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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[EPA-HQ-OPPT-2019-0228; FRL-9998-64]

RIN 2070-AB27

Significant New Use Rules on Certain Chemical Substances (19-3.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 31 chemical substances which were the subject of premanufacture notices (PMNs). Eight of these chemical substances are subject to TSCA Orders issued by EPA and the remaining 23 of these chemical substances received a “not likely to present an unreasonable risk” determination. This action would require persons who intend to manufacture (defined by statute to include import) or process any of these 31 chemical substances for an activity that is proposed as a significant new use to notify EPA at least 90 days before commencing that activity. Persons may not commence manufacture or processing for the significant new use until EPA has conducted a review of the notice, made an appropriate determination on the notice, and has taken such actions as are 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-2019-0228, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online

instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail*: Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Kenneth Moss, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-9232; email address: moss.kenneth@epa.gov.

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

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action 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.

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Chemical importers are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements promulgated at 19 CFR 12.118 through 12.127 and 19 CFR 127.28. Chemical importers must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA. Importers of chemicals subject to final SNURs must certify their compliance with the SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, 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)) (see 40 CFR 721.20), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through *regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the

information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <http://www.epa.gov/dockets/comments.html>.

II. Background

A. What Action is the Agency Taking?

EPA is proposing these SNURs under TSCA section 5(a)(2) for chemical substances that were the subject of PMNs. These proposed SNURs would require persons to notify EPA at least 90 days before commencing the manufacture or processing of a chemical substance for any activity proposed as a significant new use. Receipt of such notices would allow EPA to assess risks and, if appropriate, to regulate the significant new use before it may occur. Additional background regarding SNURs is more fully set out in the preamble to EPA's first direct final SNUR published in the **Federal Register** issue of April 24, 1990 (55 FR 17376) (FRL-3658-5). Consult that preamble for further general information on the objectives, rationale, and procedures for SNURs and on the basis for significant new use designations, including provisions for developing test data.

B. What is the Agency's Authority for Taking this Action?

Section 5(a)(2) of TSCA (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 four bulleted TSCA section 5(a)(2) factors listed in Unit III.

C. Applicability of General Provisions

General provisions for SNURs appear in 40 CFR part 721, subpart A. These provisions

describe persons subject to the proposed rule, recordkeeping requirements, and exemptions to reporting requirements, and applicability of the rule to uses occurring before the effective date of the rule. Provisions relating to user fees appear at 40 CFR part 700. Pursuant to 40 CFR 721.1(c), persons subject to SNURs must comply with the same SNUN requirements and EPA regulatory procedures as submitters of PMNs under TSCA section 5(a)(1)(A) (15 U.S.C. 2604(a)(1)(A)). In particular, these requirements include the information submission requirements of TSCA section 5(b) and 5(d)(1) (15 U.S.C. 2604(b) and 2604(d)(1)), the exemptions authorized by TSCA section 5(h)(1), (h)(2), (h)(3), and (h)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUN, EPA must either determine that the 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 before the manufacture or processing for the significant new use can commence. In the case of a determination other than not likely to present unreasonable risk, the applicable review period must also expire before manufacturing or processing for the new use may commence. If EPA determines that the use 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.

III. Significant New Use Determination

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 significant new uses for the 31 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 addition to the factors in TSCA section 5(a)(2). Consistent with TSCA section 5(f)(4), for the eight chemical substances subject to an order under TSCA section 5(e), EPA is proposing to identify any use not conforming to the restrictions of the order as a significant new use. For the 23 chemical substances that EPA has determined “not likely” to present an unreasonable risk under the conditions of use, EPA is proposing to identify other circumstances that, while not reasonably foreseen, would warrant further EPA review before manufacture or processing for such a use is commenced.

IV. Substances Subject to this Proposed Rule

EPA is proposing significant new use and recordkeeping requirements for 31 chemical substances in 40 CFR part 721, subpart E. In this unit, EPA provides the following information for each chemical substance:

- PMN number.
- Chemical name (generic name, if the specific name is claimed as CBI).
- Chemical Abstracts Service (CAS) Registry number (if assigned for non-confidential chemical identities).
- Basis for the SNUR or basis for the TSCA section 5(e) Order.
- Potentially Useful Information. This is information identified by EPA that would help

characterize the potential health and/or environmental effects of the chemical substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use designated by the SNUR.

- CFR citation assigned in the regulatory text section of the proposed rule. The regulatory text section of each proposed rule specifies the activities that would be designated as significant new uses. Certain new uses, including exceedance of production volume limits (i.e., limits on manufacture volume) and other uses designated in this proposed rule, may be claimed as CBI.

These proposed rules include 8 PMN substances that are subject to orders issued under TSCA section 5(e)(1)(A), as required by the determinations made under TSCA section 5(a)(3)(B). Those TSCA section 5(e) Orders require protective measures to limit exposures or otherwise mitigate the potential unreasonable risk. The proposed SNURs would identify as significant new uses any manufacturing, processing, use, distribution in commerce, or disposal that does not conform to the restrictions imposed by the underlying TSCA section 5(e) Orders, consistent with TSCA section 5(f)(4).

These proposed rules also include 23 PMN substances that received “not likely to present an unreasonable risk” determination in TSCA section 5(a)(3)(c). However, during the course of these reviews, EPA identified concerns for certain health and/or environmental risks if the chemicals were not used following the limitations identified by the submitters in the notices. EPA did not deem such uses as reasonably foreseen in the TSCA section 5(a)(3)(C) determinations. The proposed SNURs would identify as significant new uses any manufacturing, processing, use, distribution in commerce, or disposal that does not conform to those same limitations.

The chemicals subject to these proposed SNURs are as follows:

PMN Numbers: P-16-151, P-16-152, P-16-153, P-16-154, and P-16-155.

Chemical names: Perfluoropolyether halide (generic) (P-16-151), Perfluoropolyether aryl (generic) (P-16-152), Substituted aryl-perfluoropolyether (generic) (P-16-153), Sulfonated perfluoropolyether aromatic transition metal salt (generic) (P-16-154), and Sulfonated perfluoropolyether aryl alkali metal salt (generic) (P-16-155).

CAS numbers: Not available.

Effective date of TSCA section 5(e) Order: April 30, 2019.

Basis for TSCA section 5(e) Order: The PMNs state that the generic (non-confidential) use of the substances P-16-151 and P-16-152 will be as intermediates and P-16-153, P-16-154, P-16-155 will be as lubricant additives. Based on the physical/chemical properties of the PMN substances (as described in the New Chemical Program's PBT category at 64 FR 60194; November 4, 1999) and test data on structurally similar substances, the PMN substances are potentially persistent, bioaccumulative, and toxic (PBT) chemicals. EPA estimates that the PMN substances will persist in the environment more than 2 months and estimates a bioaccumulation factor of greater than or equal to 1,000. Based on results of testing on analogous small fluorinated polyether substances, EPA has identified concerns for the possible degradation products of the PMN substances for liver toxicity, kidney effects, hematology and clinical chemistry changes, pancreatic and testicular cell tumor formation, and reproductive and developmental effects. Based on estimated ecotoxicity values for the possible degradation products, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 153 parts per billion (ppb). The TSCA section 5(e) Order was issued under TSCA sections 5(a)(3)(B)(i) and 5(e)(1)(A)(i), based on a finding that the available information is insufficient to permit a reasoned evaluation of the human health and environmental effects of the PMN substances. The TSCA section 5(e) Order was also

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

1. Submission to EPA of certain fate testing within one year after the Notice of Commencement of the PMN P-16-155;
 2. Establishment and use of a hazard communication program, including environmental hazard precautionary statements on each label and in the Safety Data Sheet (SDS);
 3. Dispose of the PMN substances only with Hazardous Waste, High Temperature Incineration with a control efficiency of 99.99% efficiency or greater;
 4. No release of the PMN substances to surface waters;
 5. Manufacture the PMN substances only for the confidential uses specified in the PMNs;
- and
6. No manufacture beyond the annual production volumes specified in the TSCA section 5(e) Order.

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

Potentially useful information: EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the TSCA section 5(e) Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this SNUR. The submitter has agreed not to manufacture (including import) the P-16-155 substance beyond one year after the Notice of Commencement without performing an indirect photolysis screening test (OCSPP Test Guideline 835.5270). EPA has

also determined that the results of hydrolysis testing, photodegradation in soil, chronic aquatic toxicity, and reproductive toxicity testing would help EPA determine the potential human and environmental effects of the PMN substances. Although the TSCA section 5(e) Order does not require these tests, the TSCA section 5(e) Order's restrictions remain in effect until the TSCA section 5(e) Order is modified or revoked by EPA based on submission of this or other relevant information.

CFR citations: 40 CFR 721.11346 (P-16-151); 40 CFR 721.11347 (P-16-152); 40 CFR 721.11348 (P-16-153); 40 CFR 721.11349 (P-16-154) and 40 CFR 721.11350 (P-16-155).

PMN Number: P-16-225.

Chemical names: Cyclohexanol, 4-ethylidene-2-propoxy- (P-16-225, chemical A) and Cyclohexanol, 5-ethylidene-2-propoxy- (P-16-225, chemical B).

CAS numbers: 1631145-48-6 (P-16-225, chemical A) and 1631145-49-7 (P-16-225, chemical B).

Basis for action: The PMN states that the use of the substance will be as a fragrance ingredient, being blended (mixed) with other fragrance ingredients to make fragrance oils that will be sold to industrial and commercial customers for their incorporation into soaps, detergents, cleaners, air fresheners, candles and other similar industrial, household and consumer products. Based on the physical/chemical properties of the PMN substances, test data on the PMN substances, and Structure Analysis Relationships (SAR) analysis of test data on analogous substances, EPA has identified concerns for systemic toxicity, and aquatic toxicity at surface water concentrations exceeding 300 ppb, if the chemical substance is not used following the limitations noted. The conditions of use of the PMN substances as described in the PMN include the following protective measures:

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

2. No import of the PMN substances at more than 10,000 kg annual production volume;
3. No use of the PMN substances other than for the fragrance use stated in the PMN submission; and
4. No processing of the PMN substances to greater than 10% in compounded fragrance oil formulation.

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 health and environmental effects of the PMN substances in support of a request by the PMN submitter to modify the TSCA section 5(e) Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of absorption testing and aquatic toxicity testing would help characterize the potential health and environmental effects of the PMN substances.

CFR citation: 40 CFR 721.11351 (P-16-225, chemical A) and 40 CFR 721.11352 (P-16-225, chemical B).

PMN Number: P-16-314.

Chemical Name: Ethanone, 1-(5-propyl-1,3-benzodioxol-2-yl)-.

CAS Number: 1370699-98-1.

Basis for action: The PMN states that the generic (non-confidential) use of the PMN substance will be as part of a fragrance formula. Based on test data on the new chemical substance, the estimated physical/chemical properties of the PMN, and SAR analysis on analogous neutral organics, EPA has identified concerns for liver toxicity for the intact new chemical substance,

oncogenicity for the ketone/aldehyde hydrolysis product(s) that may be formed under the acidic conditions in the stomach, 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:

1. No domestic manufacture of the PMN substance (i.e., import only);
2. Less than 10% of the PMN substance in any formulation from processing; and
3. No manufacture (including import) beyond an annual production volume of 10,000 kilograms per year.

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 health and environmental effects of the PMN substance if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of absorption testing and aquatic toxicity testing would help characterize the potential health and environmental effects of the PMN substance.

CFR Citation: 40 CFR 721.11353.

PMN Number: P-16-429.

Chemical Name: Endcapped polysiloxane (generic).

CAS Number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the PMN substance will be as a universal tint paste resin having high solids. Based on the estimated physical/chemical properties of the PMN substance, structural information, and information on

analogous alkoxysilanes, EPA has identified lung effects and irritation to the eye, skin, lung, and mucous membranes if the 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:

- Use of the PMN substance only for the confidential use specified in the PMN.

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 health effects of the PMN substance if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of pulmonary effects and skin irritation testing would help characterize the potential health effects of the PMN substance.

CFR Citation: 40 CFR 721.11354.

PMN Number: P-16-470.

Chemical Name: 2,7-Nonadien-4-ol, 4,8-dimethyl-.

CAS Number: 103983-77-3.

Basis for action: The PMN states that the generic (non-confidential) use of the PMN substance will be as part of a fragrance formula. Based on the estimated physical/chemical properties of the PMN substance and available data on the new chemical substance, EPA has identified concerns for skin irritation, eye irritation, liver and thyroid 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 measure:

- No release of the PMN substance from manufacturing or processing resulting in surface

water concentrations that exceed 113 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 health and environmental effects of the PMN substance if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of specific organ toxicity and aquatic toxicity testing would help characterize the potential health and environmental effects of the PMN substance.

CFR Citation: 40 CFR 721.11355.

PMN Number: P-17-108.

Chemical Name: Carbonodithioic acid, O-[2-[(dithiocarboxy)amino]-2-methylpropyl] ester, sodium salt (1:2).

CAS Number: 1947332-67-3.

Basis for action: The PMN states that the generic (non-confidential) use of the PMN substance will be for use in ore processing. Based on the estimated physical/chemical properties of the PMN substance, available PMN data, comparison with structurally analogous chemical substances, and SAR analysis of test data on analogous dithiocarbamates, EPA has identified concerns for irritation and corrosion to all tissues, developmental and neurological 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 measure:

- No release of the PMN substance resulting in surface water concentrations exceeding 2

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 health and environmental effects of the PMN substance if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of reproductive/developmental toxicity, neurotoxicity, skin irritation/corrosion, and toxicokinetics and chronic aquatic ecotoxicity testing would help characterize the potential health and environmental effects of the PMN substance.

CFR Citation: 40 CFR 721.11356.

PMN Number: P-17-253.

Chemical Name: Oxirane, 2-methyl-, polymer with oxirane, methyl 2-(substituted carbomonocycle isoquinolin-2(3H)-yl) propyl ether (generic).

CAS Number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the PMN substance will be to enhance formulation solubilization properties. Based on its estimated physical/chemical properties, data on analogous chemicals, and other structural information, EPA has identified concerns for lung effects and 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 measures:

- No processing of the substance to a concentration greater than 5 % by weight in the final formulated product, for any use; and

- No consumer use.

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 health effects of the PMN substance if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that pulmonary effects testing would help characterize the potential health effects of the PMN substance.

CFR Citation: 40 CFR 721.11357.

PMN Number: P-18-91.

Chemical Name: Vegetable oil, polymers with diethylene glycol- and polyol- and polyethylene glycol-depolymerized poly(ethylene terephthalate) waste plastics and arylcarboxylic acid anhydride (generic).

CAS Number: Not available.

Basis for action: The PMN states that the use of the PMN substance will be as a chemical intermediate (polyol) for use in the manufacture of polyurethane polymers. Based on the estimated physical/chemical properties of the PMN substance, comparison with structurally analogous chemical substances, test data on analogous substances, and SAR analysis on esters, EPA has identified concerns for lung effects, irritation to eye, mucous membranes and lung, anesthetization of the eye, developmental, renal and bladder toxicity, kidney toxicity, and renal cancer 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 modification of manufacture, processing or use if it results in inhalation exposures

to vapors, particulate, mist or aerosols.

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 health effects of the PMN substance if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of *in vitro* skin irritation and eye damage testing using human derived cells would help characterize the potential health effects of the PMN substance.

CFR Citation: 40 CFR 721.11358.

PMN Number: P-18-120.

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

CAS Number: 1911605-95-2.

Basis for action: The PMN states that the generic (non-confidential) use of the PMN substance will be as an adhesive component. Based on the available data for the new chemical substance, estimated physical/chemical properties of the PMN substance, and comparison with structurally analogous chemical substances, EPA has identified concerns for developmental toxicity and sensitization if the 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 manufacturing, processing, or use of the substance that results in inhalation exposures.

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 health effects of the PMN substance if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of developmental toxicity and sensitization testing would help characterize the potential health effects of the PMN substance.

CFR Citation: 40 CFR 721.11359.

PMN Number: P-18-129.

Chemical name: Benzenepropanal, .alpha.,.alpha.,3-trimethyl-.

CAS number: 107737-97-3.

Effective date of TSCA section 5(e) Order: April 30, 2019.

Basis for TSCA section 5(e) Order: The PMN states that the generic (non-confidential) use of the substance will be as an intermediate used for chemical production. Based on test data on the PMN substance and analogue data, EPA has identified concerns for sensitization and developmental toxicity. In addition, based on SAR analysis of test data on analogous neutral organics, EPA predicts toxicity to aquatic organisms may occur at concentrations greater than 99 ppb. The TSCA section 5(e) Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the TSCA section 5(e) Order requires:

- No manufacture (including import) of the PMN substance beyond the confidential annual production volume specified in the TSCA section 5(e) Order.

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 in support of a request by the PMN submitter to modify the TSCA section 5(e) Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this SNUR. EPA has determined that the results of biodegradability, chronic aquatic toxicity, and reproductive toxicity testing would help EPA determine the potential human and environmental effects of the PMN substance. Although the TSCA section 5(e) Order does not require this information, the TSCA section 5(e) Order's restrictions remain in effect until the TSCA section 5(e) Order is modified or revoked by EPA based on submission of this or other relevant information.

CFR citation: 40 CFR 721.11360.

PMN Number: P-18-182.

Chemical name: Multiwalled carbon nanotubes (generic).

CAS number: Not available.

Effective date of TSCA section 5(e) Order: May 3, 2019.

Basis for TSCA section 5(e) Order: The PMN states that substance will be used in heat transfer, heat storage, thermal emission, and general temperature management in heat-generating systems such as electronics, to improve mechanical properties or electrical conductivities of other materials or products, and for light absorption properties. EPA has identified concerns for pulmonary toxicity based on carbon nanotube analogues. EPA has also identified concerns for aquatic toxicity when the substance is at low concentrations and in the presence of natural organic matter. The TSCA section 5(e) Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health

and the environment. To protect against these risks, the TSCA section 5(e) Order requires:

1. Use of personal protective equipment by workers to prevent dermal exposure where there is potential dermal exposure;
2. Use of a National Institute of Occupational Safety and Health (NIOSH) certified respirators with an Assigned Protection Factor (APF) of at least 50 workers to prevent inhalation exposure where there is potential inhalation exposure;
3. Refrain from using the PMN in applications that generates a dust, vapor, mist, or aerosol, unless such application method occurs in an enclosed process;
4. Process and use of the PMN substance only as described in the PMN;
5. No release of the PMN substance to surface waters; and
6. Disposal only by incineration or landfill.

The proposed SNUR designates as a “significant new use” the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the human health and environmental effects of the PMN substance may be potentially useful in support of a request by the PMN submitter to modify the TSCA section 5(e) Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this SNUR. EPA has determined that the results of pulmonary toxicity and chronic aquatic toxicity testing would help EPA determine the potential human and environmental effects of the PMN substance. Although the TSCA section 5(e) Order does not require this information, the TSCA section 5(e) Order’s restrictions remain in effect until the TSCA section 5(e) Order is modified or revoked by EPA based on submission of this or other relevant information.

CFR citation: 40 CFR 721.11361.

PMN Number: P-18-186.

Chemical Name: Polyolefin ester (generic).

CAS Number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the PMN substance will be as a fuel additive. Based on the estimated physical/chemical properties of the PMN substance and comparison with structurally analogous substances, EPA has identified concerns for lung surfactancy and irritation to the eye and skin 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:

1. No use involving an application method that generates a vapor, mist, or aerosol; and
2. No manufacture (including import) of the substance at less than the confidential average molecular weight identified 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 health effects of the PMN substance if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of absorption, distribution, metabolism, and excretion (ADME)/toxicokinetic and lung toxicity testing would help characterize the potential health effects of the PMN substance.

CFR Citation: 40 CFR 721.11362.

PMN Numbers: P-18-247, P-18-248, P-18-249, P-18-250, P-18-251, and P-18-252.

Chemical Names: Isocyanic acid, polymethylenepolyphenylene ester, polymer with 2-ethyl-2-

(hydroxymethyl)-1,3-propanediol, polyetherpolyol, .alpha.,.alpha.'-[(1-methylethylidene)di-4,1-phenylene]bis[.omega.-hydroxypoly(oxy-1,2-ethanediyl)] and 1,2-propanediol, iso-Bu alc.- and 2-butoxyethanol- and 2-(2-butoxyethoxy)ethanol- and Et alc.- and methanol- and 1-methoxy-2-propanol-blocked (generic) (P-18-247); Isocyanic acid, polymethylenepolyphenylene ester, polymer with polyetherpolyol, 2-butoxyethanol- and 2-(2-butoxyethoxy)ethanol- and methanol-blocked (generic) (P-18-248); Isocyanic acid, polymethylenepolyphenylene ester, polymer with polyetherpolyol, 2-butoxyethanol- and 2-(2-butoxyethoxy)ethanol- and methanol- and 1-methoxy-2-propanol-blocked (generic) (P-18-249); Isocyanic acid, polymethylenepolyphenylene ester, polymer with polyetherpolyol, 2-butoxyethanol- and 2-(2-butoxyethoxy)ethanol- and 1(or 2)-(2-methoxymethylethoxy)propanol-blocked (generic) (P-18-250); Isocyanic acid, polymethylenepolyphenylene ester, 2-butoxyethanol- and 2-(2-butoxyethoxy)ethanol- and methanol- and 1(or 2)-(2-methoxymethylethoxy)propanol-blocked (generic) (P-18-251); Isocyanic acid, polymethylenepolyphenylene ester, 2-butoxyethanol- and 2-(2-butoxyethoxy)ethanol- and methanol- and 1-methoxy-2-propanol-blocked (generic) (P-18-252).

CAS Numbers: Not available.

Basis for action: The PMNs state that the use of the PMN substances will be as crosslinkers for automotive electrocoats. Based on the physical/chemical properties, chemical structure of the substances, submitted data on the substances, and comparison to structurally analogous substances, EPA has identified concerns for lung effects, skin sensitization, and aquatic toxicity if the 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:

1. No manufacture, processing, or use in a manner that results in inhalation exposure; and
2. No release of the PMN substance to surface waters exceeding 200 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 health and environmental effects of the PMN substances if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of chronic ecotoxicity testing and lung effects tiered testing for surfactants would help characterize the potential health and environmental effects of the PMN substances.

CFR citations: 40 CFR 721.11363 (P-18-247); 40 CFR 721.11364 (P-18-248); 40 CFR 721.11365 (P-18-249); 40 CFR 721.11366 (P-18-250); 40 CFR 721.11367 (P-18-251); and 40 CFR 721.11368 (P-18-252).

PMN Number: P-18-282.

Chemical Name: Fatty acid ester, polyether, diisocyanate polymer (generic).

CAS Number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the PMN substance will be as an adhesive. Based on the estimated physical/chemical properties of the PMN substance, test data on an analogue of the residual isocyanate, and comparison with structurally analogous chemical substances, EPA has identified concerns for irritation/sensitization for the skin, eyes, mucous membrane, and lungs, and respiratory effects if the 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 manufacturing, processing, or use of the PMN substance containing greater than the confidential percentage of residual isocyanate identified in the PMN.

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 health effects of the PMN substance if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of skin irritation, eye damage, skin sensitization, and pulmonary effects testing would help characterize the potential health effects of the PMN substance.

CFR Citation: 40 CFR 721.11369.

PMN Number: P-18-305.

Chemical Name: Alkenoic acid, alkyl-, alkyl ester, polymer with alkyl alkenoate, substituted heteromonocycle, substituted carbomonocycle, substituted alkanediol and alkenoic acid, alkali metal salt (generic).

CAS Number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the PMN substance will be as a component of ink. Based on the estimated physical/chemical properties of the PMN substance and comparison with structurally analogous chemical substances, EPA has identified 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 manufacturing, processing, or use of the substance that results in inhalation exposures.

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 health effects of the PMN substance if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of pulmonary effects testing would help characterize the potential health effects of the PMN substance.

CFR Citation: 40 CFR 721.11370.

PMN Number: P-18-339.

Chemical Name: Alkyl heteromonocycle with heteroatom substituted alkyl cycloalkane and 2-hydroxyethyl heteromonocycle methacrylate-blocked homopolymer (generic).

CAS Number: Not available.

Basis for action: The PMN states that the use of the PMN substance will be as an immobilizing agent for the microbial promoter of nitrogen decomposition. Based on the estimated physical/chemical properties of the PMN substance and comparison with structurally analogous chemical substances, EPA has identified 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 manufacture, processing, or use that results in inhalation exposures.

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 health effects of the PMN substance if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of specific target organ toxicity including

pulmonary effects testing would help characterize the potential health effects of the PMN substance.

CFR Citation: 40 CFR 721.11371.

PMN Number: P-19-5.

Chemical Name: Phenol-formaldehyde epoxy, polymer with an alkyl polyether polysulfide (generic).

CAS Number: Not available.

Effective date of TSCA section 5(e) Order: March 29, 2019.

Basis for TSCA section 5(e) Order: The PMN states that the use of the PMN substance will be as an adhesive for automotive parts. EPA identified concerns for reproductive/developmental toxicity, mutagenicity, and carcinogenicity for the low molecular weight components based on the epoxides chemical category and submitted test data. EPA also identified concerns for skin and lung sensitization and systematic toxicity based on the epoxide moieties. In addition, based on analysis of test data on the PMN substance and SAR analysis on analogous thiols/mercaptans, polyepoxides, and monoepoxides, EPA predicts chronic toxicity to aquatic organisms may occur at concentrations greater than 1 ppb. The TSCA section 5(e) Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation the substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the TSCA section 5(e) Order requires:

1. Use of personal protective equipment where there is a potential for dermal exposure;
2. Refraining from manufacture, processing or use of the PMN substance in a manner that would result in inhalation exposure;

3. No release of the PMN substance to surface waters exceeding 1 ppb; and
4. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.

The SNUR designates as a “significant new use” the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the health and environmental effects of the PMN substance may be potentially useful in support of a request by the PMN submitter to modify the TSCA section 5(e) Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this SNUR. EPA has also determined that specific ecological hazard, reproductive/developmental toxicity, sensitization, and carcinogenicity effects testing of the PMN substance would be useful in determining the health and environmental effects of the PMN substance. Although the TSCA section 5(e) Order does not require these tests, the TSCA section 5(e) Order’s restrictions remain in effect until the TSCA section 5(e) Order is modified or revoked by EPA based on submission of this or other relevant information.

CFR citation: 40 CFR 721.11372.

PMN Number: P-19-20.

Chemical Name: Alkylphenol, reaction products with carbon dioxide, distn. residues from manuf. of alkylphenol derivs. and calcium alkylphenol derivs. (generic).

CAS Number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the PMN substance will be as a lubricating additive. Based on the estimated physical/chemical properties of the PMN substance and comparison to structurally analogous chemical substances, EPA has

identified concerns for irritation, sensitization, blood and liver toxicity, lung toxicity, and developmental toxicity if the 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 use of the PMN substance involving an application method that generates a vapor, mist, or aerosol.

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 health effects of the PMN substance if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of sensitization, irritation, target organ toxicity/pulmonary effects, and reproduction/developmental effects testing would help characterize the potential health effects of the PMN substance.

CFR Citation: 40 CFR 721.11373.

PMN Number: P-19-35.

Chemical Name: Acetamide, 2-(4-methylphenoxy)-N-1H-pyrazol-3-yl-N-(2-thienylmethyl)-.

CAS Number: 1374760-95-8.

Basis for action: The PMN states that the generic (non-confidential) use of the PMN substance will be as a fragrance. Based on the estimated physical/chemical properties of the PMN substance, available test data on the new chemical substance, and SAR analysis on analogous thiophenes, EPA has identified concerns for severe eye irritation, sensitization, lung effects, histopathological effects on the nasal passages, 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:

1. No domestic manufacture of the PMN substance; and
2. No release of the PMN substance to surface waters exceeding 15 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 health effects of the PMN substance if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of pulmonary effects testing would help characterize the potential health effects of the PMN substance.

CFR Citation: 40 CFR 721.11374.

PMN Number: P-19-54.

Chemical Names: Polyamines, reaction products with succinic anhydride polyalkenyl derivs., metal salts (generic) (P-19-54, chemical A) and Polyamines, reaction products with succinic anhydride polyalkenyl derivs., metal salts (generic) (P-19-54, chemical B).

CAS Numbers: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the PMN substances will be as an automotive lubricant additive. Based on the available data for the new chemical substance, estimated physical/chemical properties of the PMN substances, comparison with structurally analogous chemical substances and other structural information, EPA has identified irritation to all tissues if the chemical substance is not used following the limitations noted. The conditions of use of the PMN substances as described in the PMN include the following

protective measure:

- Exceeding the concentration of the PMN substances in a formulated lubricant fluid for consumer use greater than the confidential percentage identified in the PMN.

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 health effects of the PMN substances if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of skin and eye irritation testing would help characterize the potential health effects of the PMN substances.

CFR Citation: 40 CFR 721.11381 (P-19-54, chemical A) and 40 CFR 721.11382 (P-19-54, chemical B).

V. Rationale and Objectives of the Proposed Rule

A. Rationale

During review of the PMNs submitted for the chemical substances that are subject to these proposed SNURs, EPA concluded that for 8 chemical substances regulation was warranted under TSCA section 5(e), pending the development of information sufficient to make reasoned evaluations of the health or environmental effects of the chemical substances. The basis for such findings is outlined in Unit IV. Based on these findings, TSCA section 5(e) Orders requiring the use of appropriate exposure controls were negotiated with the PMN submitters. As a general matter, EPA believes it is necessary to follow TSCA section 5(e) Orders with a SNUR that identifies the absence of those protective measures as Significant New Uses to ensure that all manufacturers and processors – not just the original submitter – are held to the same standard.

During review of the other 23 chemical substances that are the subject of these SNURs and as further discussed in Unit IV, EPA identified certain circumstances different from the intended conditions of use that raised potential risk concerns. EPA determined that deviations from the protective measures identified in the submissions could result in changes in the type or form of exposure to the chemical substances and/or increased exposures to the chemical substances and/or changes in the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of the chemical substances, and therefore warranted SNURs. The SNURs would identify as significant new uses any manufacturing, processing, use, distribution in commerce, or disposal that does not conform to the protective measures in the submission.

B. Objectives

EPA is proposing these SNURs for specific chemical substances which have undergone premanufacture review because the Agency wants:

- To receive notice of any person's intent to manufacture or process a listed chemical substance for the described significant new use before that activity begins.
- To review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing or processing a listed chemical substance for the described significant new use.
- To either determine that the prospective manufacture or processing is not likely to present an unreasonable risk, or to take necessary regulatory action associated with any other determination, before the described significant new use of the chemical substance occurs.

Issuance of a 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 on the Internet at

<http://www.epa.gov/opptintr/existingchemicals/pubs/tscainventory/index.html>.

VI. Applicability of the Proposed Significant New Use Designation

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.

When 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. However, TSCA section 5(e) Orders have been issued for 8 of the 31 chemical substances, and the PMN submitters are prohibited by the TSCA section 5(e) Orders from undertaking activities which would be designated as significant new uses. The identities of 25 of the 31 chemical substances subject to this proposed rule have been claimed as confidential (per 40 CFR 720.85) for a chemical substance covered by this action. 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.

Therefore, EPA designates [INSERT DATE OF PUBLICATION IN THE *Federal Register*] as the cutoff date for determining whether the new use is ongoing. The objective of EPA's approach is to ensure that a person cannot defeat a SNUR by initiating a significant new use before the effective date of the final rule.

Persons who begin commercial manufacture or processing of the chemical substances for a significant new use identified as of that date 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 wait until EPA has conducted a review of the notice, made an appropriate determination on the notice, and has taken such actions as are required with that determination.

VII. Development and Submission of Information

EPA recognizes that TSCA section 5 does not require developing any particular new information (e.g., generating test data) before submission of a SNUN. There is an exception: development of test data is required where the chemical substance subject to the SNUR is also subject to a rule, order or consent agreement under TSCA section 4 (see TSCA section 5(b)(1)).

In the absence of a TSCA section 4 test rule 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 identified by EPA that would help characterize the potential health and/or environmental effects of the PMN/SNUN substance for all the listed SNURs. EPA recognizes that the 2016 Lautenberg Amendments have led to modifications in our approach to testing requirements, including an increased consideration of alternatives to vertebrate testing. Descriptions of tests/information needs are provided for informational purposes only and EPA strongly encourages persons, before performing any testing, to consult with the Agency pertaining to protocol selection. 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 potentially useful information. EPA encourages dialogue

with Agency representatives to help determine how best the submitter can meet both the data needs and the objective of TSCA section 4(h). To access the OCSPP test guidelines referenced in this document electronically, please go to <http://www.epa.gov/ocspp> and select “Test Methods and Guidelines.” The Organisation for Economic Co-operation and Development test guidelines are available from the OECD Bookshop at <http://www.oecdbookshop.org> or SourceOECD at <http://www.sourceoecd.org>.

The potentially useful information listed in Unit IV. may not be the only means of addressing the potential risks of the chemical substance. 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.

VIII. SNUN Submissions

According to 40 CFR 721.1(c), persons submitting a SNUN must comply with the same notification requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in 40 CFR 720.50. 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 <http://www.epa.gov/opptintr/newchems>.

IX. Economic Analysis

EPA has evaluated the potential costs of establishing SNUN requirements for potential manufacturers and processors of the chemical substances subject to this proposed rule. EPA's

complete economic analysis is available in the docket identified for this rulemaking under **ADDRESSES**.

X. 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 13563: Improving Regulations and Regulatory Review

This proposed rule would establish SNURs for several new chemical substances that were the subject of PMNs and TSCA section 5(e) Orders. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011).

B. Paperwork Reduction Act (PRA)

According to 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 this proposed rule have already been approved by OMB pursuant to PRA under OMB control number 2070-0012 (EPA ICR No. 574). 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 response. 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.

Send any comments about the accuracy of the burden estimate, and any suggested methods for minimizing respondent burden, including the use of automated collection techniques, to the Director, Regulatory Support Division, Office of Mission Support (2822T), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. Please remember to include the OMB control number in any correspondence, but do not submit any completed forms to this address.

C. Regulatory Flexibility Act (RFA)

Pursuant to section 605(b) of the RFA (5 U.S.C. 601 *et seq.*), the Agency hereby certifies that promulgation of this proposed SNUR would not have a significant adverse economic impact on a substantial number of small entities. 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, it appears 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 seven in Federal fiscal year (FY) 2013, 13 in FY2014, six in FY2015, 10 in FY2016, 14 in FY2017, and 18 in FY2018 and only a fraction of these were from small businesses. In addition, the Agency currently offers relief to qualifying

small businesses by reducing the SNUN submission fee from \$16,000 to \$2,800. This lower fee reduces the total reporting and recordkeeping of cost of submitting a SNUN to about \$10,116 for qualifying small firms. Therefore, the potential economic impacts of complying with this proposed SNUR 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 final 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 proposed rule would 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. 1501 *et seq.*).

E. Executive Order 13132: Federalism

This action would not 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, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999).

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

This action would not have Tribal implications because it is not expected to have substantial direct effects on Indian Tribes. This proposed rule would not significantly nor

uniquely affect the Indian Tribal governments, nor would it involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of Executive Order 13175 (65 FR 67249, November 9, 2000), 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 this is not an economically significant regulatory action as defined by Executive Order 12866, and this action does not address environmental health or safety risks disproportionately affecting children.

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

This action is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001), because this proposed rule is not expected to affect energy supply, distribution, or use.

I. National Technology Transfer and Advancement Act (NTTAA)

In addition, since this proposed rule would not involve any technical standards, NTTAA section 12(d) (15 U.S.C. 272 note), does not apply to this action.

J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

This action does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898 (59 FR 7629, February 16, 1994).

List of Subjects

40 CFR Part 721

Environmental protection, Chemicals, Hazardous substances, Reporting and

recordkeeping requirements.

Dated: September 26, 2019.

Tala Henry,

Deputy Director, Office of Pollution Prevention and Toxics.

Therefore, it is proposed that 40 CFR chapter I be amended as follows:

PARTS 721 - [AMENDED]

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

Authority: 15 U.S.C. 2604, 2607, 2613, and 2625(c).

2. Add §§721.11346 through 721.11374, 721.11381 and 721.11382 to subpart E to read as follows:

Subpart E –Significant New Uses for Specific Chemical Substances

Sec.

§721.11346 Perfluoropolyether halide (generic).

§721.11347 Perfluoropolyether aryl (generic).

§721.11348 Substituted aryl-perfluoropolyether (generic).

§721.11349 Sulfonated perfluoropolyether aromatic transition metal salt (generic).

§721.11350 Sulfonated perfluoropolyether aryl alkali metal salt (generic).

§721.11351 Cyclohexanol, 4-ethylidene-2-propoxy- (P-16-225, chemical A).

§721.11352 Cyclohexanol, 5-ethylidene-2-propoxy- (P-16-225, chemical B).

§721.11353 Ethanone, 1-(5-propyl-1,3-benzodioxol-2-yl)-.

§721.11354 Endcapped polysiloxane (generic).

§721.11355 2,7-Nonadien-4-ol, 4,8-dimethyl-.

§721.11356 Carbonodithioic acid, O-[2-[(dithiocarboxy)amino]-2-methylpropyl] ester, sodium salt (1:2).

§721.11357 Oxirane, 2-methyl-, polymer with oxirane, methyl 2-(substituted carbomonocycle isoquinolin-2(3H)-yl) propyl ether (generic).

§721.11358 Vegetable oil, polymers with diethylene glycol- and polyol- and polyethylene glycol-depolymd. poly(ethylene terephthalate) waste plastics and arylcarboxylic acid anhydride (generic).

§721.11359 1H-Pyrrole-2,5-dione, 1,1'-C36-alkylenebis-.

§721.11360 Benzenepropanal, .alpha.,.alpha.,3-trimethyl-.

§721.11361 Multiwalled carbon nanotubes (generic).

§721.11362 Polyolefin ester (generic).

§721.11363 Isocyanic acid, polymethylenepolyphenylene ester, polymer with 2-ethyl-2-(hydroxymethyl)-1,3-propanediol, polyetherpolyol, .alpha.,.alpha.'-[(1-methylethylidene)di-4,1-phenylene]bis[.omega.-hydroxypoly(oxy-1,2-ethanediyl)] and 1,2-propanediol, iso-Bu alc.- and 2-butoxyethanol- and 2-(2-butoxyethoxy)ethanol- and Et alc.- and methanol- and 1-methoxy-2-propanol-blocked, (generic).

§721.11364 Isocyanic acid, polymethylenepolyphenylene ester, polymer with polyetherpolyol, 2-butoxyethanol- and 2-(2-butoxyethoxy)ethanol- and methanol-blocked, (generic).

§721.11365 Isocyanic acid, polymethylenepolyphenylene ester, polymer with polyetherpolyol, 2-butoxyethanol- and 2-(2-butoxyethoxy)ethanol- and methanol- and 1-

methoxy-2-propanol-blocked (generic).

§721.11366 Isocyanic acid, polymethylenepolyphenylene ester, polymer with polyetherpolyol, 2-butoxyethanol- and 2-(2-butoxyethoxy)ethanol- and 1(or 2)-(2-methoxymethylethoxy)propanol-blocked (generic).

§721.11367 Isocyanic acid, polymethylenepolyphenylene ester, 2-butoxyethanol- and 2-(2-butoxyethoxy)ethanol- and methanol- and 1(or 2)-(2-methoxymethylethoxy)propanol-blocked (generic).

§721.11368 Isocyanic acid, polymethylenepolyphenylene ester, 2-butoxyethanol- and 2-(2-butoxyethoxy)ethanol- and methanol- and 1-methoxy-2-propanol-blocked (generic).

§721.11369 Fatty acid ester, polyether, diisocyanate polymer (generic).

§721.11370 Alkenoic acid, alkyl-, alkyl ester, polymer with alkyl alkenoate, substituted heteromonocycle, substituted carbomonocycle, substituted alkanediol and alkenoic acid, alkali metal salt (generic).

§721.11371 Alkyl heteromonocycle with heteroatom substituted alkyl cycloalkane and 2-hydroxyethyl heteromonocycle methacrylate-blocked homopolymer (generic).

§721.11372 Phenol-formaldehyde epoxy, polymer with an alkyl polyether polysulfide (generic).

§721.11373 Alkylphenol, reaction products with carbon dioxide, distn. residues from manuf. of alkylphenol derivs. and calcium alkylphenol derivs. (generic).

§721.11374 Acetamide, 2-(4-methylphenoxy)-N-1H-pyrazol-3-yl-N-(2-thienylmethyl)-.

§721.11375 [Reserved]

§721.11376 [Reserved]

§721.11377 [Reserved]

§721.11378 [Reserved]

§721.11379 [Reserved]

§721.11380 [Reserved]

§721.11381 Polyamines, reaction products with succinic anhydride polyalkenyl derivs. metal salts (generic) (P-19-54, chemical A).

§721.11382 Polyamines, reaction products with succinic anhydride polyalkenyl derivs., metal salts (generic) (P-19-54, chemical B).

Subpart E –Significant New Uses for Specific Chemical Substances

§721.11346 Perfluoropolyether halide (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as perfluoropolyether halide (PMN P-16-151) 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) *Hazard communication.* Requirements as specified in § 721.72(a) through (d), (e)

(concentration set at 1.0%), (f), (g)(3)(i), (ii), (4)(i), (iii), and (5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k) and (t). It is a significant new use to manufacture the substance for more than one year.

(iii) *Disposal.* Requirements as specified in § 721.85 (a)(1), (b)(1), and (c)(1). Incineration must be hazardous waste high temperature incineration where the treatment efficiency is no less than 99.99%.

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

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

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

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

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(ii) of this section.

§721.11347 Perfluoropolyether aryl (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as perfluoropolyether aryl (PMN P-16-152) 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) *Hazard Communication*. Requirements as specified in § 721.72(a) through (d), (e) (concentration set at 1.0%), (f), (g)(3)(i), (ii), (4)(i), (iii), and (5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(ii) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(k) and (t).

(iii) *Disposal*. Requirements as specified in § 721.85 (a)(1), (b)(1), and (c)(1). Incineration must be hazardous waste high temperature incineration where the treatment efficiency is no less than 99.99%.

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

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

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

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

(3) *Determining whether a specific use is subject to this section*. The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(ii) of this section.

§721.11348 Substituted aryl-perfluoropolyether (generic).

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified generically as substituted aryl-perfluoropolyether (PMN P-16-153) 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) *Hazard communication*. Requirements as specified in § 721.72(a) through (d), (e) (concentration set at 1.0%), (f), (g)(3)(i), (ii), (4)(i), (iii), and (5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(ii) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(k) and (t).

(iii) *Disposal*. Requirements as specified in § 721.85 (a)(1), (b)(1), and (c)(1). Incineration must be hazardous waste high temperature incineration where the treatment efficiency is no less than 99.99%.

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

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

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

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

(3) *Determining whether a specific use is subject to this section*. The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(ii) of this section.

§721.11349 Sulfonated perfluoropolyether aromatic transition metal salt (generic).

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified generically as sulfonated perfluoropolyether aromatic transition metal salt (PMN P-16-154) is subject to reporting under this section for the significant new uses described

in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Hazard communication*. Requirements as specified in § 721.72(a) through (d), (e) (concentration set at 1.0%), (f), (g)(3)(i), (ii), (4)(i), (iii), and (5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(ii) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(k) and (t).

(iii) *Disposal*. Requirements as specified in § 721.85 (a)(1), (b)(1), and (c)(1). Incineration must be hazardous waste high temperature incineration where the treatment efficiency is no less than 99.99%.

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

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

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

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

(3) *Determining whether a specific use is subject to this section*. The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(ii) of this section.

§721.11350 Sulfonated perfluoropolyether aryl alkali metal salt (generic).

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified generically as sulfonated perfluoropolyether aryl alkali metal salt (PMN P-

16-155) 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) *Hazard communication*. Requirements as specified in § 721.72(a) through (d), (e) (concentration set at 1.0%), (f), (g)(3)(i), (ii), (4)(i), (iii), and (5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(ii) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(k) and (t).

(iii) *Disposal*. Requirements as specified in § 721.85 (a)(1), (b)(1), and (c)(1). Incineration must be hazardous waste high temperature incineration where the treatment efficiency is no less than 99.99%.

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

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

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

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

(3) *Determining whether a specific use is subject to this section*. The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(ii) of this section.

§721.11351 Cyclohexanol, 4-ethylidene-2-propoxy- (P-16-225, chemical A).

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical

substance identified as cyclohexanol, 4-ethylidene-2-propoxy- (PMN P-16-225, chemical A; CAS No. 1631145-48-6) 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) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f) and (s)(10,000 kg). It is a significant new use to use other than as a fragrance and process the substance to greater than 10% in compounded fragrance oil formulations.

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

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

§721.11352 Cyclohexanol, 5-ethylidene-2-propoxy- (P-16-225, chemical B).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as cyclohexanol, 5-ethylidene-2-propoxy- (PMN P-16-225, chemical B; CAS No. 1631145-49-7) 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(f) and (s)(10,000 kg). It is a significant new use to use other than as a fragrance and process the substance to greater than 10% in compounded fragrance oil formulations.

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

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

§721.11353 Ethanone, 1-(5-propyl-1,3-benzodioxol-2-yl)-.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as ethanone, 1-(5-propyl-1,3-benzodioxol-2-yl)- (PMN P-16-314, CAS No. 1370699-98-1) 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.* Requirements as specified in §721.80(f) and (s)(10,000 kg). It is a significant new use to exceed 10% of the PMN substance in processing formulations.

(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 notification requirements.* The provisions of §721.185 apply to this section.

§721.11354 Endcapped polysiloxane (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as endcapped polysiloxane (PMN P-16-429) 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).

(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 notification requirements.* The provisions of §721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of §721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.

§721.11355 2,7-Nonadien-4-ol, 4,8-dimethyl-

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 2,7-nonadien-4-ol, 4,8-dimethyl- (PMN P-16-470, CAS No. 103983-77-3) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Release to water.* Requirements as specified in §721.90 (a)(4) and (b)(4) where N=113.

(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 notification requirements.* The provisions of §721.185 apply to this section.

§721.11356 Carbonodithioic acid, O-[2-[(dithiocarboxy)amino]-2-methylpropyl] ester, sodium salt (1:2).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as carbonodithioic acid, O-[2-[(dithiocarboxy)amino]-2-methylpropyl] ester, sodium salt (1:2) (PMN P-17-108; CAS No. 1947332-67-3) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

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

(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 notification requirements.* The provisions of §721.185 apply to this section.

§721.11357 Oxirane, 2-methyl-, polymer with oxirane, methyl 2-(substituted carbomonocycle isoquinolin-2(3H)-yl) propyl ether (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance is identified generically as oxirane, 2-methyl-, polymer with oxirane, methyl 2-(substituted carbomonocycle isoquinolin-2(3H)-yl) propyl ether (PMN P-17-253) 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 process the substance to a concentration greater than 5% by weight in the final formulated product 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 notification requirements.* The provisions of §721.185 apply to this section.

§721.11358 Vegetable oil, polymers with diethylene glycol- and polyol- and polyethylene glycol-depolymd. poly(ethylene terephthalate) waste plastics and arylcarboxylic acid anhydride (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as vegetable oil, polymers with diethylene glycol- and polyol- and polyethylene glycol-depolymd. poly(ethylene terephthalate) waste plastics and arylcarboxylic acid anhydride (PMN P-18-91) 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 modify the manufacture, process, or use of the substance that results in inhalation exposure to vapors, particulate, mist or aerosols.

(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 notification requirements.* The provisions of §721.185 apply to this section.

§721.11359 1H-Pyrrole-2,5-dione, 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, 1,1'-C36-alkylenebis- (PMN P-18-120, CAS No. 1911605-95-2) 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 substance in any manner that results in inhalation exposures.

(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 notification requirements.* The provisions of §721.185 apply to this section.

§721.11360 Benzenepropanal, .alpha.,.alpha.,3-trimethyl-

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as benzenepropanal, .alpha.,.alpha.,3-trimethyl- (P-18-129; CAS No. 107737-97-3) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

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

(ii) [Reserved]

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

(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 notification requirements.* The provisions of §721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of §721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.

§721.11361 Multiwalled carbon nanotubes (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as multiwalled carbon nanotubes (PMN P-18-182) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance that have been:

- (i) embedded or incorporated into a polymer matrix that itself has been reacted (cured);
- (ii) embedded in a permanent solid/polymer form that is not intended to undergo further processing, except mechanical processing; or
- (iii) incorporated into an article as defined at 40 CFR 720.3(c).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (3), when determining which persons are reasonably likely to be exposed as required for §721.63(a)(1) and, (a)(4), engineering control measures (*e.g.*, enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.*, workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (5)(respirators must provide a National Institute for Occupational Safety and Health assigned protection factor of at least 50), (6)(particulate), and (c).

(ii) *Industrial, commercial, and consumer activities.* It is a significant new use to use an application method that generates a dust, mist, or aerosol, unless such application method occurs in an enclosed process. It is a significant new use to use the substance other than for heat

transfer, heat storage, thermal emission, and general temperature management in heat-generating systems such as electronics, to improve mechanical properties or electrical conductivities of other materials or products, and for light absorption properties.

(iii) *Disposal*. Requirements as specified in § 721.85 (a)(1), (2), (b)(1), (2), (c)(1), and (2).

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

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

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

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

§721.11362 Polyolefin ester (generic).

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified generically as polyolefin ester (PMN P-18-186) 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 (y)(1). It is a significant new use to manufacture (including import) the substance at less than the confidential average molecular weight identified 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 notification requirements*. The provisions of §721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section*. The provisions of §721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.

§721.11363 Isocyanic acid, polymethylenepolyphenylene ester, polymer with 2-ethyl-2-(hydroxymethyl)-1,3-propanediol, polyetherpolyol, .alpha.,.alpha.'-[(1-methylethylidene)di-4,1-phenylene]bis[.omega.-hydroxypoly(oxy-1,2-ethanediyl)] and 1,2-propanediol, iso-Bu alc.- and 2-butoxyethanol- and 2-(2-butoxyethoxy)ethanol- and Et alc.- and methanol- and 1-methoxy-2-propanol-blocked (generic).

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified generically as isocyanic acid, polymethylenepolyphenylene ester, polymer with 2-ethyl-2-(hydroxymethyl)-1,3-propanediol, polyetherpolyol, .alpha.,.alpha.'-[(1-methylethylidene)di-4,1-phenylene]bis[.omega.-hydroxypoly(oxy-1,2-ethanediyl)] and 1,2-propanediol, iso-Bu alc.- and 2-butoxyethanol- and 2-(2-butoxyethoxy)ethanol- and Et alc.- and methanol- and 1-methoxy-2-propanol-blocked (PMN P-18-247) 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 substance in a manner results in inhalation exposure.

(ii) *Release to water*. Requirements as specified in §721.90 (a)(4), (b)(4), and (c)(4) where N = 200.

(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 notification requirements.* The provisions of §721.185 apply to this section.

§721.11364 Isocyanic acid, polymethylenepolyphenylene ester, polymer with polyetherpolyol, 2-butoxyethanol- and 2-(2-butoxyethoxy)ethanol- and methanol-blocked, (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as isocyanic acid, polymethylenepolyphenylene ester, polymer with polyetherpolyol, 2-butoxyethanol- and 2-(2-butoxyethoxy)ethanol- and methanol-blocked, (PMN P-18-248) 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 substance in a manner results in inhalation exposure.

(ii) *Release to water.* Requirements as specified in §721.90 (a)(4), (b)(4), and (c)(4) where $N = 200$.

(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 notification requirements.* The provisions of §721.185 apply to this section.

§721.11365 Isocyanic acid, polymethylenepolyphenylene ester, polymer with polyetherpolyol, 2-butoxyethanol- and 2-(2-butoxyethoxy)ethanol- and methanol- and 1-methoxy-2-propanol-blocked (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as isocyanic acid, polymethylenepolyphenylene ester, polymer with polyetherpolyol, 2-butoxyethanol- and 2-(2-butoxyethoxy)ethanol- and methanol and 1-methoxy-2-propanol-blocked (PMN P-18-249) 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 substance in a manner results in inhalation exposure.

(ii) *Release to water.* Requirements as specified in §721.90 (a)(4), (b)(4), and (c)(4) where N = 200.

(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 notification requirements.* The provisions of §721.185 apply to this section.

§721.11366 Isocyanic acid, polymethylenepolyphenylene ester, polymer with polyetherpolyol, 2-butoxyethanol- and 2-(2-butoxyethoxy)ethanol- and 1(or 2)-(2-

methoxymethylethoxy)propanol-blocked (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as isocyanic acid, polymethylenepolyphenylene ester, polymer with polyetherpolyol, 2-butoxyethanol- and 2-(2-butoxyethoxy)ethanol- and 1(or 2)-(2-methoxymethylethoxy)propanol-blocked. (PMN P-18-250) 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 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 = 200.

(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 notification requirements.* The provisions of §721.185 apply to this section.

§721.11367 Isocyanic acid, polymethylenepolyphenylene ester, 2-butoxyethanol- and 2-(2-butoxyethoxy)ethanol- and methanol- and 1(or 2)-(2-methoxymethylethoxy)propanol-blocked (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as isocyanic acid, polymethylenepolyphenylene ester, 2-butoxyethanol- and 2-(2-butoxyethoxy)ethanol- and methanol- and 1(or 2)-(2-

methoxymethylethoxy)propanol-blocked (PMN P-18-251) 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 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 = 200.

(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 notification requirements.* The provisions of §721.185 apply to this section.

§721.11368 Isocyanic acid, polymethylenepolyphenylene ester, 2-butoxyethanol- and 2-(2-butoxyethoxy)ethanol- and methanol- and 1-methoxy-2-propanol-blocked (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as isocyanic acid, polymethylenepolyphenylene ester, 2-butoxyethanol- and 2-(2-butoxyethoxy)ethanol- and methanol- and 1-methoxy-2-propanol-blocked. (PMN P-18-252) 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 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 = 200.

(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 notification requirements.* The provisions of §721.185 apply to this section.

§721.11369 Fatty acid ester, polyether, diisocyanate polymer (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as fatty acid ester, polyether, diisocyanate polymer (PMN P-18-282) 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 substance containing greater than the confidential residual isocyanate percentage identified 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 notification requirements.* The provisions of

§721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of §721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.

§721.11370 Alkenoic acid, alkyl-, alkyl ester, polymer with alkyl alkenoate, substituted heteromonocycle, substituted carbomonocycle, substituted alkanediol and alkenoic acid, alkali metal salt (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as alkenoic acid, alkyl-, alkyl ester, polymer with alkyl alkenoate, substituted heteromonocycle, substituted carbomonocycle, substituted alkanediol and alkenoic acid, alkali metal salt (PMN P-18-305) 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 substance that results in inhalation exposures.

(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 notification requirements.* The provisions of §721.185 apply to this section.

§721.11371 Alkyl heteromonocycle with heteroatom substituted alkyl cycloalkane and 2-hydroxyethyl heteromonocycle methacrylate-blocked homopolymer (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as alkyl heteromonocycle with heteroatom substituted alkyl cycloalkane and 2-hydroxyethyl heteromonocycle methacrylate-blocked homopolymer (PMN P-18-339) 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 substance for any use 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 notification requirements.* The provisions of §721.185 apply to this section.

§721.11372 Phenol-formaldehyde epoxy, polymer with an alkyl polyether polysulfide (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as phenol-formaldehyde epoxy, polymer with an alkyl polyether polysulfide (PMN P-19-5) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1) and (3).

(ii) *Hazard communication.* Requirements as specified in §721.72 (a) through (d), (f), (g)(1)(iv), (vi), (vii), (skin and respiratory sensitization), (germ cell mutagenicity), (2)(i), (ii), (v), (3)(i), (ii), (4)(water release restrictions apply), and (5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture, process, or use the PMN substance in any manner that results in inhalation exposure.

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

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

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

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

§721.11373 Alkylphenol, reaction products with carbon dioxide, distn. residues from manuf. of alkylphenol derivs. and calcium alkylphenol derivs. (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as alkylphenol, reaction products with carbon dioxide, distn. residues from manuf. of alkylphenol derivs. and calcium alkylphenol derivs. (PMN P-19-20) 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(y)(1).

(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 notification requirements.* The provisions of §721.185 apply to this section.

§721.11374 Acetamide, 2-(4-methylphenoxy)-N-1H-pyrazol-3-yl-N-(2-thienylmethyl)-.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as acetamide, 2-(4-methylphenoxy)-N-1H-pyrazol-3-yl-N-(2-thienylmethyl)- (PMN P-19-35, CAS No. 1374760-95-8) 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).

(ii) *Release to water.* Requirements as specified in §721.90 (a)(4), (b)(4), and (c)(4) where N=15.

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

(1) *Recordkeeping.* Recordkeeping requirements as specified in §721.125(a) through (c),

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

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

§721.11375 [Reserved]

§721.11376 [Reserved]

§721.11377 [Reserved]

§721.11378 [Reserved]

§721.11379 [Reserved]

§721.11380 [Reserved]

§721.11381 Polyamines, reaction products with succinic anhydride polyalkenyl derivs., metal salts (generic) (P-19-54, chemical A).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as polyamines, reaction products with succinic anhydride polyalkenyl derivs., metal salts (PMN P-19-54, chemical A) 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 exceed the confidential concentration percentage of the substance in a formulated lubricant fluid for consumer use identified in P-19-54.

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

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

§721.11382 Polyamines, reaction products with succinic anhydride polyalkenyl derivs., metal salts (generic) (P-19-54, chemical B).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as polyamines, reaction products with succinic anhydride polyalkenyl derivs., metal salts (PMN P-19-54, chemical B) 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 exceed the confidential concentration percentage of the substance in a formulated lubricant fluid for consumer use identified in P-19-54.

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

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