



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[EPA-HQ-OPPT-2024-0332; FRL-12563-01-OCSPP]

RIN 2070-AB27

Significant New Use Rules on Certain Chemical Substances (24-4.5e)

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 **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2024-0332 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: Ira L. Lyons, New Chemicals Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 566-1481; email address: lyons.ira@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 identified in Unit III. 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-export-requirements>).

Chemical importers are subject to TSCA section 13 (15 U.S.C. 2612), the requirements in 19 CFR 12.118 through 12.127 (e.g., 19 CFR 127.28) and 40 CFR part 707, Subpart B).

Importers of chemical substances in bulk form, as part of a mixture, or as part of an article (if required by rule) 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 **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** 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.

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.

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.

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 these 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 parts 2 and 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 ask EPA to identify the confidential significant new use subject to the SNUR. 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(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 as 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-and-managing-chemicals-under-tsca/alternative-test-methods-and-strategies-reduce>.

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 about 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 [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER] 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) or Accession Number (if assigned for non-confidential chemical identities).
- Basis for the SNUR (e.g., 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 as CBI.

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). 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 SNURs?

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

PMN Number: P-18-360 (40 CFR 721.12077).

Chemical Name: Oxirane, 2-methyl-, polymer with 2,4-diisocyanato-1-methylbenzene, 2-methyloxirane polymer with oxirane ether with 1,2,3-propanetriol (3:1), and oxirane, cashew nutshell liq.- and Pr alc. -blocked.

CASRN: 1227870-90-7.

Effective Date of TSCA Order: May 2, 2024.

Basis for TSCA Order: The PMN states that the use will be as a two-component adhesive and protective coating for marine and infrastructure applications. Based on test data for the residual, EPA has identified concerns for skin sensitization, and skin, eye, and respiratory tract irritation for the feedstock residual. 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 use of the PMN substance other than as a two component adhesives and protective coating for marine and infrastructure applications;
 - Use of a NIOSH-certified combination particulate and gas/vapor 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 skin sensitization, skin irritation, and eye irritation 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: P-20-87 (40 CFR 721.12078).

Chemical Name: Alcohols, C8-10-iso-, C9-rich, ethoxylated.

CASRN: 2368929-19-3.

Effective Date of TSCA Order: March 21, 2024.

Basis for TSCA Order: The PMN states that the use will be as a component in hard surface cleaners and laundry detergent. Based on a structural alert and the category of use, EPA has identified concerns for lung effects (surfactancy) and irritation to the skin, eyes, and respiratory tract. Based on comparison to analogous chemical substances, EPA has also identified concerns for acute toxicity (mortality), skin and eye irritation, systemic effects, and reproductive/developmental effects. Based on comparison to analogous nonionic surfactants, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 142 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 of the PMN substance to a concentration of 3% or greater in formulation

for use in a consumer product;

- No use of the PMN substance other than as a surfactant in hard surface cleaners and laundry detergents;
 - No release of the PMN substance, or any waste stream containing the PMN substance, in surface water concentrations that exceed 142 ppb;
 - Use of a NIOSH-certified gas/vapor respirator with an APF of at least 1000 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, skin irritation, eye damage, 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: P-21-198 (40 CFR 721.12079).

Chemical Name: Reaction product of polyester with alpha.-hydro.-omega.-hydroxypoly (oxy-1,4- butanediyl) and 1,1'-methylenebis[isocyanatobenzene] (generic)

CASRN: 302217.

Effective Date of TSCA Order: February 23, 2024.

Basis for TSCA Order: The PMN states that the use will be as a hot melt moisture cure adhesive for the industrial floor and door industry. Based on comparison to analogous chemical substances for the residual, EPA has identified skin and respiratory sensitization, skin, eye, and respiratory tract irritation, acute toxicity, and pulmonary effects for the residual. 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;

- 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 sensitization, skin irritation, eye damage, 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: P-21-205 (40 CFR 721.12080).

Chemical Name: Benzene, [2-[(2-methyl-1-undecen-1-yl) oxy]ethyl]-.

CASRN: 2489743-82-8.

Effective Date of TSCA Order: February 29, 2024.

Basis for TSCA Order: The PMN states that the generic (non-confidential) use will be as an additive in household consumer products. Based on submitted test data on the PMN substance, EPA has identified concerns for skin sensitization, systemic, and developmental 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 or use of the PMN substance in consumer products where the concentration of the PMN substance exceeds 1% by weight;
 - 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 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: P-21-213 (40 CFR 721.12081).

Chemical Name: Siloxanes and silicones, alkyl methyl, dimethyl (generic).

CASRN or Accession No.: Not available.

Effective Date of TSCA Order: April 26, 2024.

Basis for TSCA Order: The PMN states that the generic (non-confidential) use will be as a textile finishing agent. Based on the use of the PMN substance and the structural alert for siloxanes, EPA has identified concerns for lung waterproofing. Based on the structural alert for siloxanes and information provided in the SDS, EPA has also identified concerns for acute toxicity, skin irritation, and eye irritation. 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;

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

- 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, skin irritation, and eye damage 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: P-22-19 (40 CFR 721.12082).

Chemical Name: Protein sodium complexes, polymers with aromatic acid chloride, ethylene diamine and amino acid (generic).

CASRN: 302206.

Effective Date of TSCA Order: December 12, 2023.

Basis for TSCA Order: The PMN states that the generic (non-confidential) use will be as a film-forming polymer. Based on structure, EPA has identified concerns for lung overload. Based on physical/chemical properties and protein structure of the PMN substance and a feedstock residual, EPA has also identified concerns for lung surfactancy, irritation to the skin, eyes, and respiratory tract, and skin 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 manufacture, processing, or use of the PMN substance in any manner that results in inhalation exposure to workers;

- No processing of the PMN substance for use in a consumer product where the concentration of a confidential component of the New Chemical Substance listed in the Order in the consumer product exceeds 0.1% and to the extent that remaining unknown components do not exhibit sensitizing properties;

- No use of the PMN substance in consumer products where the concentration of the confidential component listed in the Order exceeds 0.1%;

- 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, skin irritation, eye irritation, 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: P-22-22 (40 CFR 721.12083).

Chemical Name: Aryl-substituted-heterocyclic-polyamine, reaction products with polyethylene glycol alkyl-ether, and nitrogen and alkyl-substituted benzene (generic).

Accession No.: 302046.

Effective Date of TSCA Order: September 28, 2023.

Basis for TSCA Order: The PMN states that the generic (non-confidential) use will be as a dispersing additive. Based on comparison to analogous chemical substances and the surfactant-like structure of the PMN substance, EPA has identified concerns for lung effects. Based on the surfactant-like structure of the PMN substance, EPA has also identified concerns for irritation to the skin, eyes, and respiratory tract. 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;

- 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 damage, 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: P-22-59 (40 CFR 721.12084).

Chemical Name: Thermomycolin, *Malbranchea cinnamomea* origin, expressed in genetically modified *Trichoderma reesei*.

CASRN or Accession No.: Not available.

Effective Date of TSCA Order: May 16, 2024.

Basis for TSCA Order: The PMN states that the use will be as an enzyme in laundry and dishwashing detergents. Based on comparison to analogous chemical substances, EPA has identified concerns for irritation to the skin, eyes, and respiratory tract, respiratory sensitization and allergenic effects, and point-of-contact effects in the Gastrointestinal (GI) tract. Based on comparison to analogous chemical substances, 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 of the PMN substance other than by import into the United States (i.e., no domestic manufacture) in a liquid formulation;

- No processing for use or use of the PMN substance in consumer products unless the concentration of the PMN substance in the consumer product is less than 0.1% by weight;

- 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, into water during processing unless the PMN substance is deactivated before releasing to water.

To deactivate the New Chemical Substance, adjust the pH to 2 or below and incubate for 30 minutes; 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, skin 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: P-22-83 (40 CFR 721.12085).

Chemical Name: Oils, sandalwood, santalene synthase-modified *Rhodobacter sphaeroides*-fermented, from D-Glucose, oxidized.

CASRN: 2576531-09-2.

Effective Date of TSCA Order: May 8, 2024.

Basis for TSCA Order: The PMN states that the generic (non-confidential) use will be as a perfume. Based on submitted test data on the PMN substance and information provided in the SDS, EPA has identified concerns for skin irritation and skin sensitization. Based on the hydrocarbon structure of the PMN substance, EPA has also identified concerns for solvent neurotoxicity. Based on comparison to analogous chemical substances and components of the PMN substance, EPA has also identified concerns for acute neurotoxicity, skin irritation, skin sensitization, and systemic effects. Based on comparison to analogous vinyl/allyl/propargyl alcohols, 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:

- No processing for use or use of the PMN substance in consumer products where the concentration of the PMN substance exceeds 1% by weight;
 - Use of a NIOSH-certified combination particulate and gas/vapor 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 1 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 specific target organ toxicity, neurotoxicity, 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: P-22-89 (40 CFR 721.12086).

Chemical Name: Carboxylic acid substituted carbomonocycles, polymer with dialkyl-alkanediol and alkanediol, hydroxy-alkyl-oxo-alkenyl) oxy]alkyl ester (generic)

CASRN or Accession No.: Not available.

Effective Date of TSCA Order: January 2, 2024.

Basis for TSCA Order: The PMN states that the use will be as a UV cured resin for dry toner printing. Based on comparison to analogous acrylates/methacrylates, EPA has identified concerns for skin, eye, and respiratory tract irritation 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;
 - 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 eye irritation, pulmonary effects, skin sensitization, 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: P-22-90 (40 CFR 721.12087).

Chemical Name: 4,8,11-Dodecatrienal.

CASRN: 1000399-21-2.

Effective Date of TSCA Order: April 5, 2024.

Basis for TSCA Order: The PMN states that the generic (non-confidential) use will be as a perfume. Based on submitted test data on the PMN substance, EPA has identified concerns for skin irritation and skin sensitization. Based on comparison to analogous chemical substances, EPA has also identified concerns for systemic effects. Based on submitted test data on the PMN substance, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 13 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:

- Processing of the PMN substance for use in consumer products only where the concentration of the PMN substance is less than 1% concentration by weight;
- Use of the PMN substance only where the concentration of the PMN substance in the

product is less than 1% concentration by weight;

- 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,

in surface water concentrations that exceed 13 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 specific target organ toxicity, toxicokinetics, and chronic 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: P-22-91 (40 CFR 721.12088).

Chemical Name: Alkanol, polymer with isocyanato-(isocyanatoalkyl)-trialkylcarbomonocycle, alkylene glycol monoacrylate-blocked (generic).

CASRN or Accession No.: Not available.

Effective Date of TSCA Order: March 18, 2024.

Basis for TSCA Order: The PMN states that the use will be as a UV cured resin for dry toner printing. Based on comparison to analogous acrylates/methacrylates, EPA has identified concerns for skin, eye, and respiratory tract irritation and skin sensitization. Based on

comparison to analogous acrylates/methacrylates, 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 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, in surface water concentrations that exceed 3 ppb;
 - 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 eye irritation, skin irritation, skin sensitization, 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: P-22-93 (40 CFR 721.12089).

Chemical Name: Alkenoic acid, alkyl-substituted alkyl ester, polymer with

(polyalkylamino)alkyl alkylalkenoate, alkyl-substituted alkylalkenoate, .alpha.-(alkyl-oxo-alkenyl)-.omega.-alkoxypoly(oxy-1,2-ethanediyl), [(alkoxy-alkyl-alkenyl)oxy]polyalkylsilane-initiated, compds. with polyethylene glycol phosphoric acid-based alkyl ether (generic).

Accession No.: 302499.

Effective Date of TSCA Order: April 11, 2024.

Basis for TSCA Order: The PMN states that the generic (non-confidential) use will be as an additive used for pigment stabilization. Based on comparison to analogous chemical substances, EPA has identified concerns for lung effects (surfactancy) and eye irritation. Based on comparison to analogous cationic polymers and the standard toxicity profile for phosphate, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 18 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. The requirements of this section do not apply to quantities of the substance after they have been incorporated into an article. 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 release of the PMN substance, or any waste stream containing the PMN substance, in surface water concentrations that exceed 18 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 pulmonary effects, eye irritation, 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: P-22-130 (40 CFR 721.12090), P-22-131 (40 CFR 721.12091), P-22-132 (40 CFR 721.12092), P-22-133 (40 CFR 721.12093), P-22-134 (40 CFR 721.12094), and P-22-135 (40 CFR 721.12095).

Chemical Names: Maltodextrin, octanoate (P-22-130), Maltodextrin, hexadecanoate (P-22-131), Maltodextrin, decanoate (P-22-132), Maltodextrin, octadecanoate (P-22-133), Maltodextrin, dodecanoate (P-22-134), and Maltodextrin, tetradecanoate (P-22-135).

CASRN: 2736503-99-2 (P-22-130), 1516876-50-8 (P-22-131), 1516876-47-3 (P-22-132), 1159570-68-9 (P-22-133), 512180-33-5 (P-22-134), and 2736504-00-8 (P-22-135).

Effective Date of TSCA Order: April 9, 2024.

Basis for TSCA Order: The PMNs state that the uses will be as surface tension reducing agents for use in production enhancement in oil wells, surfactants for use in the manufacture of industrial products, consumer, and household products, wetting agents in agriculture, wetting agents/emulsifiers in personal care products, and as emulsifiers/surface reduction in household and industrial products. Based on intended use and structure, EPA has identified concerns for lung toxicity (surfactant effects). Based on comparison to analogous chemical substances, EPA has also identified concerns for serious eye damage for P-22-130, P-22-132, and P-22-134. 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. To protect against these risks, the Order requires:

- Use of a NIOSH-certified particulate respirator with an APF of at least 1000 where there is a potential for inhalation exposure;

- Manufacture, processing, or use of the PMN substances only in aqueous dispersions;

- No processing for use or use of the PMN substances in consumer products that are spray applied;

- No processing for use or use of the PMN substances in consumer products if the concentration of the PMN substances is equal to or exceeds 3% by weight in the consumer product;

- No use of the PMN substances as agricultural wetting agents;

- 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, eye irritation, and toxicokinetics testing may be potentially useful to characterize the health 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: P-22-139 (40 CFR 721.12096).

Chemical Name: Dialkylhydroxylamine (generic).

Accession No.: 302353.

Effective Date of TSCA Order: March 11, 2024.

Basis for TSCA Order: The PMN states that the generic (non-confidential) use will be as an antioxidant/process stabilizer. Based on comparison to analogous chemical substances, EPA has identified concerns for skin sensitization and 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:

- Manufacture of the PMN substance only when using local exhaust ventilation (LEV) and particulate filters with at least 90% efficiency to control dust released to air;

- The form giving process may be conducted on the PMN substance only when using LEV and HEPA dust filters with at least 99% efficiency to control dust released to air during transfer;

- The form giving process may be conducted on the PMN substance only when using an enclosed system with HEPA dust filters with at least 99% efficiency to control dust released to air during all processing steps other than transfer;

- No use of the PMN substance other than as an antioxidant process stabilizer;

- 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 skin sensitization 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: P-22-154 (40 CFR 721.12097).

Chemical Name: Acetyl, alkyl, alkenoic acid, ethyl ester (generic).

CASRN or Accession No.: Not available.

Effective Date of TSCA Order: November 29, 2023.

Basis for TSCA Order: The PMN states that the generic (non-confidential) use will be as a fragrance ingredient for use in laundry applications. Based on submitted test data on the PMN substance, EPA has identified concerns for acute toxicity, skin sensitization, systemic effects, and developmental effects. Based on comparison to analogous esters, 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 processing for use or use of the PMN substance in consumer products where the concentration of the PMN substance exceeds 1%;
- No manufacture or processing 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.
- 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 pulmonary effects, developmental 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: P-22-155 (40 CFR 721.12098).

Chemical Name: 2-Alkyl-1,2-heteropolycycle-3-one (generic).

CASRN or Accession No.: Not available.

Effective Date of TSCA Order: April 11, 2024.

Basis for TSCA Order: The PMN states that the generic (non-confidential) use will be as a physical property modifier for polyurethanes and as a modifier for polyurethane blends. Based on submitted test data on the PMN substance, EPA has identified concerns for skin corrosion and portal-of-entry (oral) effects. Based on comparison to analogous chemical substances, EPA has also identified concerns for acute toxicity, eye corrosion, skin sensitization, portal-of-entry (oral and inhalation) effects, and systemic effects. 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:

- Processing or use of the PMN substance only in the form of a liquid;
 - Manufacture of the PMN substance only by import into the United States (i.e., no domestic manufacture) in the form of a liquid;
 - No processing for use or use of the PMN substance in a consumer product formulation;
 - No release of the PMN substance, or any waste stream containing the PMN substance, in surface water concentrations that exceed 1 ppb;
 - Use of a NIOSH-certified particulate 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 neurotoxicity, skin irritation/corrosion, eye irritation/corrosion, skin sensitization, 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: P-22-157 (40 CFR 721.12099).

Chemical Name: 1,2-Ethanediamine, N1, N2-dimethyl-N1-(1-methylethyl)-N2-[2-[methyl(1-methylethyl)amino]ethyl]-.

CASRN: 1042950-30-0.

Effective Date of TSCA Order: May 9, 2024.

Basis for TSCA Order: The PMN states that the use will be as a polyurethane catalyst. Based on submitted test data on the PMN substance, EPA has identified concerns for acute toxicity, skin corrosion, and systemic and developmental effects. Based on comparison to analogous chemical substances, EPA has also identified concerns for eye and respiratory tract corrosion and skin sensitization. Based on submitted test data on the PMN substance and comparison to analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 650 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 650 ppb;
 - Use of a NIOSH-certified respirator with an APF of at least 1,000 during manufacturing and processing (a respirator with an APF of at least 50 may be used if a minimum ventilation airflow of 3,500 standard cubic feet per minute is maintained in the work area) and a respirator with an APF of at least 50 during use where there is a potential for inhalation exposure;
 - No processing for use or use of the PMN substance in a consumer product;
 - Use of the PMN substance only as a polyurethane catalyst;
 - No processing for use or use of the PMN substance at a concentration > 3% by weight;
 - 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 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: P-22-167 (40 CFR 721.12100).

Chemical Name: 1,2-Cycloalkanedicarboxylic acid, 1,2-bis(2-oxiranylalkyl) ester, reaction products with unsaturated carboxylic acid (generic).

CASRN or Accession No.: Not available.

Effective Date of TSCA Order: March 29, 2024.

Basis for TSCA Order: The PMN states that the generic (non-confidential) use will be in photolithography. Based on comparison to analogous acrylates/methacrylates, EPA has identified concerns for skin, eyes, and respiratory irritation and skin and respiratory tract sensitization. Based on submitted test data on the PMN substance and comparison to analogous acrylates/methacrylates and esters, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 460 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 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, in surface water concentrations that exceed 460 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 eye irritation/corrosion, skin irritation, skin sensitization, 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: P-22-192 (40 CFR 721.12101).

Chemical Name: Sulfonium, tricyclobicyclic-, polyfluoro-heteroatom-substituted polycarbocyclicalkanesulfonate (1:1) (generic).

CASRN: 302579.

Effective Date of TSCA Order: April 26, 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 anion, the incineration product, the cation, and the cation photodegradation product of the PMN substance will persist in the environment for more than six months, estimates a bioaccumulation factor for the cation photodegradation product of the PMN substance of greater than or equal to 1,000, and estimates an unknown bioaccumulation factor for the cation and anion of the PMN substance. Based on sulfonium compounds, EPA has identified concerns for acute toxicity, irritation to the skin, eyes, and respiratory tract, eye corrosion, ocular lethality, neurological effects, and systemic effects for the sulfonium cation of the PMN substance. Based on the photo reactivity of the PMN substance, EPA has also identified concerns for photosensitization for the sulfonium cation of the PMN substance. Based on the reactivity of the PMN substance, EPA has also identified concerns for irritation to the skin, eyes, and respiratory tract for the sulfonium cation of the PMN substance. Based on comparison to analogous chemical substances, EPA has also identified concerns for mutagenicity for the sulfonium cation of the PMN substance. Based on comparison to analogous chemical substances for the perfluoro anion, EPA has also identified concerns for acute toxicity, skin irritation, eye corrosion, GI tract irritation, and systemic, reproductive, and developmental effects for the anion. Based on a potential incineration by-product, EPA has also identified concerns for local, neurotoxic, and systemic effects. EPA was unable to estimate the environmental hazard of the PMN substance. 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 or use 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, unless 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.

PMN Number: P-23-38 (40 CFR 721.12102).

Chemical Name: Formaldehyde, polymer with phenol, carboxyalkyl ethers, alkali salts, compds. with (dialkylamino)alkanol (generic).

CASRN or Accession No.: Not available.

Effective Date of TSCA Order: January 2, 2024.

Basis for TSCA Order: The PMN states that the use will be as a crosslinker (hardener) for various water dilutable backbone binders to obtain high chemical resistant protective layers for heat curing metal application. Based on test data for the cation of the PMN substance, EPA has

identified concerns for acute toxicity, portal-of-entry (inhalation) effects, skin corrosion, eye corrosion, skin sensitization, neurotoxicity, systemic effects, and reproductive/developmental effects for the cation of the PMN substance. Based on comparison to analogous phenols and to the physical/chemical properties of the PMN substance, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 120 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 for commercial use;
 - No manufacture or processing of the PMN substance in any manner that results in the generation of a vapor, mist, dust, or aerosol;
 - No processing for use or use of the PMN substance as a consumer product;
 - Use of the PMN substance only in an enclosed process;
 - No release of the PMN substance, or any waste stream containing the PMN substance, in surface water concentrations that exceed 120 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, developmental toxicity, eye irritation/corrosion, neurotoxicity, pulmonary effects, reproductive toxicity, skin corrosion, skin

sensitization, 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: P-23-42 (40 CFR 721.12103).

Chemical Name: Oxirane, alkyl-, polymer with oxirane, monoethers with polyethylene glycol alkenyl ether (generic).

CASRN or Accession No.: Not available.

Effective Date of TSCA Order: April 29, 2024.

Basis for TSCA Order: The PMN states that the use will be as an intermediate to produce polymers. Based on submitted test data on the PMN substance, EPA has identified concerns for skin corrosion. Based on comparison to analogous chemical substances, EPA has also identified concerns for systemic and developmental effects. Based on the structure of the PMN substance, EPA has also identified concerns for lung effects. Based on comparison to analogous nonionic surfactants and on submitted test data on the PMN substance, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 982 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;
 - Use of the PMN substance only as an intermediate for use in producing polymers;
 - 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, developmental 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: P-23-43 (40 CFR 721.12104).

Chemical Name: Oxirane, alkyl-, polymer with oxirane, sulfate, ethers with polyethylene glycol alkenyl ether, salt (generic).

CASRN or Accession No.: Not available.

Effective Date of TSCA Order: April 29, 2024.

Basis for TSCA Order: The PMN states that the use will be as an intermediate to produce polymers. Based on structure and submitted test data on the PMN substance, EPA has identified concerns for lung effects (surfactancy). Based on submitted test data on the PMN substance, EPA has also identified concerns for skin irritation. Based on comparison to analogous chemical substances, EPA has also identified concerns for clinical signs and portal-of-entry (oral) effects. Based on comparison to analogous anionic surfactants and on comparison to analogous chemical substances, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1,000 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;

- Use of the PMN substance only as an intermediate for use in producing polymers;
- 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 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: P-23-61 (40 CFR 721.12105).

Chemical Name: Alkanoic acid, substituted, polymer with substituted alkanoic acid, from fermentation of fermentable sugars (generic).

CASRN: 302397.

Effective Date of TSCA Order: March 22, 2024.

Basis for TSCA Order: The PMN states that the generic (non-confidential) use will be as a plastic resin. Based on comparison to analogous chemical substances, EPA has identified concerns for

skin irritation, eye irritation, 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 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 eye irritation, skin irritation, 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: P-23-74 (40 CFR 721.12106).

Chemical Name: 2-Propenoic acid, 2-methyl-, C13-15-branched and linear alkyl esters.

CASRN: 90552-04-8.

Effective Date of TSCA Order: April 8, 2024.

Basis for TSCA Order: The PMN states that the use will be as a monomer used in the production of polymers. Based on submitted test data on the PMN substance and comparison to analogous methacrylates, EPA predicts toxicity to aquatic organisms may occur at concentrations that

exceed 0.13 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 the environment. To protect against these risks, the Order requires:

- 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 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 chronic aquatic toxicity testing may be potentially useful to characterize the 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: P-23-126 (40 CFR 721.12107).

Chemical Name: Alken-1-ol (generic).

CASRN: 302580.

Effective Date of TSCA Order: May 21, 2024.

Basis for TSCA Order: The PMN states that the generic (non-confidential) use will be as a chemical raw material used in pheromone production. Based on submitted test data on the PMN substance, EPA has identified concerns for irritation/corrosion to skin, respiratory tract, and eyes. Based on submitted test data on the PMN substance and comparison to analogous neutral organics, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed

238 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 processing for use or use of the PMN substance in a consumer product;
- Use of a NIOSH-certified 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, 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 eye irritation, pulmonary effects, and chronic 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: P-23-176 (40 CFR 721.12108) and P-23-179 (40 CFR 721.12109).

Chemical Names: Sulfonium, bis (dihalo carbomonocycle) carbomonocycle-, salt with dihalo-sulfoalkyl trisubstituted benzoate (generic) (P-23-176) and Sulfonium, bis(dihalocarbomonocycle)carbomonocycle-, salt with substituted-dihalobenzoate (generic) (P-

23-179).

CASRN: 302386 (P-23-176), not available (P-23-179).

Effective Date of TSCA Order: March 6, 2024.

Basis for TSCA Order: The PMNs state that the generic (non-confidential) use of the PMN substances will be as ingredients used in the manufacture of photoresist. 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 substances 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 estimates a bioaccumulation factor of greater than or equal to 1,000. Based on sulfonium compounds, EPA has identified concerns for acute toxicity, irritation to the skin, eyes, and respiratory tract, eye corrosion, neurological effects, and systemic effects for the sulfonium cation of the PMN substances. Based on comparison to analogous chemical substances, EPA has also identified concerns for genetic toxicity. Based on the photo reactivity of the PMN substances, EPA has also identified concerns for photosensitization. Based on comparison to analogous chemical substances, EPA has also identified concerns for systemic and developmental effects for the anion component of the PMN substances. Based on a potential incineration product, EPA has also identified concerns for local and systemic effects via inhalation exposure. Based on OECD Toolbox results, EPA also identified concerns for skin sensitization (P-23-176) for the anion. Based on DEREK prediction for the anion, EPA has also identified systemic (thyroid) toxicity (P-23-179) for the anion. 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 processing 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, unless 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: P-24-42 (40 CFR 721.12110).

Chemical Name: Sulfonium, bis(dihalocarbomonocycle)carbomonocycle-, salt with (dihalo-sulfoalkyl) (halo-substituted carbomonocycle) carbopolycycle (generic).

CASRN or Accession No.: Not available.

Effective Date of TSCA Order: March 6, 2024.

Basis for TSCA Order: The PMN states that the generic (non-confidential) use of the PMN substance will be as an ingredient used in the manufacture of photoresist. 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 anion, the cation, the incineration product, and the cation photodegradation product of the PMN substance will persist in the environment for more than six months. EPA estimates that the anion and the cation have unknown bioaccumulation potential, that the incineration product may accumulate in organisms by mechanisms other than lipophilic partitioning, and that the cation photodegradation product has a bioaccumulation factor of greater than or equal to 1,000. Based on 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 of the PMN substance. Based on comparison to analogous chemical substances, EPA has also identified concerns for genetic toxicity for the sulfonium cation of the PMN substance. Based on the photo reactivity of the PMN substance, EPA has also identified concerns for photosensitization for the sulfonium cation of the PMN substance. Based on OECD QSAR Toolbox results, EPA has also identified concerns for skin and respiratory tract sensitization for the anion. Based on an incineration product, EPA has 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 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, unless 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.

PMN Number: P-24-97 (40 CFR 721.12111).

Chemical Name: Sulfonium, tris(4-fluorophenyl)-, (substitutedphenoxy)alkyl substitutedbenzoate (1:1) (generic).

CASRN or Accession No.: Not available.

Effective Date of TSCA Order: May 13, 2024.

Basis for TSCA Order: The PMN states that the generic (non-confidential) use of the PMN substance will be for contained use for microlithography for electronic device manufacturing.

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 anion, cation, incineration product, and cation photodegradation product of the PMN substance will persist in the environment for more than six months. EPA estimates that the anion and the cation have unknown bioaccumulation potential, that the incineration product may accumulate in organisms by mechanisms other than lipophilic partitioning, and that the cation photodegradation product has a bioaccumulation factor of greater than or equal to 1,000. Based on sulfonium compounds, EPA has identified concerns for acute toxicity, irritation to the skin and respiratory tract, eye corrosion, genetic toxicity, and neurological and systemic effects for the sulfonium cation of the PMN substance. Based on the photoreactivity of the PMN substance, EPA has also identified concerns for photosensitization for the sulfonium cation of the PMN substance. Based on OECD Toolbox results, EPA has also identified concerns for skin sensitization for the anion. 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 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, unless 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

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).

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 using 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 7 in Federal fiscal year (FY) 2020, 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 the identified chemical substances for an activity that is designated as a significant new use by the SNUR. 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).

List of Subjects in 40 CFR Part 721

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

Dated: March 26, 2025.

Mary Elissa Reaves,

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 §§ 721.12077 through 721.12111 to Subpart E to read as follows:

Subpart E – Significant New Uses for Specific Chemical Substances

Sec.

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721.12077 Oxirane, 2-methyl-, polymer with 2,4-diisocyanato-1-methylbenzene, 2-methyloxirane polymer with oxirane ether with 1,2,3-propanetriol (3:1), and oxirane, cashew nutshell liq.- and Pr alc. -blocked.

721.12078 Alcohols, C8-10-iso-, C9-rich, ethoxylated.

721.12079 Reaction product of polyester with alpha.-hydro.-omega.-hydroxypoly (oxy-1,4-butanediyl) and 1,1'-methylenebis[isocyanatobenzene] (generic).

721.12080 Benzene, [2-[(2-methyl-1-undecen-1-yl) oxy]ethyl]-.

721.12081 Siloxanes and Silicones, alkyl methyl, dimethyl (generic).

721.12082 Protein sodium complexes, polymers with aromatic acid chloride, ethylene diamine and amino acid (generic).

721.12083 Aryl-substituted-heterocyclic-polyamine, reaction products with polyethylene glycol alkyl-ether, and nitrogen and alkyl-substituted benzene (generic).

721.12084 Thermomycolin, *Malbranchea cinnamomea* origin, expressed in genetically modified *Trichoderma reesei*.

721.12085 Oils, sandalwood, santalene synthase-modified *Rhodobacter sphaeroides*-fermented, from D-Glucose, oxidized.

721.12086 Carboxylic acid substituted carbomonocycles, polymer with dialkyl-alkanediol and alkanediol, hydroxy-alkyl-oxo-alkenyl) oxy]alkyl ester (generic).

721.12087 4,8,11-Dodecatrienal.

721.12088 Alkanol, polymer with isocyanato-(isocyanatoalkyl)-trialkylcarbomonocycle, alkylene glycol monoacrylate-blocked (generic).

721.12089 Alkenoic acid, alkyl-substituted alkyl ester, polymer with (polyalkylamino)alkyl alkylalkenoate, alkyl-substituted alkylalkenoate, .alpha.-(alkyl-oxo-alkenyl)-.omega.-alkoxypoly(oxy-1,2-ethanediyl), [(alkoxy-alkyl-alkenyl)oxy]polyalkylsilane-initiated, compds. with polyethylene glycol phosphoric acid-based alkyl ether (generic).

721.12090 Maltodextrin, octanoate.

721.12091 Maltodextrin, hexadecanoate.

721.12092 Maltodextrin, decanoate.

721.12093 Maltodextrin, octadecanoate.

721.12094 Maltodextrin, dodecanoate.

721.12095 Maltodextrin, tetradecanoate.

721.12096 Dialkylhydroxylamine (generic).

721.12097 Acetyl, alkyl, alkenoic acid, ethyl ester (generic).

721.12098 2-Alkyl-1,2-heteropolycycle-3-one (generic).

721.12099 1,2-Ethanediamine, N1, N2-dimethyl-N1-(1-methylethyl)-N2-[2-[methyl(1-methylethyl)amino]ethyl]-.

721.12100 1,2-Cycloalkanedicarboxylic acid, 1,2-bis(2-oxiranylalkyl) ester, reaction products with unsaturated carboxylic acid (generic).

721.12101 Sulfonium, tricyclic-, polyfluoro-heteroatom-substituted polycarbocyclicalkanesulfonate (1:1) (generic).

721.12102 Formaldehyde, polymer with phenol, carboxyalkyl ethers, alkali salts, compds. with (dialkylamino)alkanol (generic).

721.12103 Oxirane, alkyl-, polymer with oxirane, monoethers with polyethylene glycol alkenyl ether (generic).

721.12104 Oxirane, alkyl-, polymer with oxirane, sulfate, ethers with polyethylene glycol alkenyl ether, salt (generic).

721.12105 Alkanoic acid, substituted, polymer with substituted Alkanoic acid, from fermentation of fermentable sugars (generic).

721.12106 2-Propenoic acid, 2-methyl-, C13-15-branched and linear alkyl esters.

721.12107 Alken-1-ol (generic).

721.12108 Sulfonium, bis (dihalo carbomonocycle) carbomonocycle-, salt with dihalo-sulfoalkyl trisubstituted benzoate (generic).

721.12109 Sulfonium, bis(dihalocarbomonocycle)carbomonocycle-, salt with substituted-dihalobenzoate (generic).

721.12110 Sulfonium, bis(dihalocarbomonocycle)carbomonocycle-, salt with (dihalo-sulfoalkyl) (halo-substituted carbomonocycle) carbopolycycle (generic).

721.12111 Sulfonium, tris(4-fluorophenyl)-, (substitutedphenoxy)alkyl substitutedbenzoate (1:1) (generic).

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§ 721.12077 Oxirane, 2-methyl-, polymer with 2,4-diisocyanato-1-methylbenzene, 2-methyloxirane polymer with oxirane ether with 1,2,3-propanetriol (3:1), and oxirane, cashew nutshell liq.- and Pr alc. -blocked.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as oxirane, 2-methyl-, polymer with 2,4-diisocyanato-1-methylbenzene, 2-methyloxirane polymer with oxirane ether with 1,2,3-propanetriol (3:1), and oxirane, cashew nutshell liq.- and Pr alc. -blocked (PMN P-18-360; CASRN 1227870-90-7) 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) through (5), 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), and (g)(1) and (5). For purposes of § 721.72(g)(1), this substance may cause: skin irritation, eye irritation, 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). It is a significant new use to use the substance other than as a two component adhesives and protective coating for marine and infrastructure applications.

(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.

§ 721.12078 Alcohols, C8-10-iso-, C9-rich, ethoxylated.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as alcohols, C8-10-iso-, C9-rich, ethoxylated (PMN P-20-87; CASRN 2368929-19-3) 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) through

(5), (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 1000. 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)(iii) 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, serious eye damage, 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*. It is a significant new use to process the substance to a concentration of 3% or greater in formulation for use in a consumer product. It is a significant new use to use the substance other than as a surfactant in hard surface cleaners and laundry detergents.

(iv) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where $N=142$.

(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.

§ 721.12079 Reaction product of polyester with alpha.-hydro.-omega.-hydroxypoly (oxy-

1,4- butanediyl) and 1,1'-methylenebis[isocyanatobenzene] (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as reaction product of polyester with alpha.-hydro-.omega.-hydroxypoly (oxy-1,4- butanediyl) and 1,1'-methylenebis[isocyanatobenzene] (PMN P-21-198; Accession No. 302217) 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), and (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, 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.

(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.

§ 721.12080 Benzene, [2-[(2-methyl-1-undecen-1-yl) oxy]ethyl]-.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as benzene, [2-[(2-methyl-1-undecen-1-yl) oxy]ethyl]- (PMN P-21-205; CASRN 2489743-82-8) 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), and (g)(1) and (5). For purposes of § 721.72(g)(1), this substance may cause: skin sensitization, specific target organ toxicity, and reproductive 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 consumer products where the concentration of the substance exceeds 1% by weight. It is a significant new use to use the substance in consumer products where the concentration of the substance exceeds 1% by weight.

(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.

§ 721.12081 Siloxanes and Silicones, alkyl methyl, dimethyl (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as siloxanes and silicones, alkyl methyl, dimethyl (PMN P-21-213) 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) 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) 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. 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.

(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.

§ 721.12082 Protein sodium complexes, polymers with aromatic acid chloride, ethylene diamine and amino acid (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as protein sodium complexes, polymers with aromatic acid chloride, ethylene diamine and amino acid (PMN P-22-19; Accession No. 302206) 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), 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), and (g)(1) and (5). For purposes of § 721.72(g)(1), this substance may cause: skin irritation, eye irritation, respiratory sensitization, 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.* It is a significant new use to manufacture, process, or use the substance in any manner that results in inhalation exposure to workers. It is a significant new use to process the substance for use in consumer products where the concentration of the confidential component of the substance listed in the Order in the consumer product exceeds 0.1%. It is a significant new use to use the substance in consumer

products where the concentration of the confidential component listed in the Order exceeds 0.1%.

(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) 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.

§ 721.12083 Aryl-substituted-heterocyclic-polyamine, reaction products with polyethylene glycol alkyl-ether, and nitrogen and alkyl-substituted benzene (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as aryl-substituted-heterocyclic-polyamine, reaction products with polyethylene glycol alkyl-ether, and nitrogen and alkyl-substituted benzene (PMN P-22-22; Accession No. 302046) 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 completely reacted or cured ink.

(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) 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. 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.

(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.

§ 721.12084 Thermomycolin, *Malbranchea cinnamomea* origin, expressed in genetically modified *Trichoderma reesei*.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as thermomycolin, *Malbranchea cinnamomea* origin, expressed in genetically modified *Trichoderma reesei* (PMN P-22-59) 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 when in a formulation at a concentration of 0.1% or less.

(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), and

(g)(1), (3)(iii) and (5). For purposes of § 721.72(g)(1), this substance may cause: skin irritation, eye irritation, 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.* 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. It is a significant new use to process for use or use the substance in consumer products unless the concentration of the substance in the consumer products is less than 0.1% by weight.

(iv) *Release to water.* It is a significant new use to release the substance, or any waste stream containing the substance, into water during processing unless the substance is deactivated before releasing to water. To deactivate the New Chemical Substance, adjust the pH to 2 or below and incubate for 30 minutes.

(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.

§ 721.12085 Oils, sandalwood, santalene synthase-modified Rhodobacter sphaeroides-fermented, from D-Glucose, oxidized.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as oils, sandalwood, santalene synthase-modified Rhodobacter sphaeroides-fermented, from D-Glucose, oxidized (PMN P-22-83; CASRN 2576531-09-2) 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) through (5), 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), and (g)(1), (3)(iii) and (5). For purposes of § 721.72(g)(1), this substance may cause: skin irritation, 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.* It is a significant new use to process for use or use the substance in consumer products where the concentration of the substance exceeds 1% by weight.

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

§ 721.12086 Carboxylic acid substituted carbomonocycles, polymer with dialkyl-alkanediol and alkanediol, hydroxy-alkyl-oxo-alkenyl) oxy]alkyl ester (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as carboxylic acid substituted carbomonocycles, polymer with dialkyl-alkanediol and alkanediol, hydroxy-alkyl-oxo-alkenyl) oxy]alkyl ester (PMN P-22-89) 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) through (5), 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), and (g)(1) and (5). For purposes of § 721.72(g)(1), this substance may cause: skin irritation, eye irritation, 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).

(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.

§ 721.12087 4,8,11-Dodecatrienal.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 4,8,11-dodecatrienal (PMN P-22-90; CASRN 1000399-21-2) 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), 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), and (g)(1), (3)(iii) and (5). For purposes of § 721.72(g)(1), this substance may cause: skin irritation, 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(k). It is a significant new use to process the substance for use in a consumer product unless the concentration of the substance is less than 1% concentration by weight. It is a significant new use to use the substance unless the concentration of the substance in the product is less than 1% concentration by weight.

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where N=13.

(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.

§ 721.12088 Alkanol, polymer with isocyanato-(isocyanatoalkyl)-trialkylcarbomonocycle, alkylene glycol monoacrylate-blocked (generic).

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified generically as alkanol, polymer with isocyanato-(isocyanatoalkyl)-trialkylcarbomonocycle, alkylene glycol monoacrylate-blocked (PMN P-22-91) 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 (5), 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), and (g)(1), (3)(iii) and (5). For purposes of § 721.72(g)(1), this substance may cause: skin irritation, eye irritation, 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).

(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.

§ 721.12089 Alkenoic acid, alkyl-substituted alkyl ester, polymer with (polyalkylamino)alkyl alkylalkenoate, alkyl-substituted alkylalkenoate, .alpha.-(alkyl-oxo-alkenyl)-.omega.-alkoxypoly(oxy-1,2-ethanediyl), [(alkoxy-alkyl-alkenyl)oxy]polyalkylsilane-initiated, compds. with polyethylene glycol phosphoric acid-based alkyl ether (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as alkenoic acid, alkyl-substituted alkyl ester, polymer with (polyalkylamino)alkyl alkylalkenoate, alkyl-substituted alkylalkenoate, .alpha.-(alkyl-oxo-alkenyl)-.omega.-alkoxypoly(oxy-1,2-ethanediyl), [(alkoxy-alkyl-alkenyl)oxy]polyalkylsilane-initiated, compds. with polyethylene glycol phosphoric acid-based alkyl ether (PMN P-22-93; Accession No. 302499) 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)(iii) 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: eye irritation 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.

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where N=18.

(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.

§ 721.12090 Maltodextrin, octanoate.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as maltodextrin, octanoate (PMN P-22-130; CASRN 2736503-99-2) 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) through (5), (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 1000. 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) 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: serious eye damage 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.* It is a significant new use to manufacture, process, or use the substance unless in aqueous dispersions. It is a significant new use to process for use or use the substance in consumer products that are spray applied. It is a significant new use to process for use or use the substance in consumer products if the concentration of the substance is equal to or exceeds 3% by weight. It is a significant new use to use the substance as an agricultural wetting agent.

(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.

§ 721.12091 Maltodextrin, hexadecanoate.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as maltodextrin, hexadecanoate (PMN P-22-131; CASRN 1516876-50-8) 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) through (5), (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 1000. 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) 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: serious eye damage 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.* It is a significant new use to manufacture, process, or use the substance unless in aqueous dispersions. It is a significant new use to process for use or use the substance in consumer products that are spray applied. It is a significant new use to process for use or use the substance in consumer products if the concentration of the substance is equal to or exceeds 3% by weight. It is a significant new use to use the substance as an agricultural wetting agent.

(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.

§ 721.12092 Maltodextrin, decanoate.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as maltodextrin, decanoate (PMN P-22-132; CASRN 1516876-47-3) 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) and (3) through (5), (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 1000. 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) 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: serious eye damage 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.* It is a significant new use to manufacture, process, or use the substance unless in aqueous dispersions. It is a significant new use to process for use or use the substance in consumer products that are spray applied. It is a significant new use to process for use or use the substance in consumer products if the concentration of the substance is equal to or exceeds 3% by weight. It is a significant new use to use the substance as an agricultural wetting agent.

(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.

§ 721.12093 Maltodextrin, octadecanoate.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as maltodextrin, octadecanoate (PMN P-22-133; CASRN 1159570-68-9) 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) through (5), (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 1000. 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) 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: serious eye damage 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.* It is a significant new use to

manufacture, process, or use the substance unless in aqueous dispersions. It is a significant new use to process for use or use the substance in consumer products that are spray applied. It is a significant new use to process for use or use the substance in consumer products if the concentration of the substance is equal to or exceeds 3% by weight. It is a significant new use to use the substance as an agricultural wetting agent.

(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.

§ 721.12094 Maltodextrin, dodecanoate.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as maltodextrin, dodecanoate (PMN P-22-134; CASRN 512180-33-5) 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) through (5), (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 1000. 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) 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: serious eye damage 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.* It is a significant new use to manufacture, process, or use the substance unless in aqueous dispersions. It is a significant new use to process for use or use the substance in consumer products that are spray applied. It is a significant new use to process for use or use the substance in consumer products if the concentration of the substance is equal to or exceeds 3% by weight. It is a significant new use to use the substance as an agricultural wetting agent.

(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.

§ 721.12095 Maltodextrin, tetradecanoate.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as maltodextrin, tetradecanoate (PMN P-22-135; CASRN 2736504-00-8) 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) through (5), (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 1000. 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) 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: serious eye damage 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.* It is a significant new use to manufacture, process, or use the substance unless in aqueous dispersions. It is a significant new use to process for use or use the substance in consumer products that are spray applied. It is a significant new use to process for use or use the substance in consumer products if the concentration of the substance is equal to or exceeds 3% by weight. It is a significant new use to use the substance as an agricultural wetting agent.

(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.

§ 721.12096 Dialkylhydroxylamine (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as Dialkylhydroxylamine (PMN P-22-139; Accession No. 302353) 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 an article.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1) and (3) through (5), 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), and (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.* It is a significant new use to manufacture the substance without using local exhaust ventilation (LEV) and particulate filters with at least 90% efficiency to control dust released to air. It is a significant new use to conduct the form giving process on the substance without using LEV and HEPA dust filters with at least 99% efficiency to control dust released to air during transfer. It is a significant new use to conduct the form giving process on the substance without using an enclosed system with HEPA dust filters with at least 99% efficiency to control dust released to air during all processing steps other than transfer. It is a significant new use to use the substance other than as an antioxidant process stabilizer.

(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.

§ 721.12097 Acetyl, alkyl, alkenoic acid, ethyl ester (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as acetyl, alkyl, alkenoic acid, ethyl ester (PMN P-22-154) 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), 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), and (g)(1), (3)(iii) and (5). For purposes of § 721.72(g)(1), this substance may cause: acute toxicity, 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.* It is a significant new use to manufacture or process the substance in any manner that results in inhalation exposure. It is a significant new use to process for use or use the substance in consumer products where the concentration of the substance exceeds 1%.

(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.

§ 721.12098 2-Alkyl-1,2-heteropolycycle-3-one (generic).

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified generically as 2-alkyl-1,2-heteropolycycle-3-one (PMN P-22-155) 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) and (3) through (5), 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), and (g)(1), (3) and (5). For purposes of § 721.72(g)(1), this substance may cause: acute toxicity, skin corrosion, serious eye damage, skin sensitization, 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(f), (o), (v)(1), (2) and (4), (w)(1), (2) and (4), and (x)(1), (2) and (4).

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

§ 721.12099 1,2-Ethanediamine, N1, N2-dimethyl-N1-(1-methylethyl)-N2-[2-[methyl(1-methylethyl)amino]ethyl]-.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 1,2-ethanediamine, N1, N2-dimethyl-N1-(1-methylethyl)-N2-[2-[methyl(1-methylethyl)amino]ethyl]- (PMN P-22-157; CASRN 1042950-30-0) 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) through (5), 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 during manufacturing and processing (a respirator with an APF of at least 50 may be used if a minimum ventilation airflow of 3,500 standard cubic feet per minute is maintained in the work area), and a respirator with an APF of at least 50 during use.

(ii) *Hazard communication*. Requirements as specified in § 721.72(a) through (d), (f), and (g)(1), (3) and (5). For purposes of § 721.72(g)(1), this substance may cause: acute toxicity, skin corrosion, serious eye damage, reproductive toxicity, specific target organ toxicity, and skin sensitization. For the 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 other than as a polyurethane catalyst. It is a significant new use to process for use or use the substance at a concentration > 3% by weight.

(iv) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where N=650.

(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.

§ 721.12100 1,2-Cycloalkanedicarboxylic acid, 1,2-bis(2-oxiranylalkyl) ester, reaction products with unsaturated carboxylic acid (generic).

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified generically as 1,2-cycloalkanedicarboxylic acid, 1,2-bis(2-oxiranylalkyl) ester, reaction products with unsaturated carboxylic acid (PMN P-22-167) are 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), 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), and (g)(1), (3)(iii) and (5). For purposes of § 721.72(g)(1), this substance may cause: skin irritation, eye irritation, respiratory sensitization, 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). It is a significant new use to manufacture, process, or use the substance in any manner that results in inhalation exposure.

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where N=460.

(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.

§ 721.12101 Sulfonium, tricyclic-, polyfluoro-heteroatom-substituted polycarbocyclicalkanesulfonate (1:1) (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as sulfonium, tricyclic-, polyfluoro-heteroatom-substituted polycarbocyclicalkanesulfonate (1:1) (PMN P-22-192; Accession No. 302579) 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), 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 (f), and (g)(1), (2)(i) through (iii) and (v), (3)(i) and (ii) 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, 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, unless in sealed containers weighing 5 kilograms or less. It is a significant new use to process the substance in any way that generates a dust, mist, or aerosol in a non-enclosed process. It is a significant new use to manufacture the substance longer than 9 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.

§ 721.12102 Formaldehyde, polymer with phenol, carboxyalkyl ethers, alkali salts, compds. with (dialkylamino)alkanol (generic).

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified generically as formaldehyde, polymer with phenol, carboxyalkyl ethers, alkali salts, compds. with (dialkylamino)alkanol (PMN P-23-38) 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), and (g)(1), (3)(iii) and (5). For purposes of § 721.72(g)(1), this substance may cause: acute toxicity, skin corrosion, serious eye damage, skin 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(a), (m), and (o). It is a significant new use to manufacture or process the substance in any manner that results in the generation of a vapor, mist, dust, or aerosol. It is a significant new use

to manufacture, process, or use the substance for commercial use. It is a significant new use to process the substance for use by a consumer as a consumer product.

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where N=120.

(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.

§ 721.12103 Oxirane, alkyl-, polymer with oxirane, monoethers with polyethylene glycol alkenyl ether (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as oxirane, alkyl-, polymer with oxirane, monoethers with polyethylene glycol alkenyl ether (PMN P-23-42) 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), (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)(iii) 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 corrosion, 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. It is a significant new use to use the substance other than as an intermediate for use in producing polymers.

(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.

§ 721.12104 Oxirane, alkyl-, polymer with oxirane, sulfate, ethers with polyethylene glycol alkenyl ether, salt (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as oxirane, alkyl-, polymer with oxirane, sulfate, ethers with polyethylene glycol alkenyl ether, salt (PMN P-23-43) 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), (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)(iii) 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. 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. It is a significant new use to use the substance other than as an intermediate for use in producing polymers.

(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.

§ 721.12105 Alkanoic acid, substituted, polymer with substituted Alkanoic acid, from fermentation of fermentable sugars (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as alkanoic acid, substituted, polymer with substituted Alkanoic acid, from fermentation of fermentable sugars (PMN P-23-61; Accession No. 302397) 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 reacted or cured or when incorporated into an article.

(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), and (g)(1) and (5). For purposes of § 721.72(g)(1), this substance may cause: skin irritation, skin sensitization, and eye irritation. 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).

(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.

§ 721.12106 2-Propenoic acid, 2-methyl-, C13-15-branched and linear alkyl esters.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 2-propenoic acid, 2-methyl-, C13-15-branched and linear alkyl esters (PMN P-23-74; CASRN 90552-04-8) 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 reacted such that less than 1 percent of the substance remains.

(2) The significant new uses are:

(i) *Hazard communication*. Requirements as specified in § 721.72(a) through (f), and (g)(3)(iii) and (5). For purposes of § 721.72(e), the concentration is set at 1.0%. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(ii) *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 (c), (f) through (h), 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.

§ 721.12107 Alken-1-ol (generic).

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified generically as alken-1-ol (PMN P-23-126; Accession No. 302580) 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) through (5), (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), and (g)(1), (3)(iii) 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 corrosion, skin irritation, serious eye damage, eye irritation, 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).

(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.

§ 721.12108 Sulfonium, bis (dihalo carbomonocycle) carbomonocycle-, salt with dihalo-sulfoalkyl trisubstituted benzoate (generic).

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified generically as sulfonium, bis (dihalo carbomonocycle) carbomonocycle-, salt with dihalo-sulfoalkyl trisubstituted benzoate (PMN P-23-176; Accession No. 302386) 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) 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 (f), and (g)(1), (2)(i) through (iii) and (v), (3)(i) and (ii) 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, 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, unless in sealed containers weighing 5 kilograms or less. It is a significant new use to process the substance in any way that generates a 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.

§ 721.12109 Sulfonium, bis(dihalocarbomonocycle)carbomonocycle-, salt with substituted-dihalobenzoate (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as sulfonium, bis(dihalocarbomonocycle)carbomonocycle-, salt with substituted-dihalobenzoate (PMN P-23-179) 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) 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 (f), and (g)(1), (2)(i) through (iii) and (v), (3)(i) and (ii) 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, 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, unless in sealed containers weighing 5 kilograms or less. It is a significant new use to process the substance in any way that generates a 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.

§ 721.12110 Sulfonium, bis(dihalocarbomonocycle)carbomonocycle-, salt with (dihalo-sulfoalkyl) (halo-substituted carbomonocycle) carbopolycycle (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as sulfonium, bis(dihalocarbomonocycle)carbomonocycle-, salt with (dihalo-sulfoalkyl) (halo-substituted carbomonocycle) carbopolycycle (PMN P-24-42) 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) 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 (f), and (g)(1), (2)(i) through (iii) and (v), (3)(i) and (ii) 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, 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, unless in sealed containers weighing 5 kilograms or less. It is a significant new use to process the substance in any way that generates a 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.

§ 721.12111 Sulfonium, tris(4-fluorophenyl)-, (substitutedphenoxy)alkyl substitutedbenzoate (1:1) (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as sulfonium, tris(4-fluorophenyl)-, (substitutedphenoxy)alkyl substitutedbenzoate (1:1) (PMN P-24-97) 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) 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 (f), and (g)(1), (2)(i) through (iii) and (v), (3)(i) and (ii), 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, 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, unless in sealed containers weighing 5 kilograms or less. It is a significant new use to process 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 9 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.