



## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 721

[EPA-HQ-OPPT-2021-0228; FRL-11762-01-OCSPP]

RIN 2070-AB27

### Significant New Use Rules on Certain Chemical Substances (21-4.F)

**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 chemical substances that were the subject of premanufacture notices (PMNs). The chemical substances received “not likely to present an unreasonable risk” determinations 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 use, under the conditions of 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-2021-0228, through the Federal eRulemaking Portal 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 contact:* 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](mailto:wysong.william@epa.gov).

*For general information contact:* The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: [TSCA-Hotline@epa.gov](mailto:TSCA-Hotline@epa.gov).

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

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

##### *1. General applicability.*

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

readers determine whether this document applies to them. Potentially affected entities may include:

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

*2. Applicability to importers and exporters.*

This action may also apply to certain entities through pre-existing import certification and export notification rules under TSCA (<https://www.epa.gov/tsca-import-export-requirements>).

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

Pursuant to 40 CFR 721.20, any persons who export or intend to export a chemical substance that is the subject of this proposed rule on or after **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** are subject to the export notification provisions of 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 significant new use notice (SNUN) reporting requirements for potential manufacturers (including importers) and processors of the chemical substances subject to these proposed SNURs. This analysis, which is available in the docket, is briefly summarized here.

*1. Estimated costs for SNUN submissions.*

If a SNUN is submitted, costs are an estimated \$26,700 per SNUN submission for large business submitters and \$11,000 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 \$19,020 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 \$3,300 (40 CFR 700.45(c)(1)(ii) and (d)) per fiscal year 2022. The costs of submission for SNUNs will not be incurred by any company unless a company decides to pursue a significant new use as defined in these SNURs. Additionally, these estimates reflect the costs and fees as they are known at the time of this rulemaking.

## *2. Estimated costs for export notifications.*

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

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

### *1. Submitting CBI.*

Do not submit CBI to EPA through email or <https://www.regulations.gov>. If you wish to include CBI in your comment, please follow the applicable instructions at <https://www.epa.gov/dockets/commenting-epa-dockets#rules> and clearly mark the information that you claim to be CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR parts 2 and 704.

### *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 received a "not likely to present an unreasonable risk" determination in TSCA section 5(a)(3)(c). During its review of these chemicals, EPA identified certain conditions of use that are not intended by the submitters, but reasonably foreseen to occur. EPA is proposing to designate those reasonably foreseen conditions of use as well as certain other circumstances of use as significant new uses.

## *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 for the chemical substances that are the subject of these proposed SNURs and as further discussed in Unit III., EPA identified certain other conditions of use, in addition to those conditions of use intended by the submitter. EPA has determined that the chemical under the conditions of use is not likely to present an unreasonable risk. However, EPA has not assessed risks associated with certain conditions of use. EPA is proposing to designate these other circumstances of use as significant new uses. As a result, those significant new uses cannot occur without going through a separate, subsequent EPA review and determination process associated with a SNUN.

### *2. Objectives.*

EPA is proposing these SNURs because the Agency wants:

- To be able to complete its review and determination on each of the PMN substances, while deferring analysis on the significant new uses proposed in these rules unless and until the Agency receives a SNUN.

- To have an opportunity to review and evaluate data submitted in a SNUN before the submitter begins manufacturing or processing a listed chemical substance for the described significant new use.

- To be obligated to make a determination under TSCA section 5(a)(3) regarding the use described in the SNUN, under the conditions of use. The Agency will either determine under

TSCA section 5(a)(3)(C) that the significant new use is not likely to present an unreasonable risk, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, or make a determination under TSCA section 5(a)(3)(A) or (B) and take the required regulatory action associated with the determination, before manufacture or processing for the significant new use of the chemical substance can occur.

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

### *C. Significant New Uses Claimed as CBI.*

EPA is proposing to establish certain significant new uses which have been claimed as CBI subject to Agency confidentiality regulations at 40 CFR part 2 and 40 CFR part 720, subpart E. Absent a final determination or other disposition of the confidentiality claim under 40 CFR part 2 procedures, EPA is required to keep this information confidential. EPA promulgated a procedure to deal with the situation where a specific significant new use is CBI, at 40 CFR 721.1725(b)(1) and has referenced it to apply to other SNURs.

Under these procedures a manufacturer or processor may request EPA to determine whether a specific use would be a significant new use under the rule. The manufacturer or processor must show that it has a *bona fide* intent to manufacture or process the chemical substance and must identify the specific use for which it intends 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 tell the person whether the use identified in the *bona fide* submission would be a significant new use under the rule. 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 721.1725(b)(1) with that under 40 CFR 721.11 into a single step.

If EPA determines that the use identified in the *bona fide* submission would not be a significant new use, i.e., the use does not meet the criteria specified in the rule for a significant new use, that person can manufacture or process the chemical substance so long as the significant new use trigger is not met. In the case of a production volume trigger, this means that the aggregate annual production volume does not exceed that identified in the *bona fide* submission to EPA. Because of confidentiality concerns, EPA does not typically disclose the actual production volume that constitutes the use trigger. Thus, if the person later intends to exceed that volume, a new *bona fide* submission would be necessary to determine whether that higher volume would be a significant new use.

#### *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 intended 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 intended 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. In cases where EPA has not received a notice of commencement (NOC) and the chemical substance has not been added to the TSCA Inventory, no person may commence such activities without first submitting a PMN. Therefore, for chemical substances for which an NOC has not been submitted, EPA concludes that the designated significant new uses are not ongoing. The identities of many of the chemical substances subject to this proposed rule have been claimed as confidential per 40 CFR 720.85 and the PMN submitter did not intend to engage in the other circumstances of use that are designated as significant new uses for the chemical substances subject to the proposed rule. Based on this, the Agency believes that it is highly unlikely that any of the significant new uses described in the regulatory text of this proposed rule are ongoing.

When the chemical substances identified in this proposed rule 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. Unit IV. lists potentially useful information for all SNURs listed here. Descriptions are provided for informational purposes. The potentially useful information identified in Unit IV. will be useful to EPA's evaluation in the event that someone submits a SNUN for the significant new use. Companies who are considering submitting a SNUN are encouraged, but not required, to develop the information on the substance, which may assist with EPA's analysis of the SNUN.

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 which provide detailed information on the following:

- 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 determining whether the new use is ongoing for these chemical substances?*

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.D.

*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 this document).

- Chemical name (generic name if the specific name is claimed as CBI).
- Chemical Abstracts Service Registry Number (CASRN) (if assigned for non-confidential chemical identities).

- Basis for the SNUR.
- Potentially useful information.

The regulatory text section of this document 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.

The chemical substances that are the subject of these proposed SNURs have undergone premanufacture review. In addition to those conditions of use intended by the submitter, EPA has identified certain other circumstances of use. EPA has preliminarily determined that the chemicals under their conditions of use are not likely to present an unreasonable risk. However, EPA has not assessed risks associated with the other circumstances of use for these chemicals. EPA is proposing to designate these other circumstances of use as significant new uses. As a result, those significant new uses cannot occur without first going through a separate, subsequent EPA review and determination process associated with a SNUN.

*C. Which chemical substances are subject to this proposed rule?*

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

**PMN Number (proposed CFR citation): P-16-449 (40 CFR 721.11799).**

*Chemical Name:* 2,7-Decadienal, (2E,7Z)-.

*CASRN:* 52711-52-1.

*Basis for action:* The PMN states that the use of the PMN substance will be in cosmetics and as a fragrance for scented papers, detergents, candles, etc. Based on estimated physical/chemical properties of the PMN substance, submitted test data on the new chemical substance, comparison to analogous aldehydes, and comparison to structurally analogous chemical substances, EPA has identified concerns for systemic and developmental effects, skin sensitization, skin irritation, eye

irritation, severe respiratory tract irritation, and aquatic toxicity if the chemical substance is not used following the limitations noted. The conditions of use of the PMN substance as described in the PMN include the following protective measures:

- No processing of the PMN substance to a concentration of greater than or equal to 1.0% in the final end use formulation; and
- No release of the PMN substance resulting in surface water concentrations that exceed 1 ppb.

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 to characterize the human health and environmental effects of the PMN substance 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, reproductive toxicity, and aquatic toxicity testing may be potentially useful to characterize the health and environmental effects of the PMN substance.

**PMN Number (proposed CFR citation): P-16-512 (40 CFR 721.11800).**

*Chemical Name:* Fatty acid dimers, polymer with acrylic acid and pentaerythritol reaction products (generic).

*CASRN:* Not available.

*Basis for action:* The PMN states that the use of the PMN substance will be as a component of UV curable printing inks. Based on estimated physical/chemical properties of the PMN substance, test data on a component of the new chemical substance and a potential metabolite, and comparison to structurally analogous chemical substances, EPA has identified concerns for skin and eye corrosion, skin and respiratory tract sensitization, systemic effects, nasal effects, and reproductive and developmental toxicity if the chemical substance is not used following the limitations noted. The conditions of use of the PMN substance as described in the PMN include

the following protective measures:

- Use of the PMN substance only as a component of UV curable printing inks; and
- Use of a National Institute for Occupational Safety and Health (NIOSH)-certified respirator with an Assigned Protection Factor (APF) of at least 50, or 1,000 in spray applications, where there is a potential for inhalation exposure.

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 to characterize the human health effects of the PMN substance 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 damage, reproductive toxicity (developmental effects), skin sensitization, and specific target organ toxicity testing may be potentially useful to characterize the health effects of the PMN substance.

**PMN Number (proposed CFR citation): P-17-115 (40 CFR 721.11801).**

*Chemical Name:* Aminoalkyl alkoxysilane (generic).

*CASRN:* Not available.

*Basis for action:* The PMN states that the use of the PMN substance will be as an adhesion promoter for coating formulations. Based on the estimated physical/chemical properties of the PMN substance and comparison to analogous chemical substances, EPA has identified concerns for eye and respiratory tract irritation, developmental toxicity, and lung toxicity if the chemical substance is not used following the limitations noted. The condition of use of the PMN substance as described in the PMN includes the following protective measure:

- No consumer use of the PMN substance.

The proposed SNUR would designate as a “significant new use” the absence of this protective measure.

*Potentially Useful Information:* EPA has determined that certain information may be potentially

useful to characterize the human health effects of the PMN substance 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 and reproductive/developmental toxicity testing may be potentially useful to characterize the health effects of the PMN substance.

**PMN Number (proposed CFR citation): P-18-36 (40 CFR 721.11802).**

*Chemical Name:* Siloxanes and Silicones, di-Me, 3-[3-carboxy-2(or 3)-(octenyl)-1-oxopropoxy]propyl group-terminated.

*CASRN:* 403616-34-2.

*Basis for action:* The PMN states that the generic (non-confidential) use of the PMN substance will be as a water repellent. Based on estimated physical/chemical properties of the PMN substance and comparison to structurally analogous chemical substances, EPA has identified concerns for lung effects, systemic effects, and skin irritation if the chemical substance is not used following the limitations noted. The condition of use of the PMN substance as described in the PMN includes the following protective measure:

- No manufacturing, processing, or use of the PMN substance in a manner that results in inhalation exposure.

The proposed SNUR would designate as a “significant new use” the absence of this protective measure.

*Potentially Useful Information:* EPA has determined that certain information may be potentially useful to characterize the human health effects of the PMN substance 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 and skin irritation testing may be potentially useful to characterize the health effects of the PMN substance.

**PMN Number (proposed CFR citation): P-18-263 (40 CFR 721.11803).**

*Chemical Name:* Mixed alkyl esters-, polymer with N1-(2-aminoethyl)- 1,2-ethanediamine, aziridine, N-acetyl derivs., acetates (salts) (generic).

*CASRN:* Not available.

*Basis for action:* The PMN states that the generic (non-confidential) use of the PMN substance will be as a solution additive. Based on estimated physical/chemical properties of the PMN substance, comparison to structurally analogous chemical substances, and comparison to analogous polycationic polymers, EPA has identified concerns for lung effects, irritation to the skin, eyes, and respiratory tract, and aquatic toxicity if the new chemical substance is not used following the limitation noted. The condition of use of the PMN substance as described in the PMN includes the following protective measure:

- No release of the PMN substance resulting in surface water concentrations that exceed 5 ppb.

The proposed SNUR would designate as a “significant new use” the absence of this protective measure.

*Potentially Useful Information:* EPA has determined that certain information may be potentially useful to characterize the human health and environmental effects of the PMN substance 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.

**PMN Number (proposed CFR citation): P-18-336 (40 CFR 721.11804).**

*Chemical Name:* Propanedioic acid, 2,2-bis(hydroxymethyl)-, 1,3-dihexyl ester.

*CASRN:* 2222732-45-6.

*Basis for action:* The PMN states that the use of the PMN substance will be as an intermediate. Based on estimated physical/chemical properties of the PMN substance, comparison to analogous chemical substances, and comparison to analogous esters, EPA has identified

concerns for systemic effects, eye irritation, and aquatic toxicity if the new chemical substance is not used following the limitations noted. The condition of use of the PMN substance as described in the PMN includes the following protective measure:

- No release of the PMN substance resulting in surface water concentrations that exceed 54 ppb.

The proposed SNUR would designate as a “significant new use” the absence of this protective measure.

*Potentially Useful Information:* EPA has determined that certain information may be potentially useful to characterize the human health and environmental effects of the PMN substance 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, specific target organ toxicity, and aquatic toxicity testing may be potentially useful to characterize the health and environmental effects of the PMN substance.

**PMN Number (proposed CFR citation): P-18-355 (40 CFR 721.11805).**

*Chemical Name:* Alkanediol, substituted alkyl, polymer with carbomonocycle, alkanedioate substituted carbomonocycle, ester with substituted alkanooate (generic).

*CASRN:* Not available.

*Basis for action:* The PMN states that the generic (non-confidential) use of the PMN substance will be as paint. Based on the estimated physical/chemical properties of the PMN substance and comparison to analogous chemical substances, EPA has identified concerns for irritation to the skin, eyes, and respiratory tract, and lung effects if the chemical substance is not used following the limitations noted. The condition of use of the PMN substance as described in the PMN includes the following protective measure:

- No consumer use of the PMN substance.

The proposed SNUR would designate as a “significant new use” the absence of this protective measure.

*Potentially Useful Information:* EPA has determined that certain information may be potentially useful to characterize the human health effects of the PMN substance if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of skin irritation, eye irritation, and pulmonary effects testing may be potentially useful to characterize the health effects of the PMN substance.

**PMN Number (proposed CFR citation): P-18-359 (40 CFR 721.11806).**

*Chemical Name:* Ethene, 1-[difluoro(trifluoromethoxy)methoxy]-1,2,2-trifluoro-, polymer with 1,1-difluoroethene.

*CASRN:* 874290-13-8.

*Basis for action:* The PMN states that the generic (non-confidential) use of the PMN substance will be for molded or extruded items. Based on estimated physical/chemical properties of the PMN substance and comparison to structurally analogous chemical substances, EPA has identified concerns for lung overload, lung waterproofing, systemic effects, neurotoxicity, and aquatic toxicity if the chemical substance is not used following the limitations noted. The conditions of use of the PMN substance as described in the PMN include the following protective measures:

- No manufacturing, processing, or use of the PMN substance in a manner that results in inhalation exposure; and
- No disposal of the PMN substance to media other than landfill.

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 to characterize the human health and environmental effects of the PMN substance 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 and aquatic toxicity testing may be potentially useful to characterize the health and

environmental effects of the PMN substance.

**PMN Number (proposed CFR citation): P-18-369 (40 CFR 721.11807).**

*Chemical Name:* Maleic anhydride - substituted alkene copolymer (generic).

*CASRN:* Not available.

*Basis for action:* The PMN states that the generic (non-confidential) use of the PMN substance will be as a processing aid. Based on estimated physical/chemical properties of the PMN substance and comparison to structurally analogous chemical substances, EPA has identified concerns for corrosion to all tissues and aquatic toxicity if the chemical substance is not used following the limitations noted. The condition of use of the PMN substance as described in the PMN includes the following protective measure:

- No manufacturing, processing, or use of the PMN substance in a manner that results in inhalation exposure.

The proposed SNUR would designate as a “significant new use” the absence of this protective measure.

*Potentially Useful Information:* EPA has determined that certain information may be potentially useful to characterize the human health and environmental effects of the PMN substance 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 and aquatic toxicity testing may be potentially useful to characterize the health and environmental effects of the PMN substance.

**PMN Number (proposed CFR citation): P-18-382 (40 CFR 721.11808).**

*Chemical Name:* Xanthylum, bis[dicarboxycyclic]sulfonlamino-alkylcyclicamino-disulfocyclic-, inner salt, monocationic salt (generic).

*CASRN:* Not available.

*Basis for action:* The PMN states that the generic (non-confidential) use of the PMN substance will be as a dye for printing ink. Based on estimated physical/chemical properties of the PMN

substance, submitted test data on the new chemical substance, comparison to structurally analogous chemical substances, and comparison to analogous acid dyes and amphoteric dyes, EPA has identified concerns for systemic effects and aquatic toxicity if the chemical substance is not used following the limitations noted. The condition of use of the PMN substance as described in the PMN includes the following protective measure:

- No manufacturing, processing, or use of the PMN substance in a manner that results in inhalation exposure.

The proposed SNUR would designate as a “significant new use” the absence of this protective measure.

*Potentially Useful Information:* EPA has determined that certain information may be potentially useful to characterize the human health and environmental effects of the PMN substance 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 and aquatic toxicity may be potentially useful to characterize the health and environmental effects of the PMN substance.

**PMN Number (proposed CFR citation): P-19-147 (40 CFR 721.11809).**

*Chemical Name:* Alkoxylated butyl alkyl ester (generic).

*CASRN:* Not available.

*Basis for action:* The PMN states that the generic (non-confidential) use of the PMN substance will be as a cleaning additive. Based on estimated physical/chemical properties of the PMN substance, submitted test data on the new chemical substance, comparison to structurally analogous chemical substances, and comparison to analogous esters, EPA has identified concerns for systemic, reproductive, and developmental effects, and aquatic toxicity if the chemical substance is not used following the limitations noted. The conditions of use of the PMN substance as described in the PMN include the following protective measures:

- Use of the PMN substance only for the confidential use described in the PMN;

- No use of the PMN substance in formulations at a higher percentage than the confidential percentage stated in the PMN; and
- No release of the PMN substance resulting in surface water concentrations that exceed 16 ppb.

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 to characterize the human health and environmental effects of the PMN substance 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, reproductive/developmental toxicity, and aquatic toxicity testing may be potentially useful to characterize the health and environmental effects of the PMN substance.

**PMN Number (proposed CFR citation): P-19-162 (40 CFR 721.11810).**

*Chemical Name:* Fatty acid alkyl amide, (dialkyl) amino alkyl, alkyl quaternized, salts (generic).

*CASRN:* Not available.

*Basis for action:* The PMN states that the generic (non-confidential) use of the PMN substance will be as a component in oil production. Based on estimated physical/chemical properties of the PMN substance, comparison to structurally analogous chemical substances, and comparison to analogous cationic surfactants, EPA has identified concerns for lung effects (surfactancy), irritation to all tissues, skin sensitization, neurological, systemic, reproductive, and developmental effects, corrosion to skin and eyes, and aquatic toxicity if the chemical substance is not used following the limitations noted. The conditions of use of the PMN substance as described in the PMN include the following protective measures:

- No manufacturing, processing, or use of the PMN substance in a manner that results in inhalation exposure;
- No release of the PMN substance resulting in freshwater surface water concentrations

that exceed 1 ppb; and

- No release of the PMN substance resulting in marine surface water concentrations that exceed 17 ppb.

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 to characterize the human health and environmental effects of the PMN substance 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, reproductive toxicity, skin irritation, skin corrosion, eye irritation, skin sensitization, and freshwater aquatic toxicity testing may be potentially useful to characterize the health and environmental effects of the PMN substance.

**PMN Number (proposed CFR citation): P-20-11 (40 CFR 721.11811).**

*Chemical Name:* Tetraoxaspiro[5.5]alkyl-3,9-diylbis(alkyl-2,1-diyl) bis(2-cyano-3-(3,4-dimethoxyphenyl)acrylate) (generic).

*CASRN:* Not available.

*Basis for action:* The PMN states that the generic (non-confidential) use of the PMN substance will be as a light stabilizer. Based on estimated physical/chemical properties of the PMN substance, submitted test data on the new chemical substance, comparison to analogous esters and vinyl nitriles, and comparison to structurally analogous chemical substances, EPA has identified concerns for neurotoxicity, developmental effects, and aquatic toxicity if the chemical substance is not used following the limitations noted. The conditions of use of the PMN substance as described in the PMN include the following protective measures:

- Use of the PMN substance only for the confidential use described in the PMN; and
- No exceedance of the confidential production volume described in the PMN.

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 to characterize the human health and environmental effects of the PMN substance 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, reproductive toxicity (developmental effects for potential metabolite), and aquatic toxicity testing may be potentially useful to characterize the health and environmental effects of the PMN substance.

PMN Numbers (proposed CFR citations): P-20-48 and P-20-49 (40 CFR 721.11812 and 721.11813).

*Chemical Names:* Reaction products of alkyl-terminated alkylaluminumoxanes and dihalogeno(alkylcyclopentadienyl)(tetraalkylcyclopentadienyl)transition metal coordination compound (generic) (P-20-48) and Reaction products of alkyl-aluminumoxanes and bis(alkylcycloalkylene)dihalogenozirconium (generic) (P-20-49).

*CASRN:* Not available.

*Basis for action:* The PMNs state that the generic (non-confidential) use of the PMN substances will be as catalysts. Based on the estimated physical/chemical properties of the PMN substances, comparison to analogous aluminum and other structurally analogous chemical substances, EPA has identified concerns for lung effects, skin sensitization, acute toxicity, developmental effects, systemic effects, neurotoxicity, corrosion to skin, eyes, and respiratory tract, lung toxicity, kidney toxicity, and aquatic toxicity if the new chemical substances are not used following the limitations noted. The conditions of use of the PMN substances as described in the PMNs include the following protective measures:

- No release of PMN substance P-20-48 resulting in surface water concentrations that exceed 6 ppb;
- No release of PMN substance P-20-49 resulting in surface water concentrations that exceed 3 ppb; and

- No manufacturing, processing, or use of the PMN substances other than in an enclosed process.

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 to characterize the human health and environmental effects of the PMN substances if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of specific target organ toxicity, skin corrosion, skin irritation, skin sensitization, eye damage, and aquatic toxicity testing may be potentially useful to characterize the health and environmental effects of the PMN substances.

**PMN Number (proposed CFR citation): P-20-61 (40 CFR 721.11814).**

*Chemical Name:* Formaldehyde, polymer with alkylphenols, alkyl ether (generic).

*CASRN:* Not available.

*Basis for action:* The PMN states that the use of the PMN substance will be as a coating resin crosslinking agent. Based on estimated physical/chemical properties of the PMN substance, comparison to structurally analogous chemical substances, and comparison to analogous phenols, EPA has identified concerns for irritation, sensitization, reproductive toxicity, and systemic effects if the new chemical substance is not used following the limitation noted. The condition of use of the PMN substance as described in the PMN includes the following protective measure:

- No release of the PMN substance resulting in surface water concentrations that exceed 330 ppb.

The proposed SNUR would designate as a “significant new use” the absence of this protective measure.

*Potentially Useful Information:* EPA has determined that certain information may be potentially useful to characterize the human health effects of the PMN substance 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, reproductive/developmental toxicity, skin sensitization, endocrine effects, skin irritation, and eye damage testing may be potentially useful to characterize the health effects of the PMN substance.

**PMN Number (proposed CFR citation): P-20-66 (40 CFR 721.11815).**

*Chemical Name:* 2-Propenoic acid, 2-hydroxyethyl ester, reaction products with dialkyl hydrogen heterosubstituted phosphate and dimethyl phosphonate (generic).

*CASRN:* Not available.

*Basis for action:* The PMN states that the generic (non-confidential) use of the PMN substance will be as an antiwear additive for lubricants. Based on estimated physical/chemical properties of the PMN substance, submitted test data on the new chemical substance, and comparison to structurally analogous chemical substances, EPA has identified concerns for skin and eye irritation, systemic toxicity, reproductive/developmental toxicity, and aquatic toxicity if the chemical substance is not used following the limitations noted. The conditions of use of the PMN substance as described in the PMN include the following protective measures:

- Use of the PMN substance only for the confidential use described in the PMN;
- No manufacture or processing of the PMN substance in consumer products at a concentration greater than 3% (by weight); and
- No release of the PMN substance from manufacturing or processing sites resulting in surface water concentrations that exceed 6 ppb.

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 to characterize the human health and environmental effects of the PMN substance 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, reproductive/developmental toxicity, and aquatic toxicity testing may be potentially useful to characterize the health and environmental effects of the PMN substance.

**PMN Number (proposed CFR citation): P-20-86 (40 CFR 721.11816).**

*Chemical Name:* 2-Oxepanone, homopolymer, ester with hydroxyalkyl trioxo heteromonocyclic (3:1) (generic).

*CASRN:* Not available.

*Basis for action:* The PMN states that the generic (non-confidential) use of the PMN substance will be as a component of polymers. Based on estimated physical/chemical properties of the PMN substance, comparison to structurally analogous chemical substances, and comparison to analogous esters, EPA has identified concerns for aquatic toxicity if the new chemical substance is not used following the limitation noted. The condition of use of the PMN substance as described in the PMN includes the following protective measure:

- No release of the PMN substance resulting in surface water concentrations that exceed 92 ppb.

The proposed SNUR would designate as a “significant new use” the absence of this protective measure.

*Potentially Useful Information:* EPA has determined that certain information may be potentially useful to characterize the environmental effects of the PMN substance 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 aquatic toxicity testing may be potentially useful to characterize the environmental effects of the PMN substance.

**PMN Number (proposed CFR citation): P-20-90 (40 CFR 721.11817).**

*Chemical Name:* Poly(oxy-1,2-ethanediyl), .alpha.-(alkyl-hydroxyalkyl)-.omega.-hydroxy-, .omega.-alkyl ethers (generic).

*CASRN:* Not available.

*Basis for action:* The PMN states that the use of the PMN substance will be as a surfactant for

use in dishwashing detergents. Based on estimated physical/chemical properties of the PMN substance, submitted test data on the new chemical substance, comparison to structurally analogous chemical substances, and comparison to analogous nonionic surfactants, EPA has identified concerns for lung effects (surfactancy), irritation to the eyes and respiratory tract, and aquatic toxicity if the new chemical substance is not used following the limitation noted. The condition of use of the PMN substance as described in the PMN includes the following protective measure:

- No release of the PMN substance resulting in surface water concentrations that exceed 77 ppb.

The proposed SNUR would designate as a “significant new use” the absence of this protective measure.

*Potentially Useful Information:* EPA has determined that certain information may be potentially useful to characterize the human health and environmental effects of the PMN substance 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.

**PMN Number (proposed CFR citation): P-20-97 (40 CFR 721.11818).**

*Chemical Name:* Butanedioic acid, monopolyisobutylene derivs., mixed dihydroxyalkyl and hydroxyalkoxyalkyl diesters (generic).

*CASRN:* Not available.

*Basis for action:* The PMN states that the use of the PMN substance will be as an emulsifier for applications in explosives. Based on estimated physical/chemical properties of the PMN substance, comparison to structurally analogous chemical substances, and comparison to analogous esters, EPA has identified concerns for lung effects (surfactancy), irritation to the skin, eyes, and respiratory tract, systemic toxicity, developmental toxicity, and aquatic toxicity if the

chemical substance is not used following the limitations noted. The conditions of use of the PMN substance as described in the PMN include the following protective measures:

- No manufacturing, processing, or use of the PMN substance in a manner that results in inhalation exposure to workers; and
- No release of the PMN substance resulting in surface water concentrations that exceed 6 ppb.

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 to characterize the human health and environmental effects of the PMN substance if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of metabolism or pharmacokinetics, skin irritation/corrosion, eye irritation/corrosion, specific target organ and aquatic toxicity testing may be potentially useful to characterize the health and environmental effects of the PMN substance.

**PMN Number (proposed CFR citation): P-20-99 (40 CFR 721.11819).**

*Chemical Name:* Mixed metal oxide (generic).

*CASRN:* Not available.

*Basis for action:* The PMN states that the use of the PMN substance will be as a material used for the production of lithium ion conductive separators for rechargeable batteries. Based on the estimated physical/chemical properties of the PMN substance and comparison to analogous chemical substances, EPA has identified concerns for lung effects including lung cancer, neurotoxicity, reproductive and development effects, and systemic effects if the chemical substance is not used following the limitations noted. The condition of use of the PMN substance as described in the PMN includes the following protective measure:

- No manufacture of the PMN substance with greater than 1% of particles less than 10

microns.

The proposed SNUR would designate as a “significant new use” the absence of this protective measure.

*Potentially Useful Information:* EPA has determined that certain information may be potentially useful to characterize the human health effects of the PMN substance 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.

**PMN Number (proposed CFR citation): P-20-102 (40 CFR 721.11820).**

*Chemical Name:* Coal, brown, ammoxidized.

*CASRN:* 2413186-32-8.

*Basis for action:* The PMN states that the use of the PMN substance will be as a fertilizer/soil amendment. Based on estimated physical/chemical properties of the PMN substance and comparison to structurally analogous chemical substances, EPA has identified concerns for systemic effects, reproductive/developmental effects, lung toxicity, and carcinogenicity if the chemical substance is not used following the limitations noted. The conditions of use of the PMN substance as described in the PMN include the following protective measures:

- No domestic manufacture (i.e., import only); and
- Use of the PMN substance only as a fertilizer/soil amendment.

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 to characterize the human health effects of the PMN substance if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of reproductive/developmental, carcinogenicity and specific target organ toxicity testing may be potentially useful to characterize the health

effects of the PMN substance.

**PMN Number (proposed CFR citation): P-20-103 (40 CFR 721.11821).**

*Chemical Name:* Cycloaliphatic amine formate (generic).

*CASRN:* Not available.

*Basis for action:* The PMN states that the generic (non-confidential) use of the PMN substance will be as an onsite intermediate for the production of finished goods. Based on estimated physical/chemical properties of the PMN substance, comparison to structurally analogous chemical substances, and comparison to analogous aliphatic amines, EPA has identified concerns for irritation/corrosion to the skin, eyes, and respiratory tract, potential lung and respiratory tract toxicity, acute toxicity (mortality), systemic effects, neurotoxicity, reproductive/developmental effects and aquatic toxicity if the chemical substance is not used following the limitations noted. The conditions of use of the PMN substance as described in the PMN include the following protective measures:

- No manufacturing, processing, or use of the PMN substance in a manner that results in inhalation exposure; and
- No release of the PMN substance resulting in surface water concentrations that exceed 66 ppb.

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 to characterize the human health and environmental effects of the PMN substance 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, reproductive/developmental, and aquatic toxicity testing may be potentially useful to characterize the environmental effects of the PMN substance.

**PMN Number (proposed CFR citation): P-20-107 (40 CFR 721.11822).**

*Chemical Name:* Carbimide, polyalkylenepolyarylene ester, polymer with 1,2-alkanediol, 2-alkoxyalkyl methacrylate- and 3-(2-alkoxyalkyl)-2-heterocycle-blocked (generic).

*CASRN:* Not available.

*Basis for action:* The PMN states that the generic (non-confidential) use of the PMN substance will be as a crosslinking polymer. Based on estimated physical/chemical properties of the PMN substance, comparison to analogous acrylates/methacrylates, and comparison to structurally analogous chemical substances, EPA has identified concerns for skin and respiratory sensitization and skin, eye, and respiratory tract irritation if the chemical substance is not used following the limitations noted. The conditions of use of the PMN substance as described in the PMN include the following protective measures:

- No manufacturing, processing, or use of the PMN substance in a manner that results in inhalation exposure; and
- No consumer use of the PMN substance.

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 to characterize the human health effects of the PMN substance if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of skin irritation, eye irritation/corrosion, and sensitization testing may be potentially useful to characterize the health effects of the PMN substance.

**PMN Number (proposed CFR citation): P-20-132 (40 CFR 721.11823).**

*Chemical Name:* 1H-Pyrrole-2,5-dione, 3-methyl-, 1,1'-C36-alkylenebis.

*CASRN:* 2414071-06-8.

*Basis for action:* The PMN states that the generic (non-confidential) use of the PMN substance will be as an adhesive component. Based on estimated physical/chemical properties of the PMN

substance, comparison to analogous imides, and comparison to structurally analogous chemical substances, EPA has identified concerns for acute toxicity, liver, and kidney effects, genotoxicity, skin and respiratory sensitization, skin and eye irritation, systemic effects, and reproductive/developmental effects if the chemical substance is not used following the limitations noted. The conditions of use of the PMN substance as described in the PMN include the following protective measures:

- No manufacturing, processing, or use of the PMN substance in a manner that results in inhalation exposure; and

- No consumer use of the PMN substance.

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 to characterize the human health effects of the PMN substance 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, reproductive /developmental, and genetic toxicity testing may be potentially useful to characterize the health effects of the PMN substance.

**PMN Number (proposed CFR citation): P-20-136 (40 CFR 721.11824).**

*Chemical Name:* Arylcarboxylic acid, alkyl ester, polymer with alkanediol, ester with methyloxirane polymer with oxirane alkyl ether (generic).

*CASRN:* Not available.

*Basis for action:* The PMN states that the use of the PMN substance will be as a surface treatment compound for textiles. Based on estimated physical/chemical properties of the PMN substance and comparison to structurally analogous chemical substances, EPA has identified concerns for lung surfactancy, cardiovascular effects, systemic effects, and neurotoxicity if the chemical substance is not used following the limitations noted. The condition of use of the PMN

substance as described in the PMN includes the following protective measure:

- No manufacturing or processing of the PMN substance in a manner that results in inhalation exposures to workers.

The proposed SNUR would designate as a “significant new use” the absence of this protective measure.

*Potentially Useful Information:* EPA has determined that certain information may be potentially useful to characterize the human health effects of the PMN substance 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 pulmonary effects testing may be potentially useful to characterize the health effects of the PMN substance.

**PMN Number (proposed CFR citation): P-20-143 (40 CFR 721.11825).**

*Chemical Name:* Cyclohexanemethanamine, 5-amino-1,3,3-trimethyl-, polymer with a-hydro-w-hydroxypoly(oxy-1,4-butanediyl), 5- isocyanato-1-(isocyanatomethyl)-1,3,3-trimethylcyclohexane and 1,1-methylenebis[4-isocyanatobenzene].

*CASRN:* 2417925-50-7.

*Basis for action:* The PMN states that the use of the PMN substance will be as a binder for thermoplastic coatings and inks/adhesives. Based on the estimated physical/chemical properties of the PMN substance and comparison to analogous polycationic polymers, EPA has identified concerns for irritation to the eyes, skin, and respiratory tract if the chemical substance is not used following the limitations noted. The condition of use of the PMN substance as described in the PMN includes the following protective measure:

- No consumer use of the PMN substance.

The proposed SNUR would designate as a “significant new use” the absence of this protective measure.

*Potentially Useful Information:* EPA has determined that certain information may be potentially

useful to characterize the human health effects of the PMN substance 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 and eye damage testing may be potentially useful to characterize the health effects of the PMN substance.

**PMN Number (proposed CFR citation): P-20-146 (40 CFR 721.11826).**

*Chemical Name:* Alkanoic acid, alkyl, carbopolycyclic alkyl ester (generic).

*CASRN:* Not available.

*Basis for action:* The PMN states that the generic (non-confidential) use of the PMN substance will be as an insulating material for electrical parts. Based on estimated physical/chemical properties of the PMN substance, comparison to structurally analogous chemical substances EPA has identified concerns for corrosion, skin, eye, respiratory tract irritation, skin sensitization, and aquatic toxicity if the chemical substance is not used following the limitations noted. The conditions of use of the PMN substance as described in the PMN include the following protective measures:

- No manufacturing, processing, or use of the PMN substance in a manner that results in worker inhalation exposure; and
- No release of the PMN substance resulting in surface water concentrations that exceed 13 ppb.

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 to characterize the human health and environmental effects of the PMN substance 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 aquatic toxicity testing may be potentially useful to characterize the health and environmental effects of the PMN substance.

**PMN Number (proposed CFR citation): P-20-161 (40 CFR 721.11827).**

*Chemical Name:* Propanedioic acid, 2-methylene-, 1,3-diethyl ester, polymer with 1,4-butanediol.

*CASRN:* 2364431-09-2.

*Basis for action:* The PMN states that the use of the PMN substance will be as a crosslinker additive used in waterborne emulsions and as a film former or crosslinker additive used in coatings and adhesives. Based on the estimated physical/chemical properties of the PMN substance, comparison to analogous chemical substances, and comparison to analogous acrylates/methacrylates, EPA has identified concerns skin, respiratory tract, and eye irritation, skin sensitization, local stomach effects, and acute inhalation toxicity if the chemical substance is not used following the limitations noted. The condition of use of the PMN substance as described in the PMN includes the following protective measure:

- No consumer use of the PMN substance.

The proposed SNUR would designate as a “significant new use” the absence of this protective measure.

*Potentially Useful Information:* EPA has determined that certain information may be potentially useful to characterize the human health effects of the PMN substance 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, sensitization, and eye damage testing may be potentially useful to characterize the health effects of the PMN substance.

**PMN Number (proposed CFR citation): P-21-12 (40 CFR 721.11828).**

*Chemical Name:* Multialkylbicycloalkenyl substituted propanenitrile (generic).

*CASRN:* Not available.

*Basis for action:* The PMN states that the generic (non-confidential) use of the PMN substance will be as a fragrance ingredient. Based on estimated physical/chemical properties of the PMN substance, submitted test data on the new chemical substance, comparison to analogous neutral

organics, and comparison to structurally analogous chemical substances, EPA has identified concerns for eye irritation, acute toxicity, liver effects, and aquatic toxicity if the chemical substance is not used following the limitations noted. The condition of use of the PMN substance as described in the PMN includes the following protective measure:

- No manufacture for any use greater than 10,000 kilograms per year of the PMN substance.

The proposed SNUR would designate as a “significant new use” the absence of this protective measure.

*Potentially Useful Information:* EPA has determined that certain information may be potentially useful to characterize the human health and environmental effects of the PMN substance 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, and chronic aquatic toxicity testing may be potentially useful to characterize the health and environmental effects of the PMN substance.

#### **IV. Statutory and Executive Order Reviews**

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

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

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

*B. Paperwork Reduction Act (PRA)*

According to the PRA (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval

under PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the *Federal Register*, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable.

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

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

### *C. Regulatory Flexibility Act (RFA)*

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

A SNUR requires that any person who intends to engage in such activity in the future must first notify EPA by submitting a SNUN. Although some small entities may decide to pursue a significant new use in the future, EPA cannot presently determine how many, if any, there may be. However, EPA's experience to date is that, in response to the promulgation of SNURs

covering over 1,000 chemicals, the Agency receives only a small number of notices per year. For example, the number of SNUNs received was 16 in Federal fiscal year (FY) FY2018, five in FY2019, seven in FY2020, and 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 \$19,020 to \$3,330. This lower fee reduces the total reporting and recordkeeping cost of submitting a SNUN to about \$11,164 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)*

Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reasons to believe that any State, local, or Tribal government will be impacted by this action. As such, EPA has determined that this action does not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the requirements of UMRA sections 202, 203, 204, or 205 (2 U.S.C. 1531-1538 *et seq.*).

#### *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 human health, EPA's 2021 Policy on Children's Health also does not apply. Although the establishment of these SNURs do not address an existing children's environmental health concern because the chemical uses involved are not ongoing uses, SNURs require that persons notify EPA at least 90 days before commencing manufacture (defined by statute to include import) or processing of any of these chemical substances for an activity that is designated as a significant new use by this rulemaking. This notification allows EPA to assess the intended uses to identify potential risks and take appropriate actions before the activities commence.

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

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

*I. National Technology Transfer and Advancement Act (NTTAA)*

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

*J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority*

*Populations and Low-Income Populations and Executive Order 14096: Revitalizing Our Nation's Commitment to Environmental Justice for All*

This action does not concern human health or environmental conditions and therefore cannot be evaluated with respect to the potential for disproportionate impacts on non-white and low-income populations in accordance with Executive Order 12898 (59 FR 7629, February 16, 1994) and Executive Order 14096 (88 FR 25251, April 26, 2023). Although this action does not concern human health or environmental conditions, the premanufacture notifications required by these SNURs allows EPA to assess the intended uses to identify potential disproportionate risks and take appropriate actions before the activities commence.

**List of Subjects in 40 CFR Part 721**

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

Dated: April 1, 2024.

**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 §§ 721.11799 through 721.11828 to subpart E to read as follows:

### **Subpart E—Significant New Uses for Specific Chemical Substances**

#### **§ 721.11799 2,7-Decadienal, (2E,7Z)-.**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 2,7-decadienal, (2E,7Z)- (PMN P-16-449; CASRN 52711-52-1) 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) *Industrial, commercial, and consumer activities.* It is a significant new use to process the PMN substance to a concentration of greater than or equal to 1.0% in the final end use formulation.

(ii) *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 (c), (i), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

#### **§ 721.11800 Fatty acid dimers, polymer with acrylic acid and pentaerythritol reaction products (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as fatty acid dimers, polymer with acrylic acid and pentaerythritol reaction products (PMN P-16-512) 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)(4) and (5), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(4), engineering control measures (e.g., enclosure of 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, or 1,000 when spray-applied.

(ii) *Industrial, commercial, and consumer activities.* It is a significant new use to use the PMN substance other than as a component of UV curable printing inks.

(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 (d), and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

#### **§ 721.11801 Aminoalkyl alkoxysilane (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as aminoalkyl alkoxysilane (PMN P-17-115) 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) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o).

(ii) [Reserved]

(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), and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

**§ 721.11802 Siloxanes and Silicones, di-Me, 3-[3-carboxy-2(or 3)-(octenyl)-1-oxopropoxy]propyl group-terminated.**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as siloxanes and silicones, di-Me, 3-[3-carboxy-2(or 3)-(octenyl)-1-oxopropoxy]propyl group-terminated (PMN P-18-36; CASRN 403616-34-2) 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) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture, process, or use the PMN substance in a manner that results in inhalation exposure.

(ii) [Reserved]

(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), and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain modification requirements.* The provisions of §

721.185 apply to this section.

**§ 721.11803 Mixed alkyl esters-, polymer with N1-(2-aminoethyl)- 1,2-ethanediamine, aziridine, N-acetyl derivs., acetates (salts) (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as mixed alkyl esters-, polymer with N1-(2-aminoethyl)- 1,2-ethanediamine, aziridine, N-acetyl derivs., acetates (salts) (PMN P-18-263) 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) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where N=5.

(ii) [Reserved]

(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), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

**§ 721.11804 Propanedioic acid, 2,2-bis(hydroxymethyl)-, 1,3-dihexyl ester.**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as propanedioic acid, 2,2-bis(hydroxymethyl)-, 1,3-dihexyl ester (PMN P-18-336; CASRN 2222732-45-6) 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) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where N=54.

(ii) [Reserved]

(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), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

**§ 721.11805 Alkanediol, substituted alkyl, polymer with carbomonocycle, alkanedioate substituted carbomonocycle, ester with substituted alkanoate (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as alkanediol, substituted alkyl, polymer with carbomonocycle, alkanedioate substituted carbomonocycle, ester with substituted alkanoate (PMN P-18-355) 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) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o).

(ii) [Reserved]

(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), and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

**§ 721.11806 Ethene, 1-[difluoro(trifluoromethoxy)methoxy]-1,2,2-trifluoro-, polymer with 1,1-difluoroethene.**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as Ethene, 1-[difluoro(trifluoromethoxy)methoxy]-1,2,2-trifluoro-, polymer with 1,1-difluoroethene (PMN P-18-359; CASRN 874290-13-8) 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) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture, process, or use the PMN substance in a manner that results in inhalation exposure.

(ii) *Disposal.* Requirements as specified in § 721.85(a)(2), (b)(2), and (c)(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 (c), (i), (k), and (j) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

#### **§ 721.11807 Maleic anhydride - substituted alkene copolymer (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as maleic anhydride - substituted alkene copolymer (PMN P-18-369) 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) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture, process, or use the PMN substance in a manner that results in inhalation exposure.

(ii) [Reserved]

(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), and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain modification requirements*. The provisions of § 721.185 apply to this section.

**§ 721.11808 Xanthylium, bis[dicarboxycyclic]sulfonylamino-alkylcyclicamino-disulfo-sulfocyclic-, inner salt, monocationic salt (generic).**

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance generically identified as xanthylium, bis[dicarboxycyclic]sulfonylamino-alkylcyclicamino-disulfo-sulfocyclic-, inner salt, monocationic salt (PMN P-18-382) 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) *Industrial, commercial, and consumer activities*. It is a significant new use to manufacture, process, or use the PMN substance in a manner that results in inhalation exposure.

(ii) [Reserved]

(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), and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain modification requirements*. The provisions of § 721.185 apply to this section.

**§ 721.11809 Alkoxyated butyl alkyl ester (generic).**

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance generically identified as alkoxyated butyl alkyl ester (PMN P-19-147) 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) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(j). It is a significant new use to use the PMN substance in formulation at a higher percentage than the confidential percentage stated in the PMN.

(ii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where N=16.

(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), (i), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

**§ 721.11810 Fatty acid alkyl amide, (dialkyl) amino alkyl, alkyl quaternized, salts (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as fatty acid alkyl amide, (dialkyl) amino alkyl, alkyl quaternized, salts (PMN P-19-162) 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) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture, process, or use the PMN substance in a manner that results in inhalation exposure.

(ii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where N=1 (freshwater) and N=17 (marine).

(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), (i), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

**§ 721.11811 Tetraoxaspiro[5.5]alkyl-3,9-diylbis(alkyl-2,1-diyl) bis(2-cyano-3-(3,4-dimethoxyphenyl)acrylate) (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as tetraoxaspiro[5.5]alkyl-3,9-diylbis(alkyl-2,1-diyl) bis(2-cyano-3-(3,4-dimethoxyphenyl)acrylate) (PMN P-20-11) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(j). It is a significant new use to exceed the confidential production volume stated in the PMN.

(ii) [Reserved]

(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), and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

**§ 721.11812 Reaction products of alkyl-terminated alkylaluminoxanes and dihalogeno(alkylcyclopentadienyl)(tetraalkylcyclopentadienyl)transition metal coordination compound (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as reaction products of alkyl-terminated alkylaluminoxanes and dihalogeno(alkylcyclopentadienyl)(tetraalkylcyclopentadienyl)transition metal coordination compound (generic) (PMN P-20-48) 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) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(a), (b), and (c).

(ii) *Releases to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where N=6.

(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), (i), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

**§ 721.11813 Reaction products of alkyl-aluminoxanes and bis(alkylcycloalkylene)dihalogenozirconium (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as reaction products of alkyl-aluminoxanes and bis(alkylcycloalkylene)dihalogenozirconium (generic) (PMN P-20-49) 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) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(a), (b), and (c).

(ii) *Releases 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 (c),

(i), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

**§ 721.11814 Formaldehyde, polymer with alkylphenols, alkyl ether (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as formaldehyde, polymer with alkylphenols, alkyl ether (PMN P-20-61) 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) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where N=330.

(ii) [Reserved]

(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), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

**§ 721.11815 2-Propenoic acid, 2-hydroxyethyl ester, reaction products with dialkyl hydrogen heterosubstituted phosphate and dimethyl phosphonate (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as 2-propenoic acid, 2-hydroxyethyl ester, reaction products with dialkyl hydrogen heterosubstituted phosphate and dimethyl phosphonate (PMN P-20-66) 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) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(j). It is a significant new use to manufacture or process the PMN substance in consumer products at a concentration greater than 3% (by weight).

(ii) *Release to water.* Requirements as specified in § 721.90(a)(4) and (b)(4), where N=6.

(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), (i), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

**§ 721.11816 2-Oxepanone, homopolymer, ester with hydroxyalkyl trioxo heteromonocyclic (3:1) (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as 2-oxepanone, homopolymer, ester with hydroxyalkyl trioxo heteromonocyclic (3:1) (PMN P-20-86) 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) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where N=92.

(ii) [Reserved]

(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), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

**§ 721.11817 Poly(oxy-1,2-ethanediyl), .alpha.-(alkyl-hydroxyalkyl)-.omega.-hydroxy-, .omega.-alkyl ethers (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as poly(oxy-1,2-ethanediyl), .alpha.-(alkyl-hydroxyalkyl)-.omega.-hydroxy-, .omega.-alkyl ethers (PMN P-20-90) 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) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where N=77.

(ii) [Reserved]

(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), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

**§ 721.11818 Butanedioic acid, monopolyisobutylene derivs., mixed dihydroxyalkyl and hydroxyalkoxyalkyl diesters (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as alkyl oil, polymer with butanedioic acid, monopolyisobutylene derivs., mixed dihydroxyalkyl and hydroxyalkoxyalkyl diesters (PMN P-20-97) 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) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture, process, or use the PMN substance in a manner that results in inhalation exposure

to workers.

(ii) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where N=6.

(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), (i), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain modification requirements*. The provisions of § 721.185 apply to this section.

#### **§ 721.11819 Mixed metal oxide (generic).**

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance generically identified as a mixed metal oxide (PMN P-20-99) 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) *Industrial, commercial, and consumer activities*. It is a significant new use to manufacture the PMN substance with greater than 1% of particles less than 10 microns.

(ii) [Reserved]

(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), and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain modification requirements*. The provisions of § 721.185 apply to this section.

#### **§ 721.11820 Coal, brown, ammoxidized.**

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified as coal, brown, ammoxidized (PMN P-20-102; CASRN 2413186-32-8) 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) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f). It is a significant new use to use the PMN substance other than as a fertilizer/soil amendment.

(ii) [Reserved]

(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), and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

#### **§ 721.11821 Cycloaliphatic amine formate (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as cycloaliphatic amine formate (PMN P-20-103) 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) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture, process, or use the PMN substance in a manner that results in inhalation exposure.

(ii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where N=66.

(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),

(i), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

**§ 721.11822 Carbimide, polyalkylenepolyarylene ester, polymer with 1,2-alkanediol, 2-alkoxyalkyl methacrylate- and 3-(2-alkoxyalkyl)-2-heterocycle-blocked (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as carbimide, polyalkylenepolyarylene ester, polymer with 1,2-alkanediol, 2-alkoxyalkyl methacrylate- and 3-(2-alkoxyalkyl)-2-heterocycle-blocked (PMN P-20-107) 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) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o). It is a significant new use to manufacture, process, or use the PMN substance in a manner that results in inhalation exposure.

(ii) [Reserved]

(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), and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

**§ 721.11823 1H-Pyrrole-2,5-dione, 3-methyl-, 1,1'-C36-alkylenebis-**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 1H-pyrrole-2,5-dione, 3-methyl-, 1,1'-C36-alkylenebis- (PMN P-20-132; CASRN 2414071-06-8) 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) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o). It is a significant new use to manufacture, process, or use the PMN substance in a manner that results in inhalation exposure.

(ii) [Reserved]

(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), and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

**§ 721.11824 Arylcarboxylic acid, alkyl ester, polymer with alkanediol, ester with methyloxirane polymer with oxirane alkyl ether (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as arylcarboxylic acid, alkyl ester, polymer with alkanediol, ester with methyloxirane polymer with oxirane alkyl ether (PMN P-20-136) 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) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture or process the PMN substance in a manner that results in inhalation exposures to workers.

(ii) [Reserved]

(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), and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

**§ 721.11825 Cyclohexanemethanamine, 5-amino-1,3,3-trimethyl-, polymer with a-hydro-w-hydroxypoly(oxy-1,4-butanediyl), 5- isocyanato-1-(isocyanatomethyl)-1,3,3-trimethylcyclohexane and 1,1-methylenebis[4-isocyanatobenzene].**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as cyclohexanemethanamine, 5-amino-1,3,3-trimethyl-, polymer with a-hydro-w-hydroxypoly(oxy-1,4-butanediyl), 5- isocyanato-1-(isocyanatomethyl)-1,3,3-trimethylcyclohexane and 1,1-methylenebis[4-isocyanatobenzene] (PMN P-20-143; CASRN 2417925-50-7) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

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

(ii) [Reserved]

(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), and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

**§ 721.11826 Alkanoic acid, alkyl, carbopolycyclic alkyl ester (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as alkanoic acid, alkyl, carbopolycyclic alkyl ester (PMN P-20-146) 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) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture, process, or use the PMN substance in a manner that results in worker inhalation exposure.

(ii) *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 (c), (i), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

**§ 721.11827 Propanedioic acid, 2-methylene-, 1,3-diethyl ester, polymer with 1,4-butanediol.**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as propanedioic acid, 2-methylene-, 1,3-diethyl ester, polymer with 1,4-butanediol (PMN P-20-161; CASRN 2364431-09-2) 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) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o).

(ii) [Reserved]

(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), and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

**§ 721.11828 Multialkylbicycloalkenyl substituted propanenitrile (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as multialkylbicycloalkenyl substituted propanenitrile (PMN P-21-12) 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) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture more than 10,000 kilograms per year for any use.

(ii) [Reserved]

(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), and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.