances subject to these proposed SNURs. This analysis, which is available in the docket, is briefly summarized here.

1. Estimated Costs for SNUN Submissions

If a SNUN is submitted, costs are an estimated \$45,000 per SNUN submission for large business submitters and \$14,500 for small business submitters. These estimates include the cost to prepare and submit the SNUN (including registration for EPA's Central Data Exchange (CDX)), and the payment of a user fee. Businesses that submit a SNUN would be subject to either a \$37,000 user fee required by 40 CFR 700.45(c)(2)(ii) and (d), or, if they are a small business as defined at 13 CFR 121.201, a reduced user fee of \$6,480 (40 CFR 700.45(c)(1)(ii) and (d)) per fiscal year 2022. The costs of submission for SNUNs will not be incurred by any company unless a company decides to pursue a significant new use as defined in these SNURs. Additionally, these estimates reflect the costs and fees as they are known at the time of this rulemaking.

2. Estimated Costs for Export Notifications

EPA has also evaluated the potential costs associated with the export notification requirements under TSCA

section 12(b) and the implementing regulations at 40 CFR part 707, subpart D. For persons exporting a substance that is the subject of a SNUR, a one-time notice to EPA must be provided for the first export or intended export to a particular country. The total costs of export notification will vary by chemical, depending on the number of required notifications (i.e., the number of countries to which the chemical is exported). While EPA is unable to make any estimate of the likely number of export notifications for the chemical substances covered by these SNURs, as stated in the accompanying economic analysis, the estimated cost of the export notification requirement on a per unit basis is approximately \$106.

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

1. Submitting CBI

Do not submit CBI to EPA through email or https://www.regulations.gov. If you wish to include CBI in your comment, please follow the applicable instructions at https://www.epa.gov/dockets/commenting-epa-dockets#rules and clearly mark the information that you claim to be CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR parts 2 and 703.

2. Tips for Preparing Your Comments

When preparing and submitting your comments, see the commenting tips at https://www.epa.gov/dockets/commenting-epa-dockets.

II. Background

This unit provides general information about SNURs. For additional information about EPA's new chemical program go to https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca.

A. Significant New Use Determination Factors

TSCA section 5(a)(2) states that EPA's determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors, including:

- The projected volume of manufacturing and processing of a chemical substance.
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.
- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.
- The reasonably anticipated manner and methods of manufacturing,

processing, distribution in commerce, and disposal of a chemical substance.

In determining what would constitute a significant new use for the chemical substances that are the subject of these SNURs, EPA considered relevant information about the toxicity of the chemical substances, and potential human exposures and environmental releases that may be associated with the substances, in the context of the four bulleted TSCA section 5(a)(2) factors listed in this unit and discussed in Unit III.

These proposed SNURs include PMN substances that are subject to orders issued under TSCA section 5(e)(1)(A), as required by the determinations made under TSCA section 5(a)(3)(B). The TSCA orders require protective measures to limit exposures or otherwise mitigate the potential unreasonable risk. The proposed SNURs identify as significant new uses any manufacturing, processing, use, distribution in commerce, or disposal that does not conform to the restrictions imposed by the underlying TSCA orders, consistent with TSCA section 5(f)(4).

B. Rationale and Objectives of the SNURs

1. Rationale

Under TSCA, no person may manufacture a new chemical substance or manufacture or process a chemical substance for a significant new use until EPA makes a determination as described in TSCA section 5(a) and takes any required action. The issuance of a SNUR is not a risk determination itself, only a notification requirement for "significant new uses," so that the Agency has the opportunity to review the SNUN for the significant new use and make a TSCA section 5(a)(3) risk determination.

During review of the PMNs submitted that are the subject to these proposed SNURs, EPA concluded that regulation was warranted under TSCA section 5(e), pending the development of information sufficient to make reasoned evaluations of the health or environmental effects of the chemical substances. Based on the findings outlined in Unit III., TSCA section 5(e) Orders requiring the use of appropriate exposure controls were negotiated with the PMN submitters. As a general matter, EPA believes it is necessary to follow the TSCA Orders with a SNUR that identifies the absence of those protective measures as significant new uses to ensure that all manufacturers and processors—not just the original submitter—are held to the same standard.

2. Objectives

EPA is proposing these SNURs because the Agency wants:

- To identify as significant new uses any manufacturing, processing, use, distribution in commerce, or disposal that does not conform to the restrictions imposed by the underlying TSCA Orders, consistent with TSCA section 5(f)(4).
- To have an opportunity to review and evaluate data submitted in a SNUN before the submitter begins manufacturing or processing a listed chemical substance for the described significant new use.
- To be obligated to make a determination under TSCA section 5(a)(3) regarding the use described in the SNUN, under the conditions of use. The Agency will either determine under TSCA section 5(a)(3)(C) that the significant new use is not likely to present an unreasonable risk, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, or make a determination under TSCA section 5(a)(3)(A) or (B) and take the required regulatory action associated with the determination, before manufacture or processing for the significant new use of the chemical substance can occur.

Issuance of a proposed SNUR for a chemical substance does not signify that the chemical substance is listed on the TSCA Chemical Substance Inventory (TSCA Inventory). Guidance on how to determine if a chemical substance is on the TSCA Inventory is available at https://www.epa.gov/tsca-inventory.

C. Significant New Uses Claimed as CBI

EPA is proposing to establish certain significant new uses which have been claimed as CBI subject to Agency confidentiality regulations at 40 CFR part 2 and 40 CFR part 703. Absent a final determination or other disposition of the confidentiality claim under these regulations, EPA is required to keep this information confidential. EPA promulgated a procedure at 40 CFR 721.11 to deal with the situation where a specific significant new use is CBI. Under these procedures, a manufacturer or processor may request EPA to identify the confidential significant new use under the rule. The manufacturer or processor must show that it has a bona fide intent to manufacture or process the chemical substance. If EPA concludes that the person has shown a bona fide intent to manufacture or process the chemical substance, EPA will identify the confidential significant new use to

that person. Since most of the chemical identities of the chemical substances subject to these SNURs are also CBI, manufacturers and processors can combine the *bona fide* submission under the procedure in 40 CFR 721.11 into a single step.

D. Applicability of General Provisions

General provisions for SNURs appear in 40 CFR part 721, subpart A. These provisions describe persons subject to SNURs, recordkeeping requirements, exemptions to reporting requirements, and applicability of the rule to uses occurring before the effective date of the rule. Pursuant to 40 CFR 721.1(c), persons subject to SNURs must comply with the same requirements and EPA regulatory procedures as submitters of PMNs under TSCA section 5(a)(1)(A). In particular, these requirements include the information submission requirements of TSCA sections 5(b) and $5(\bar{d})(1)$, the exemptions authorized by TSCA sections 5(h)(1), 5(h)(2), 5(h)(3), and 5(h)(5) and the regulations at 40 CFR part 720. In addition, provisions relating to user fees appear at 40 CFR part 700.

Once EPA receives a SNUN, EPA must either determine that the significant new use is not likely to present an unreasonable risk of injury under the conditions of use for the chemical substance or take such regulatory action as is associated with an alternative determination under TSCA section 5 before the manufacture (including import) or processing for the significant new use can commence. If EPA determines that the significant new use of the chemical substance is not likely to present an unreasonable risk, EPA is required under TSCA section 5(g) to make public, and submit for publication in the Federal Register, a statement of EPA's findings.

As discussed in Unit I.C.2., persons who export or intend to export a chemical substance identified in a proposed or final SNUR are subject to the export notification provisions of TSCA section 12(b), and persons who import a chemical substance identified in a final SNUR are subject to the TSCA section 13 import certification requirements. See also https://www.epa.gov/tsca-import-export-requirements.

E. Applicability of the Proposed SNURs to Uses Occurring Before the Effective Date of the Final Rule

To establish a significant new use, EPA must determine that the use is not ongoing. The chemical substances subject to this proposed rule have undergone premanufacture review and received determinations under TSCA section 5(a)(3)(C). TSCA Orders have been issued for these chemical substances and the PMN submitters are required by the TSCA Orders to submit a SNUN before undertaking activities that would be designated as significant new uses in these SNURs. Additionally, the identities of many of the chemical substances subject to this proposed rule have been claimed as confidential per 40 CFR 720.85, further reducing the likelihood that another party would manufacture or process the substances for an activity that would be designated as a significant new use. Based on this, the Agency believes that it is highly unlikely that any of the significant new uses identified in Unit III. are ongoing.

When the chemical substances identified in Unit III. are added to the TSCA Inventory, EPA recognizes that, before the rule is effective, other persons might engage in a use that has been identified as a significant new use. Persons who begin manufacture or processing of the chemical substances for a significant new use identified on or after the designated cutoff date specified in Unit III.A. would have to cease any such activity upon the effective date of the final rule. To resume their activities, these persons would have to first comply with all applicable SNUR notification requirements and EPA would have to take action under TSCA section 5 allowing manufacture or processing to proceed.

F. Important Information About SNUN Submissions

1. SNUN Submissions

SNUNs must be submitted on EPA Form No. 7710–25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in 40 CFR 720.40 and 721.25. E–PMN software is available electronically at https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca.

2. Development and Submission of Information

EPA recognizes that TSCA section 5 does not require development of any particular new information (e.g., generating test data) before submission of a SNUN. There is an exception: If a person is required to submit information for a chemical substance pursuant to a rule, order or consent agreement under TSCA section 4, then TSCA section 5(b)(1)(A) requires such information to be submitted to EPA at the time of submission of the SNUN.

In the absence of a rule, TSCA order, or consent agreement under TSCA section 4 covering the chemical substance, persons are required only to submit information in their possession or control and to describe any other information known to or reasonably ascertainable by them (see 40 CFR 720.50). However, upon review of PMNs and SNUNs, the Agency has the authority to require appropriate testing. To assist with EPA's analysis of the SNUN, submitters are encouraged, but not required, to provide the potentially useful information identified for the chemical substance in Unit III.C.

EPA strongly encourages persons, before performing any testing, to consult with the Agency pertaining to protocol selection. Furthermore, pursuant to TSCA section 4(h), which pertains to reduction of testing in vertebrate animals, EPA encourages consultation with the Agency on the use of alternative test methods and strategies (also called New Approach Methodologies, or NAMs), if available, to generate the recommended test data. EPA encourages dialog with Agency representatives to help determine how best the submitter can meet both the data needs and the objective of TSCA section 4(h). For more information on alternative test methods and strategies to reduce vertebrate animal testing, visit https://www.epa.gov/assessing-andmanaging-chemicals-under-tsca/ alternative-test-methods-and-strategies-

The potentially useful information described in Unit III. may not be the only means of providing information to evaluate the chemical substance associated with the significant new uses. However, submitting a SNUN without any test data may increase the likelihood that EPA will take action under TSCA sections 5(e) or 5(f). EPA recommends that potential SNUN submitters contact EPA early enough so that they will be able to conduct the appropriate tests.

SNUN submitters should be aware that EPA will be better able to evaluate SNUNs that provide detailed information on the human exposure and environmental release that may result from the significant new use of the chemical substances.

III. Chemical Substances Subject to These Proposed SNURs

A. What is the designated cutoff date for ongoing uses?

EPA designates December 17, 2024 as the cutoff date for determining whether the new use is ongoing. This designation is explained in more detail in Unit II.E.

B. What information is provided for each chemical substance?

For each chemical substance identified in Unit III.C., EPA provides the following information:

- PMN number (the proposed CFR citation assigned in the regulatory text section of the proposed rule).
- Chemical name (generic name, if the specific name is claimed as CBI).
- Chemical Abstracts Service Registry Number (CASRN) (if assigned for nonconfidential chemical identities).
- Basis for the action (effective date of and basis for the TSCA Order).
- Potentially useful information.
 The regulatory text section of the proposed rule specifies the activities designated as significant new uses.

 Certain new uses, including production volume limits and other uses designated in the proposed rules, may be claimed

These proposed rules include PMN substances that are subject to orders issued under TSCA section 5(e)(1)(A), as required by the determinations made under TSCA section 5(a)(3)(B). Those TSCA Orders require protective measures to limit exposures or otherwise mitigate the potential unreasonable risk. The proposed SNURs identify as significant new uses any manufacturing, processing, use, distribution in commerce, or disposal that does not conform to the restrictions imposed by the underlying TSCA Orders, consistent with TSCA section 5(f)(4).

C. Which chemical substances are subject to these proposed rules?

The substances subject to the proposed rules in this document are as follows:

PMN Number (Proposed CFR Citation): P-18-127 (40 CFR 721.12043)

Chemical Name: Heptane, 2-methoxy-2-methyl-.

CASRN: 76589–16–7. Effective Date of TSCA Order: December 15, 2023.

Basis for TSCA Order: The PMN states that the use will be as a fragrance for household and consumer products, mainly laundry detergents. Based on submitted test data on the PMN substance, EPA has identified concerns for skin sensitization. Based on comparison to analogous chemical substances, EPA has also identified concerns for systemic and developmental effects. Based on submitted test data on the PMN substance, EPA predicts toxicity to

aquatic organisms may occur at concentrations that exceed 210 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

- Manufacture of the PMN substance only by import into the United States in a solution of no greater than 5% by weight (*i.e.*, no domestic manufacture);
- Processing of the PMN substance only in a solution of no greater than 5% by weight of the PMN substance;
- Processing for use or use of the PMN substance in consumer products only if the concentration of the PMN substance is less than 1% by weight;
- No release of the PMN substance, or any waste stream containing the PMN substance, in surface water concentrations that exceed 210 ppb;
- Use of personal protective equipment where there is a potential for dermal exposure; and
- Establishment of a hazard communication program, including human health precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a "significant new use" the absence of these protective measures.

Potentially Useful Information: EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of developmental toxicity, specific target organ toxicity, and pulmonary effects testing may be potentially useful to characterize the health and environmental effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

PMN Number (Proposed CFR Citation): P–18–325 (40 CFR 721.12044)

Chemical Name: Benzenesulfonic acid, alkyl-, compd. with 1,1'-iminobis[2-propanol] (1:1) (generic).

CASRN: Not available. Effective Date of TSCA Order: January 9, 2024.

Basis for TSCA Order: The PMN states that the use will be as an industrial crosslinking catalyst. Based on the structure of the anion, EPA identified

concerns for lung toxicity (surfactant effects). Based on test data for the neutral form of the cation and analogues for the anion, EPA also identified concerns for skin and eye irritation, and systemic and reproductive effects. Based on comparison to analogous anionic surfactants, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 0.4 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

- No manufacture, processing, or use of the PMN substance in any manner that results in inhalation exposure to the PMN substance;
- No processing for use or use of the PMN substance other than as an industrial cross-linking catalyst;
- No release of the PMN substances, or any waste stream containing the PMN substances, into waters of the United
- Use of personal protective equipment where there is a potential for dermal exposure; and
- Establishment of a hazard communication program, including human health precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a "significant new use" the absence of these protective measures.

Potentially Useful Information: EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of skin irritation/corrosion, eye irritation/ corrosion, pulmonary effects, specific target organ toxicity, and aquatic toxicity testing may be potentially useful to characterize the health and environmental effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

PMN Number (Proposed CFR Citation): P-20-14 (40 CFR 721.12045)

Chemical Name: Sugars, polymer with alkanetriamine (generic). CASRN: Not available.

Effective Date of TSCA Order: January 27, 2023.

Basis for TSCA Order: The PMN states that the generic (non-confidential) use will be as a water resistant resin additive. Based on comparison to analogous chemical substances, EPA has identified concerns for systemic effects (body weight). Based on potential chelation to nutrient metals, EPA has also identified concerns for developmental and systemic effects. Based on submitted test data on the PMN substance, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 191 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

• No use of the PMN substance in a consumer product;

- No release of the PMN substance, or any waste stream containing the PMN substance, in surface water concentrations that exceed 191 ppb;
- Use of personal protective equipment where there is a potential for dermal exposure; and
- Establishment of a hazard communication program, including human health precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a "significant new use" the absence of these protective measures.

Potentially Useful Information: EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of reproductive toxicity and specific target organ toxicity testing may be potentially useful to characterize the health and environmental effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

PMN Number (Proposed CFR Citation): P-21-86 (40 CFR 721.12046)

Chemical Name: Isooctadecanamide, N,N-bis(2-ethylhexyl)-.

CASRN: 1616494–50–8. Effective Date of TSCA Order: February 6, 2024.

Basis for TSCA Order: The PMN states that the generic (non-confidential) use will be as an automotive engine additive. Based on test data for the metabolite, EPA has identified concerns for systemic effects. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health. To protect against these risks, the Order requires:

- No processing for use of the PMN substance in a consumer product where the concentration of the PMN substance in the consumer product formulation exceeds the confidential percentage listed in the Order;
- No use of the PMN substance in a consumer product where the concentration of the PMN substance exceeds the confidential percentage listed in the Order;
- Use of personal protective equipment where there is a potential for dermal exposure; and
- Establishment of a hazard communication program, including human health precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a "significant new use" the absence of these protective measures.

Potentially Useful Information: EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of metabolism or pharmacokinetics and specific target organ toxicity testing may be potentially useful to characterize the health effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

PMN Number (Proposed CFR Citation): P-21-164 (40 CFR 721.12047)

Chemical Name: 2-Butanone, oxime, reaction products with trimethoxymethylsilane.

CASRN: 2639393–45–4.

Effective Date of TSCA Order:

November 13, 2023.

Basis for TSCA Order: The PMN states that the use will be as a crosslinker for waterproofing. Based on comparison to analogous chemical substances, EPA has identified concerns for irritation to skin and eyes and systemic effects. Based on test data for hydrolysis products, EPA has also identified concerns for acute toxicity, skin irritation, eye corrosion,

respiratory tract irritation and corrosion, skin sensitization, systemic effects, developmental effects, neurotoxicity and carcinogenicity. Based on test data for hydrolysis products, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 102 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

- No use of the PMN substance unless at 4% or less by weight in formulation;
- No loading or unloading of the PMN substance for manufacture, processing, or use unless under a gas (e.g., nitrogen) blanket;
- Application of the PMN substance for use only by roll, brush, or dip coating;
- Use of personal protective equipment where there is a potential for dermal exposure;
- Use of a NIOSH-certified combination particulate and gas/vapor respirator with an APF of at least 50 where there is a potential for inhalation exposure;
- Disposal of the PMN substance, or waste streams containing the PMN substance, only by incineration;
- No release of the PMN substance, or any waste stream containing the PMN substance, into waters of the United States; and
- Establishment of a hazard communication program, including human health precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a "significant new use" the absence of these protective measures.

Potentially Useful Information: EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of acute toxicity, carcinogenicity, eve damage, pulmonary effects, skin irritation, specific target organ toxicity, and aquatic toxicity testing may be potentially useful to characterize the health and environmental effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

PMN Number (Proposed CFR Citation): P-21-170 (40 CFR 721.12048)

Chemical Name: 2,6-Bis(dialkyl)-4-[2-(1-alkyl-4(1H)-pyridinylidene)alkylidene]-2,5-cycloalkyladien-1-one (generic).

CASRN: Not available.

Effective Date of TSCA Order: January

Basis for TSCA Order: The PMN states that the use will be as a color indicator for frying oil breakdown. Based on comparison to analogous chemical substances, EPA has identified concerns for irritation to skin and eyes, skin sensitization, neurotoxicity, systemic effects (respiratory tract, lung, liver, kidney, spleen, and body weight effects), reproductive and developmental effects, genotoxicity, carcinogenicity, and acute toxicity (mortality). Based on OECD Toolbox results, EPA identified concerns for skin sensitization and based on information provided in the SDS, EPA has also identified concerns for acute toxicity and irritation to skin, eyes, and respiratory tract. Based on comparison to analogous chemical substances, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

- Manufacture of the PMN substance only below an annual volume of 10 kg;
- No manufacture, processing, or use of the PMN substance resulting in releases to air except with the use of a HEPA filtration system;
- No processing for use or use of the PMN substance other than as a color indicator for frying oil breakdown;
- No processing for use or use of the PMN substance where the concentration of the PMN substance in the final product exceeds 0.008%;
- No release of the PMN substance, or any waste stream containing the PMN substance, into waters of the United
- Use of a NIOSH-certified particulate respirator with an APF of at least 10 where there is a potential for inhalation exposure;
- Use of personal protective equipment where there is a potential for dermal exposure; and
- Establishment of a hazard communication program, including human health precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a "significant new use" the absence of these protective measures.

Potentially Useful Information: EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of biodegradation, bioaccumulation, log P, and aquatic toxicity testing may be potentially useful to characterize the physical/chemical properties and environmental fate/effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

PMN Number (Proposed CFR Citation): P-21-184 (40 CFR 721.12049)

Chemical Name: Fatty acids, soya, reaction products with ammoniaethanolamine reaction by-products.

CASRN: 2378512-59-3.

Effective Date of TSCA Order: November 16, 2023.

Basis for TSCA Order: The PMN states that the generic (non-confidential) use will be in asphalt emulsion applications. Based on comparison to analogous chemical substances, EPA has identified concerns for acute toxicity, skin and eye irritation/corrosion, skin sensitization, point-of-contact effects, lung effects, and systemic effects. Based on the surfactant-like properties of the PMN substance and its use as an emulsifier, EPA has also identified concerns for lung effects (surfactancy). Based on information in the SDS, EPA has also identified concerns for skin irritation, eye corrosion, and respiratory irritation. Based on comparison to analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 2 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

- No manufacture, processing, or use of the PMN substance in any manner that results in the generation of vapor, mist, dust, or aerosol;
- No processing for use or use of the PMN substance in a consumer product;

- Use of personal protective equipment where there is a potential for dermal exposure;
- No release of the PMN substance, or any waste stream containing the PMN substance, in surface water concentrations that exceed 2 ppb; and
- Establishment of a hazard communication program, including human health precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a "significant new use" the absence of these protective measures.

Potentially Useful Information: EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of acute toxicity, specific target organ toxicity, pulmonary effects, skin irritation/ corrosion, eye damage, neurotoxicity, skin sensitization, and aquatic toxicity testing may be potentially useful to characterize the health and environmental effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

PMN Numbers (Proposed CFR Citations): P–22–3 (40 CFR 721.12050), P–22–4 (40 CFR 721.12051), P–22–5 (40 CFR 721.12052), and P–22–6 (40 CFR 721.12053)

Chemical Names: 1,5-Pentanediamine, 2-methyl-, hydrochloride (1:2) (P–22–3), 1,5-Pentanediamine, 2-methyl-, hydrochloride (1:1) (P–22–4), Formic acid, compd. with 2-methyl-1,5-pentanediamine (2:1) (P–22–5), and Formic acid, compd. with 2-methyl-1,5-pentanediamine (1:1) (P–22–6).

CASRNs: 34813–63–3 (P–22–3), 1840915–04–9 (P–22–4), 1836131–73–7 (P–22–5), and 1836131–75–9 (P–22–6). Effective Date of TSCA Order: December 4, 2023.

Basis for TSCA Order: The PMNs state that the uses will be as clay stabilizers for oil and gas fracking. Based on submitted test data on the P-22-3 substance, comparison to analogous chemical substances, structure and expected acidity or basicity of components, physical/chemical properties of components, and information provided in the SDS, EPA has identified concerns for acute toxicity, irritation or corrosion to skin, eyes, and respiratory tract, and systemic

effects. Based on submitted test data for the P–22–3 substance, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 570 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substances may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

- No processing for use or use of the PMN substances in consumer products;
- No manufacture, processing, or use of the PMN substances in any manner that results in inhalation exposure to the PMN substances;
- Use of personal protective equipment where there is a potential for dermal exposure;
- No release of the PMN substances, or any waste stream containing the PMN substances, in surface water concentrations that exceed 570 ppb combined; and
- Establishment of a hazard communication program, including human health precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a "significant new use" the absence of these protective measures.

Potentially Useful Information: EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of eye irritation/corrosion, skin irritation/ corrosion, specific target organ toxicity, pulmonary effects, and aquatic toxicity testing may be potentially useful to characterize the health and environmental effects of the PMN substances. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

PMN Number (Proposed CFR Citation): P-22-11 (40 CFR 721.12054)

Chemical Name: Alkadiene, homopolymer, hydroxy-terminated, bis[N-[2-[(1-oxo-2-propen-1yl)oxylethyl]carbamates] (generic). CASRN: Not available. Effective Date of TSCA Order:

November 27, 2023.

Basis for TSCA Order: The PMN states that the generic (non-confidential) use will be as a functionalized rubber in the resin side of two component epoxy modified acrylic adhesive and as a functionalized rubber in the resin side of two component acrylic adhesive. Based on test data on one or both of the two components in the formulation, EPA has identified concerns for skin sensitization, and systemic, reproductive, and developmental effects. Based on the weight of the scientific evidence, EPA has also identified concerns for respiratory sensitization. Based on information in the SDS, EPA has also identified concerns for skin sensitization and reproductive toxicity. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health. To protect against these risks, the Order requires:

 No use of the PMN substance in a consumer product;

• No manufacture, processing, or use of the PMN substance in any manner that results in inhalation exposure;

 Use of personal protective equipment where there is a potential for dermal exposure; and

• Establishment of a hazard communication program, including human health precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a "significant new use" the absence of these protective measures.

Potentially Useful Information: EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of skin sensitization, developmental toxicity, reproductive toxicity, and specific target organ toxicity testing may be potentially useful to characterize the health effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

PMN Number (Proposed CFR Citation): P-22-25 (40 CFR 721.12055)

Chemical Name: Oxirane, 2-(chloromethyl)-, homopolymer, ether with dialkyl-alkanediol (2:1) (generic).

CASRN: Not available. Effective Date of TSCA Order: February 20, 2024.

Basis for TSCA Order: The PMN states that the use will be as a chemical intermediate. Based on comparison to

analogous chemical substances and structural alerts, EPA has identified concerns for acute toxicity, irritation to the respiratory tract, skin, and eyes, systemic effects, genetic toxicity, and carcinogenicity. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health. To protect against these risks, the Order requires:

- No exceedance of the confidential annual production volume listed in the Order:
- No manufacture, processing, or use of the PMN substance in any manner that results in the generation of a vapor, mist, dust, or aerosol;
- Use of the PMN substance only as a chemical intermediate;
- Disposal of the PMN substance, or waste streams containing the PMN substance, only by hazardous waste incineration;
- No release of the PMN substance, or any waste stream containing the PMN substance, into waters of the United States:
- Use of personal protective equipment where there is a potential for dermal exposure; and
- Establishment of a hazard communication program, including human health precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a "significant new use" the absence of these protective measures.

Potentially Useful Information: EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of acute toxicity, specific target organ toxicity, pulmonary effects, eye irritation, skin irritation, genetic toxicity, and carcinogenicity testing may be potentially useful to characterize the health effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

PMN Number (Proposed CFR Citation): P–22–49 (40 CFR 721.12056)

Chemical Name: Aryl, polymer with formaldehyde, glycidyl ether, reaction products with amino alkyl-alkane diamine, cyclohexanediamine and alkylene (alkylcyclohexanamine) (generic).

CASRN: Not available.

Effective Date of TSCA Order: January 11, 2024.

Basis for TSCA Order: The PMN states that the use will be as a hardener in coatings for oil and gas, power, and chemical/petrochemical industries for tank and pipe linings and for asset protection, in coatings in wastewater applications industries for tank and pipe linings and for asset protection, in coatings used in manufacturing industries for tank and pipe linings and for asset protection, and in OEM automotive and heavy industrial machinery coatings. Based on submitted test data on the PMN substance, EPA has identified concerns for acute toxicity. Based on residual data, EPA has also identified concerns for irritation to the skin, eye, and respiratory tract, skin and respiratory sensitization, systemic, developmental, and reproductive effects, corrosion to all tissues, and genetic toxicity. Based on submitted test data on the PMN substance and comparison to analogous polycationic polymers, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 2 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health or the environment. To protect against these risks, the Order requires:

 No release of the PMN substance, or any waste stream containing the PMN substance, in surface water concentrations that exceed 2 ppb;

• Use of a NIOSH-certified particulate respirator with an APF of at least 1,000 where there is a potential for inhalation exposure:

 No use of the PMN substance in a consumer product;

• Use of personal protective equipment where there is a potential for dermal exposure; and

• Establishment of a hazard communication program, including human health precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a "significant new use" the absence of these protective measures.

Potentially Useful Information: EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has

determined that the results of skin irritation, skin corrosion, eye irritation, eye corrosion, specific target organ toxicity, pulmonary effects, and aquatic toxicity testing may be potentially useful to characterize the health and environmental effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

PMN Number (Proposed CFR Citation): P-22-50 (40 CFR 721.12057)

Chemical Name: Alkene, alkoxy-, polymer with alkoxyalkene (generic). CASRN: Not available.

Effective Date of TSCA Order: January 8, 2024.

Basis for TSCA Order: The PMN states that the generic (non-confidential) use will be as a lubricant. Based on comparison to analogous chemical substances, EPA has identified concerns for skin, eye, and respiratory tract irritation and systemic effects. Based on comparison to analogous neutral organics, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 32 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

- No processing for use or use of the PMN substance in a consumer product;
- No manufacture, processing, or use of the PMN substance in any manner that results in inhalation exposure to the PMN substance;
- No processing for use or use of the PMN substance other than for the confidential use listed in the Order;
- No release of the PMN substance, or any waste stream containing the PMN substance, into waters of the United States:
- Use of personal protective equipment where there is a potential for dermal exposure; and
- Establishment of a hazard communication program, including human health precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a "significant new use" the absence of these protective measures.

Potentially Useful Information: EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer

or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of specific target organ toxicity, skin irritation, eye irritation, pulmonary effects, and aquatic toxicity testing may be potentially useful to characterize the health and environmental effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

PMN Number (Proposed CFR Citation): P-22-58 (40 CFR 721.12058)

Chemical Name:

Methanesulfonamide, 1,1,1-trifluoro-N-[(trifluoromethyl)sulfonyl]-, sodium salt (1:1).

CASRN: 91742–21–1. Effective Date of TSCA Order: February 13, 2024.

Basis for TSCA Order: The PMN states that the generic (non-confidential) use will be as a process chemical. Based on submitted test data on the PMN substance, EPA has identified concerns for acute toxicity and serious eve damage. Based on comparison to analogous chemical substances, EPA has also identified concerns for respiratory tract and skin irritation, neurotoxicity, systemic, reproductive, and developmental effects. Based on comparison to analogous chemical substances, EPA has also identified concerns for respiratory, systemic, and neurological effects for the potential incineration product of the anion. Based on submitted test data on the PMN substance and comparison to analogous substances, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 140 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

- No manufacture of the PMN substance other than in an enclosed process;
- No processing or use of the PMN substance other than in a manner that does not generate a vapor, mist, dust, or aerosol that results in inhalation exposure to workers;
- No use of the PMN substance other than for the confidential use listed in the Order;
- No use of the PMN substance other than in the form of a liquid;

- No release of the PMN substance, or any waste stream containing the PMN substance, in surface water concentrations that exceed 100 ppb;
- Use of a NIOSH-certified combination particulate and gas/vapor respirator with an APF of at least 50 where there is a potential for inhalation exposure;
- Use of personal protective equipment where there is a potential for dermal exposure; and
- Establishment of a hazard communication program, including human health precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a "significant new use" the absence of these protective measures.

Potentially Useful Information: EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of specific target organ toxicity, pulmonary effects, reproductive toxicity, developmental toxicity, neurotoxicity, sediment toxicity, and aquatic toxicity testing may be potentially useful to characterize the health and environmental effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

PMN Number (Proposed CFR Citation): P-22-75 (40 CFR 721.12059)

Chemical Name: 1H-Isoindole-1,3(2H)-dione, 3a,4,7,7a-tetrahydro-2-(2-hydroxyethyl)-.

CASŘN: 15458–48–7.

Effective Date of TSCA Order: January 19, 2024.

Basis for TSCA Order: The PMN states that the use will be as a monomer used to produce an unsaturated polyester resin. Based on comparison to analogous chemical substances, EPA has identified concerns for acute toxicity, skin and eye irritation, and systemic effects. Based on comparison to analogous imides, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 21 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

- Manufacture of the PMN substance only at or below an annual volume of 3,000 kg;
- No domestic manufacture of the PMN substance (*i.e.*, import only);
- No use of the PMN substance other than as a monomer used to produce an unsaturated polyester resin;
- Use of personal protective equipment where there is a potential for dermal exposure; and
- Establishment of a hazard communication program, including human health precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a "significant new use" the absence of these protective measures.

Potentially Useful Information: EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of acute toxicity, eye irritation, skin irritation, pulmonary effects, specific target organ toxicity, and aquatic toxicity testing may be potentially useful to characterize the health and environmental effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

PMN Number (Proposed CFR Citation): P-22-78 (40 CFR 721.12060)

Chemical Name: Oxirane, 2-methyl-, polymer with oxirane, mono-isoalkyl ethers, phosphates, salt (generic).

CASRN: Not available.

Effective Date of TSCA Order: November 27, 2023.

Basis for TSCA Order: The PMN states that the use will be as a dispersing agent for pesticide formulations. Based on structure, EPA has identified concerns for lung effects (surfactancy). Based on comparison to analogous chemical substances, EPA has also identified concerns for skin irritation and systemic effects. Based on comparison to analogous anionic surfactants, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 23 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

- No processing for use or use of the PMN substance other than as a dispersing agent for pesticide formulations;
- No manufacture or processing of the PMN substance in any manner that results in the generation of a vapor, mist, dust, or aerosol;
- Use of personal protective equipment where there is a potential for dermal exposure;
- No release of the PMN substance, or any waste stream containing the PMN substance, in surface water concentrations that exceed 23 ppb; and
- Establishment of a hazard communication program, including human health precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a "significant new use" the absence of these protective measures.

Potentially Useful Information: EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of pulmonary effects, skin irritation, specific target organ toxicity, and aquatic toxicity testing may be potentially useful to characterize the health and environmental effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

PMN Number (Proposed CFR Citation): P-22-80 (40 CFR 721.12061)

Chemical Name: Poly(oxy-1,2-ethanediyl), .alpha.-(2-aminoethyl)-.omega.-(2-aminoethoxy)- and Poly(oxy-1,2-ethanediyl), .alpha.,.alpha.',-(iminodi-2,1-ethanediyl)bis[.omega.-(2-aminoethoxy)-.

CASRNs: 24991–53–5 and 90350–34–

Effective Date of TSCA Order: December 1, 2023.

Basis for TSCA Order: The PMN states that the use will be as an industrial intermediate used in the manufacture of polyamides as a monomer. Based on the pH of the PMN substance, EPA has identified concerns for skin, eye, and respiratory tract corrosion. Based on comparison to analogous chemical substances, EPA has also identified concerns for acute toxicity and skin sensitization. Based on comparison to analogous polycationic polymers, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed

- 0.7 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:
- No manufacture, processing, or use of the PMN substance in any manner that results in inhalation exposure;
- No release of the PMN substance, or any waste stream containing the PMN substance, in surface water concentrations that exceed 0.7 ppb;
- Use of personal protective equipment where there is a potential for dermal exposure; and
- Establishment of a hazard communication program, including human health precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a "significant new use" the absence of these protective measures.

Potentially Useful Information: EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of acute toxicity, skin corrosion, eye corrosion, pulmonary effects, skin sensitization, and aquatic toxicity testing may be potentially useful to characterize the health and environmental effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

PMN Number (Proposed CFR Citation): P-22-82 (40 CFR 721.12062)

Chemical Name: Alkenoic acid, alkyl, carbopolycyclic alkyl ester, polymer with trihalo (trihaloalkyl) alkyl alkyl alkenoate (generic).

CASRN: Not available. Effective Date of TSCA Order: November 3, 2023.

Basis for TSCA Order: The PMN states that the generic (non-confidential) use will be as a component of photoresist. Based on test data on the degradation product and an analogue of the degradation product, EPA has identified concerns for neurotoxicity, reproductive, developmental, and systemic effects. Based on the potential incineration product, EPA has also identified concerns for systemic effects, and neurotoxicity. The Order was issued under TSCA sections

5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health. To protect against these risks, the Order requires:

- No manufacture of the PMN substance other than by import into the United States (*i.e.*, no domestic manufacture) in a liquid formulation;
- No processing or use of the PMN substance other than in a liquid formulation;
- Use of the PMN substance only for the confidential use listed in the Order:
- No release of the PMN substance, or any waste stream containing the PMN substance, into waters of the United States:
- Disposal of the PMN substance, or waste streams containing the PMN substance, only by incineration;
- Use of personal protective equipment where there is a potential for dermal exposure; and
- Establishment of a hazard communication program, including human health precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a "significant new use" the absence of these protective measures.

Potentially Useful Information: EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of pulmonary effects, reproductive and developmental effects, and neurotoxicity testing may be potentially useful to characterize the health effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

PMN Number (Proposed CFR Citation): P-22-121 (40 CFR 721.12063)

Chemical Name: Polychloroalkene (generic).

CASRN: Not available.
Effective Date of TSCA Order:
February 6, 2024.

Basis for TSCA Order: The PMN states that the generic (non-confidential) use will be as a process intermediate. Based on submitted test data on the PMN substance and information in the SDS, EPA has identified concerns for acute toxicity (oral) and skin sensitization. Based on test data for analogues, EPA identified concerns for acute toxicity

(oral, inhalation), skin irritation, eve corrosion, respiratory irritation, genotoxicity, carcinogenicity, and systemic effects. Based on submitted acute test data and comparison to analogous chemical substances, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 0.15 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

- No domestic manufacture of the PMN substance (*i.e.*, import only);
- No processing, use, loading, or unloading of the PMN substance unless under a gas (e.g., nitrogen) blanket or in a closed system except that sampling may occur outside the closed system resulting in exposures;
- No use of the PMN substance other than for the confidential use listed in the Order;
- Use of a NIOSH-certified combination particulate and gas/vapor respirator with an APF of at least 50 where there is a potential for inhalation exposure;
- Use of personal protective equipment where there is a potential for dermal exposure;
- No release of the PMN substance, or any waste stream containing the PMN substance, in surface water concentrations that exceed 0.15 ppb; and
- Establishment of a hazard communication program, including human health precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a "significant new use" the absence of these protective measures.

Potentially Useful Information: EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results carcinogenicity, eye irritation/corrosion, genetic toxicity, pulmonary effects, skin irritation, specific target organ toxicity, toxicokinetics, and aquatic toxicity testing may be potentially useful to characterize the health and environmental effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA

based on submission of this or other relevant information.

PMN Number (Proposed CFR Citation): P-22-145 (40 CFR 721.12064)

Chemical Name: Alkanoic acid, trialkyl-, diester with carbomonocycle bis(alkyleneoxy)]bis[alkanediol] (generic).

CASRN: Not available. Effective Date of TSCA Order: February 21, 2024.

Basis for TSCA Order: The PMN states that the use will be as a reactive-diluent in a polyol component of a 2K (Isocyanate-Polyol) Urethane coating system for interior concrete floor sealant or interior/exterior paver sealer. Based on the physical/chemical properties of the PMN substance (as described in the New Chemical Program's PBT category at 64 FR 60194; November 1999) and test data on structurally similar substances, the PMN substance is a potentially persistent, bioaccumulative, and toxic (PBT) chemical. EPA estimates that the PMN substance will persist in the environment for more than six months and estimates a bioconcentration factor of greater than or equal to 5,000. Based on test data for a potential hydrolysis product, EPA has identified concerns for acute toxicity and systemic, reproductive, and developmental effects. Based on comparison to analogous esters, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 0.14 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

- No use of the PMN substance in any manner that generates a spray, mist, vapor, or aerosol containing the PMN substance unless the concentration of the PMN substance is less than 5.7% by weight;
- No processing for use or use of the PMN substance in a consumer product;
- No release of the PMN substance, or any waste stream containing the PMN substance, into waters of the United States:
- Disposal of the PMN substance, or waste streams containing the PMN substance, only by incineration;
- Use of personal protective equipment where there is a potential for dermal exposure; and
- Establishment of a hazard communication program, including human health precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a "significant new use" the absence of these protective measures.

Potentially Useful Information: EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of acute toxicity, reproductive toxicity, developmental toxicity, specific target organ toxicity, toxicokinetics, and aquatic toxicity testing may be potentially useful to characterize the health and environmental effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

PMN Number (Proposed CFR Citation): P-22-175 (40 CFR 721.12065)

Chemical Name: Modified Silsesquioxane, alkoxy-terminated (generic).

CASRN: Not available. Effective Date of TSCA Order: January 30, 2024.

Basis for TSCA Order: The PMN states that the use will be as a curable binder resin for composite stone articles (engineered stone). Based on comparison to analogous alkoxysilanes and other analogous chemical substances, EPA has identified concerns for lung toxicity. Based on the reactivity of the PMN substance and the low molecular weight fraction content, EPA has also identified concerns for irritation to the skin, eyes, and respiratory tract. Based on comparison with analogous chemical substances, EPA has also identified concerns for hematological effects (i.e., increased neutrophils, eosinophils, lymphocytes) associated with lung toxicity. Based on comparison to analogous alkoxysilanes, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 7 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

 No domestic manufacture of the PMN substance (i.e., import only);

 Use of the PMN substance only if the concentration of the PMN substance does not exceed 10% by weight in formulation;

- Use of a NIOSH-certified respirator with an APF of at least 10 where there is a potential for inhalation exposure;
- No release of the PMN substance, or any waste stream containing the PMN substance, in surface water concentrations that exceed 7 ppb;
- Use of personal protective equipment where there is a potential for dermal exposure; and
- Establishment of a hazard communication program, including human health precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a "significant new use" the absence

of these protective measures.

Potentially Useful Information: EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of skin irritation, eye irritation, specific target organ toxicity, and aquatic toxicity testing may be potentially useful to characterize the health and environmental effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

PMN Number (Proposed CFR Citation): P-23-18 (40 CFR 721.12066)

Chemical Name: Vegetable oil, polymer with pimelin ketone, oxymethylene and polymethylenepolyphenylene isocyanate (generic).

CASRN: Not applicable. Effective Date of TSCA Order:

February 23, 2024.

Basis for TSCA Order: The PMN states that the use will be as an industrial adhesive. Based on the weight of the scientific evidence, EPA has identified concerns for skin and respiratory sensitization and lung toxicity for the PMN substance and the low molecular weight fraction. Based on test data for residuals and comparison to analogous chemical substances of the residuals, EPA has also identified acute toxicity, irritation to the skin, eyes, and respiratory tract, skin sensitization, respiratory sensitization, neurotoxicity, lung effects, systemic effects, reproductive and developmental effects, genetic toxicity, and carcinogenicity for the residuals. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information

- to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health. To protect against these risks, the Order requires:
- No manufacture, processing, or use of the PMN substance in any manner that results in inhalation exposure to the PMN substance:
- No processing for use or use of the PMN substance in a consumer product;
- Use of personal protective equipment where there is a potential for dermal exposure; and
- Establishment of a hazard communication program, including human health precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a "significant new use" the absence of these protective measures.

Potentially Useful Information: EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of skin irritation, skin sensitization, and pulmonary effects testing may be potentially useful to characterize the health effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

PMN Number (Proposed CFR Citation): P-23-20 (40 CFR 721.12067)

Chemical Name: Silsesquioxanes, 3-mercaptopropyl, polymers with silicic acid (H4SiO4) tetra-Et ester, [(trimethylsilyl)oxy]-terminated.

CASRN: 2796383–42–9. Effective Date of TSCA Order: November 21, 2023.

Basis for TSCA Order: The PMN states that the generic (non-confidential) use will be as an additive/intermediate. Based on comparison to analogous chemical substances and alkoxysilanes, EPA has identified concerns for lung effects. Based on analogue data for the hydrolysis product, EPA has also identified concerns for skin sensitization and systemic effects. Based on comparison to analogous alkoxysilanes and thiols, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 3 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may

present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

- Use of the PMN substance only for the confidential use listed in the Order;
- No manufacture, processing, or use of the PMN substance in any manner that results in inhalation exposure to the PMN substance;
- Use of personal protective equipment where there is a potential for dermal exposure;
- No release of the PMN substance, or any waste stream containing the PMN substance, in surface water concentrations that exceed 3 ppb; and
- Establishment of a hazard communication program, including human health precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a "significant new use" the absence of these protective measures.

Potentially Useful Information: EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of specific target organ toxicity, pulmonary effects, skin sensitization, and aquatic toxicity testing may be potentially useful to characterize the health and environmental effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

PMN Number (Proposed CFR Citation): P-23-36 (40 CFR 721.12068).

Chemical Name: Castor oil, polymer with dicyclopentadiene, maleic anhydride, 2-methyl-1,3-propanediol, 3a,4,7,7a-tetrahydro-2-(2-hydroxyethyl)-1H-isoindole-1,3(2H)-dione and triethylene glycol.

CASRN: 2794200–69–2. Effective Date of TSCA Order: January 9, 2024.

Basis for TSCA Order: The PMN states that the use will be as a resin used in an electrical insulation coating to insulate electrical components (motors) in automobiles. Based on test data for the expected hydrolysis product and an analogue of the expected hydrolysis product, EPA has identified concerns for skin irritation, eye irritation, systemic effects, and reproductive/developmental effects. Based on comparison to analogous nonionic polymers, EPA predicts toxicity to

aquatic organisms may occur at concentrations that exceed 27 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

- No processing for use or use of the PMN substance in a consumer product;
- No manufacture, processing, or use of the PMN substance in any manner that generates a vapor, mist, dust, or aerosol;
- Use of personal protective equipment where there is a potential for dermal exposure;
- No release of the PMN substance, or any waste stream containing the PMN substance, in surface water concentrations that exceed 27 ppb; and
- Establishment of a hazard communication program, including human health precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a "significant new use" the absence of these protective measures.

Potentially Useful Information: EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of skin irritation, eye irritation, specific target organ toxicity, toxicokinetics, and aquatic toxicity testing may be potentially useful to characterize the health and environmental effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

PMN Numbers (Proposed CFR Citations): P-23-37 (40 CFR 721.12069), P-23-44 (40 CFR 721.12070), P-23-80 (40 CFR 721.12071), and P-23-93 (40 CFR 721.12072)

Chemical Names: Monoaromatic cyclic alkylene sulfonium fluoroalkyl sulfonic acid salt (generic) (P–23–37 and P–23–44), Aromatic sulfonium tricyclo fluoroalkyl sulfonic acid salt (generic) (P–23–80), and Aromatic dibenzothiophenium fluoroalkyl carbopolycycle sulfonic acid salt (generic) (P–23–93).

CASRNs: Not available. Effective Date of TSCA Order: December 22, 2023.

Basis for TSCA Order: The PMNs state that the generic (non-confidential) use of the PMN substances will be as photoacid generators (PAGs) for use in electronics industry. Based on the physical/chemical properties of the PMN substances (as described in the New Chemical Program's PBT category at 64 FR 60194; November 1999) and test data on structurally similar substances, the PMN substance are potentially persistent, bioaccumulative, and toxic (PBT) chemicals. EPA estimates that the PMN substances will persist in the environment for more than six months and have unknown bioaccumulation. Based on comparison to analogous chemical compounds, EPA has identified concerns for acute toxicity, irritation to the skin and respiratory tract, neurological effects, and systemic effects for the cation of the PMN substances, as well as eye corrosion for P-23-44, P-23-80, and P-23-93. Based on comparison to analogous chemical substances, EPA has also identified concerns for genetic toxicity for the PMN substances, and skin sensitization and portal-of-entry (respiratory) effects for P-23-93. Based on the photoreactivity of the PMN substances, EPA has also identified concerns for photosensitization. Based on comparison to analogous compounds, EPA has also identified concerns for systemic and reproductive effects for the anion of P-23-44 and P-23-93. Based on data on a potential incineration product, EPA identified concerns for local and systemic effects via inhalation exposure. Based on a lack of scientific data, there is unknown toxicity to aquatic organisms. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substances may present an unreasonable risk of injury to human health or the environment. To protect against these risks, the Order requires:

- No manufacture of the PMN substances beyond the time limits specified in the Order without submittal to EPA the results of certain testing described in the Testing section of the Order;
- Use of personal protective equipment where there is a potential for dermal exposure;
- Establishment of a hazard communication program, including human health precautionary statements on each label and in the SDS;
- No modification of the processing or use of the PMN substances in any way that generates a vapor, dust, mist, or aerosol in a non-enclosed process;

- Use of the PMN substances only for the confidential uses listed in the Order;
- No domestic manufacture of the PMN substances (*i.e.*, import only);
- Import of the PMN substances only in solution or in sealed containers weighing 5 kilograms or less; and
- No exceedance of the confidential annual importation volumes listed the Order.

The proposed SNUR would designate as a "significant new use" the absence of these protective measures.

Potentially Useful Information: EPA has determined that certain information about the physical/chemical properties, fate, bioaccumulation, environmental hazard, and human health effects of the PMN substances may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. The submitter has agreed not to exceed the time limits specified in the Order without performing the required Tier I and Tier II testing outlined in the Testing section of the Order.

PMN Number (Proposed CFR Citation): P-23-64 (40 CFR 721.12073)

Chemical Name: Alkanediol, substituted, polymer with diisocyanatoalkane, substituted heterocycle-modified (generic).

CASRN: Not available. Effective Date of TSCA Order: February 21, 2024.

Basis for TSCA Order: The PMN states that the generic (non-confidential) use will be as a component in aerospace coatings. Based on comparison to analogous chemical substances, EPA has identified concerns for pulmonary effects, systemic effects, and skin sensitization. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health. To protect against these risks, the Order requires:

- No processing for use or use of the PMN substance in consumer products;
- No manufacture, processing, or use of the PMN substance in any manner that results in the generation of a vapor, mist, dust, or aerosol;
- Use of personal protective equipment where there is a potential for dermal exposure; and
- Establishment of a hazard communication program, including human health precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a "significant new use" the absence of these protective measures.

Potentially Useful Information: EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of pulmonary effects and specific target organ toxicity testing may be potentially useful to characterize the health effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

PMN Number (Proposed CFR Citation): P-23-72 (40 CFR 721.12074)

Chemical Name: Halosubstituted carbopolycycle, polymer with substituted carbomonocycles and oxybis[alkanol] (generic).

CASRN: Not available. Effective Date of TSCA Order: February 22, 2024.

Basis for TSCA Order: The PMN states that the use will be as a UV resin for offset lithographic printing on plastic substrates. Based on the physical/ chemical properties of the PMN substance (as described in the New Chemical Program's PBT category at 64 FR 60194; November 1999) and test data on structurally similar substances, the PMN substance is a potentially persistent, bioaccumulative, and toxic (PBT) chemical. EPA estimates that the PMN substance will persist in the environment for more than six months and estimates a bioaccumulation factor of greater than or equal to 5,000. Based on test data for hydrolysis products of the low molecular weight fraction of the PMN substance, EPA has identified concerns for genetic toxicity, carcinogenicity, and systemic, reproductive, and developmental effects. Based on comparison to analogous esters, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 0.4 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

 No processing for use or use of the PMN substance in a consumer product;

- No processing for use or use of the PMN substance other than in an enclosed roll-coating lithographic printing machine;
- No processing for use or use of the PMN substance in a final coating formulation that exceeds 40% by weight;
- Disposal of the PMN substance only by landfill;
- No release of the PMN substance, or any waste stream containing the PMN substance, into waters of the United States;
- Use of a NIOSH-certified respirator with an APF of at least 10 where there is a potential for inhalation exposure;
- Use of personal protective equipment where there is a potential for dermal exposure; and
- Establishment of a hazard communication program, including human health precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a "significant new use" the absence of these protective measures.

Potentially Useful Information: EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of carcinogenicity, developmental toxicity, genetic toxicity, reproductive toxicity, specific target organ toxicity, toxicokinetics, and aquatic toxicity testing may be potentially useful to characterize the health and environmental effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

PMN Number (Proposed CFR Citation): P-23-94 (40 CFR 721.12075)

Chemical Name: Polymer of benzenedicarboxylic acid, substitutedbenzenedicarboxylic acid, branchedalkyldiol, alkyldiol and triisocyanate (generic).

CASRN: Not available. Effective Date of TSCA Order: January 9, 2024.

Basis for TSCA Order: The PMN states that the use will be as a reactive polymer for use in surface pretreatment. Based on test data for the feedstock residual, EPA has identified concerns for lung effects for the residual. Based on OECD QSAR Toolbox results and the structural alert for diisocyanates, EPA has also identified

concerns for dermal and respiratory sensitization. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health. To protect against these risks, the Order requires:

- No processing for use or use of the PMN substance in a consumer product;
- No manufacture, processing, or use of the PMN substance in any manner that results in inhalation exposure to the PMN substance:
- Use of personal protective equipment where there is a potential for dermal exposure; and
- Establishment of a hazard communication program, including human health precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a "significant new use" the absence of these protective measures.

Potentially Useful Information: EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of specific target organ toxicity, pulmonary effects, and skin sensitization testing may be potentially useful to characterize the health effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

PMN Number (Proposed CFR Citation): P-23-172 (40 CFR 721.12076)

Chemical Name: Sulfonium, tricarbocyclic-, alkylcarbomonocyclic-polyfluoro-heteropolycyclic-alkyl sulfonate (1:1), polymer with alkylaryl and carbomonocyclic alkylalkanoate, di-Me 2,2'-(1,2-diazenediyl)bis[2-alkylalkanoate]-initiated (generic).

ČASRN: Not available.

Effective Date of TSCA Order: January 29, 2024.

Basis for TSCA Order: The PMN states that the generic (non-confidential) use of the PMN substance will be for photolithography. Based on the physical/chemical properties of the PMN substance (as described in the New Chemical Program's PBT category at 64 FR 60194; November 1999) and test data on structurally similar substances, the PMN substance is a potentially persistent, bioaccumulative,

and toxic (PBT) chemical, EPA estimates that the PMN substance will persist in the environment for more than six months and estimates unknown bioaccumulation. Based on comparison to analogous sulfonium compounds, EPA has identified concerns for acute toxicity, irritation to the skin and respiratory tract, eye corrosion, neurological effects, and systemic effects for the sulfonium cation. Based on comparison to analogous chemical substances, EPA has also identified concerns for genetic toxicity. Based on the photoreactivity of the PMN substance, EPA has also identified concerns for photosensitization. Based on a potential incineration product (trifluroacetate), EPA has also identified concerns for local, neurological, developmental and systemic effects via inhalation exposure. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health or the environment. To protect against these risks, the Order requires:

- No manufacture of the PMN substance beyond the time limits specified in the Order without submittal to EPA the results of certain testing described in the Testing section of the Order:
- Use of personal protective equipment where there is a potential for dermal exposure;
- Establishment of a hazard communication program, including human health precautionary statements on each label and in the SDS;
- No modification of the processing of the PMN substance in any way that generates a vapor, dust, mist, or aerosol in a non-enclosed process;
- Use of the PMN substance only for the confidential use listed in the Order:
- No domestic manufacture of the PMN substance (*i.e.*, import only);
- Import of the PMN substance only in solution or in sealed containers weighing 5 kilograms or less; and
- No exceedance of the confidential annual importation volume listed the Order

The proposed SNUR would designate as a "significant new use" the absence of these protective measures.

Potentially Useful Information: EPA has determined that certain information about the physical/chemical properties, fate, bioaccumulation, environmental hazard, and human health effects of the PMN substance may be potentially useful in support of a request by the PMN submitter to modify the Order, or

if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. The submitter has agreed not to exceed the time limits specified in the Order without performing the required Tier I and Tier II testing outlined in the Testing section of the Order.

IV. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at https://www.epa.gov/laws-regulations-and-executive-orders.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 14094: Modernizing Regulatory Review

This action proposes to establish SNURs for new chemical substances that were the subject of PMNs. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866 (58 FR 51735, October 4, 1993), as amended by Executive Order 14094 (88 FR 21879, April 11, 2023).

B. Paperwork Reduction Act (PRA)

According to the PRA (44 U.S.C. 3501 et seq.), an agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the Federal Register, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable.

The information collection requirements related to SNURs have already been approved by OMB pursuant to PRA under OMB control number 2070-0038 (EPA ICR No. 1188). This action does not impose any burden requiring additional OMB approval. If an entity were to submit a SNUN to the Agency, the annual burden is estimated to average between 30 and 170 hours per submission. This burden estimate includes the time needed to review instructions, search existing data sources, gather and maintain the data needed, and complete, review, and submit the required SNUN.

EPA always welcomes your feedback on the burden estimates. Send any comments about the accuracy of the burden estimate, and any suggested methods for improving the collection instruments or instruction or minimizing respondent burden, including through the use of automated collection techniques.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA (5 U.S.C. 601 et seq.). The requirement to submit a SNUN applies to any person (including small or large entities) who intends to engage in any activity described in the final rule as a "significant new use." Because these uses are "new," based on all information currently available to EPA, EPA has concluded that no small or large entities presently engage in such activities.

A SNUR requires that any person who intends to engage in such activity in the future must first notify EPA by submitting a SNUN. Although some small entities may decide to pursue a significant new use in the future, EPA cannot presently determine how many, if any, there may be. However, EPA's experience to date is that, in response to the promulgation of SNURs covering over 1,000 chemicals, the Agency receives only a small number of notices per year. For example, the number of SNUNs received was 16 in Federal fiscal year (FY) FY2018, five in FY2019, seven in FY2020, 13 in FY2021, 11 in FY2022, and 15 in FY2023, and only a fraction of these submissions were from small businesses.

In addition, the Agency currently offers relief to qualifying small businesses by reducing the SNUN submission fee from \$37,000 to \$6,480. This lower fee reduces the total reporting and recordkeeping cost of submitting a SNUN to about \$14,500 per SNUN submission for qualifying small firms. Therefore, the potential economic impacts of complying with these proposed SNURs are not expected to be significant or adversely impact a substantial number of small entities. In a SNUR that published in the Federal **Register** of June 2, 1997 (62 FR 29684) (FRL-5597-1), the Agency presented its general determination that SNURs are not expected to have a significant economic impact on a substantial number of small entities, which was provided to the Chief Counsel for Advocacy of the Small Business Administration.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of \$100 million or more (in 1995 dollars) in any one year as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments.

Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by SNURs, and EPA does not have any reasons to believe that any State, local, or Tribal government will be impacted by these SNURs. In addition, the estimated costs of this action to the private sector do not exceed \$183 million or more in any one year (the 1995 dollars are adjusted to 2023 dollars for inflation using the GDP implicit price deflator). The estimated costs for this action are discussed in Unit I.D.

E. Executive Order 13132: Federalism

This action will not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it is not expected to have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the requirements of Executive Order 13132 do not apply to this action.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action will not have Tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000), because it is not expected to have substantial direct effects on Indian Tribes, significantly or uniquely affect the communities of Indian Tribal governments and does not involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of Executive Order 13175 do not apply to this action.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it does not concern an environmental health or safety risk. Since this action does not concern a human health risk, EPA's 2021 Policy on Children's Health also does not apply. Although the establishment of these SNURs do not address an existing children's environmental health concern because the chemical uses involved are not ongoing uses, SNURs require that persons notify EPA at least 90 days before commencing manufacture (defined by statute to include import) or processing of any of these chemical substances for an activity that is designated as a significant new use by this rulemaking. This notification allows EPA to assess

the intended uses to identify potential risks and take appropriate actions before the activities commence.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not a "significant energy action" as defined in Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

I. National Technology Transfer and Advancement Act (NTTAA)

This action does not involve any technical standards subject to NTTAA section 12(d) (15 U.S.C. 272 note).

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations and Executive Order 14096: Revitalizing Our Nation's Commitment to Environmental Justice for All

EPA believes that this type of action does not concern human health or environmental conditions and therefore cannot be evaluated with respect to the potentially disproportionate and adverse effects on communities with environmental justice concerns in accordance with Executive Orders 12898 (59 FR 7629, February 16, 1994) and 14096 (88 FR 25251, April 26, 2023). Although this action does not concern human health or environmental conditions, the premanufacture notifications required by these SNURs will allow EPA to assess the intended uses to identify potential disproportionate risks and take appropriate actions before the activities commence.

List of Subjects in 40 CFR part 721

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Kevin DeBell,

Acting Director, Office of Pollution Prevention and Toxics.

Therefore, for the reasons stated in the preamble, EPA proposes to amend 40 CFR chapter I as follows:

PART 721—SIGNIFICANT NEW USES OF CHEMICAL SUBSTANCES

■ 1. The authority citation for part 721 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

■ 2. Add §§ 721.12043 through 721.12076 to Subpart E to read as follows:

Subpart E—Significant New Uses for Specific Chemical Substances

Sec.

* * * * * *

- 721.12043 Heptane, 2-methoxy-2-methyl-.
 721.12044 Benzenesulfonic acid, alkyl-,
 compd. with 1,1'-iminobis[2-propanol]
 (1:1) (generic).
- 721.12045 Sugars, polymer with alkanetriamine (generic).
- 721.12046 Isooctadecanamide, N,N-bis(2-ethylhexyl)-.
- 721.12047 2-Butanone, oxime, reaction products with trimethoxymethylsilane.
- 721.12048 2,6-Bis(dialkyl)-4-[2-(1-alkyl-4(1H)-pyridinylidene)alkylidene]-2,5-cycloalkyladien-1-one (generic).
- 721.12049 Fatty acids, soya, reaction products with ammonia-ethanolamine reaction by-products.
- 721.12050 1,5-Pentanediamine, 2-methyl-, hydrochloride (1:2).
- 721.12051 1,5-Pentanediamine, 2-methyl-, hydrochloride (1:1).
- 721.12052 Formic acid, compd. with 2-methyl-1,5-pentanediamine (2:1).
- 721.12053 Formic acid, compd. with 2-methyl-1,5-pentanediamine (1:1).
- 721.12054 Alkadiene, homopolymer, hydroxy-terminated, bis[N-[2-[(1-oxo-2-propen-1-yl)oxylethyl]carbamates] (generic).
- 721.12055 Oxirane, 2-(chloromethyl)-, homopolymer, ether with dialkylalkanediol (2:1) (generic).
- 721.12056 Aryl, polymer with formaldehyde, glycidyl ether, reaction products with amino alkyl-alkane diamine, cyclohexanediamine and alkylene (alkylcyclohexanamine) (generic).
- 721.12057 Alkene, alkoxy-, polymer with alkoxyalkene (generic).
- 721.12058 Methanesulfonamide, 1,1,1-trifluoro-N-[(trifluoromethyl)sulfonyl]-, sodium salt (1:1).
- 721.12059 1H-Isoindole-1,3(2H)-dione, 3a,4,7,7a-tetrahydro-2-(2-hydroxyethyl).
- 721.12060 Oxirane, 2-methyl-, polymer with oxirane, mono-isoalkyl ethers, phosphates, salt (generic).
- 721.12061 Poly(oxy-1,2-ethanediyl), .alpha.-(2-aminoethyl)-.omega.-(2-aminoethoxy)- and Poly(oxy-1,2-ethanediyl), .alpha.,.alpha.',-(iminodi-2,1-ethanediyl)bis[.omega.-(2-aminoethoxy)-.
- 721.12062 Alkenoic acid, alkyl, carbopolycyclic alkyl ester, polymer with trihalo (trihaloalkyl) alkyl alkyl alkenoate (generic).
- 721.12063 Polychloroalkene (generic).
- 721.12064 Alkanoic acid, trialkyl-, diester with carbomonocycle bis(alkyleneoxy)]bis[alkanediol] (generic).
- 721.12065 Modified Silsesquioxane, alkoxy-terminated (generic).
- 721.12066 Vegetable oil, polymer with pimelin ketone, oxymethylene and

- polymethylenepolyphenylene isocyanate (generic).
- 721.12067 Silsesquioxanes, 3mercaptopropyl, polymers with silicic acid (H4SiO4) tetra-Et ester, [(trimethylsilyl)oxy]-terminated.
- 721.12068 Castor oil, polymer with dicyclopentadiene, maleic anhydride, 2-methyl-1,3-propanediol, 3a,4,7,7a-tetrahydro-2-(2-hydroxyethyl)-1H-isoindole-1,3(2H)-dione and triethylene glycol.
- 721.12069 Monoaromatic cyclic alkylene sulfonium fluoroalkyl sulfonic acid salt (generic).
- 721.12070 Monoaromatic cyclic alkylene sulfonium fluoroalkyl sulfonic acid salt (generic).
- 721.12071 Aromatic sulfonium tricyclo fluoroalkyl sulfonic acid salt (generic).
- 721.12072 Aromatic dibenzothiophenium fluoroalkyl carbopolycycle sulfonic acid salt (generic).
- 721.12073 Alkanediol, substituted, polymer with diisocyanatoalkane, substituted heterocycle-modified (generic).
- 721.12074 Halosubstituted carbopolycycle, polymer with substituted carbomonocycles and oxybis[alkanol] (generic).
- 721.12075 Polymer of benzenedicarboxylic acid, substituted-benzenedicarboxylic acid, branched-alkyldiol, alkyldiol and triisocyanate (generic).
- 721.12076 Sulfonium, tricarbocyclic-, alkylcarbomonocyclic-polyfluoro-heteropolycyclic-alkyl sulfonate (1:1), polymer with alkylaryl and carbomonocyclic alkylalkanoate, di-Me 2,2'-(1,2-diazenediyl)bis[2-alkylalkanoate]-initiated (generic).

§721.12043 Heptane, 2-methoxy-2-methyl-.

(a) Chemical substance and significant new uses subject to reporting.

(1) The chemical substance identified as Heptane, 2-methoxy-2-methyl- (PMN P–18–127; CASRN 76589–16–7) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:
(i) Protection in the workplace.
Requirements as specified in § 721.63(a)(1), (3), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible.

(ii) Hazard communication.

Requirements as specified in § 721.72(a) through (d), (f), (g)(1), (3), and (5). For purposes of § 721.72(g)(1), this substance may cause: skin sensitization and specific target organ toxicity. For purposes of § 721.72(g)(3), this

substance may be: toxic to aquatic life. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) Industrial, commercial, and consumer activities. Requirements as specified in § 721.80(f). It is a significant new use to manufacture the substance unless by import into the United States in a solution of no greater than 5% by weight (i.e., no domestic manufacture). It is a significant new use to process the substance unless in a solution of no greater than 5% by weight of the substance. It is a significant new use to process for use or use the substance in consumer products unless the concentration of the substance is less than 1% by weight.

(iv) Release to water. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where N=210.

(b) Specific requirements. The provisions of Subpart A of this part apply to this section except as modified by this paragraph (b).

(1) Recordkeeping. Recordkeeping requirements as specified in § 721.125(a) through (i), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) Limitation or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.

§ 721.12044 Benzenesulfonic acid, alkyl-, compd. with 1,1'-iminobis[2-propanol] (1:1) (generic).

(a) Chemical substance and significant new uses subject to reporting.

(1) The chemical substance identified generically as benzenesulfonic acid, alkyl-, compd. with 1,1'-iminobis[2-propanol] (1:1) (PMN P–18–325) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

- (i) Protection in the workplace.
 Requirements as specified in § 721.63(a)(1) and (3), (b), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(b), the concentration is set at 1.0%.
- (ii) *Hazard communication*. Requirements as specified in § 721.72(a) through (f), and (g)(1), (3) and (5). For

purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), this substance may cause: skin irritation, eye irritation, and specific target organ toxicity. For purposes § 721.72(g)(3), this substance may be: toxic to aquatic life. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) Industrial, commercial, and consumer activities. Requirements as specified in § 721.80(k). It is a significant new use to manufacture, process, or use the substance in any manner that results in inhalation exposure to the substance. It is a significant new use to process for use or use the substance other than as an industrial cross-linking catalyst.

(iv) Release to water. Requirements as specified in § 721.90(a)(1), (b)(1), and

(c)(1).

(b) Specific requirements. The provisions of Subpart A of this part apply to this section except as modified by this paragraph (b).

- (1) Recordkeeping. Recordkeeping requirements as specified in § 721.125(a) through (i), and (k) are applicable to manufacturers, importers, and processors of this substance.
- (2) Limitation or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.

§721.12045 Sugars, polymer with alkanetriamine (generic).

(a) Chemical substance and significant new uses subject to reporting.

- (1) The chemical substance identified generically as sugars, polymer with alkanetriamine (PMN P-20-14) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted or cured.
 - (2) The significant new uses are:
- Protection in the workplace. Requirements as specified in § 721.63(a)(1) and (3), (b), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(b), the concentration is set at 1.0%.

- (ii) Hazard communication. Requirements as specified in § 721.72(a) through (f), (g)(1), (3), and (5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), this substance may cause: reproductive toxicity and specific target organ toxicity. For purposes of § 721.72(g)(3), this substance may be: toxic to aquatic life. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.
- (iii) Industrial, commercial, and consumer activities. Requirements as specified in $\S721.80(o)$.
- (iv) Release to water. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where N=191.
- (b) Specific requirements. The provisions of Subpart A of this part apply to this section except as modified by this paragraph (b).
- (1) Recordkeeping. Recordkeeping requirements as specified in § 721.125(a) through (i), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) Limitation or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.

§721.12046 Isooctadecanamide, N,Nbis(2-ethylhexyl)-.

(a) Chemical substance and significant new uses subject to reporting.

(1) The chemical substance identified as isooctadecanamide, N,N-bis(2ethylhexyl)- (PMN P-21-86; CASRN 1616494-50-8) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been entrained in a polymer.

(2) The significant new uses are:

- (i) Protection in the workplace. Requirements as specified in § 721.63(a)(1) and (3), (b), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(b), the concentration is set at 1.0%.
- (ii) Hazard communication. Requirements as specified in § 721.72(a) through (f), (g)(1), and (5). For purposes of § 721.72(e), the concentration is set at

1.0%. For purposes of § 721.72(g)(1), this substance may cause: specific target organ toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) Industrial, commercial, and consumer activities. It is a significant new use to process the substance for use in a consumer product where the concentration of the substance in the consumer product formulation exceeds the confidential percentage listed in the Order. It is a significant new use to use the substance in a consumer product where the concentration of the substance exceeds the confidential percentage listed in the Order.

(b) Specific requirements. The provisions of Subpart A of this part apply to this section except as modified

by this paragraph (b).

(1) Recordkeeping. Recordkeeping requirements as specified in § 721.125(a) through (i) are applicable to manufacturers, importers, and processors of this substance.

(2) Limitation or revocation of certain notification requirements. The provisions of § 721.185 apply to this

section.

§721.12047 2-Butanone, oxime, reaction products with trimethoxymethylsilane.

- (a) Chemical substance and significant new uses subject to reporting.
- (1) The chemical substance identified as 2-butanone, oxime, reaction products with trimethoxymethylsilane (PMN P-21-164; CASRN 2639393-45-4) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted or cured.
 - (2) The significant new uses are:
- (i) Protection in the workplace. Requirements as specified in § 721.63(a)(1), (3) through (6), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) and (4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 50.
- (ii) Hazard communication. Requirements as specified in § 721.72(a)

through (d), (f), (g)(1), (3), and (5). For purposes of $\S721.72(g)(1)$, this substance may cause: acute toxicity, carcinogenicity, serious eye damage, reproductive toxicity, skin irritation, skin sensitization, and specific target organ toxicity. For purposes of $\S 721.72(g)(3)$, this substance may be: toxic to aquatic life. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard

Communication Standard may be used. (iii) Industrial, commercial, and consumer activities. It is a significant new use to load or unload the substance for manufacture, processing, or use in any manner unless under a gas (e.g. nitrogen) blanket. It is a significant new use to use the substance unless at 4% or less by weight in formulation. It is a significant new use to apply the substance for use unless by roll, brush, or dip coating.

(iv) Disposal. Requirements as specified in § 721.85(a)(1), (b)(1), and

(c)(1).

(v) Release to water. Requirements as specified in § 721.90(a)(1), (b)(1), and

(b) Specific requirements. The provisions of Subpart A of this part apply to this section except as modified by this paragraph (b).

- (1) Recordkeeping. Recordkeeping requirements as specified in § 721.125(a) through (k) are applicable to manufacturers, importers, and processors of this substance.
- (2) Limitation or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.

§ 721.12048 2,6-Bis(dialkyl)-4-[2-(1-alkyl-4(1H)-pyridinylidene)alkylidene]-2,5cycloalkyladien-1-one (generic).

(a) Chemical substance and significant new uses subject to reporting.

- (1) The chemical substance identified generically as 2,6-bis(dialkyl)-4-[2-(1alkyl-4(1H)-pyridinylidene)alkylidene]-2,5-cycloalkyladien-1-one (generic) (PMN P-21-170) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) Protection in the workplace. Requirements as specified in § 721.63(a)(1), (3) through (6), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) and (4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures)

- shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 10.
- (ii) Hazard communication. Requirements as specified in § 721.72(a) through (d), (f), (g)(1), (3), and (5). For purposes of § 721.72(g)(1), this substance may cause: acute toxicity, skin irritation, eye irritation, skin sensitization, genetic toxicity, carcinogenicity, reproductive toxicity, and specific target organ toxicity. For purposes of § 721.72(g)(3), this substance may be: toxic to aquatic life. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may
- (iii) Industrial, commercial, and consumer activities. Requirements as specified in § 721.80(k), (t). It is a significant new use to manufacture the substance in excess of an annual volume of 10 kg. It is a significant new use to process for use or use the substance other than as a color indicator for frying oil breakdown. It is a significant new use to manufacture, process, or use the substance in any manner that results in the release of the substance to air except with the use of a HEPA filtration system.
- (iv) Release to water. Requirements as specified in § 721.90(a)(1), (b)(1), and
- (b) Specific requirements. The provisions of Subpart A of this part apply to this section except as modified by this paragraph (b).
- (1) Recordkeeping. Recordkeeping requirements as specified in § 721.125(a) through (i), and (k) are applicable to manufacturers, importers, and processors of this substance.
- (2) Limitation or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.

§721.12049 Fatty acids, soya, reaction products with ammonia-ethanolamine reaction by-products.

- (a) Chemical substance and significant new uses subject to reporting.
- (1) The chemical substance identified as fatty acids, soya, reaction products with ammonia-ethanolamine reaction by-products (PMN P-21-184; CASRN 2378512-59-3) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:

(i) Protection in the workplace. Requirements as specified in § 721.63(a)(1), (3), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible.

(ii) Hazard communication. Requirements as specified in § 721.72(a) through (d), (f), (g)(1), (3), and (5). For purposes of § 721.72(g)(1), this substance may cause: acute toxicity, skin corrosion, skin irritation, serious eve damage, eve irritation, skin sensitization, and specific target organ toxicity. For purposes of § 721.72(g)(3), this substance may be: toxic to aquatic life. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may

be used.

(iii) Industrial, commercial, and consumer activities. Requirements as specified in § 721.80(o), and (y)(1) and (2). It is a significant new use to manufacture, process, or use the substance in any manner that results in the generation of vapor, mist, aerosol, or dust.

(iv) Release to water. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where N=2.

(b) Specific requirements. The provisions of Subpart A of this part apply to this section except as modified by this paragraph (b).

(1) Recordkeeping. Recordkeeping requirements as specified in § 721.125(a) through (i), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) Limitation or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.

§ 721.12050 1,5-Pentanediamine, 2-methyl-, hydrochloride (1:2).

(a) Chemical substance and significant new uses subject to reporting.

(1) The chemical substance identified as 1,5-pentanediamine, 2-methyl-, hydrochloride (1:2) (PMN P-22-3; CASRN 34813-63-3) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are: (i) Protection in the workplace. Requirements as specified in § 721.63(a)(1), (3), (b), and (c). When determining which persons are

reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(b), the concentration is set at 1.0%.

(ii) Hazard communication.
Requirements as specified in § 721.72(a) through (f), (g)(1), (3), and (5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), this substance may cause: acute toxicity, skin irritation, and eye irritation. For purposes of § 721.72(g)(3), this substance may be: toxic to aquatic life. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) Industrial, commercial, and consumer activities. Requirements as specified in § 721.80(o). It is a significant new use to manufacture, process, or use the substance in any manner that results in inhalation exposure to the substance.

(iv) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where N=570 of P-22-3, P-22-4, P-22-5, and P-22-6 combined.

(b) Specific requirements. The provisions of Subpart A of this part apply to this section except as modified by this paragraph (b).

(1) Recordkeeping. Recordkeeping requirements as specified in § 721.125(a) through (i), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) Limitation or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.

§ 721.12051 1,5-Pentanediamine, 2-methyl-, hydrochloride (1:1).

(a) Chemical substance and significant new uses subject to reporting.

(1) The chemical substance identified as 1,5-pentanediamine, 2-methyl-, hydrochloride (1:1) (PMN P-22-4; CASRN 1840915-04-9) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:
(i) Protection in the workplace.
Requirements as specified in § 721.63(a)(1), (3), (b), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering

control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(b), the concentration is set at 1.0%.

(ii) Hazard communication. Requirements as specified in § 721.72(a) through (f), (g)(1), (3), and (5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), this substance may cause: acute toxicity, skin irritation, eye irritation, serious eye damage, skin corrosion, and specific target organ toxicity. For purposes of $\S721.72(g)(3)$, this substance may be: toxic to aquatic life. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) Industrial, commercial, and consumer activities. Requirements as specified in § 721.80(o). It is a significant new use to manufacture, process, or use the substance in any manner that results in inhalation exposure to the substance.

(iv) Release to water. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where N=570 of P-22-3, P-22-4, P-22-5, and P-22-6 combined.

(b) Specific requirements. The provisions of Subpart A of this part apply to this section except as modified by this paragraph (b).

(1) Recordkeeping. Recordkeeping requirements as specified in § 721.125(a) through (i), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) Limitation or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.

§ 721.12052 Formic acid, compd. with 2-methyl-1,5- pentanediamine (2:1).

(a) Chemical substance and significant new uses subject to reporting.

(1) The chemical substance identified as formic acid, compd. with 2-methyl-1,5- pentanediamine (2:1) (PMN P-22-5; CASRN 1836131-73-7) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:
(i) Protection in the workplace.
Requirements as specified in § 721.63(a)(1) and (3), (b), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (e.g., enclosure or

confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(b), the concentration is set at 1.0%.

(ii) Hazard communication. Requirements as specified in § 721.72(a) through (f), (g)(1), (3), and (5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), this substance may cause: acute toxicity, skin irritation, eye irritation, and specific target organ toxicity. For purposes of § 721.72(g)(3), this substance may be: toxic to aquatic life. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) Industrial, commercial, and consumer activities. Requirements as specified in § 721.80(o). It is a significant new use to manufacture, process, or use the substance in any manner that results in inhalation exposure to the substance.

(iv) Release to water. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where N=570 of P-22-3, P-22-4, P-22-5, and P-22-6 combined.

(b) Specific requirements. The provisions of Subpart A of this part apply to this section except as modified by this paragraph (b).

(1) Recordkeeping. Recordkeeping requirements as specified in § 721.125(a) through (i), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) Limitation or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.

§ 721.12053 Formic acid, compd. with 2-methyl-1,5-pentanediamine (1:1).

(a) Chemical substance and significant new uses subject to reporting.

(1) The chemical substance identified as formic acid, compd. with 2-methyl-1,5-pentanediamine (1:1) (PMN P–22–6; CASRN 1836131–75–9) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are: (i) Protection in the workplace.
Requirements as specified in § 721.63(a)(1) and (3), (b), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (e.g., enclosure or confinement of the operation, general

and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(b), the concentration is set at 1.0%.

(ii) Hazard communication. Requirements as specified in § 721.72(a) through (f), (g)(1), (3), and (5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), this substance may cause: acute toxicity, skin corrosion, skin irritation, serious eye damage, eye irritation, and specific target organ toxicity. For purposes of $\S721.72(g)(3)$, this substance may be: toxic to aquatic life. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) Industrial, commercial, and consumer activities. Requirements as specified in § 721.80(o). It is a significant new use to manufacture, process, or use the substance in any manner that results in inhalation exposure to the substance.

(iv) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where N=570 of P-22-3, P-22-4, P-22-5, and P-22-6 combined.

(b) Specific requirements. The provisions of Subpart A of this part apply to this section except as modified by this paragraph (b).

(1) Recordkeeping. Recordkeeping requirements as specified in § 721.125(a) through (i), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) Limitation or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.

§ 721.12054 Alkadiene, homopolymer, hydroxy-terminated, bis[N-[2-[(1-oxo-2-propen-1-yl)oxylethyl]carbamates] (generic).

(a) Chemical substance and significant new uses subject to reporting.

- (1) The chemical substance identified generically as alkadiene, homopolymer, hydroxy-terminated, bis[N-[2-[(1-oxo-2-propen-1-yl)oxylethyl]carbamates] (PMN P-22-11) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
- (2) The significant new uses are:
 (i) Protection in the workplace.
 Requirements as specified in § 721.63(a)(1), (3), and (c). When determining which persons are reasonably likely to be exposed as

required for § 721.63(a)(1), engineering

control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible.

- (ii) Hazard communication.
 Requirements as specified in § 721.72(a) through (d), (f), (g)(1), and (5). For purposes of § 721.72(g)(1), this substance may cause: skin sensitization, respiratory sensitization, reproductive toxicity, and specific target organ toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.
- (iii) Industrial, commercial, and consumer activities. Requirements as specified in § 721.80(o). It is a significant new use to manufacture, process, or use the substance in any manner that results in inhalation exposure to the substance.
- (b) Specific requirements. The provisions of Subpart A of this part apply to this section except as modified by this paragraph (b).
- (1) Recordkeeping. Recordkeeping requirements as specified in § 721.125(a) through (i) are applicable to manufacturers, importers, and processors of this substance.
- (2) Limitation or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.

§ 721.12055 Oxirane, 2-(chloromethyl)-, homopolymer, ether with dialkyl-alkanediol (2:1) (generic).

(a) Chemical substance and significant new uses subject to reporting.

- (1) The chemical substance identified generically as oxirane, 2-(chloromethyl)-, homopolymer, ether with dialkylalkanediol (2:1) (PMN P–22–25) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) Protection in the workplace. Requirements as specified in § 721.63(a)(1), (3), (b), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(b), the concentration is set at 0.1%.

- (ii) Hazard communication.
 Requirements as specified in § 721.72(a) through (f), (g)(1), and (5). For purposes of § 721.72(e), the concentration is set at 0.1%. For purposes of § 721.72(g)(1), this substance may cause: acute toxicity, skin irritation, eye irritation, genetic toxicity, carcinogenicity, and specific target organ toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.
- (iii) Industrial, commercial, and consumer activities. Requirements as specified in § 721.80(g), (t), (y)(1), and (2). It is a significant new use to manufacture, process, or use the substance in any manner that generates a vapor, mist, aerosol, or dust.
- (iv) Disposal. It is a significant new use to dispose of the substance, or waste streams containing the substance, other than by hazardous waste incineration.
- (v) *Release to water*. Requirements as specified in § 721.90(a)(1), (b)(1), and (c)(1).
- (b) Specific requirements. The provisions of Subpart A of this part apply to this section except as modified by this paragraph (b).
- (1) Recordkeeping. Recordkeeping requirements as specified in § 721.125(a) through (k) are applicable to manufacturers, importers, and processors of this substance.
- (2) Limitation or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.

§ 721.12056 Aryl, polymer with formaldehyde, glycidyl ether, reaction products with amino alkyl-alkane diamine, cyclohexanediamine and alkylene (alkylcyclohexanamine) (generic).

- (a) Chemical substance and significant new uses subject to reporting.
- (1) The chemical substance identified generically as aryl, polymer with formaldehyde, glycidyl ether, reaction products with amino alkyl-alkane diamine, cyclohexanediamine and alkylene (alkylcyclohexanamine) (PMN P–22–49) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted or cured.
- (2) The significant new uses are: (i) Protection in the workplace. Requirements as specified in § 721.63(a)(1), (3) through (6), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) and (4), engineering control measures (e.g.,

enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 1,000.

(ii) Hazard communication. Requirements as specified in § 721.72(a) through (d), (f), (g)(1), (3), and (5). For purposes of § 721.72(g)(1), this substance may cause: acute toxicity, skin irritation, eye irritation, skin corrosion, serious eye damage, respiratory sensitization, skin sensitization, genetic toxicity, reproductive toxicity, and specific target organ toxicity. For purposes of $\S721.72(g)(3)$, this substance may be: toxic to aquatic life. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) Industrial, commercial, and consumer activities. Requirements as specified in § 721.80(o).

(iv) Release to water. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where N=2.

(b) Specific requirements. The provisions of Subpart A of this part apply to this section except as modified by this paragraph (b).

(1) Recordkeeping. Recordkeeping requirements as specified in § 721.125(a) through (i), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) Limitation or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.

§721.12057 Alkene, alkoxy-, polymer with alkoxyalkene (generic).

(a) Chemical substance and significant new uses subject to reporting.

(1) The chemical substance identified generically as alkene, alkoxy-, polymer with alkoxyalkene (PMN P-22-50) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) Protection in the workplace. Requirements as specified in § 721.63(a)(1) and (3), (b), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace

policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(b), the concentration is set at 1.0%.

(ii) Hazard communication. Requirements as specified in § 721.72(a) through (f), (g)(1), (3), and (5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), this substance may cause: skin irritation, eye irritation, and specific target organ toxicity. For purposes of § 721.72(g)(3), this substance may be: toxic to aquatic life. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) Industrial, commercial, and consumer activities. Requirements as specified in § 721.80(k) and (o). It is a significant new use to manufacture, process, or use the substance in any manner that results in inhalation exposure to the substance.

(iv) Release to water. Requirements as specified in § 721.90(a)(1), (b)(1), and

(b) Specific requirements. The provisions of Subpart A of this part apply to this section except as modified by this paragraph (b).

(1) Recordkeeping. Recordkeeping requirements as specified in § 721.125(a) through (i), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) Limitation or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.

§ 721.12058 Methanesulfonamide, 1,1,1trifluoro-N-[(trifluoromethyl)sulfonyl]-, sodium salt (1:1).

(a) Chemical substance and significant new uses subject to reporting.

(1) The chemical substance identified as Methanesulfonamide, 1,1,1-trifluoro-N-[(trifluoromethyl)sulfonyl]-, sodium salt (1:1) (PMN P-22-58; CASRN 91742-21-1) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been incorporated into an article.

(2) The significant new uses are: (i) Protection in the workplace. Requirements as specified in § 721.63(a)(1), (3) through (6), (b), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) and (4), engineering control measures (e.g., enclosure or confinement of the

operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 50. For purposes of § 721.63(b), the concentration is set at 1.0%.

(ii) Hazard communication. Requirements as specified in § 721.72(a) through (f), (g)(1), $\bar{(}3)$, and (5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), this substance may cause: acute toxicity, serious eye damage, skin irritation, reproductive toxicity, and specific target organ toxicity. For purposes of $\S721.72(g)(3)$, this substance may be: toxic to aquatic life. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) Industrial, commercial, and consumer activities. Requirements as specified in § 721.80(b), (k), (v)(2), and (v)(1) and (2). It is a significant new use to process the substance in a manner that generates a vapor, mist, aerosol, or dust that results in inhalation to workers.

(iv) Release to water. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where N=100.

(b) Specific requirements. The provisions of Subpart A of this part apply to this section except as modified by this paragraph (b).

(1) Recordkeeping. Recordkeeping requirements as specified in § 721.125(a) through (i), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) Limitation or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.

§721.12059 1H-Isoindole-1,3(2H)-dione, 3a,4,7,7a-tetrahydro-2-(2-hydroxyethyl)-.

(a) Chemical substance and significant new uses subject to reporting.

(1) The chemical substance identified as 1H-Isoindole-1,3(2H)-dione, 3a,4,7,7a-tetrahydro-2-(2-hydroxyethyl)-(PMN P-22-75; CASRN 15458-48-7) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted or cured.

(2) The significant new uses are:

- (i) Protection in the workplace. Requirements as specified in § 721.63(a)(1), (3), (b), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(b), the concentration is set at
- (ii) Hazard communication. Requirements as specified in § 721.72(a) through (f), (g)(1), (3), and (5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), this substance may cause: acute toxicity, skin irritation, eye irritation, and specific target organ toxicity. For purposes of § 721.72(g)(3), this substance may be: toxic to aquatic life. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.
- (iii) Industrial, commercial, and consumer activities. Requirements as specified in § 721.80(f), (k), and (t). It is a significant new use to manufacture the substance in excess of an annual volume of 3,000 kg. It is a significant new use to use the substance other than as a monomer used to produce an unsaturated polyester resin.

(b) Specific requirements. The provisions of Subpart A of this part apply to this section except as modified

by this paragraph (b).

- (1) Recordkeeping. Recordkeeping requirements as specified in § 721.125(a) through (i) are applicable to manufacturers, importers, and processors of this substance.
- (2) Limitation or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.

§721.12060 Oxirane, 2-methyl-, polymer with oxirane, mono-isoalkyl ethers, phosphates, salt (generic).

(a) Chemical substance and significant new uses subject to reporting.

- (1) The chemical substance identified generically as oxirane, 2-methyl-, polymer with oxirane, mono-isoalkyl ethers, phosphates, salt (PMN P-22-78) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
- (2) The significant new uses are: (i) Protection in the workplace. Requirements as specified in

- § 721.63(a)(1) and (3), (b), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(b), the concentration is set at
- (ii) Hazard communication. Requirements as specified in § 721.72(a) through (f), (g)(1), (3), and (5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), this substance may cause: skin irritation and specific target organ toxicity. For purposes of § 721.72(g)(3), this substance may be: toxic to aquatic life. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.
- (iii) Industrial. commercial. and consumer activities. Requirements as specified in § 721.80(k). It is a significant new use to manufacture or process the substance in a manner that generates a vapor, mist, aerosol, or dust. It is a significant new use to process for use or use the substance other than as a dispersing agent for pesticide formulations.
- (iv) Release to water. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where N=23.
- (b) Specific requirements. The provisions of Subpart A of this part apply to this section except as modified by this paragraph (b).
- (1) Recordkeeping. Recordkeeping requirements as specified in § 721.125(a) through (i), and (k) are applicable to manufacturers, importers, and processors of this substance.
- (2) Limitation or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.

§721.12061 Poly(oxy-1,2-ethanediyl), .alpha.-(2-aminoethyl)-.omega.-(2aminoethoxy)- and Poly(oxy-1,2-ethanediyl), .alpha.,.alpha.',-(iminodi-2,1ethanediyl)bis[.omega.-(2-aminoethoxy)-.

(a) Chemical substance and significant new uses subject to reporting.

(1) The chemical substance identified as poly(oxy-1,2-ethanediyl), .alpha.-(2aminoethyl)-.omega.-(2-aminoethoxy)and poly(oxy-1,2-ethanediyl), .alpha.,.alpha.',-(iminodi-2,1ethanediyl)bis[.omega.-(2-aminoethoxy)-(PMN P-22-80; CAS Nos. 24991-53-5

- and 90350-34-8) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted or destroyed.
 - (2) The significant new uses are:
- (i) Protection in the workplace. Requirements as specified in § 721.63(a)(1), (3), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible.
- (ii) Hazard communication. Requirements as specified in § 721.72(a) through (d), (f), (g)(1), (3), and (5). For purposes of § 721.72(g)(1), this substance may cause: acute toxicity, skin corrosion, serious eye damage, and skin sensitization. For purposes of $\S721.72(g)(3)$, this substance may be: toxic to aquatic life. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.
- (iii) Industrial, commercial, and consumer activities. It is a significant new use to manufacture, process, or use the substance in any manner that results in inhalation exposure to the substance.
- (iv) Release to water. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where N=0.7.
- (b) Specific requirements. The provisions of Subpart A of this part apply to this section except as modified by this paragraph (b).
- (1) Recordkeeping. Recordkeeping requirements as specified in § 721.125(a) through (i), and (k) are applicable to manufacturers, importers. and processors of this substance.
- (2) Limitation or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.

§721.12062 Alkenoic acid, alkyl, carbopolycyclic alkyl ester, polymer with trihalo (trihaloalkyl) alkyl alkyl alkenoate (generic).

(a) Chemical substance and significant new uses subject to reporting.

(1) The chemical substance identified generically as alkenoic acid, alkyl, carbopolycyclic alkyl ester, polymer with trihalo (trihaloalkyl) alkyl alkyl alkenoate (PMN P-22-82) is subject to reporting under this section for the significant new uses described in

paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been entrained in dried photoresist.

- (2) The significant new uses are:
- (i) Protection in the workplace. Requirements as specified in § 721.63(a)(1), (3), (b), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(b), the concentration is set at 1.0%.
- (ii) Hazard communication.
 Requirements as specified in § 721.72(a) through (f), (g)(1), and (5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), this substance may cause: reproductive toxicity and specific target organ toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.
- (iii) Industrial, commercial, and consumer activities. Requirements as specified in § 721.80(f), (k), (v)(1), (2) and (4), (w)(1), (2) and (4), and (x)(1), (2) and (4). It is a significant new use to manufacture the substance other than by import into the United States (i.e., no domestic manufacture) in a liquid formulation.
- (iv) *Disposal*. Requirements as specified in § 721.85(a)(1), (b)(1), and (c)(1).
- (v) Release to water. Requirements as specified in § 721.90(a)(1), (b)(1), and (c)(1).
- (b) Specific requirements. The provisions of Subpart A of this part apply to this section except as modified by this paragraph (b).
- (1) Recordkeeping. Recordkeeping requirements as specified in § 721.125(a) through (k) are applicable to manufacturers, importers, and processors of this substance.
- (2) Limitation or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.

§721.12063 Polychloroalkene (generic).

(a) Chemical substance and significant new uses subject to reporting.

(1) The chemical substance identified generically as polychloroalkene (PMN P–22–121) is subject to reporting under this section for the significant new uses

- described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted.
 - (2) The significant new uses are:
- (i) Protection in the workplace. Requirements as specified in § 721.63(a)(1), (3) through (6), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) and (4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 50.
- (ii) Hazard communication.
 Requirements as specified in § 721.72(a) through (d), (f), (g)(1), (3), and (5). For purposes of § 721.72(g)(1), this substance may cause: acute toxicity, skin irritation, serious eye damage, skin sensitization, genetic toxicity, carcinogenicity, and specific target organ toxicity. For purposes of § 721.72(g)(3), this substance may be: toxic to aquatic life. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.
- (iii) Industrial, commercial, and consumer activities. Requirements as specified in § 721.80(f) and (k). It is a significant new use to process, use, load, or unload the substance unless under a gas (e.g., nitrogen) blanket or in a closed system except that sampling may occur outside the closed system resulting in exposures.
- (iv) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where N=0.15.
- (b) Specific requirements. The provisions of Subpart A of this part apply to this section except as modified by this paragraph (b).
- (1) Recordkeeping. Recordkeeping requirements as specified in § 721.125(a) through (i), and (k) are applicable to manufacturers, importers, and processors of this substance.
- (2) Limitation or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.

§ 721.12064 Alkanoic acid, trialkyl-, diester with carbomonocycle bis(alkyleneoxy)]bis[alkanediol] (generic).

- (a) Chemical substance and significant new uses subject to reporting.
- (1) The chemical substance identified generically as alkanoic acid, trialkyl-, diester with carbomonocycle bis(alkyleneoxy)]bis[alkanediol] (PMN P-22-145) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) Protection in the workplace. Requirements as specified in § 721.63(a)(1), (3), (b), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(b), the concentration is set at 1.0%.
- (ii) Hazard communication.
 Requirements as specified in § 721.72(a) through (f), (g)(1), (3), and (5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), this substance may cause: acute toxicity, reproductive toxicity, and specific target organ toxicity. For purposes of § 721.72(g)(3), this substance may be: toxic to aquatic life. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.
- (iii) Industrial, commercial, and consumer activities. Requirements as specified in § 721.80(o). It is a significant new use to use the substance in any manner that may generate a spray, mist, vapor, or aerosol containing the substance unless the concentration of the substance is less than 5.7% by weight.
- (iv) Disposal. Requirements as specified in § 721.85(a)(1), (b)(1), and (c)(1).
- (v) Release to water. Requirements as specified in § 721.90(a)(1), (b)(1), and (c)(1).
- (b) Specific requirements. The provisions of Subpart A of this part apply to this section except as modified by this paragraph (b).
- (1) Recordkeeping. Recordkeeping requirements as specified in § 721.125(a) through (k) are applicable to manufacturers, importers, and processors of this substance.

(2) Limitation or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.

§ 721.12065 Modified Silsesquioxane, alkoxy-terminated (generic).

(a) Chemical substance and significant new uses subject to reporting.

(1) The chemical substance identified generically as modified silsesquioxane, alkoxy-terminated (PMN P–22–175) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

- Protection in the workplace. Requirements as specified in § 721.63(a)(1), (3) through (6), (b), and (c). When determining which persons are reasonably likely to be exposed as required for $\S721.63(a)(1)$ and (4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 10. For purposes of § 721.63(b), the concentration is set at 1.0%.
- (ii) Hazard communication.
 Requirements as specified in § 721.72(a) through (f), (g)(1), (3), and (5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), this substance may cause: skin irritation, eye irritation, and specific target organ toxicity. For purposes of § 721.72(g)(3), this substance may be: toxic to aquatic life. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.
- (iii) Industrial, commercial, and consumer activities. Requirements as specified in § 721.80(f). It is a significant new use to use the substance unless the concentration of the substance does not exceed 10% by weight in formulation.

(iv) Release to water. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where N=7.

(b) Specific requirements. The provisions of Subpart A of this part apply to this section except as modified by this paragraph (b).

(1) Recordkeeping. Recordkeeping requirements as specified in § 721.125(a) through (i), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) Limitation or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.

§ 721.12066 Vegetable oil, polymer with pimelin ketone, oxymethylene and polymethylenepolyphenylene isocyanate (generic).

(a) Chemical substance and significant new uses subject to reporting.

- (1) The chemical substance identified generically as vegetable oil, polymer with pimelin ketone, oxymethylene and polymethylenepolyphenylene isocyanate (PMN P–23–18) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted or cured.
 - (2) The significant new uses are:
- (i) Protection in the workplace.
 Requirements as specified in § 721.63(a)(1) and (3), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible.

(ii) Hazard communication.
Requirements as specified in § 721.72(a) through (d), (f), (g)(1), and (5). For purposes of § 721.72(g)(1), this substance may cause: acute toxicity, skin irritation, eye irritation, respiratory sensitization, skin sensitization, genetic toxicity, carcinogenicity, reproductive toxicity, and specific target organ toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) Industrial, commercial, and consumer activities. Requirements as specified in § 721.80(o). It is a significant new use to manufacture, process, or use the substance in any manner that results in inhalation exposure to the substance.

(b) Specific requirements. The provisions of Subpart A of this part apply to this section except as modified by this paragraph (b).

(1) Recordkeeping. Recordkeeping requirements as specified in § 721.125(a) through (i) are applicable to manufacturers, importers, and processors of this substance.

(2) Limitation or revocation of certain notification requirements. The

provisions of § 721.185 apply to this section.

§ 721.12067 Silsesquioxanes, 3-mercaptopropyl, polymers with silicic acid (H4SiO4) tetra-Et ester, [(trimethylsilyl)oxy]-terminated.

(a) Chemical substance and significant new uses subject to reporting.

(1) The chemical substance identified as silsesquioxanes, 3-mercaptopropyl, polymers with silicic acid (H4SiO4) tetra-Et ester, [(trimethylsilyl)oxy]-terminated (PMN P-23-20; CASRN 2796383-42-9) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted or cured.

(2) The significant new uses are:

(i) Protection in the workplace.
Requirements as specified in § 721.63(a)(1), (3), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible.

(ii) Hazard communication.
Requirements as specified in § 721.72(a) through (d), (f), (g)(1), (3), and (5). For purposes of § 721.72(g)(1), this substance may cause: skin sensitization and specific target organ toxicity. For purposes of § 721.72(g)(3), this substance may be: toxic to aquatic life. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) Industrial, commercial, and consumer activities. Requirements as specified in § 721.80(k). It is a significant new use to manufacture, process, or use the substance in any manner that results inhalation exposure.

(iv) Release to water. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where N=3.

(b) Specific requirements. The provisions of Subpart A of this part apply to this section except as modified by this paragraph (b).

(1) Recordkeeping. Recordkeeping requirements as specified in § 721.125(a) through (i), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) Limitation or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.

§721.12068 Castor oil, polymer with dicyclopentadiene, maleic anhydride, 2methyl-1,3-propanediol, 3a,4,7,7atetrahydro-2-(2-hydroxyethyl)-1H-isoindole-1,3(2H)-dione and triethylene glycol.

(a) Chemical substance and significant new uses subject to reporting.

(1) The chemical substance identified as castor oil, polymer with dicyclopentadiene, maleic anhydride, 2methyl-1,3-propanediol, 3a,4,7,7atetrahydro-2-(2-hydroxyethyl)-1Hisoindole-1,3(2H)-dione and triethylene glycol (PMN P-23-36; CASRN 2794200–69–2) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted or cured.

(2) The significant new uses are: (i) Protection in the workplace. Requirements as specified in § 721.63(a)(1), (3), (b), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(b), the concentration is set at 1.0%.

(ii) Hazard communication. Requirements as specified in § 721.72(a) through (f), (g)(1), (3), and (5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), this substance may cause: skin irritation, eye irritation, and specific target organ toxicity. For purposes of § 721.72(g)(3), this substance may be: toxic to aquatic life. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) Industrial, commercial, and consumer activities. Requirements as specified in § 721.80(o), (y)(1), and (2). It is a significant new use to manufacture or process the substance in a manner that generates a vapor, mist, aerosol, or dust.

(iv) Release to water. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where N=27.

(b) Specific requirements. The provisions of Subpart A of this part apply to this section except as modified by this paragraph (b).

(1) Recordkeeping. Recordkeeping requirements as specified in § 721.125(a) through (i), and (k) are

applicable to manufacturers, importers, and processors of this substance.

(2) Limitation or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.

§721.12069 Monoaromatic cyclic alkylene sulfonium fluoroalkyl sulfonic acid salt

(a) Chemical substance and significant new uses subject to reporting.

(1) The chemical substance identified generically as monoaromatic cyclic alkylene sulfonium fluoroalkyl sulfonic acid salt (PMN P-23-37) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted or adhered (during photolithographic processes) onto a semiconductor wafer surface or similar manufactured article used in the production of semiconductor technologies.

(2) The significant new uses are:

(i) Protection in the workplace. Requirements as specified in § 721.63(a)(1), (2)(i) and (iii), (3), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible.

(ii) Hazard communication. Requirements as specified in § 721.72(a) through (d), (f), (g)(1), (2)(i) through (iii), (v), (3)(i) and (ii), and (5). For purposes of § 721.72(g)(1), this substance may cause: acute toxicity, skin irritation, skin sensitization, genetic toxicity, and specific target organ toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may he used

(iii) Industrial, commercial, and consumer activities. Requirements as specified in § 721.80(f), (k), and (t). It is a significant new use to import the substance other than in solution, or in sealed containers weighing 5 kilograms or less. It is a significant new use to modify the processing or use of the substance in any way that generates dust, mist, or aerosol in a non-enclosed process. It is a significant new use to manufacture the substance longer than 18 months.

(b) Specific requirements. The provisions of Subpart A of this part apply to this section except as modified by this paragraph (b).

(1) Recordkeeping. Recordkeeping requirements as specified in § 721.125(a) through (i) are applicable to manufacturers, importers, and processors of this substance.

(2) Limitation or revocation of certain notification requirements. The provisions of § 721.185 apply to this

section.

§721.12070 Monoaromatic cyclic alkylene sulfonium fluoroalkyl sulfonic acid salt (generic).

(a) Chemical substance and significant new uses subject to reporting.

- (1) The chemical substance identified generically as monoaromatic cyclic alkylene sulfonium fluoroalkyl sulfonic acid salt (PMN P-23-44) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted or adhered (during photolithographic processes) onto a semiconductor wafer surface or similar manufactured article used in the production of semiconductor technologies.
- (2) The significant new uses are: (i) Protection in the workplace. Requirements as specified in § 721.63(a)(1), (2)(i) and (iii), (3), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace

policies and procedures) shall be considered and implemented to prevent exposure, where feasible.

(ii) Hazard communication. Requirements as specified in § 721.72(a) through (d), (f), (g)(1), (2)(i) through (iii), (v), (3)(i) and (ii), and (5). For purposes of § 721.72(g)(1), this substance may cause: acute toxicity, skin irritation, serious eye damage, reproductive toxicity, skin sensitization, genetic toxicity, and specific target organ toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may

(iii) Industrial, commercial, and consumer activities. Requirements as specified in § 721.80(f), (k), and (t). It is a significant new use to import the substance other than in solution, or in sealed containers weighing 5 kilograms or less. It is a significant new use to modify the processing or use of the substance in any way that generates

dust, mist, or aerosol in a non-enclosed process. It is a significant new use to manufacture the substance longer than 18 months.

(b) Specific requirements. The provisions of Subpart A of this part apply to this section except as modified

by this paragraph (b).

(1) Recordkeeping. Recordkeeping requirements as specified in § 721.125(a) through (i) are applicable to manufacturers, importers, and processors of this substance.

(2) Limitation or revocation of certain notification requirements. The provisions of § 721.185 apply to this

section.

§ 721.12071 Aromatic sulfonium tricyclo fluoroalkyl sulfonic acid salt (generic).

(a) Chemical substance and significant new uses subject to reporting.

- (1) The chemical substance identified generically as aromatic sulfonium tricyclo fluoroalkyl sulfonic acid salt (PMN P–23–80) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted or adhered (during photolithographic processes) onto a semiconductor wafer surface or similar manufactured article used in the production of semiconductor technologies.
 - (2) The significant new uses are:
- (i) Protection in the workplace. Requirements as specified in § 721.63(a)(1), (2)(i) and (iii), (3), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible.

(ii) Hazard communication.
Requirements as specified in § 721.72(a) through (d), (f), (g)(1), (2)(i) through (iii), (v), (3)(i) and (ii), and (5). For purposes of § 721.72(g)(1), this substance may cause: acute toxicity, skin irritation, serious eye damage, skin sensitization, genetic toxicity, and specific target organ toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) Industrial, commercial, and consumer activities. Requirements as specified in § 721.80(f), (k), and (t). It is a significant new use to import the substance other than in solution, or in

sealed containers weighing 5 kilograms or less. It is a significant new use to modify the processing or use of the substance in any way that generates dust, mist, or aerosol in a non-enclosed process. It is a significant new use to manufacture the substance longer than 18 months.

(b) Specific requirements. The provisions of Subpart A of this part apply to this section except as modified

by this paragraph (b).

(1) Recordkeeping. Recordkeeping requirements as specified in § 721.125(a) through (i) are applicable to manufacturers, importers, and processors of this substance.

(2) Limitation or revocation of certain notification requirements. The provisions of § 721.185 apply to this

section.

§ 721.12072 Aromatic dibenzothiophenium fluoroalkyl carbopolycycle sulfonic acid salt (generic).

(a) Chemical substance and significant new uses subject to reporting.

- (1) The chemical substance identified generically as aromatic dibenzothiophenium fluoroalkyl carbopolycycle sulfonic acid salt (PMN P-23-93) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted or adhered (during photolithographic processes) onto a semiconductor wafer surface or similar manufactured article used in the production of semiconductor technologies.
- (2) The significant new uses are:
 (i) Protection in the workplace.
 Requirements as specified in § 721.63(a)(1), (2)(i) and (iii), (3), and (c).
 When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be

considered and implemented to prevent

exposure, where feasible.

(ii) Hazard communication.

Requirements as specified in § 721.72(a) through (d), (f), (g)(1), (2)(i) through (iii), (v), (3)(i) and (ii), and (5). For purposes of § 721.72(g)(1), this substance may cause: acute toxicity, skin irritation, serious eye damage, reproductive toxicity, skin sensitization, genetic toxicity, and specific target organ toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA

Hazard Communication Standard may be used.

- (iii) Industrial, commercial, and consumer activities. Requirements as specified in § 721.80(f), (k), and (t). It is a significant new use to import the substance other than in solution, or in sealed containers weighing 5 kilograms or less. It is a significant new use to modify the processing or use of the substance in any way that generates dust, mist, or aerosol in a non-enclosed process. It is a significant new use to manufacture the substance longer than 18 months.
- (b) Specific requirements. The provisions of Subpart A of this part apply to this section except as modified by this paragraph (b).
- (1) Recordkeeping. Recordkeeping requirements as specified in § 721.125(a) through (i) are applicable to manufacturers, importers, and processors of this substance.
- (2) Limitation or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.

§ 721.12073 Alkanediol, substituted, polymer with diisocyanatoalkane, substituted heterocycle-modified (generic).

- (a) Chemical substance and significant new uses subject to reporting.
- (1) The chemical substance identified generically as alkanediol, substituted, polymer with diisocyanatoalkane, substituted heterocycle-modified (PMN P-23-64) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted or cured.
 - (2) The significant new uses are:
- (i) Protection in the workplace.
 Requirements as specified in § 721.63(a)(1), (3), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible.
- (ii) Hazard communication.
 Requirements as specified in § 721.72(a) through (d), (f), (g)(1), and (5). For purposes of § 721.72(g)(1), this substance may cause: skin sensitization and specific target organ toxicity.
 Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA

Hazard Communication Standard may be used.

(iii) Industrial, commercial, and consumer activities. Requirements as specified in § 721.80(o), and (y)(1) and (2). It is a significant new use to manufacture or process the substance in a manner that generates a vapor, mist, aerosol, or dust.

(b) Specific requirements. The provisions of Subpart A of this part apply to this section except as modified

by this paragraph (b).

(1) Recordkeeping. Recordkeeping requirements as specified in § 721.125(a) through (i) are applicable to manufacturers, importers, and processors of this substance.

(2) Limitation or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.

§ 721.12074 Halosubstituted carbopolycycle, polymer with substituted carbomonocycles and oxybis[alkanol] (generic).

(a) Chemical substance and significant new uses subject to reporting.

- (1) The chemical substance identified generically as halosubstituted carbopolycycle, polymer with substituted carbomonocycles and oxybis[alkanol] (PMN P–23–72) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted or cured.
 - (2) The significant new uses are:
- (i) Protection in the workplace. Requirements as specified in § 721.63(a)(1), (3) through (6), (b), and (c). When determining which persons are reasonably likely to be exposed as required for $\S721.63(a)(1)$ and (4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 10. For purposes of § 721.63(b), the concentration is set at
- (ii) Hazard communication. Requirements as specified in § 721.72(a) through (f), (g)(1), (3), and (5). For purposes of § 721.72(e), the concentration is set at 0.1%. For purposes of § 721.72(g)(1), this substance may cause: genetic toxicity,

carcinogenicity, and specific target organ toxicity. For purposes of § 721.72(g)(3), this substance may be: toxic to aquatic life. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

- (iii) Industrial, commercial, and consumer activities. Requirements as specified in § 721.80(o). It is a significant new use to process for use or use the substance other than in an enclosed roll-coating lithographic printing machine. It is a significant new use to process for use or use the substance to a final formulation for coating application that exceeds 40% by weight.
- (iv) Disposal. Requirements as specified in § 721.85(a)(2), (b)(2), and (c)(2).
- (v) Release to water. Requirements as specified in § 721.90(a)(1), (b)(1), and (c)(1).
- (b) Specific requirements. The provisions of Subpart A of this part apply to this section except as modified by this paragraph (b).
- (1) Recordkeeping. Recordkeeping requirements as specified in § 721.125(a) through (k) are applicable to manufacturers, importers, and processors of this substance.
- (2) Limitation or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.

§ 721.12075 Polymer of benzenedicarboxylic acid, substitutedbenzenedicarboxylic acid, branchedalkyldiol, alkyldiol and triisocyanate (generic).

(a) Chemical substance and significant new uses subject to reporting.

- (1) The chemical substance identified generically as polymer of benzenedicarboxylic acid, substituted-benzenedicarboxylic acid, branched-alkyldiol, alkyldiol and triisocyanate (PMN P–23–94) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted or cured.
 - (2) The significant new uses are:
- (i) Protection in the workplace. Requirements as specified in § 721.63(a)(1), (3), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace

policies and procedures) shall be considered and implemented to prevent exposure, where feasible.

- (ii) Hazard communication.
 Requirements as specified in § 721.72(a) through (d), (f), (g)(1), and (5). For purposes of § 721.72(g)(1), this substance may cause: skin sensitization, respiratory sensitization, and specific target organ toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.
- (iii) Industrial, commercial, and consumer activities. Requirements as specified in § 721.80(o). It is a significant new use to manufacture, process, or use the substance in any manner that results inhalation exposure.
- (b) Specific requirements. The provisions of Subpart A of this part apply to this section except as modified by this paragraph (b).
- (1) Recordkeeping. Recordkeeping requirements as specified in § 721.125(a) through (i) are applicable to manufacturers, importers, and processors of this substance.
- (2) Limitation or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.
- § 721.12076 Sulfonium, tricarbocyclic-, alkylcarbomonocyclic-polyfluoro-heteropolycyclic-alkyl sulfonate (1:1), polymer with alkylaryl and carbomonocyclic alkylalkanoate, di-Me 2,2'-(1,2-diazenediyl)bis[2-alkylalkanoate]-initiated (generic).
- (a) Chemical substance and significant new uses subject to reporting.
- (1) The chemical substance identified generically as sulfonium, tricarbocyclic-, alkylcarbomonocyclic-polyfluoroheteropolycyclic-alkyl sulfonate (1:1), polymer with alkylaryl and carbomonocyclic alkylalkanoate, di-Me 2,2'-(1,2-diazenediyl)bis[2alkylalkanoate]-initiated (PMN P-23-172) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted or adhered (during photolithographic processes) onto a semiconductor wafer surface or similar manufactured article used in the production of semiconductor technologies.
 - (2) The significant new uses are:
- (i) Protection in the workplace. Requirements as specified in § 721.63(a)(1), (2)(i) and (iii), (3), and (c). When determining which persons are reasonably likely to be exposed as

required for § 721.63(a)(1), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible.

(ii) Hazard communication.
Requirements as specified in § 721.72(a) through (d), (f), (g)(1), (2)(i) through (iii), (v), (3)(i) and (ii), and (5). For purposes of § 721.72(g)(1), this substance may cause: acute toxicity, skin irritation, serious eye damage, skin sensitization, genetic toxicity, reproductive toxicity, and specific target organ toxicity.

Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) Industrial, commercial, and consumer activities. Requirements as specified in § 721.80(f), (k), and (t). It is a significant new use to import the substance other than in solution, or in sealed containers weighing 5 kilograms or less. It is a significant new use to modify the processing of the substance in any way that generates dust, mist, or aerosol in a non-enclosed process. It is a significant new use to manufacture the substance longer than 18 months.

(b) Specific requirements. The provisions of Subpart A of this part apply to this section except as modified

by this paragraph (b).

(1) Recordkeeping. Recordkeeping requirements as specified in § 721.125(a) through (i) are applicable to manufacturers, importers, and processors of this substance.

(2) Limitation or revocation of certain notification requirements. The provisions of § 721.185 apply to this

section.

[FR Doc. 2024–29275 Filed 12–16–24; 8:45 am]

BILLING CODE 6560-50-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS-R7-ES-2024-0117; FXES1111090FEDR-256-FF09E21000]

RIN 1018-BI15

Endangered and Threatened Wildlife and Plants; Endangered Species Status for Suckley's Cuckoo Bumble Bee

AGENCY: Fish and Wildlife Service,

Interior.

ACTION: Proposed rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), propose to list the Suckley's cuckoo bumble bee (Bombus suckleyi), an invertebrate species from North America, as an endangered species under the Endangered Species Act of 1973, as amended (Act). This determination also serves as our 12-month finding on a petition to list the Suckley's cuckoo bumble bee. After a review of the best available scientific and commercial information, we find that listing the species is warranted. Accordingly, we propose to list the species as an endangered species under the Act. If we finalize this rule as proposed, it would add this species to the List of Endangered and Threatened Wildlife and extend the Act's protections to the species. Due to the current lack of data sufficient to perform required analyses, we conclude that the designation of critical habitat for the species is not determinable at this time.

DATES: We will accept comments received or postmarked on or before February 18, 2025. Comments submitted electronically using the Federal eRulemaking Portal (see ADDRESSES, below) must be received by 11:59 p.m. eastern time on the closing date. We must receive requests for a public hearing, in writing, at the address shown in FOR FURTHER INFORMATION CONTACT by January 31, 2025.

ADDRESSES: You may submit comments by one of the following methods:

(1) *Electronically:* Go to the Federal eRulemaking Portal:

https://www.regulations.gov. In the Search box, enter FWS–R7–ES–2024–0117, which is the docket number for this rulemaking. Then, click on the Search button. On the resulting page, in the panel on the left side of the screen, under the Document Type heading, check the Proposed Rule box to locate this document. You may submit a comment by clicking on "Comment."

(2) By hard copy: Submit by U.S. mail to: Public Comments Processing, Attn: FWS-R7-ES-2024-0117, U.S. Fish and Wildlife Service, MS: PRB/3W, 5275 Leesburg Pike, Falls Church, VA 22041-3803.

We request that you send comments only by the methods described above. We will post all comments on https://www.regulations.gov. This generally means that we will post any personal information you provide us (see Information Requested, below, for more information).

Availability of supporting materials: Supporting materials, such as the species status assessment report, are available at https://www.regulations.gov at Docket No. FWS-R7-ES-2024-0117.

FOR FURTHER INFORMATION CONTACT:

Mike Daigneault, Acting Field Supervisor, Southern Alaska Fish and Wildlife Field Office, 4700 BLM Road, Anchorage, AK 99507; telephone 907-271–1467. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-ofcontact in the United States. Please see Docket No. FWS-R7-ES-2024-0117 on https://www.regulations.gov for a document that summarizes this proposed rule.

SUPPLEMENTARY INFORMATION:

Executive Summary

Why we need to publish a rule. Under the Act, a species warrants listing if it meets the definition of an endangered species (in danger of extinction throughout all or a significant portion of its range) or a threatened species (likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range). If we determine that a species warrants listing, we must list the species promptly and designate the species' critical habitat to the maximum extent prudent and determinable. We have determined that Suckley's cuckoo bumble bee meets the Act's definition of an endangered species; therefore, we are proposing to list it as such. Listing a species as an endangered or threatened species can be completed only by issuing a rule through the Administrative Procedure Act rulemaking process (5 U.S.C. 551 et seq.).

What this document does. We propose to list Suckley's cuckoo bumble bee as an endangered species under the Act.

The basis for our action. Under the Act, we may determine that a species is an endangered or a threatened species because of any of five factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence. We have determined that Suckley's cuckoo bumble bee meets the Act's definition of an endangered species due to threats