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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[EPA-HQ-OPPT-2018-0650; FRL-9985-22]

RIN 2070-AB27

Significant New Use Rules on Certain Chemical Substances

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 66 chemical substances which were the subject of premanufacture notices (PMNs). The chemical substances are subject to Orders issued by EPA pursuant to section 5(e) of TSCA. This action would require persons who intend to manufacture (defined by statute to include import) or process any of these 66 chemical substances for an activity that is proposed as a significant new use to notify EPA at least 90 days before commencing that activity. The required notification initiates EPA's evaluation of the intended use within the applicable review period. 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 with that determination.

DATES: Comments must be received on or before *[insert date 45 days after date of publication in the Federal Register]*.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2018-0650, 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 § 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 that may be presented by the intended uses and, if appropriate, to regulate the proposed use before it occurs. Additional rationale and background to these proposed rules are 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). Consult that preamble for further 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. Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1)(B) requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture or process the chemical substance for that use (15 U.S.C. 2604(a)(1)(B)(i)). TSCA furthermore prohibits such manufacturing or processing from commencing until EPA has conducted a review of the notice, made an appropriate determination on the notice, and taken such actions as are required in association with that determination (15 U.S.C. 2604(a)(1)(B)(ii)). As described in Unit V., the general SNUR provisions are found at 40 CFR part 721, subpart A.

C. Applicability of General Provisions

General provisions for SNURs appear in 40 CFR part 721, subpart A. These provisions describe persons subject to the rule, recordkeeping requirements, and exemptions to reporting requirements. Provisions relating to user fees appear at 40 CFR part 700. According to § 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). In particular, these requirements include the information submission requirements of TSCA section 5(b) and 5(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 significant new use is not likely to present an unreasonable risk of injury or take such regulatory action as is

associated with an alternative determination before the manufacture or processing for the significant new use can commence. If EPA determines that the significant new 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. Proposed Significant New Use Determination

Section 5(a)(2) of TSCA 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 addition to these factors enumerated in TSCA section 5(a)(2), the statute authorizes EPA to consider any other relevant factors.

To preliminarily determine what would constitute a significant new use for the 66 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 conditions of use of the

substances, in the context of the four bulleted TSCA section 5(a)(2) factors listed in this unit.

IV. Substances Subject to this Proposed Rule

EPA is proposing significant new use and recordkeeping requirements for 66 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 TSCA section 5(e) Order.
- 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 that would be designated by the SNUR. This information may include testing required in a TSCA section 5(e) Order to be conducted by the PMN submitter, as well as testing not required to be conducted but which would also help characterize the potential health and/or environmental effects of the PMN substance. Any recommendation for information identified by EPA was made based on EPA's consideration of available screening-level data, if any, as well as other available information on appropriate testing for the chemical substance. Further, any such testing identified by EPA that includes testing on vertebrates was made after consideration of available toxicity information, computational toxicology and

bioinformatics, and high-throughput screening methods and their prediction models. EPA also recognizes that whether testing/further information is needed will depend on the specific exposure and use scenario in the SNUN. EPA encourages all SNUN submitters to contact EPA to discuss any potential future testing. See Unit VII. for more information.

- 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 66 PMN substances that are subject to Orders issued under TSCA section 5(e)(1)(A) or section 5(f)(3)(A). Each Order is based on one or more of the findings in TSCA section 5(a)(3)(A) or section 5(a)(3)(B): there is insufficient information to permit a reasoned evaluation; in the absence of sufficient information to permit a reasoned evaluation, the activities associated with the PMN substances may present unreasonable risk to health or the environment; the substance is or will be produced in substantial quantities, and enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant (substantial) human exposure to the substance; presents an unreasonable risk of injury to health or environment. Those 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 Orders, consistent with TSCA section 5(f)(4).

Where EPA determined that the PMN substance may present an unreasonable risk of injury to human health via inhalation exposure, the underlying TSCA section 5(e) Order usually requires, among other things, that potentially exposed employees wear specified respirators unless actual measurements of the workplace air show that air-borne concentrations of the PMN substance are below a New Chemical Exposure Limit (NCEL) that is established by EPA to provide adequate protection to human health. In addition to the actual NCEL concentration, the comprehensive NCELS provisions in TSCA section 5(e) Orders, which are modeled after Occupational Safety and Health Administration (OSHA) Permissible Exposure Limits (PELs) provisions, include requirements addressing performance criteria for sampling and analytical methods, periodic monitoring, respiratory protection, and recordkeeping. However, no comparable NCEL provisions currently exist in 40 CFR part 721, subpart B, for SNURs. Therefore, for these cases, the individual SNURs in 40 CFR part 721, subpart E, will state that persons subject to the SNUR who wish to pursue NCELS as an alternative to the § 721.63 respirator requirements may request to do so under § 721.30. EPA expects that persons whose § 721.30 requests to use the NCELS approach for SNURs that are approved by EPA will be required to comply with NCELS provisions that are comparable to those contained in the corresponding TSCA section 5(e) Order for the same chemical substance.

PMN Number: P-15-106.

Chemical Name: Alkene reaction and distillation by-products and residues (generic).

CAS Number: Not available.

Effective date of TSCA section 5(e) Order: May 17, 2018.

Basis for TSCA section 5(e) Order: The PMN states that the generic (non-confidential) use of the substance will be as a mining and fuel additive. Based on test data for analogous chemicals, EPA identified concerns for developmental toxicity, irritation to the eyes, mucous membranes, and lungs, and dermal sensitization. EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 part per billion (ppb). The Order was issued under sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I) of TSCA, 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 health and the environment. The Order was also issued under TSCA sections 5(a)(3)(B)(ii)(II) and 5(e)(1)(A)(ii)(II), based on a finding that the substance is or will be produced in substantial quantities and that the substance either enters or may reasonably be anticipated to enter the environment in substantial quantities, or there is or may be significant (or substantial) human exposure to the substance. To protect against these risks, the Order requires:

1. Submit to EPA certain toxicity testing before manufacturing the confidential aggregate production volume specified in the Order;
2. Use of personal protective equipment to prevent dermal exposure where there is a potential for dermal exposure;
3. Use of a National Institute of Occupational Safety and Health (NIOSH) certified respirator with an assigned protection factor (APF) of 10 where there is a potential for inhalation exposure or compliance with a NCEL of 2 mg/m^3 as an 8-hour time-weighted average to prevent inhalation exposure;

4. Release of the PMN substance to water without resulting in surface water concentrations that exceed 1 ppb; and

5. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the Safety Data Sheet (SDS).

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

Potentially useful information: EPA has determined that certain information about the health and environmental effects of the PMN substance may be potentially useful to characterize the effects of the PMN 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 that would be that would be designated by this proposed SNUR. The submitter has agreed not to exceed a certain production volume limit without performing specific developmental toxicity testing. EPA has also determined that the results of acute aquatic toxicity testing would help characterize the potential environmental effects of the PMN substance. Although the Order does not require these tests, the Order’s restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or relevant information.

CFR citation: 40 CFR 721.11194.

PMN Number: P-15-726.

Chemical name: Oxirane, 2-methyl-, polymer with oxirane, monobutyl ether, monoether with propylene oxide-2-[[3-(triethoxysilyl)propoxy]methyl]oxirane polymer.

CAS Number: 1644400-33-8.

Effective date of TSCA section 5(e) Order: March 7, 2018.

Basis for TSCA section 5(e) Order: The PMN states that the use of the substance will be as a co-polymer for use in adhesives and sealant formulations. Based on the reactivity of the triethoxysilyl group of the PMN substance, EPA identified concerns for respiratory irritation. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to health and the environment. To protect against these risks, the Order requires:

1. No manufacturing, processing, or use of the PMN substance in any manner that generates a vapor, dust, mist, or aerosol; and
2. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.

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

Potentially useful information: EPA has determined that certain information about the health effects of the PMN substance may be potentially useful to characterize the effects of the PMN 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 this SNUR. EPA has also determined that the results of specific target organ toxicity or pulmonary effects testing would help characterize the potential health effects of the PMN substance. Although the Order does not require this testing, the Order’s restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or relevant information.

CFR citations: 40 CFR 721.11195.

PMN Number: P-16-337.

Chemical name: Aliphatic acrylate (generic).

CAS Number: Not available.

Effective date of TSCA section 5(e) Order: April 17, 2018.

Basis for TSCA section 5(e) Order: The PMN states that the use of the substance will be as a monomer. Based on analogy to acrylates, EPA has identified concerns for mutagenicity, oncogenicity, developmental, liver, and kidney toxicity, sensitization, irritation/corrosion, and aquatic/terrestrial toxicity. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to health and the environment. To protect against these risks, the Order requires:

1. Use of personal protective equipment to prevent dermal exposure where there is potential for dermal exposure;
2. Use of a NIOSH-certified respirator with an APF of at least 50 where there is a potential for inhalation exposure;
3. No use of the PMN substance other than as a chemical intermediate;
4. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS; and
5. No release of the PMN substance resulting in surface water concentrations that exceed 1 ppb.

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

Potentially useful information: EPA has determined that certain information about the health and environmental effects of the PMN substance may be potentially useful to characterize the effects of the PMN 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 that would be designated by this proposed SNUR. EPA has also determined that the results of specific pulmonary effects and skin sensitization testing would help characterize the potential health effects of the PMN substance and results of chronic aquatic toxicity testing would help characterize the potential environmental effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or relevant information.

CFR citation: 40 CFR 721.11196.

PMN Number: P-16-421.

Chemical name: Flue dust, glass manufg. Desulfurization. *Definition:* The dust produced from the flue gas exhaust cleaning of a glass manufacturing process using carbonate containing substances. It consists primarily of Na₂SO₄, Na₂CO₃, and Na₄(SO₄)(CO₃).

CAS Number: 1916486-36-6.

Effective date of TSCA section 5(e) Order: April 19, 2018.

Basis for TSCA section 5(e) Order: The PMN states that the use of the PMN substance will be as an additive to facilitate melting of sand during manufacture of glass. EPA identified concerns for reproductive, developmental, renal, neurological, hematological, gastrointestinal, and cardiovascular effects, and cancer, based on the substance containing toxic metal impurities. The Order was issued under sections 5(a)(3)(B)(ii)(I) and

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

1. Use of a NIOSH-certified respirator with an APF of at least 50 where there is a potential for inhalation exposure or when the PMN substance is in a mixture at a concentration below 1.0 percent by weight, an APF of 10;

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

3. Not modifying the processes or uses described in the PMN such that occupational exposure is increased;

4. Use of the PMN substance only as a site-limited intermediate;

5. Conducting and reporting to EPA an elemental analysis for the composition of the PMN substance six months after filing the notice of commencement and every six months, at each use site, for three years thereafter; and

6. Conducting and reporting to EPA an elemental analysis each time a change in the manufacturing process could result in the PMN substance possessing a different elemental composition.

The proposed SNUR would designate as a “significant new use” the absence of protective measures 1, 2, 3, 4, and manufacture of the substance with an elemental composition different from that described in the PMN.

Potentially useful information: EPA has determined that certain information about the composition of the PMN substance may be potentially useful to characterize the health effects of the PMN 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 that would be designated by this proposed SNUR. The submitter has agreed not to manufacture the PMN substance more than 6 months without performing an elemental analysis to characterize the elemental composition of the PMN substance.

CFR citation: 40 CFR 721.11197.

PMN Number: P-16-600.

Chemical name: Organo-titanate (generic).

CAS number: Not available.

Effective date of TSCA section 5(e) Order: May 23, 2018.

Basis for TSCA section 5(e) Order: The PMN states that the generic (non-confidential) use of the substance will be as an electrolyte. Based on submitted test data and the pH of the PMN substance, EPA identified concerns for mutagenicity, sensitization, irritation to skin, eyes and mucous membranes, and oncogenicity. EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 35 ppb based on analogy to phenols. The Order was issued under sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I) of TSCA, based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

1. Use of personal protective equipment to prevent dermal exposure where there is a potential for dermal exposure;
2. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS;
3. Manufacturing, processing, or use of the PMN substance only for the

confidential use specified in the Order;

4. No processing or use of the PMN substance in application methods that generate a vapor, mist, or aerosol; and

5. No release of the PMN substance to surface waters.

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

Potentially useful information. EPA has determined that certain information about the health and environmental effects of the PMN substance may be potentially useful to characterize the effects of the PMN 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 that would be designated by this proposed SNUR.

EPA has also determined that the results of specific aquatic toxicity and carcinogenicity tests would help characterize the potential environmental and health effects of the PMN substance. Although the Order does not require these tests, the Order’s restrictions will remain in effect until the Order is modified or revoked by EPA based on submission of this or other information.

CFR citation: 40 CFR 721.11198.

PMN Number: P-17-7.

Chemical name: Dialkyl 7,10-dioxa, dithiahexadeca diene (generic).

CAS Number: Not available.

Effective date of TSCA section 5(e) Order: April 17, 2018.

Basis for TSCA section 5(e) Order: The PMN states that the use of the substance will be as a chemical intermediate. Based on physical chemical properties and that the epoxide

may occur as an oxidation product, EPA has concerns for skin and lung sensitization, mutagenicity, oncogenicity, developmental toxicity, male reproductive toxicity, liver toxicity, and kidney toxicity. Based on structure activity relationship (SAR) analysis on analogous neutral organic chemicals, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 67 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

1. Use of personal protective equipment where there is a potential for dermal exposure;
2. Refrain from manufacturing (including import) the PMN substance for use other than as a chemical intermediate;
3. No manufacturing, processing or use of the substance that would result in inhalation exposures by vapor, dust, mist, or aerosol;
4. No release of the PMN substance resulting in surface water concentrations that exceed 67 ppb; and
5. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.

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

Potentially useful information: EPA has determined that certain information about environmental effects and health effects of the PMN substance may be potentially useful

in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of specific target organ toxicity, carcinogenicity, and acute aquatic toxicity testing would help characterize the potential human and environmental effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or relevant information.

CFR citation: 40 CFR 721.11199.

PMN Number: P-17-49.

Chemical name: Haloalkyl substituted carbomonocycle (generic).

CAS Number: Not available.

Effective date of TSCA section 5(e) Order: March 13, 2018.

Basis for TSCA section 5(e) Order: The PMN states that the generic (non-confidential) use of the substance will be as a starting material for synthesis. EPA has identified concerns for dermal and respiratory sensitization, mutagenicity, oncogenicity, and developmental toxicity based on the potential for the chemical substance to be an alkylating agent. There are also concerns for possible effects on the liver and the chemical substance is expected to be a strong irritant and corrosive to all exposed tissues based on data on analogous chemicals. EPA predicts that the substance will persist in the environment, could bioaccumulate or biomagnify, and could be toxic (PBT). The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the

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

1. Use of personal protective equipment to prevent dermal exposure where there is potential for dermal exposure;
2. Use of a NIOSH certified respirator with an APF of at least 10 where there is potential for inhalation exposure;
3. Use of the confidential engineering controls specified in the Order;
4. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS;
5. Refraining from domestic manufacture in the United States (i.e., import only);
6. Use of the PMN substance only for the confidential use specified in the Order;
7. No manufacture of the PMN substance beyond an annual production volume specified in the Order;
8. Disposal of the PMN substance only by incineration; and
9. No release of the PMN substance to surface waters.

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

Potentially useful information: EPA has determined that certain information about the fate and health effects of the PMN substance may be potentially useful to characterize the effects of the PMN 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 that would be designated by this proposed SNUR. EPA has also determined that the results of specific reproductive/developmental toxicity, genetic

toxicity, and fate testing would help characterize the potential human and environmental effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or relevant information.

CFR citation: 40 CFR 721.11200.

PMN Numbers: P-17-249, P-17-380, and P-17-381.

Chemical names: Amine- and hydroxy-functional acrylic polymer, neutralized (P-17-249), amine- and hydroxy-functional acrylic polymer (generic) (P-17-380), and hydroxy acrylic polymer, methanesulfonates (generic) (P-17-381).

CAS Numbers: Not available.

Effective date of TSCA section 5(e) Order: March 6, 2018.

Basis for TSCA section 5(e) Order: The PMNs state that the generic (non-confidential) use of the PMN substances will be open and non-dispersive. Based on analysis of test data on analogous polycationic polymers, EPA identified potential concerns for lung effects and aquatic toxicity. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substances may present an unreasonable risk of injury to human health and the environment. The Order was also issued under TSCA sections 5(a)(3)(B)(ii)(II) and 5(e)(1)(A)(ii)(II), based on a finding that the substances are or will be produced in substantial quantities and that the substances either enters or may reasonably be anticipated to enter the environment in substantial quantities, or there is or may be significant (or substantial) human exposure to the substances. To protect against these risks, the Order requires:

1. Use of the PMN substances only for the confidential uses specified in the Order;
2. Use of the confidential engineering controls specified in the Order;
3. No manufacturing or use of the PMN substances with methods that generate a dust, spray, mist, or aerosol;
4. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS; and
5. Disposal of the PMN substances only by incineration or with onsite pre-treatment of water releases at an onsite waste water treatment plant with at least 96% efficiency.

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

Potentially useful information. EPA has determined that certain information about the physical-chemical properties, health effects and environmental effects of the PMN substances may be potentially useful to characterize the potential effects of the PMN substances in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has also determined that the results of specific particle size distribution, physical-chemical property, acute and chronic pulmonary toxicity, and acute and chronic aquatic toxicity testing would help characterize the potential human and environmental effects of the PMN substances.

Although the Order does not require these tests, the Order’s restrictions will remain in

effect until the Order is modified or revoked by EPA based on submission of this or relevant information.

CFR citation: 40 CFR 721.11201 (P-17-249), 40 CFR 721.11202 (P-17-380) and 40 CFR 721.11203 (P-17-381).

PMN Number: P-17-270.

Chemical name: Alkyl perfluorinated acryloyl ester (generic).

CAS Number: Not available.

Effective date of TSCA section 5(e) Order: April 26, 2018.

Basis for TSCA section 5(e) Order: The PMN states that the generic (non-confidential) use of the substance will be as a low refractive index coating. Based analysis of test data on an analogue, EPA identified concerns for liver toxicity, blood toxicity, and male reproductive toxicity for the potential degradant product. EPA predicts environmental toxicity from the effects of the potential degradation products based on analogue test data. EPA predicts that the substance will persist in the environment, could bioaccumulate or biomagnify, and could be toxic (PBT). The Order was issued under sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I) of TSCA, 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 health and the environment. To protect against these risks, the Order requires:

1. Refraining from domestic manufacture in the United States (i.e., import only);
2. No manufacture of the PMN substance beyond a confidential maximum annual manufacture (which includes import) volume; and
3. Use the PMN substance only for the confidential uses specified in the Order.

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

Potentially useful information. EPA has determined that certain information about the environmental fate of the PMN substance may be potentially useful to characterize the potential effects of the PMN 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 that would be designated by this proposed SNUR. EPA has also determined that the results of specific characterization, fate, and bioaccumulation testing would help characterize the potential health and environmental effects of the PMN substance. Although the Order does not require these tests, the Order’s restrictions will remain in effect until the Order is modified or revoked by EPA based on submission of this or relevant information.

CFR citations: 40 CFR 721.11204.

PMN Number: P-17-271.

Chemical name: Poly(oxy-1,2-ethanediyl), .alpha.-(2-methyl-2-propen-1-yl)-.omega.-hydroxy-.

CAS Number: 31497-33-3.

Effective date of TSCA section 5(e) Order: March 15, 2018.

Basis for TSCA section 5(e) Order: The PMN states that the use of the substance will be as a polymer intermediate. Based on the surfactant properties of the PMN substance, EPA has identified concerns for lung toxicity. There are concerns for skin and lung sensitization, mutagenicity, oncogenicity, developmental toxicity, male reproductive toxicity, liver toxicity, and kidney toxicity based on the potential epoxide oxidation

product. The 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 effects of the PMN substance. To protect against these risks, the Order requires:

1. Refrain from manufacturing, processing or using the PMN substance in a manner that generates a vapor, mist, or aerosol, or that results in inhalation exposure;
2. Refraining from domestic manufacture in the United States (i.e., import only);
3. No use of the PMN substance other than as a polymer intermediate; and
4. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.

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

Potentially useful information: EPA has determined that certain information about the health effects of the PMN substance may be potentially useful to characterize the effects of the PMN 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 that would be designated by this proposed SNUR. EPA has also determined that the results of specific genetic toxicology, reproductive/developmental toxicity and pulmonary effect testing would help characterize the potential health effects of the PMN substance. Although the Order does not require these tests, the Order’s restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or relevant information.

CFR citation: 40 CFR 721.11205.

PMN Number: P-17-304.

Chemical name: Alkylidene dicarbomonocycle, polymer with halo-substituted heteromonocycle and disubstituted alkyl carbomonocycle alkenedioate alkylalkenoate (generic).

CAS Number: Not available.

Effective date of TSCA section 5(e) Order: March 20, 2018.

Basis for TSCA section 5(e) Order: The PMN states that the use of the substance will be as a chemical intermediate for thermoset plastic material. Based on analogue data for low molecular weight moieties in the polymer, EPA has identified concern for sensitization. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to health and the environment. To protect against these risks, the Order requires:

1. Refraining from domestic manufacture in the United States (i.e., import only);
2. Use of personal protective equipment to prevent dermal exposure where there is potential for dermal exposure;
3. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS;
4. Not manufacture (which under TSCA includes importing) the PMN substance to contain no more than 0.1 % residual isocyanate by weight; and
5. No use of the PMN substance other than as a chemical intermediate for thermoset plastic material.

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

Potentially useful information: EPA has determined that certain information about the health effects of the PMN substance may be potentially useful to characterize the effects of the PMN 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 that would be designated by this proposed SNUR. EPA has also determined that the results of specific skin sensitization testing would help characterize the potential health effects of the PMN substance. Although the Order does not require these tests, the Order’s restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or relevant information.

CFR citation: 40 CFR 721.11206.

PMN Numbers: P-17-337 and P-17-338.

Chemical names: Aluminum boron cobalt lithium nickel oxide (P-17-337) and Aluminum boron cobalt lithium magnesium nickel oxide (P-17-338)

CAS Numbers: 207803-51-8 (P-17-337) and 2087499-33-8 (P-17-338).

Effective date of TSCA section 5(e) Order: March 5, 2018.

Basis for TSCA section 5(e) Order: The PMNs state that use of the substances will be as cathode material for lithium ion batteries. Based on analysis of test data on the PMN substances and analysis of test data on analogous chemicals, EPA identified concerns for lung effects, oncogenicity, systemic effects, dermal corrosion and irritation. The Order was issued under sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I) of TSCA, 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 health. The Order was also issued under TSCA sections 5(a)(3)(B)(ii)(II) and 5(e)(1)(A)(ii)(II), based on a finding that the PMN substance P-17-337 is or will be produced in substantial quantities and that the substance either enters or may reasonably be anticipated to enter the environment in substantial quantities, or there is or may be significant (or substantial) human exposure to the substance. To protect against these risks, the Order requires:

1. Submit to EPA certain toxicity testing before exceeding the 24-month and 6-year time limit specified in the Order;

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

3. Use of a NIOSH certified respirator with an APF of at least 1,000 where there is a potential for inhalation exposure;

4. As an alternative to using respirators maintain workplace airborne concentrations of the PMN substances at or below a specified NCEL of 0.000092 mg/m^3 , verified by actual exposure monitoring data;

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

6. Manufacture and process the PMN substances only in a facility where all process air streams containing the PMN substances pass through control technology (such as a high-efficiency particulate air (HEPA) filter) with a rated removal efficiency of at least 99.99%.

7. Dispose of the PMN substances and manufacture, processing, and use waste streams containing the PMN substances by landfill or by metal reclamation by a person

who agrees to follow the terms of the Order.

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

Potentially useful information: EPA has determined that certain information about the health effects of the PMN substance may be potentially useful to characterize the effects of the PMN 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 that would be designated by this proposed SNUR. The submitter has agreed not to exceed certain time limits without performing specific target organ toxicity or carcinogenic effects testing. The Order’s restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or relevant information.

CFR citation: 40 CFR 721.11207 (P-17-337) and 40 CFR 721.11208 (P-17-338).

PMN Number: P-17-343.

Chemical name: Heteropolycyclic-alkanol carbomonocycle-alkanesulfonate (generic).

CAS Number: Not available.

Effective date of TSCA section 5(e) Order: April 3, 2018.

Basis for TSCA section 5(e) Order: The PMN states that the generic (non-confidential) use of the substance will be as a corrosion inhibitor in aqueous systems. Based on test data on the PMN substance and SAR analysis of analogue data, EPA has identified hazards for eye irritation, developmental toxicity, systemic toxicity, and aquatic toxicity. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to health and the environment.

The Order was also issued under TSCA sections 5(a)(3)(B)(ii)(II) and 5(e)(1)(A)(ii)(II), based on a finding that the substance is or will be produced in substantial quantities and that the substance either enters or may reasonably be anticipated to enter the environment in substantial quantities, or there is or may be significant (or substantial) human exposure to the substance. To protect against these risks, the Order requires:

1. Provide personal protective equipment to its workers to prevent dermal exposure where there is potential for dermal exposure;
 2. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS;
 3. Use of the PMN substance only for the confidential use specified in the PMN;
- and
4. Refrain from manufacturing, processing, or using the PMN substance in a manner that results in inhalation exposure to vapors, dusts, mists or aerosols.

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

Potentially useful information: EPA has determined that certain information about the health and environmental effects of the PMN substance may be potentially useful to characterize the effects of the PMN 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 that would be designated by this proposed SNUR.

EPA has also determined that the results of specific reproductive/developmental toxicity and chronic aquatic toxicity testing would help characterize the potential health effects of the PMN substance. Although the Order does not require these tests, the Order’s

restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or relevant information.

CFR citation: 40 CFR 721.11209.

PMN Number: P-17-354.

Chemical name: (Substituted-dialkyl(C=1~7)silyl)alkanenitrile (generic).

CAS Number: Not available.

Effective date of TSCA section 5(e) Order: March 14, 2018.

Basis for TSCA section 5(e) Order: The PMN states that the generic (non-confidential) use of the substance will be as a solvent in electrolyte solution in batteries which will improve the performance of the batteries in consumer electronics and automotive applications. Based on test data on the PMN substance and SAR analysis of test data on analogous substances, EPA identified hazard for mutagenicity, eye and skin irritation, sensitization, kidney toxicity, reproductive toxicity, developmental toxicity, and aquatic toxicity. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to health and the environment. To protect against these risks, the Order requires:

1. Provide personal protective equipment to its workers to prevent dermal exposure where there is potential for dermal exposure;
2. Use of a NIOSH-certified respirator with an APF of at least 50 to prevent inhalation exposure where there is potential for inhalation exposure;
3. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS;

4. Use of the PMN substance only for the confidential use specified in the Order;
and

5. Dispose of the PMN substance only by incineration with an efficiency not less than 99.9%.

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

Potentially useful information: EPA has determined that certain information about the health effects of the PMN substance may be potentially useful to characterize the effects of the PMN 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 that would be designated by this proposed SNUR. EPA has also determined that the results of specific reproductive toxicity testing would help characterize the potential health effects of the PMN substance. Although the Order does not require this test, the Order’s restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or relevant information.

CFR citation: 40 CFR 721.11210.

PMN Number: P-17-361.

Chemical name: Substituted heteromonocycle, polymer with diisocyanato alkane and alkanediol, substituted heteromonocycle homopolymer ester with substituted alkylacrylate; blocked (generic).

CAS Number: Not available.

Effective date of TSCA section 5(e) Order: April 26, 2018.

Basis for TSCA section 5(e) Order: The PMN states that the use of the substance will be as a dual-cure adhesion coating or barrier. EPA identified concerns for eye and skin irritation, and dermal and respiratory sensitization based on the isocyanate moiety. EPA also identified concerns for liver, kidney, and developmental toxicities, oncogenicity, and mutagenicity based on the presence of acrylates. The Order was issued under sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I) of TSCA, based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health. To protect against these risks, the Order requires:

1. Use of personal protective equipment to prevent dermal exposure where there is a potential for dermal exposure;
2. Use of a NIOSH-certified respirator with an APF of 50 or an APF of 1000 if spray applied where there is a potential for inhalation exposure;
3. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS;
4. Refraining from domestic manufacture in the United States (i.e., import only);
5. Not manufacturing (which under TSCA includes import) the PMN substance with more than 0.25% residual isocyanate;
6. Manufacture (which under TSCA includes import) the PMN substance to have a number average molecular weight of greater than or equal to 2,280 Daltons (weight percent); and
7. Use the PMN substance only as a dual-cure adhesion coating or barrier.

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

Potentially useful information: EPA has determined that certain information about the health effects of the PMN substance may be potentially useful to characterize the effects of the PMN 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 that would be designated by this proposed SNUR. EPA has also determined that the results of skin sensitization testing would help characterize the potential health effects of the PMN substance. Although the Order does not require this testing, the Order’s restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or relevant information.

CFR citation: 40 CFR 721.11211.

PMN Numbers: P-17-401 and P-17-402.

Chemical names: Glycolipids, sophorose-contg., candida bombicola-fermented, from C16-18 and C18-unsatd. glycerides and D-glucose, hydrolyzed, sodium salts (P-17-401) and Glycolipids, sophorose-contg., candida bombicola-fermented, from C16-18 and C18-unsatd. glycerides and D-glucose, hydrolyzed, potassium salts (P-17-402).

CAS Numbers: 2102535-74-8 (P-17-401) and 2102536-64-9 (P-17-402).

Effective date of TSCA section 5(e) Order: April 19, 2018.

Basis for TSCA section 5(e) Order: The PMNs state that the use of the substances will be as a flow-back additive, surfactant for enhanced oil recovery, and foaming agent for well deliquification. Based on physical/chemical properties of the PMN substances, and analysis of test data on the PMN substances, EPA has identified concern for irritation to

eyes, skin, mucous membranes and lungs. There is also concern for lung effects if respirable particulates or droplets are inhaled. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substances may present an unreasonable risk of injury to health and the environment. The Order was also issued under TSCA sections 5(a)(3)(B)(ii)(II) and 5(e)(1)(A)(ii)(II), based on a finding that the substances are or will be produced in substantial quantities and that the substances either enter or may reasonably be anticipated to enter the environment in substantial quantities, or there is or may be significant (or substantial) human exposure to the substances. To protect against these risks, the Order requires:

1. Use of personal protective equipment to prevent dermal exposure where there is a potential for dermal exposure;
2. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS;
3. Refrain from manufacturing (excluding import) of the PMN substances in the United States;
4. Refrain from manufacturing (including import), processing, or using the PMN substances in a manner that would generate vapors, mists, aerosols or dusts; and
5. Refrain from manufacturing, processing, or using the PMN substances for consumer use or for commercial uses that could introduce the substance into a consumer setting.

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

Potentially useful information: EPA has determined that certain information about the physical-chemical properties, environmental effects, and health effects of the PMN substances may be potentially useful to characterize the effects of the PMN substances in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has also determined that the results of specific physical-chemical property acute aquatic toxicity, and acute and chronic pulmonary effects testing would help characterize the potential health effects of the PMN substances. Although the Order does not require this testing, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or relevant information.

CFR citations: 40 CFR 721.11212 (P-17-401) and 40 CFR 721.11213 (P-17-402).

PMN Number: P-17-404.

Chemical name: 2-Propenoic acid, 2-methyl-, 2-(2-butoxyethoxy)ethyl ester, polymer with 1,3-butadiene and 2-propenenitrile.

CAS number: 2058302-39-7

Effective date of TSCA section 5(e) Order: March 27, 2018.

Basis for TSCA section 5(e) Order: The PMN states that the generic (non-confidential) use of the substance will be as an intermediate completely used on site. Based on SAR analysis of test data on analogous high molecular weight polymers, EPA has identified concerns for lung effects. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to

human health. To protect against this risk, the Order requires: No manufacturing, processing, or use of the PMN substance in any manner that generate a spray, mist, aerosol, or respirable particles.

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 about the physical-chemical properties and health effects of the PMN substance may be potentially useful to characterize the effects of the PMN 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 that would be designated by this proposed SNUR. EPA has also determined that the results of particle size testing and acute and chronic pulmonary effects testing would help characterize the potential health effects of the PMN substance. Although the Order does not require these tests, the Order’s restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or relevant information.

CFR citation: 40 CFR 721.11214.

PMN Numbers: P-17-405, P-17-406, P-17-407, P-17-408, P-17-409, P-17-410, P-17-411, P-17-412, P-17-414, P-17-415, P-17-416, P-17-417, P-17-418, P-17-420, P-17-421, P-17-422, P-17-423, P-17-441, P-17-442, P-17-444, P-17-445, P-17-446, P-17-447, P-17-448, P-17-449, P-17-450.

Chemical names and CAS Numbers:

Chemical Names	CAS Numbers
Halogenated benzoic acid ethyl ester (P-17-405)	Not available

Halogenated benzoic acid ethyl ester (P-17-406)	Not available
Halogenated benzoic acid ethyl ester (P-17-407)	Not available
Halogenated benzoic acid ethyl ester (P-17-408)	Not available
Halogenated benzoic acid ethyl ester (P-17-409)	Not available
Halogenated benzoic acid ethyl ester (P-17-410)	Not available
Halogenated benzoic acid ethyl ester (P-17-411)	Not available
Halogenated benzoic acid ethyl ester (P-17-412)	Not available
Halogenated benzoic acid (P-17-414)	Not available
Halogenated benzoic acid (P-17-415)	Not available
Halogenated benzoic acid (P-17-416)	Not available
Halogenated benzoic acid (P-17-417)	Not available
Halogenated benzoic acid (P-17-418)	Not available
Halogenated benzoic acid (P-17-420)	Not available
Halogenated benzoic acid (P-17-421)	Not available
Halogenated benzoic acid (P-17-422)	Not available
Halogenated benzoic acid ethyl ester (P-17-423)	Not available
Halogenated sodium benzoate (P-17-441)	Not available
Halogenated sodium benzoate (P-17-442)	Not available
Halogenated sodium benzoate (P-17-444)	Not available
Halogenated sodium benzoate (P-17-445)	Not available
Halogenated sodium benzoate (P-17-446)	Not available
Halogenated sodium benzoate (P-17-447)	Not available
Halogenated sodium benzoate (P-17-448)	Not available

Halogenated sodium benzoate (P-17-449)	Not available
Halogenated benzoic acid (P-17-450)	Not available

Effective date of TSCA section 5(e) Order: May 17, 2018.

Basis for TSCA section 5(e) Order: The PMNs state that the use of the substances is for oil and gas well performance or monitoring well performance. Based on test data for a structurally analogous chemical and physical/chemical properties, EPA has identified concerns for reproductive toxicity, developmental toxicity, and neurotoxicity (ataxia), lung effects, and skin irritation. Based on SAR analysis for analogous chemicals, predicts toxicity to aquatic organisms may occur at concentrations that exceed 8 ppb for certain PMN substances and 460 ppb for certain other PMN substances. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substances may present an unreasonable risk of injury to health and environment. To protect against these risks, the Order requires:

1. Refrain from using the PMN substances other than for oil and gas well performance or monitoring well performance;
2. Submit to EPA certain toxicity testing before exceeding the specified confidential production volume limits in the Order;
3. No manufacture of the PMN substances beyond an annual confidential production volume specified in the Order;
4. Use of personal protective equipment to prevent dermal exposure where there is a potential for dermal exposure;

5. Use of engineering controls as specified in the Order;
6. Use of a NIOSH certified respirator with an APF of 50 where there is a potential for inhalation exposure or compliance with a NCEL of 0.0184 mg/m^3 as an 8-hour time-weighted average to prevent inhalation exposure for P-17-414 to 418, P-17-420 to 422, and P-17-450;
7. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS;
8. Limit the amount of the PMN substances handled at processing and use sites as specified in the Order;
9. Limit manufacturing and use to liquid formulations for P-17-441 to 442 and P-17-444 to 449;
10. No release of P-17-405 to 412 and P-17-0423 resulting in surface water concentrations that exceed 8 ppb; and
11. No release of P-17-414 to 418, P-17-420-422, P-17-441 to 442 and P-17-444 to 450 resulting in surface water concentrations that exceed 460 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 about the environmental and health effects of the PMN substances may be potentially useful to characterize the effects of the PMN substances in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. The submitter has agreed not to exceed the specified production volume limits without

performing specific reproductive/developmental toxicity testing, pulmonary effect testing and acute aquatic toxicity testing for certain PMN substances. EPA has also determined that the results of additional reproductive/developmental and pulmonary effects testing would help characterize the potential health effects of the PMN substance. The Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or relevant information.

CFR citation: 40 CFR 721.11215 (P-17-405, P-17-406, P-17-407, P-17-408, P-17-409, P-17-410, P-17-411, P-17-412, P-17-423) and 40 CFR 721.11216 (P-17-414, P-17-415, P-17-416, P-17-417, P-17-418, P-17-420, P-17-421, P-17-422, P-17-441, P-17-442, P-17-444, P-17-445, P-17-446, P-17-447, P-17-448, P-17-449, P-17-450).

PMN Numbers: P-17-424, P-17-425, P-17-426, P-17-427, P-17-428, P-17-429, P-17-430, P-17-431, P-17-432, P-17-433, P-17-435, P-17-436, P-17-437, P-17-438, P-17-439, and P-17-440.

Chemical names and CAS Numbers:

Chemical Name	CAS Number
Benzoic acid, 2-chloro-3-methyl-, sodium salt (1:1) (P-17-424)	1708942-16-8
Benzoic acid, 3-chloro-2-methyl-, sodium salt (1:1) (P-17-425)	1708942-17-9
Benzoic acid, 3-chloro-4-methyl-, sodium salt (1:1) (P-17-426)	1708942-15-7
Benzoic acid, 2-chloro-5-methyl-, sodium salt (1:1) (P-17-427)	118537-88-5
Benzoic acid, 4-chloro-2-methyl-, sodium salt (1:1) (P-17-428)	203261-42-1
Benzoic acid, 3-fluoro-2-methyl-, sodium salt (1:1) (P-17-429)	1708942-24-8
Benzoic acid, 3- fluoro-4-methyl-, sodium salt (1:1) (P-17-430)	1805805-74-6
Benzoic acid, 4- fluoro-2-methyl-, sodium salt (1:1) (P-17-431)	1708942-23-7

Benzoic acid, 2- fluoro-4-methyl-, sodium salt (1:1) (P-17-432)	1708942-19-1
Benzoic acid, 2- fluoro-3-methyl-, sodium salt (1:1) (P-17-433)	1708942-18-0
Benzoic acid, 2- fluoro-3-(trifluoromethyl)-, sodium salt (1:1) (P-17-435)	1701446-41-4
Benzoic acid, 2- fluoro-4-(trifluoromethyl)-, sodium salt (1:1) (P-17-436)	1708942-20-4
Benzoic acid, 2- fluoro-6-(trifluoromethyl)-, sodium salt (1:1) (P-17-437)	1708942-21-5
Benzoic acid, 3- fluoro-5-(trifluoromethyl)-, sodium salt (1:1) (P-17-438)	1535169-59-5
Benzoic acid, 4- fluoro-3-(trifluoromethyl)-, sodium salt (1:1) (P-17-439)	1701446-39-0
Benzoic acid, 4- fluoro-2-(trifluoromethyl)-, sodium salt (1:1) (P-17-440)	1708942-22-6

Effective date of TSCA section 5(e) Order: May 7, 2018.

Basis for TSCA section 5(e) Order: The PMNs state the use of the substances will be as tracer chemicals used as a tracer in water solution, or in a solid blend with polymer, or in a solid proppant bead form to measure flow in deep oil-bearing or gas-bearing strata.

Based on test data for an analogous chemical, and physical/chemical properties, EPA has identified toxicity concerns for reproductive toxicity, developmental toxicity, neurotoxicity (ataxia), lung effects, and skin irritation. Based on SAR analysis of test data, EPA identified ecotoxicity hazards at concentrations that exceed 300 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to health and the environment. To protect against these risks, the Order requires:

1. Refrain from manufacturing (excluding import) the PMN substances in the United States;

2. Refrain from using the PMN substances other than as tracers in aqueous solution, or in a solid blend with polymer, or in a solid proppant bead form to measure flow in deep oil-bearing or gas-bearing strata;
3. Limit the amount of the PMN substances handled at processing and use sites to no more than 50 kg/day/site in aggregate for the solid formulations that generate a dust;
4. Provide personal protective equipment to its workers to mitigate dermal exposure to the PMN substances where there is potential for dermal exposure;
5. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS; and
6. No release of the PMN substances resulting in surface water concentrations that exceed 300 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 about the health effects of the PMN substances may be potentially useful to characterize the effects of the PMN substances in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of pulmonary effects, reproductive/developmental toxicity testing and acute aquatic toxicity testing would help characterize the potential health and environmental effects of the PMN substances. Although the Order does not require this

testing, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or relevant information.

CFR citation: 40 CFR 721.11217.

PMN Numbers: P-17-434 and P-17-443.

Chemical name: Benzoic acid, 2, 3, 6-trifluoro, sodium salt (1:1).

CAS Number: 1803845-07-9.

Effective date of TSCA section 5(e) Orders: May 11, 2018.

Basis for TSCA section 5(e) Orders: PMN P-17-434 states that the use of the substance is as a tracer chemical 1) used as a tracer in water solution, 2) when in a solid blend with polymer, or 3) in a solid proppant bead form, all to measure flow in deep oil or gas bearing strata. PMN P-17-443 states that the generic (non-confidential) use of the substance will be to monitor well performance. Based on test data for a structurally analogous chemical and physical/chemical properties, EPA has identified concerns for reproductive toxicity, development toxicity, and neurotoxicity (ataxia), lung effects, and skin irritation. The Orders were issued for under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health. To protect against these risks, the Orders require:

1. Submission of certain toxicity testing before exceeding the confidential production volume limit in the Order for P-17-443;
2. Manufacture the PMN substance only as a liquid formulation with the engineering controls specified in the Order for P-17-443;
3. Refrain from using the PMN substance other than as a tracer in aqueous

solution, a solid blend with polymer, or a solid proppant bead form to measure flow in deep oil-bearing or gas-bearing strata (non-confidential uses specified in the Order for P-17-434), or for the confidential use specified in the Order for P-17-443. The Order for P-17-434 allows processing and use of solid forms of the PMN substance but no more than 50 kg/site/day for those forms that generate a dust. Other manufacturers and processors would need to submit a SNUN to manufacture or process solid forms of the PMN substance.

4. Use of personal protective equipment to mitigate dermal exposure to the PMN substance where there is potential for dermal exposure; and

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

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

Potentially useful information: EPA has determined that certain information about the health effects of the PMN substance may be potentially useful to characterize the effects of the PMN 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 that would be designated by this proposed SNUR. The submitter for P-17-443 has agreed not to exceed a certain aggregated production volume limit without performing specific pulmonary effects testing. EPA has also determined that the results of pulmonary effects and reproductive/developmental toxicity testing would help characterize the potential health effects of the PMN substance. Although the Order does

not require this testing, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or relevant information.

CFR citations: 40 CFR 721.11218.

PMN number: P-18-3.

Chemical name: Fatty acids, diesters with dihydroxyalkane, fatty acids, esters with dihydroxyalkane (generic).

CAS number: Not available.

Effective date of TSCA section 5(e) Order: April 10, 2018.

Basis for TSCA section 5(e) Order: The PMN states that the use of the substance will be as a lubricant for metal working applications. Based on SAR analysis of test data on analogous esters, EPA has identified concerns for sensitization and skin and eye irritation. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the PMN substance may present an unreasonable risk of injury to health and the environment. To protect against these risks, the Order requires:

1. Provide personal protective equipment to its workers to prevent dermal exposure where there is potential for dermal exposure; and
2. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.

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

Potentially useful information: EPA has determined that certain information about the health effects of the PMN substance may be potentially useful to characterize the effects

of the PMN 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 that would be designated by this proposed SNUR. EPA has also determined that the results of specific sensitization testing would help characterize the potential health effects of the PMN substance. Although the Order does not require this test, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or relevant information.

CFR citation: 40 CFR 721.11219.

PMN Number: P-18-22.

Chemical Name: Substituted carbomonocycle, polymer with halo substituted heteromonocycle and polyoxyalkylene polymer with alkylenebis (isocyanatocarbomonocycle) bis (carbomonocycledicarboxylate), reaction products with alkylamines, hydrolyzed (generic).

CAS Number: Not available.

Effective date of TSCA section 5(e) Order: April 20, 2018.

Basis for TSCA section 5(e) Order: The PMN states that the use of the substance will be used as a primer coating used for corrosion protection. Based on the physical/chemical properties of the PMN substance, available PMN data, and comparing the substance to structurally analogous chemical substances, EPA identified concerns for dermal and ocular irritation and sensitization for the low molecular weight fraction of the PMN substance. EPA also identified concerns for ecotoxicity if the substance was manufactured differently. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I) of TSCA, based on a finding that in the absence of sufficient

information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the

Order requires:

1. Refraining from domestic manufacture in the United States (i.e., import only);
2. Use of the PMN substance only for primer coating for corrosion protection;
3. Import the PMN substance with an average molecular weight greater than 1026 daltons and with low weight fractions no more than 15.3% less than 500 daltons and 25% less than 1000 daltons;
4. Use of personal protective equipment where there is a potential for dermal exposure;
5. Use of a NIOSH-certified respirator with an APF of at least 50 where there is a potential for inhalation exposure; and
6. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.

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

Potentially useful information: EPA has determined that certain information about environmental effects and health effects of the PMN substance may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has also determined that the results of skin sensitization, fate property testing, and acute and chronic aquatic toxicity testing would help characterize the potential human and environmental effects of the PMN substance.

Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

CFR citation: 40 CFR 721.11220.

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 all 66 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. 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 Orders, consistent with TSCA section 5(f)(4).

B. Objectives

EPA is proposing these SNURs for specific chemical substances which have undergone premanufacture review because the Agency wants to achieve the following objectives with regard to the significant new uses designated in this rule:

- EPA would 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.

- EPA would have an opportunity 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.

- EPA would be able 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.

- EPA 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 Orders, consistent with TSCA section 5(f)(4).

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 all of the 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 42 of the 66 chemical substances subject to this proposed rule have been claimed as confidential and EPA has not received any post-PMN *bona fide* submission (per §§ 720.25 and 721.11) 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. In developing this proposed rule, EPA has recognized that, given EPA's general practice of posting proposed rules on its website a week or more in advance of **Federal Register** publication, this objective could be thwarted even before **Federal Register** publication of the proposed 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 of 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 (OECD) test guidelines are available from the OECD Bookshop at <http://www.oecdbookshop.org> or SourceOECD at <http://www.sourceoecd.org>.

In certain of the TSCA section 5(e) Orders for the chemical substances that would be regulated under this proposed rule, EPA has established production limits in view of the lack of data on the potential health and environmental risks that may be posed by the significant new uses or increased exposure to the chemical substances. These limits cannot be exceeded unless the PMN submitter first submits the results of specified tests that would permit a reasoned evaluation of the potential risks posed by these chemical substances. Listings of the tests specified in the TSCA section 5(e) Orders are included in Unit IV. The proposed SNURs contain the same production limits as the TSCA section 5(e) Orders. Exceeding these production limits is defined as a significant new use. Persons who intend to exceed the production limit must notify the Agency by submitting a SNUN at least 90 days in advance of commencement of non-exempt commercial manufacture or processing 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.

Any request by EPA for the testing described in the Orders was made based on EPA's consideration of available screening-level data, if any, as well as other available

information on appropriate testing for the PMN substances. Further, any such testing/information request on the part of EPA that includes testing on vertebrates was made after consideration of available toxicity information, computational toxicology and bioinformatics, and high-throughput screening methods and their prediction models.

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.
- Information on risks posed by the chemical substances compared to risks posed by potential substitutes.

VIII. SNUN Submissions

According to § 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 § 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 § 720.40 and § 721.25. E-PMN software is available electronically at

<https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca>.

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 under docket ID number EPA-HQ-OPPT-2018-0650.

X. Statutory and Executive Order Reviews

A. Executive Order 12866

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 Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993).

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 through the use of automated collection techniques, to the Director, Collection Strategies Division, Office of Environmental Information (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 Regulatory Flexibility Act (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, and 14 in FY2017, 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

This proposed rule 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, entitled “Federalism” (64 FR 43255, August 10, 1999).

F. Executive Order 13175

This proposed rule 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 communities of Indian Tribal governments, nor would it involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000), do not apply to this action.

G. Executive Order 13045

This proposed rule is not subject to Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (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

This proposed rule is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001), because this proposed rule is not expected to affect energy supply, distribution, or use and because this proposed rule is not a significant regulatory action under Executive Order 12866.

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

This proposed rule does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

List of Subjects

40 CFR Part 721

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

Dated: October 24, 2018.

Jeffery T. Morris,

Director, Office of Pollution Prevention and Toxics.

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

PART 721--[AMENDED]

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

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

2. Amend Subpart E by adding § 721.11194 through §721.11220 to read as follows:

Subpart E – Significant New Uses for Specific Chemical Substances

Sec.

§ 721.11194 Alkene reaction and distillation by-products and residues (generic).

§ 721.11195 Oxirane, 2-methyl-, polymer with oxirane, monobutyl ether, monoether with propylene oxide-2-[[3-(triethoxysilyl)propoxy)methyl]oxirane polymer.

§ 721.11196 Aliphatic acrylate (generic).

§ 721.11197 Flue dust, glass manufg. Desulfurization. Definition: The dust produced from the flue gas exhaust cleaning of a glass manufacturing process using carbonate containing substances. It consists primarily of Na₂SO₄, Na₂CO₃, and Na₄(SO₄)(CO₃).

§ 721.11198 Organo-titanate (generic).

§ 721.11199 Dialkyl 7,10-dioxa, dithiahexadeca diene (generic).

§ 721.11200 Haloalkyl substituted carbomonocycle (generic).

§ 721.11201 Amine- and hydroxy-functional acrylic polymer, neutralized (generic).

§ 721.11202 Amine- and hydroxy-functional acrylic polymer (generic).

§ 721.11203 Hydroxy acrylic polymer, methanesulfonates (generic).

- § 721.11204 Alkyl perfluorinated acryloyl ester (generic).
- § 721.11205 Poly(oxy-1,2-ethanediyl), .alpha.-(2-methyl-2-propen-1-yl)-.omega.-hydroxy-.
- § 721.11206 Alkylidene dicarbomonocycle, polymer with halo-substituted heteromonocycle and disubstituted alkyl carbomonocycle alkenedioate alkylalkenoate (generic).
- § 721.11207 Aluminum boron cobalt lithium nickel oxide.
- § 721.11208 Aluminum boron cobalt lithium magnesium nickel oxide.
- § 721.11209 Heteropolycyclic-alkanol carbomonocycle-alkanesulfonate (generic).
- § 721.11210 (Substituted-dialkyl(C=1~7)silyl)alkanenitrile (generic).
- § 721.11211 Substituted heteromonocycle, polymer with diisocyanato alkane and alkanediol, substituted heteromonocycle homopolymer ester with substituted alkylacrylate; blocked (generic).
- § 721.11212 Glycolipids, sophorose-contg., candida bombicola-fermented, from C16-18 and C18-unsatd. glycerides and D-glucose, hydrolyzed, sodium salts.
- § 721.11213 Glycolipids, sophorose-contg., candida bombicola-fermented, from C16-18 and C18-unsatd. glycerides and D-glucose, hydrolyzed, potassium salts.
- § 721.11214 2-Propenoic acid, 2-methyl-, 2-(2-butoxyethoxy)ethyl ester, polymer with 1,3-butadiene and 2-propenenitrile.
- § 721.11215 Halogenated benzoic acid ethyl ester (generic).
- § 721.11216 Halogenated benzoic acid (generic).
- § 721.11217 Certain halogenated sodium benzoate salts.
- § 721.11218 Benzoic acid, 2, 3, 6-trifluoro, sodium salt (1:1).

§ 721.11219 Fatty acids, diesters with dihydroxyalkane, fatty acids, esters with dihydroxyalkane (generic).

§ 721.11220 Substituted carbomonocycle, polymer with halo substituted heteromonocycle and polyoxyalkylene polymer with alkylenebis (isocyanatocarbomonocycle) bis (carbomonocycledicarboxylate), reaction products with alkylamines, hydrolyzed, (generic).

Subpart E – Significant New Uses for Specific Chemical Substances

§ 721.11194 Alkene reaction and distillation by-products and residues (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as alkene reaction and distillation by-products and residues (P-15-106) 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), (2)(i), (iii), (a)(3), (a)(4), (a)(5) (respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 10, (when determining which persons are reasonable likely to be exposed as required for § 721.63 (a)(1), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposures, where feasible), (a)(6)(v), (vi), (b)(concentration set at 1.0%), and (c).

(A) As an alternative to the respirator requirements in paragraph (a)(2)(i) of this section, a manufacturer or processor may choose to follow the new chemical exposure limit (NCEL) provision listed in the TSCA section 5(e) Order for this substance. The NCEL is 2 mg/m^3 as an 8-hour time weighted average. Persons who wish to pursue NCELS as an alternative to § 721.63 respirator requirements may request to do so under § 721.30. Persons whose § 721.30 requests to use the NCELS approach are approved by EPA will be required to follow NCELS provisions comparable to those contained in the corresponding TSCA section 5(e) Order.

(B) [Reserved].

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e)(concentration set at 1.0%), (f), (g)(1)(i), (ii), (ix), (g)(2)(i), (ii), (iv), (v), (use respiratory protection or maintain workplace airborne concentrations at or below an 8-hour time-weighted average of 2 mg/m^3), (g)(3)(ii), (g)(4)(do not release to water at concentrations that exceed 1 ppb), and (g)(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.* Requirements as specified in § 721.80(q).

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

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

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

(2) *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)(iii) of this section.

§ 721.11195 Oxirane, 2-methyl-, polymer with oxirane, monobutyl ether, monoether with propylene oxide-2-[[3-(triethoxysilyl)propoxy]methyl]oxirane polymer.

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified as oxirane, 2-methyl-, polymer with oxirane, monobutyl ether, monoether with propylene oxide-2-[[3-(triethoxysilyl)propoxy]methyl]oxirane polymer (P-15-726, CAS No. 1644400-33-8) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been reacted (cured).

(2) The significant new uses are:

(i) *Hazard communication*. Requirements as specified in § 721.72(a) through (e)(concentration set at 1.0%), (f), (g)(1)(ii), (2)(ii), and (g)(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. It is a significant new use to manufacture, process, or use the substance in any manner that generates a vapor, dust, mist, or aerosol.

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

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

§ 721.11196 Aliphatic acrylate (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as aliphatic acrylate (P-16-337) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified § 721.63(a)(1), (2)(i), (iii), (iv), (a)(3), (a)(4), (a)(5)(respirators must provide a National Institute for Occupational Safety and Health with assigned protection factor of at least 50), (when determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) and (4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g.,

workplace policies and procedures) shall be considered and implemented to prevent exposure where feasible), (a)(6)(v), (vi), (particulate), (b)(concentration set at 0.1%) and (c).

(ii) *Hazard communication*. Requirements as specified in § 721.72(a) through (e)(concentration set at 0.1%), (f), (g)(1)(i), (ii), (iv), (vii), (ix), (g)(2)(i), (ii), (iii), (iv), (v), (g)(3)(i), (ii), (g)(4)(release restrictions apply), and (g)(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*. Requirements as specified in § 721.80(g).

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

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

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

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

§ 721.11197 Flue dust, glass manufg. Desulfurization. Definition: The dust produced from the flue gas exhaust cleaning of a glass manufacturing process using carbonate containing substances. It consists primarily of Na_2SO_4 , Na_2CO_3 , and $\text{Na}_4(\text{SO}_4)(\text{CO}_3)$.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as flue dust, glass manufg. Desulfurization. Definition: The dust produced from the flue gas exhaust cleaning of a glass manufacturing process using carbonate containing substances. It consists primarily of Na₂SO₄, Na₂CO₃, and Na₄(SO₄)(CO₃) (P-16-421, CAS No. 1916486-36-6) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely incorporated into a glass product.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (3), (4), (5)(respirators must provide a National Institute for Occupational Safety and Health assigned protection factor of at least 50 or when the PMN substance is in a mixture at a concentration below 1.0 percent by weight, an APF of 10), (when determining which persons are reasonable 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 exposures, where feasible), (a)(6)(v), (vi), (particulate), and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (d), (f), (g)(1)(iii), (iv), (vi), (ix), (cardiovascular effects), (g)(2)(i), (ii), (iii), (iv), (v), and (g)(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.* Requirements as specified in § 721.80(h). It is a significant new use to modify the processes or uses described in the premanufacture notice such that occupational exposure is increased. It is a significant new use to manufacture the substance with an elemental composition different from that described in the PMN.

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

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

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

§ 721.11198 Organo-titanate (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as organo-titanate (P-16-600) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

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

workplace policies and procedures) shall be considered and implemented to prevent exposures, where feasible), (a)(6)(particulate), (b)(concentration set at 0.1%), and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e)(concentration set at 0.1%), (f), (g)(1)(vii), (g)(2)(i), (v), (g)(3)(ii), (g)(4)(iii), and (g)(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.* Requirements as specified in § 721.80(k). It is a significant new use to process or use the substance involving an application method that generates a vapor, mist, or aerosol.

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

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

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

(2) *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)(iii) of this section.

§ 721.11199 Dialkyl 7,10-dioxa, dithiahexadeca diene (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as dialkyl 7,10-dioxa, dithiahexadeca diene (P-

17-7) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (2)(i), (iii), (iv), (when determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible), (a)(3), (a)(6)(v), (vi), (particulate), (b)(concentration set at 0.1%), and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e)(concentration set at 0.1%), (f), (g)(1)(iv), (vi), (vii), (ix), (skin sensitization), (respiratory sensitization), (g)(2)(i), (ii), (iii), (v), (g)(3)(i), (ii), (g)(4)(i), (g)(5).

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

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(g). It is a significant new use to manufacture, process, or use the substance involving an application method that generates a vapor, mist, dust, or aerosol.

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where $N = 67$.

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

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

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

§ 721.11200 Haloalkyl substituted carbomonocycle (generic).

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified generically as haloalkyl substituted carbomonocycle (P-17-49) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace*. Requirements as specified § 721.63(a)(1), (2)(i),(ii), (iii), (iv), (a)(3), (a)(4), (a)(5)(respirators must provide a National Institute for Occupational Safety and Health with assigned protection factor of at least 10), (when determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) and (4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure where feasible), (a)(6)(particulate) and (c).

(ii) *Hazard communication*. Requirements as specified in § 721.72(a) through (d), (f), (g)(1)(ix), (irritation), (sensitization), (liver toxicity), (mutagenicity), (g)(2)(i), (ii), (iii), (iv), (v), (g)(4)(i), (iii), and (g)(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.* Requirements as specified in § 721.80(f), (k), and (t). It is a significant new use to use the substance without the confidential engineering controls specified in the Order.

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

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

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

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

(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)(iii) of this section.

§ 721.11201 Amine- and hydroxy-functional acrylic polymer, neutralized (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as amine- and hydroxy-functional acrylic polymer, neutralized (P-17-249), is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely entrained in dried coating.

(2) The significant new uses are:

(i) *Hazard communication Requirements* as specified in § 721.72(a) through (e)(concentration set at 1%), (f), (g)(1)(ii), (g)(2)(ii), (g)(3)(ii), (g)(4)(i), (do not release to water without pre-treatment of water releases at an onsite waste water treatment plant with at least 96% efficiency), and (g)(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). It is a significant new use to use the substance without the confidential engineering controls specified in the Order. It is a significant new use to manufacture or use the substance with methods that generate a dust, spray, mist, or aerosol.

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

(iv) *Release to water.* Requirements as specified in § 721.90. It is a significant new use to release to water without pretreatment at an on-site wastewater treatment plant with at least 96% efficiency.

(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 (f) through (k) are applicable to manufacturers, importers, 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.

§ 721.11202 Amine- and hydroxy-functional acrylic polymer (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as amine- and hydroxy-functional acrylic polymer (P-17-380), is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely entrained in dried coating.

(2) The significant new uses are:

(i) *Hazard communication Requirements* as specified in § 721.72(a) through (e)(concentration set at 1%), (f), (g)(1)(ii), (g)(2)(ii), (g)(3)(ii), (g)(4)(i), (do not release to water without pre-treatment of water releases at an onsite waste water treatment plant with at least 96% efficiency), and (g)(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). It is a significant new use to use the substance without the confidential engineering controls specified in the Order. It is a significant new use to manufacture or use the substance with methods that generate a dust, spray, mist, or aerosol.

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

(iv) *Release to water.* Requirements as specified in § 721.90. It is a significant new use to release to water without pretreatment at an on-site wastewater treatment plant with at least 96% efficiency.

(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 (f) through (k) are applicable to manufacturers, importers, 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.

§ 721.11203 Hydroxy acrylic polymer, methanesulfonates (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as hydroxy acrylic polymer, methanesulfonates (P-17-381), is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely entrained in dried coating.

(2) The significant new uses are:

(i) *Hazard communication* Requirements as specified in § 721.72(a) through (e)(concentration set at 1%), (f), (g)(1)(ii), (g)(2)(ii), (g)(3)(ii), (g)(4)(i), (do not release to water without pre-treatment of water releases at an onsite waste water treatment plant

with at least 96% efficiency), and (g)(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). It is a significant new use to use the substance without the confidential engineering controls specified in the Order. It is a significant new use to manufacture or use the substance with methods that generate a dust, spray, mist, or aerosol.

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

(iv) *Release to water.* Requirements as specified in § 721.90. It is a significant new use to release to water without pretreatment at an on-site wastewater treatment plant with at least 96% efficiency.

(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 (f) through (k) are applicable to manufacturers, importers, 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.

§ 721.11204 Alkyl perfluorinated acryloyl ester (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as alkyl perfluorinated acryloyl ester (P-17-270) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted (cured).

(2) The significant new uses are:

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

(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, importers, 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.

§ 721.11205 Poly(oxy-1,2-ethanediyl), .alpha.-(2-methyl-2-propen-1-yl)-.omega.-hydroxy-

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as poly(oxy-1,2-ethanediyl), .alpha.-(2-methyl-2-propen-1-yl)-.omega.-hydroxy- (P-17-271, CAS No. 31497-33-3) 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 substances after they have been reacted (cured).

(2) The significant new uses are:

(i) *Hazard communication.* Requirements as specified in § 721.72(a) through (e)(concentration set at 1.0 %), (f), (g)(1)(ii), (g)(2)(ii), (iii), and (g)(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(f). It is a significant new use to use the substance other than as a polymer intermediate. It is a significant new use to manufacture, process or use the substance in a manner that generates a vapor, mist, or aerosol, or that results in inhalation exposure.

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

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (f) through (i).

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

§ 721.11206 Alkyldene dicarbomonocycle, polymer with halo-substituted heteromonocycle and disubstituted alkyl carbomonocycle alkenedioate alkylalkenoate (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as alkyldene dicarbomonocycle, polymer with

halo-substituted heteromonocycle and disubstituted alkyl carbomonocycle alkenedioate alkylalkenoate (P-17-304) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after it has been reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified § 721.63(a)(1), (a)(2)(i), (a)(3), (when determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure where feasible), (a)(6)(v), (vi), (particulate), (b)(concentration set at 1.0%) and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e)(concentration set at 1.0%), (f), (g)(1)(ii),(skin sensitization), (g)(2)(i), (ii), (v), and (g)(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.* Requirements as specified in § 721.80(f). It is a significant new use to use the substance other than as an intermediate for thermoset plastic material. It is a significant new use to manufacture (includes importing) the substance to contain more than 0.1 % residual isocyanate by weight.

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

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

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

§ 721.11207 Aluminum boron cobalt lithium nickel oxide.

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified as aluminum boron cobalt lithium nickel oxide (P-17-337, CAS No. 207803-51-8) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace*. Requirements as specified in § 721.63(a)(1), (2)(i), (ii), (a)(3)(i), (ii), (a)(4), (a)(5), (respirators must provide a National Institute for Occupational Safety and Health assigned protection factor of at least 1,000), (when determining which persons are reasonable likely to be exposed as required for § 721.63 (a)(1), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposures, where feasible), (b)(concentration set at 0.1%), and (c).

(A) As an alternative to the respirator requirements in paragraph (a)(2)(i) of this section, a manufacturer or processor may choose to follow the new chemical exposure limit (NCEL) provision listed in the TSCA section 5(e) Order for this substance. The NCEL 0.000092 mg/m³ as an 8-hour time weighted average. Persons who wish to pursue NCELS as an alternative to § 721.63 respirator requirements may request to do so under §

721.30. Persons whose § 721.30 requests to use the NCELS approach are approved by EPA will be required to follow NCELS provisions comparable to those contained in the corresponding TSCA section 5(e) Order.

(B) [Reserved].

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e), (concentration set at 0.1%), (f), (g)(1)(i), (vii), (damage to the lung, kidney, and spleen), (g)(2)(i), (iii), (iv), (use respiratory protection or maintain workplace airborne concentrations at or below an 8-hour time-weighted average of 0.000092 mg/m³), (avoid breathing substance in the dust form), and (g)(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 the substance beyond two years. It is a significant new use to manufacture or process the substance at any facility unless all process air streams containing the substances pass through control technology such as a high-efficiency particulate air filter with a rated removal efficiency of at least 99.99%.

(iv) *Disposal.* Requirements as specified in § 721.85(a)(2), (b)(2), and (c)(2). It is a significant new use to dispose of the substances by metal reclamation unless the person reclaiming metal containing the substances complies with this section. It is a significant new use to release the substances to air unless the chemical transfer and air ventilation processes specified in the order are followed.

(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 (j) are applicable to manufacturers, importers, and processors of these substances.

(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)(iv) of this section.

§ 721.11208 Aluminum boron cobalt lithium magnesium nickel oxide.

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified as aluminum boron cobalt lithium magnesium nickel oxide (P-17-338, CAS No. 2087499-33-8) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace*. Requirements as specified in § 721.63(a)(1), (2)(i), (ii), (a)(3)(i), (ii), (a)(4), (a)(5), (respirators must provide a National Institute for Occupational Safety and Health assigned protection factor of at least 1,000), (when determining which persons are reasonable likely to be exposed as required for § 721.63(a)(1), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposures, where feasible), (b)(concentration set at 0.1%), and (c).

(A) As an alternative to the respirator requirements in paragraph (a)(2)(i) of this section, a manufacturer or processor may choose to follow the new chemical exposure

limit (NCEL) provision listed in the TSCA section 5(e) Order for this substance. The NCEL 0.000092 mg/m³ as an 8-hour time weighted average. Persons who wish to pursue NCELS as an alternative to § 721.63 respirator requirements may request to do so under § 721.30. Persons whose § 721.30 requests to use the NCELS approach are approved by EPA will be required to follow NCELS provisions comparable to those contained in the corresponding TSCA section 5(e) Order.

(B) [Reserved].

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e), (concentration set at 0.1%), (f), (g)(1)(i), (vii), (damage to the lung, kidney, and spleen), (g)(2)(i), (iii), (iv), (use respiratory protection or maintain workplace airborne concentrations at or below an 8-hour time-weighted average of 0.000092 mg/m³), (avoid breathing substance in the dust form), and (g)(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 the substance beyond two years. It is a significant new use to manufacture or process the substances at any facility unless all process air streams containing the substances pass through control technology such as a high-efficiency particulate air filter with a rated removal efficiency of at least 99.99%.

(iv) *Disposal.* Requirements as specified in § 721.85(a)(2), (b)(2), and (c)(2). It is a significant new use to dispose of the substances by metal reclamation unless the person reclaiming metal containing the substances complies with this section. It is a significant

new use to release the substances to air unless the chemical transfer and air ventilation processes specified in the order are followed.

(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 (j) are applicable to manufacturers, importers, and processors of these substances.

(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)(iv) of this section.

§ 721.11209 Heteropolycyclic-alkanol carbomonocycle-alkanesulfonate (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as heteropolycyclic-alkanol carbomonocycle-alkanesulfonate (PMN P-17-343) 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), (a)(2)(i), (iii), (a)(3), (when determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented

to prevent exposure, where feasible), (a)(6)(particulate), (b)(concentration set at 1.0%) and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e)(concentration set at 1.0%), (f), (g)(1)(i), (vi), (ix), (eye irritation), (systemic effects), (g)(2)(i), (ii), (iii), (v), (g)(3)(i), (ii), and (g)(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.* Requirements as specified in § 721.80(k). It is a significant new use to manufacture, process or use the substance in a manner that results in inhalation exposure to a vapor, mist, dust or aerosol.

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

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) are applicable to manufacturers 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)(iii) of this section.

§ 721.11210 (Substituted-dialkyl(C=1~7)silyl)alkanenitrile (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as (substituted-dialkyl(C=1~7)silyl) alkanenitrile (PMN P-17-354) 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), (a)(2)(i), (iii), (a)(3), (a)(4), (a)(5)(respirators must provide a National Institute for Occupational Safety and Health with assigned protection factor of at least 50), (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), (a)(6)(v), (vi), (particulate), (b)(concentration set at 1.0%) and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e)(concentration set at 1.0%), (f), (g)(1)(ii), (iv), (vi), (ix), (skin and eye irritation), (sensitization), (mutagenicity), (g)(2)(i), (ii), (iii), (iv), (v), (use eye protection), (g)(3)(i), (ii), (g)(4)(i), (iii), and (g)(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.* Requirements as specified in § 721.80(k).

(iv) *Disposal.* Requirements as specified in § 721.85(a)(1), (b)(1), and (c)(1)(waste streams from use must be disposed of only by incineration with no less than 99.9% efficiency).

(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 (j) 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)(iii) of this section.

§ 721.11211 Substituted heteromonocycle, polymer with diisocyanato alkane and alkanediol, substituted heteromonocycle homopolymer ester with substituted alkylacrylate; blocked (generic).

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified generically as substituted heteromonocycle, polymer with diisocyanato alkane and alkanediol, substituted heteromonocycle homopolymer ester with substituted alkylacrylate; blocked (P-17-361) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace*. Requirements as specified in § 721.63(a)(1), (2)(i), (3), (4), (5), (respirators must provide a National Institute for Occupational Safety and Health with assigned protection factor (APF) of at least 50 or an APF of at least 1,000 if spray applied), (when determining which persons are reasonable 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 exposures, where feasible), (a)(6)(v), (vi), (particulate), (b)(concentration set at 0.1%), and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e)(concentration set at 0.1%), (f), (g)(1)(i), (vii), (ix), (sensitization), (systemic effects), (g)(2)(i), (ii), (iii), (v), and (g)(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.* Requirements as specified in § 721.80(f). It is a significant new use to manufacture the substance containing greater than 0.25% residual isocyanate or an average molecular weight less than 2,280 daltons. It is a significant new use to use the substance other than as a dual-cure adhesion coating or barrier.

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

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

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

§ 721.11212 Glycolipids, sophorose-contg., candida bombicola-fermented, from C16-18 and C18-unsatd. glycerides and D-glucose, hydrolyzed, sodium salts.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as glycolipids, sophorose-contg., candida bombicola-

fermented, from C16-18 and C18-unsatd. glycerides and D-glucose, hydrolyzed, sodium salts (P-17-401, CAS No. 2102535-74-8) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i), (iii), (a)(3), (when determining which persons are reasonably likely to be exposed as required for § 721.63 (a)(1), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible), (a)(6)(v), (vi), (particulate), (b)(concentration set at 1.0%), and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.72 (a) through (e)(concentration set at 1.0%), (f), (g)(1)(i), (ii), (eye irritation), (g)(2)(i), (ii), (iii), (v), and (g)(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.* Requirements as specified in § 721.80(f). It is a significant new use to manufacture, process, or use the substance for consumer use or for commercial uses that could introduce the substance into a consumer setting. It is a significant new use to manufacture, process, or use the substance in any manner that results in generation of a vapor, dust, mist or aerosol.

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

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

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

§ 721.11213 Glycolipids, sophorose-contg., candida bombicola-fermented, from C16-18 and C18-unsatd. glycerides and D-glucose, hydrolyzed, potassium salts.

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified as glycolipids, sophorose-contg., Candida bombicola-fermented, from C16-18 and C18-unsatd. glycerides and D-glucose, hydrolyzed, sodium salts (P-17-402, CAS No. 2102536-64-9) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace*. Requirements as specified in § 721.63 (a)(1), (2)(i), (iii), (a)(3), (when determining which persons are reasonably likely to be exposed as required for § 721.63 (a)(1), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible), (a)(6)(v), (vi), (particulate), (b)(concentration set at 1.0%), and (c).

(ii) *Hazard communication*. Requirements as specified in § 721.72(a) through (e)(concentration set at 1.0%), (f), (g)(1)(i), (ii), (eye irritation), (g)(2)(i), (ii), (iii), (v), and (g)(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.* Requirements as specified in § 721.80(f). It is a significant new use to manufacture, process, or use the substance for consumer use or for commercial uses that could introduce the substance into a consumer setting. It is a significant new use to manufacture, process, or use the substance in any manner that results in generation of a vapor, dust, mist or aerosol.

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

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

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

§ 721.11214 2-Propenoic acid, 2-methyl-, 2-(2-butoxyethoxy)ethyl ester, polymer with 1,3-butadiene and 2-propenenitrile.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 2-propenoic acid, 2-methyl-, 2-(2-butoxyethoxy)ethyl ester, polymer with 1,3-butadiene and 2-propenenitrile (PMN P-17-404, CAS No. 2058302-39-7) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been reacted (cured).

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80. It is a significant new use to manufacture, process, or use the substance in any manner that results in the generation of spray, mist, aerosol, or respirable particles.

(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.

§ 721.11215 Halogenated benzoic acid ethyl ester (generic).

(a)(1) The chemical substances identified generically in the table of this section are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

Table – Halogenated benzoic acid ethyl esters

PMN Number	Chemical Name
P-17-405	Halogenated benzoic acid ethyl ester
P-17-406	Halogenated benzoic acid ethyl ester
P-17-407	Halogenated benzoic acid ethyl ester
P-17-408	Halogenated benzoic acid ethyl ester
P-17-409	Halogenated benzoic acid ethyl ester
P-17-410	Halogenated benzoic acid ethyl ester
P-17-411	Halogenated benzoic acid ethyl ester
P-17-412	Halogenated benzoic acid ethyl ester
P-17-423	Halogenated benzoic acid ethyl ester

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (2)(i), (iv), (3), (4), (when determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible), (a)(6)(v), (vi), (particulate), (b)(concentration set at 1.0%) and (c).

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(q) and (t). It is a significant new use to use the substances other than for oil and gas well performance. It is a significant new use to manufacture or process the substances without the engineering controls specified in the Order. It is a significant new use to exceed the kilograms per day limit specified in the Order of the substances handled at processing and use sites.

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where $N = 8$.

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

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

§ 721.11216 Halogenated benzoic acid (generic).

(a)(1) The chemical substances identified generically in the table of this section are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

Table –Halogenated benzoic acids

PMN number	Chemical Name
P-17-414	Halogenated benzoic acid
P-17-415	Halogenated benzoic acid
P-17-416	Halogenated benzoic acid
P-17-417	Halogenated benzoic acid
P-17-418	Halogenated benzoic acid
P-17-420	Halogenated benzoic acid
P-17-421	Halogenated benzoic acid
P-17-422	Halogenated benzoic acid
P-17-441	Halogenated sodium benzoate
P-17-442	Halogenated sodium benzoate
P-17-444	Halogenated sodium benzoate
P-17-445	Halogenated sodium benzoate
P-17-446	Halogenated sodium benzoate
P-17-447	Halogenated sodium benzoate
P-17-448	Halogenated sodium benzoate

P-17-449	Halogenated sodium benzoate
P-17-450	Halogenated benzoic acid

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i), (iv), (a)(3), (a)(4), (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), (a)(5) (respirators must provide a National Institute for Occupational Safety and Health with assigned protection factor of at least 50), (respirators are only required for P17-414 to P17-418, P17-420 to P17-422, and P17-450), (a)(6)(v), (vi), (particulate), (b)(concentration set at 1.0%) and (c).

(A) As an alternative to the respirator requirements in paragraph (a)(2)(i) of this section, a manufacturer or processor may choose to follow the new chemical exposure limit (NCEL) provision listed in the TSCA section 5(e) Order for the substances. The NCEL is 0.0184 mg/m³ as an 8-hour time weighted average. Persons who wish to pursue NCELS as an alternative to § 721.63 respirator requirements may request to do so under § 721.30. Persons whose § 721.30 requests to use the NCELS approach are approved by EPA will be required to follow NCELS provisions comparable to those contained in the corresponding TSCA section 5(e) Order.

(B) [Reserved].

(ii) *Hazard communication.* Requirements as specified in § 721.72 (a) through (e)(concentration set at 1.0%), (f), (g)(1)(i), (ii), (iii), (iv), (vi), (ix), (g)(2)(i), (ii), (iii), (v), (iv)(use respiratory protection or maintain workplace airborne concentration at or below an 8-hour time-weighted average of 0.0184 mg/m³) (This statement only required for P17-414 to P17-418, P17-420 to P17-422, and P17-450), (g)(3)(i), (ii), and (g)(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.* Requirements as specified in § 721.80(q) and (t). It is a significant new use to use the substances other than for monitoring well performance. It is a significant new use to manufacture or process the substances without the engineering controls specified in the Order. It is a significant new use to exceed the kilograms per day limit specified in the Order of the substances handled at processing and use sites. It is a significant new use to use P17-441 to 442 and P17-444 to P17-449 other than in a liquid formulation.

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

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

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

§ 721.11217 Certain halogenated sodium benzoate salts.

(a)(1) The chemical substances listed in the table of this section are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

Table – Halogenated sodium benzoate salts

PMN Number	CAS Number	Chemical Name
P-17-424	1708942-16-8	Benzoic acid, 2-chloro-3-methyl-, sodium salt (1:1)
P-17-425	1708942-17-9	Benzoic acid, 3-chloro-2-methyl-, sodium salt (1:1)
P-17-426	1708942-15-7	Benzoic acid, 3-chloro-4-methyl-, sodium salt (1:1)
P-17-427	118537-88-5	Benzoic acid, 2-chloro-5-methyl-, sodium salt (1:1)
P-17-428	203261-42-1	Benzoic acid, 4-chloro-2-methyl-, sodium salt (1:1)
P-17-429	1708942-24-8	Benzoic acid, 3-fluoro-2-methyl-, sodium salt (1:1)
P-17-430	1805805-74-6	Benzoic acid, 3- fluoro-4-methyl-, sodium salt (1:1)
P-17-431	1708942-23-7	Benzoic acid, 4- fluoro-2-methyl-, sodium salt (1:1)
P-17-432	1708942-19-1	Benzoic acid, 2- fluoro-4-methyl-, sodium salt (1:1)
P-17-433	1708942-18-0	Benzoic acid, 2- fluoro-3-methyl-, sodium salt (1:1)
P-17-435	1701446-41-4	Benzoic acid, 2- fluoro-3-(trifluoromethyl)-, sodium salt (1:1)
P-17-436	1708942-20-4	Benzoic acid, 2- fluoro-4-(trifluoromethyl)-, sodium salt (1:1)
P-17-437	1708942-21-5	Benzoic acid, 2- fluoro-6-(trifluoromethyl)-, sodium salt

		(1:1)
P-17-438	1535169-59-5	Benzoic acid, 3- fluoro-5-(trifluoromethyl)-, sodium salt (1:1)
P-17-439	1701446-39-0	Benzoic acid, 4- fluoro-3-(trifluoromethyl)-, sodium salt (1:1)
P-17-440	1708942-22-6	Benzoic acid, 4- fluoro-2-(trifluoromethyl)-, sodium salt (1:1)

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i), (iv), (a)(3), (when determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible), (a)(6)(v), (vi), (particulate), (b)(concentration set at 1.0%), and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e)(concentration set at 1.0%), (f), (g)(1)(i), (iii), (iv), (vi), (ix), (g)(2)(i), (ii), (iii), (v), (g)(3)(i), (ii), and (g)(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.* Requirements as specified in § 721.80(f). It is a significant new use to handle at a processing or use site more than 50

kilograms per day per site in aggregate of the PMN substances for solid formulations that generate a dust. It is a significant new use to use the substances other than as tracers in aqueous solution, in solid blends with polymers, or in a solid proppant bead forms to measure flow in deep oil-bearing or gas-bearing strata.

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where $N = 300$.

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

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

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

§ 721.11218 Benzoic acid, 2, 3, 6-trifluoro, sodium salt (1:1).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified benzoic acid, 2, 3, 6-trifluoro, sodium salt (1:1) (P-17-434 and P-17-443, CAS No. 1803845-07-9) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

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

to prevent exposure, where feasible), (a)(6)(v), (vi), (particulate), (b)(concentration set at 1.0%), and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e)(concentration set at 1.0%), (f), (g)(1)(i), (iii), (iv), (vi), (ix), (g)(2)(i), (ii), (iii), (v), and (g)(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.* Requirements as specified in § 721.80(q). It is a significant new use to manufacture the substance other than in a liquid formulation and without the confidential engineering controls specified in the Order for P-17-443. It is a significant new use new use to use the substance other than as a tracer in aqueous solution, a solid blend with polymer, or a solid proppant bead form to measure flow in deep oil-bearing or gas-bearing strata or for the confidential use specified in the Order for P-17-443.

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

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) are applicable to manufacturers 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)(iii) of this section.

§ 721.11219 Fatty acids, diesters with dihydroxyalkane, fatty acids, esters with dihydroxyalkane (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as fatty acids, diesters with dihydroxyalkane, fatty acids, esters with dihydroxyalkane (PMN P-18-3) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i), (iii), (iv), (a)(3), (when determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible), (a)(6)(v), (vi), (particulate), (b)(concentration set at 1.0%) and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.72 (a) through (e)(concentration set at 1.0%), (f), (g)(1), (skin and eye irritation and sensitization), (g)(2)(i), (ii), (iii), (v), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(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 (h) 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.

§ 721.11220 Substituted carbomonocycle, polymer with halo substituted heteromonocycle and polyoxyalkylene polymer with alkylenebis (isocyanatocarbomonocycle) bis (carbomonocycledicarboxylate), reaction products with alkylamines, hydrolyzed, (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as substituted carbomonocycle, polymer with halo substituted heteromonocycle and polyoxyalkylene polymer with alkylenebis(isocyanatocarbomonocycle) bis (carbomonocycledicarboxylate), reaction products with alkylamines, hydrolyzed, (P-18-22) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i), (iii), (iv), (a)(3), (a)(4), (a)(5)(respirators must provide a National Institute for Occupational Safety and Health with assigned protection factor of at least 50), (when determining which persons are reasonable 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 exposures, where feasible), (a)(6)(particulate), and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (d), (f), (g)(1)(ii), (irritation to skin, eyes, lungs, and mucous membranes), (g)(2)(i), (ii), (iii), (iv), (v), (avoid eye contact), and (g)(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.* Requirements as specified in § 721.80(f). It is a significant new use to use the substance other than as primer coating used for corrosion protection. It is a significant new use to import the substance with an average molecular weight greater less than 1026 daltons, and with low weight fractions greater than 15.3% less than 500 daltons and 25% less than 1000 daltons.

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

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

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