

TABLE 1 TO PARAGRAPH (b)—HUMAN HEALTH CRITERIA FOR WASHINGTON

| A                                      |          | B                                      |                                       |                               |                                       |  | C                        |                            |
|--|----------|--|---------------------------------------|-------------------------------|---------------------------------------|--|--------------------------|----------------------------|
| Chemical                               | CAS No.  | Cancer Slope factor, CSF (per mg/kg-d) | Relative source contribution, RSC (-) | Reference dose, RfD (mg/kg-d) | Bio-accumulation factor (L/kg tissue) | Bio-concentration factor (L/kg tissue) | Water & organisms (µg/L) | Organisms only (µg/L)      |
|  |          | (B1)                                   | (B2)                                  | (B3)                          | (B4)                                  | (B5)                                   | (C1)                     | (C2)                       |
| 1. Arsenic** .....                     | 7440382  | 1.75                                   |                                       |                               |                                       | 44                                     | <sup>a</sup> 0.018       | <sup>a</sup> 0.14          |
| 2. Bis(2-Chloro-1-Methylethyl) Ether*. | 108601   | 0.50                                   |                                       | 0.04                          | 10                                    |  | 400                      | 900.                       |
| 3. Methylmercury .....                 | 22967926 |  | 2.7E-05                               | 0.0001                        |                                       |  |                          | <sup>b</sup> 0.03 (mg/kg). |

<sup>a</sup> This criterion refers to the inorganic form of arsenic only.

<sup>b</sup> This criterion is expressed as the fish tissue concentration of methylmercury (mg methylmercury/kg fish). See *Water Quality Criterion for the Protection of Human Health: Methylmercury* (EPA-823-R-01-001, January 3, 2001) for how this value is calculated using the criterion equation in the EPA's 2000 Human Health Methodology rearranged to solve for a protective concentration in fish tissue rather than in water.

\* Bis(2-Chloro-1-Methylethyl) Ether was previously listed as Bis(2-Chloroisopropyl) Ether.

\*\* These criteria were promulgated for Washington in the National Toxics Rule at 40 CFR 131.36, and are moved into 40 CFR 131.45 to have one comprehensive human health criteria rule for Washington.

\* \* \* \* \*

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 721

[EPA-HQ-OPPT-2019-0359; FRL-9996-62]

RIN 2070-AB27

### Significant New Use Rules on Certain Chemical Substances (19-2.F)

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** EPA is proposing significant new use rules (SNURs) under the Toxic Substances Control Act (TSCA) for 31 chemical substances which were the subject of premanufacture notices. 7 of these chemical substances are subject to Orders issued by EPA pursuant to TSCA section 5(e). This action would require persons who intend to manufacture (defined by statute to include import) or process any of these 31 chemical substances for an activity that is proposed as a significant new use to notify EPA at least 90 days before commencing that activity. The required notification initiates EPA's evaluation of the use, under the conditions of use for that chemical substance, 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 by that determination.

**DATES:** Comments must be received on or before September 5, 2019.

**ADDRESSES:** Submit your comments, identified by docket identification (ID)

number EPA-HQ-OPPT-2019-0359, 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](mailto: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](mailto: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 September 5, 2019 are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)) (see 40 CFR 721.20), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

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

1. **Submitting CBI.** Do not submit this information to EPA through [regulations.gov](http://www.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 and an MCAN. These proposed SNURs would require persons to notify EPA at least 90 days before commencing the manufacture or processing of a chemical substance for any activity proposed as a significant new use. Receipt of such notices would allow EPA to assess risks and, if appropriate, to regulate the significant new use before it may occur. Additional background regarding SNURs is more fully set out in the preamble to EPA's first direct final SNUR published in the **Federal Register** issue of April 24, 1990 (55 FR 17376). Consult that preamble for further general information on the objectives, rationale, and procedures for SNURs and on the basis for significant new use designations, including provisions for developing test data.

### B. What is the Agency's authority for taking this action?

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

### C. Applicability of General Provisions

General provisions for SNURs appear in 40 CFR part 721, subpart A. These provisions describe persons subject to the proposed rule, recordkeeping requirements, and exemptions to reporting requirements, and applicability of the rule to uses occurring before the effective date of the rule. Provisions relating to user fees appear at 40 CFR part 700. Pursuant to § 721.1(c), persons subject to SNURs must comply with the same SNUN requirements and EPA regulatory procedures as submitters of PMNs under TSCA section 5(a)(1)(A) (15 U.S.C. 2604(a)(1)(A)). In particular, these requirements include the information submission requirements of TSCA sections 5(b) and 5(d)(1) (15 U.S.C. 2604(b) and 2604(d)(1)), the exemptions authorized by TSCA sections 5(h)(1), (h)(2), (h)(3), and (h)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUN, EPA must either determine that the use is not likely to present an unreasonable risk of injury under the conditions of use for the chemical substance or take such regulatory action as is associated with an alternative determination before the manufacture or processing for the significant new use can commence. In the case of a determination other than not likely to present unreasonable risk, the applicable review period must also expire before manufacturing or processing for the new use may commence. If EPA determines that the use is not likely to present an unreasonable risk, EPA is required under TSCA section 5(g) to make public, and submit for publication in the **Federal Register**, a statement of EPA's findings.

### III. Significant New Use Determination

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

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

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

In determining significant new use for the 31 chemical substances that are the subject of these SNURs, EPA considered relevant information about the toxicity of the chemical substances and potential human exposures and environmental releases that may be associated with the conditions of use for the substances, in addition to the factors in TSCA section 5(a)(2). Note that when the Agency issues an order under TSCA section 5(e), TSCA section 5(f)(4) requires that the Agency consider whether to promulgate a SNUR for any use not conforming to the restrictions of the order or publish a statement describing the reasons for not initiating the rulemaking.

### IV. Substances Subject to This Proposed Rule

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

- PMN number.
- Chemical name (generic name, if the specific name is claimed as CBI).
- Chemical Abstracts Service (CAS) Registry number (if assigned for non-confidential chemical identities).
- Basis for the SNUR or basis for the TSCA 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 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 7 PMN substances that are subject to Orders issued under TSCA section 5(e)(1)(A), as required by the determinations made under TSCA section 5(a)(3)(B). Those 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 40 CFR 721.63 respirator requirements may request to do so under 40 CFR 721.30. EPA expects that persons whose 40 CFR 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.

These proposed rules also include 24 PMN substances that received “not likely to present an unreasonable risk” determination in TSCA section 5(a)(3)(c). However, during the course of these reviews, EPA identified concerns for certain health and/or environmental risks if the chemicals were not used following the limitations identified by the submitters in the notices but the TSCA section 5(a)(3)(C) determinations did not deem those uses as reasonably foreseen. The proposed SNURs would identify as significant new uses any manufacturing, processing, use, distribution in commerce, or disposal that does not conform to those same protection measures.

The chemicals subject to these proposed SNURs are as follows:

*PMN Number: P-16-400*

*Chemical Name:* Alkanes, C11-16-branched and linear.

*CAS Number:* 1809170-78-2.

*Basis for action:* The PMN states that the use of the PMN substance will be as a chemical intermediate, in cured coatings, cleaning fluids, metalworking fluids/rolling oils, and in agrochemicals. Based on the estimated physical chemical properties of the PMN substance and analogy to structurally similar substances, EPA has identified concerns for lung effects and dermal irritation if the chemical substance is not used following the limitations noted. The conditions of use of the PMN substance as described in the PMN include the following protective measures:

1. No manufacture, processing, or use of the PMN substance other than for the uses stated in the PMN; and

2. No manufacture, processing, or use of the PMN substance for consumer use.

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

*Potentially useful information:* EPA has determined that certain information about the human health effects of the PMN substance may be potentially useful 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 irritation and pulmonary effects testing would help characterize the potential health effects of the PMN substance.

*CFR Citation:* 40 CFR 721.11300.

*PMN Number: P-17-119*

*Chemical Name:* Alkyl alkenoic acid, alkoxyalkyl ester, polymer with alkyl alkenoate, alkyl alkyl alkenoate and triis alkyl silyl alkyl alkenoate (generic).

*CAS Number:* Not available.

*Basis for action:* The PMN states that the generic (non-confidential) use of the PMN substance will be as a component of industrial coatings. Based on the estimated physical chemical properties of the PMN substance and test data on the PMN substance, EPA has identified concerns for lung effects and irritation to the eyes, skins, lung, and mucous membranes if the chemical substance is not used following the limitations noted. The conditions of use of the PMN substance as described in the PMN include the following protective measures:

1. No domestic manufacture of the PMN substance; and

2. No manufacture, processing, or use of the PMN substance that results in inhalation exposures.

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

*CFR Citation:* 40 CFR 721.11301.

*PMN Number: P-17-191*

*Chemical Name:* Alkyldiamine, aminoalkyl dimethylaminoalkyl dimethyl-, reaction products with propylene oxide (generic).

*CAS Number:* Not available.

*Basis for action:* The PMN states that the use of the PMN substance will be as a polyurethane catalyst. Based on the estimated physical chemical properties of the PMN substance and data on analogous compounds, EPA has identified concerns for skin, eye, and lung corrosion, neurotoxicity, and systemic effects if the chemical substance is not used following the limitations noted. The conditions of use of the PMN substance as described in the PMN include the following protective measure:

- No manufacture, processing, or use of the PMN substance that would generate a spray, mist, or aerosol.

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

*CFR Citation:* 40 CFR 721.11302.

*PMN Number:* P-17-220

*Chemical Name:* 2-Oxepanone, reaction products with alkylenediamine-alkyleneimine polymer, 2-[[[(2-alkyl)oxy]alkyl]oxirane and tetrahydro-2H-pyran-2-one (generic).

*CAS Number:* Not available.

*Basis for action:* The PMN states that the generic (non-confidential) use of the PMN substance will be as an additive, open, non-dispersive use. Based on the estimated physical chemical properties of the PMN substance, comparison with structurally analogous chemical substances, and Structure Analysis Relationships (SAR) analysis of test data on polycationic polymers, EPA has identified hazards for irritation to the eye, lung, and mucous membranes, lung effects, and aquatic toxicity if the chemical substance is not used following the limitations noted. The conditions of use of the PMN substance as described in the PMN include the following protective measures:

1. No domestic manufacture of the PMN substance;
2. No manufacture or import of the PMN substance other than in liquid form; and
3. No manufacture, processing, or use of the PMN substance other than for the confidential use stated in the PMN.

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

*Potentially useful information:* EPA has determined that certain information about the human health and environmental effects of the PMN substance may be potentially useful 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 aquatic toxicity and pulmonary effects testing would help characterize the potential health and environmental effects of the PMN substance.

*CFR Citation:* 40 CFR 721.11303.

*PMN Numbers:* P-17-387 and P-17-388

*Chemical Name:* Dicarboxylic acids, polymers with alkanolic acid, alkanediol, substituted-alkylalkanoic acid, substituted alkyl carbomonocycle, alkanedioic acid, alkanolamine blocked compds with alkanolamine (P-17-387 and P-17-388) (generic).

*CAS Numbers:* Not available.

*Basis for action:* The PMNs state that the generic (non-confidential) use of the substances will be as paint. Based on the estimated physical/chemical properties of the PMN substances and available PMN data, EPA has identified developmental and reproductive effects, lung toxicity, and nasal and ocular irritation if the chemical substances are not used following the limitations noted. The conditions of use of the PMN substances as described in the PMNs include the following protective measures:

1. No manufacture (including import) of the PMN substances that results in amine counter ions greater than 4% by weight;
2. No manufacture (including import) of the PMN substances that results in isocyanate residuals greater than 0.1% by weight;
3. No manufacture (including import) of the PMN substances that results in a proportion of the acid group greater than 20% by weight; and
4. No manufacture (including import) of the PMN substances that results in the average molecular weight smaller than the confidential molecular weight specified in the PMNs or proportion of the low molecular weight species greater than the confidential values specified in the PMNs for the 500 and 1000 dalton species.

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 human health effects of the PMN substances may be potentially useful if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of developmental/reproductive and pulmonary effects testing would help characterize the potential health effects of the PMN substances.

*CFR Citation:* 40 CFR 721.11304.

*PMN Number:* P-17-419

*Chemical name:* Unsaturated polycyclic hydrocarbon (generic).

*CAS number:* Not available.

*Effective date of TSCA section 5(e) Order:* February 6, 2019.

*Basis for TSCA section 5(e) Order:*

The PMN states that the generic (non-confidential) use of the substance will be as a cyclic hydrocarbon building block. Based on physical/chemical properties of the PMN substance (as described in the New Chemical Program's PBT category at 64 FR 60194; November 4, 1999) and test data on structurally similar substances, the PMN substance is a potentially persistent, bioaccumulative, and toxic (PBT) chemical. EPA estimates that the PMN substance will persist in the environment more than 2 months and estimates a bioaccumulation factor of greater than or equal to 1,000. EPA has also identified concern for skin irritation, reproductive and developmental toxicity based on analog data and concern for sensitization based on Safety Data Sheet (SDS) information. Based on SAR analysis of test data on analogous neutral organics, EPA has identified concern for aquatic toxicity. The Order was issued under 5(a)(3)(B)(i) and 5(e)(1)(A)(i), based on a finding that the available information is insufficient to permit a reasoned evaluation of the human health and environmental effects of the PMN substance. The Order was also issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that the substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

1. Submit to EPA certain toxicity testing within 9 months from the effective date of the Order.
2. Submit to EPA certain toxicity testing for within 12 months from EPA's direction to proceed with that testing.
3. Refrain from manufacturing (including import) more than the confidential annual production volume limit specified in the Order.
4. Use of the PMN substance only for the confidential use allowed by the Order.
5. No release of the PMN substance to surface waters.
6. Use of personal protective equipment to its workers to prevent dermal exposure where there is potential for dermal exposure.
7. Use of a National Institute for Occupational Safety and Health (NIOSH) certified respirator with an Assigned Protection Factor (APF) of at least 50 where there is a potential for inhalation exposure.
8. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.

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

*Potentially useful information:* EPA has determined that certain information about the health and environmental effects of the PMN substance may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this SNUR. The submitter has agreed to perform certain acute aquatic toxicity testing within 9 months of the effect of the Order, and certain chronic aquatic toxicity testing within 12 months of EPA’s direction to proceed. The Agency has determined that specific target organ toxicity, reproductive and developmental toxicity, sensitization, and fate information would help EPA determine the potential health effects of the PMN substance. Although the Order does not require this information, 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 721.11305.

*PMN Numbers:* P-18-7 and P-18-8

*Chemical Names:* Glycerides, soya mono- and di-, epoxidized, acetates (P-18-7) and Glycerides, C16-18 and C18-unsatd. mono- and di-, epoxidized, acetates (P-18-8).

*CAS Numbers:* 2097734-14-8 (P-18-7) and 2097734-15-9 (P-18-8).

*Basis for action:* The PMNs state that the use of the substances will be as plasticizers/stabilizers for flexible polyvinyl chloride. Based on the estimated physical/chemical properties of the PMN substances and comparison with structurally analogous chemical substances, EPA has identified skin irritation and kidney and liver hazards if the chemical substances are not used following the limitations noted. The conditions of use of the PMN substances as described in the PMNs include the following protective measures:

1. No manufacture, processing, or use that results in inhalation exposures; and
2. No release of a manufacturing, processing, or use stream associated with any use of the PMN substances into the waters of the United States exceeding a surface water concentration of 9,000 parts per billion (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 human effects of the PMN substances may be potentially useful 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 and skin irritation testing would help characterize the potential health effects of the PMN substances.

*CFR Citations:* 40 CFR 721.11306 (P-18-7) and 40 CFR 721.11307 (P-18-8).

*PMN Number:* P-18-55

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

*CAS Number:* Not Available.

*Effective date of TSCA section 5(e)*

*Order:* April 2, 2019.

*Basis for TSCA section 5(e) Order:* The PMN states that the generic use of the PMN substance will be as a catalyst. EPA identified concerns for lung effects including cancer, and respiratory and dermal sensitization based on the estimated physical/chemical properties, available PMN data, and by comparison to structurally analogous chemical 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 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 where there is a potential for dermal exposure;
2. Use of a NIOSH-certified respirator with an APF of at least 1,000 where there is a potential for inhalation exposure or compliance with a NCEL of 0.04 mg/m<sup>3</sup> as an 8-hour time-weighted average to prevent inhalation exposure;
3. Use of the PMN substance only for the confidential use allowed by the Order; and
4. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.

The SNUR 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 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 SNUR. EPA has also determined that specific pulmonary toxicity and sensitization effects testing of the PMN substance would be useful in determining the health effects of the

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

*CFR citation:* 40 CFR 721.11308.

*PMN Number:* P-18-77

*Chemical Name:* Urea, reaction products with N-butylphosphorothioic triamide and formaldehyde.

*CAS Number:* 2093385-47-6.

*Basis for action:* The PMN states that the use of the PMN substance will be as an additive for urea-containing fertilizer. Based on physical-chemical properties, available test data, and test data on analogous chemical substances for the PMN substance, EPA has identified concerns for neurotoxicity, reproductive toxicity, kidney toxicity, irritation and sensitization if the chemical substance is not used following the limitations noted. The conditions of use of the PMN substance as described in the PMN include the following protective measures:

1. No manufacture, processing, or use of the substance that results in inhalation exposure; and
2. No use of the substance in a consumer product.

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 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 neurotoxicity, specific target organ toxicity, irritation, sensitization, and reproductive/developmental toxicity testing would help characterize the potential health effects of the PMN substance.

*CFR Citation:* 40 CFR 721.11309.

*PMN Number:* P-18-85

*Chemical Name:* Fatty acid reaction products with ethyleneamines and dialkyl ester (generic).

*CAS Number:* Not available.

*Basis for action:* The PMN states that the generic (non-confidential) use of the PMN substance will be for industrial use in oilfields. Based on the estimated physical chemical properties of the PMN substance and comparison with structurally analogous chemical substances, EPA has identified irritation to the eyes, lungs, and skin, and lung effects if the chemical substance is not used following the limitation noted. The

condition of use of the PMN substance as described in the PMN includes the following protective measure:

- No manufacture, processing, or use that results in inhalation exposures.

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

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

*CFR Citation:* 40 CFR 721.11310.

*PMN Number:* P-18-101

*Chemical Name:* Pentaerythritol, mixed esters with linear and branched fatty acids (generic).

*CAS Number:* Not available.

*Basis for action:* The PMN states that the generic (non-confidential) use of the PMN substance will be for industrial use. Based on the estimated physical chemical properties of the PMN substance and comparison with structurally analogous chemical substances, EPA has identified concerns for developmental effects, blood and thyroid effects, and skin and eye irritation if the chemical substance is not used following the limitations noted. The conditions of use of the PMN substance as described in the PMN include the following protective measure:

- No manufacturing, processing, or use involving an application method that generates a vapor, mist, or aerosol.

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

*Potentially useful information:* EPA has determined that certain information about the health effects of the PMN substance may be potentially useful if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of specific organ toxicity and reproductive/developmental testing would help characterize the potential health effects of the PMN substance.

*CFR Citation:* 40 CFR 721.11311.

*PMN Number:* P-18-107

*Chemical Name:* Alcohol capped polycarbodiimide from diethyldiisocyanatobenzene (generic).

*CAS Number:* Not available.

*Basis for action:* The PMN states that the use of the PMN substance will be as a hydrolysis stabilizer. Based on the physical chemical properties of the PMN substance and comparison with structurally analogous chemical substances, EPA has identified concerns for systemic toxicity and developmental toxicity if the chemical substance is not used following the limitation noted. The conditions of use of the PMN substance as described in the PMN include the following protective measure:

- No manufacture (including import) of the PMN substances that results in isocyanate residuals greater than 0.1% by weight.

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

*CFR Citation:* 40 CFR 721.11312.

*PMN Numbers:* P-18-118 and P-18-119

*Chemical Names:* Oxirane, 2-methyl-, polymer with methoxirane homopolymer, 1,1'-methylenebis[4-isocyanatobenzene], and glycerol-propylene oxide polymer (generic) (P-18-118) and Oxirane, 2-methyl-, polymer with methoxirane homopolymer, 1,1'-methylenebis[isocyanatobenzene], and glycerol-propylene oxide polymer (generic) (P-18-119).

*CAS Numbers:* Not available.

*Basis for action:* The PMNs state that the generic (non-confidential) use of the substances will be as industrial adhesives. Based on the estimated physical chemical properties of the PMN substances and comparison with structurally analogous chemical substances, EPA has identified concerns for lung effects, irritation, and sensitization if the chemical substances are not used following the limitations noted. The conditions of use of the PMN substances as described in the PMNs include the following protective measures:

1. No manufacturing, processing, or use that results in inhalation exposures;
2. No manufacturing, processing, or use of the PMN substances with isocyanate residuals greater than 0.1%; and

3. Refrain from using the PMN substance for consumer use.

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

*Potentially useful information:* EPA has determined that certain information about the health effects of the PMN substances may be potentially useful if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of skin sensitization testing would help characterize the potential health effects of the PMN substances.

*CFR Citations:* 40 CFR 721.11313 (P-18-118) and 40 CFR 721.11314 (P-18-119).

*PMN Numbers:* P-18-123 and P-18-124

*Chemical Name:* Lithium nickel hydride oxide (P-18-123) and Lithium nickel potassium oxide (P-18-124).

*CAS Numbers:* 2081933-92-6 (P-18-123) and 210352-95-7 (P-18-124).

*Effective date of TSCA section 5(e)*

*Order:* December 7, 2018.

*Basis for TSCA section 5(e) Order:* The PMN states that the use of the PMN substances will be as a chemical intermediate used in the production of battery electrodes (P-18-123) and a cathode material for standard and premium (P-18-124). Based on physical/chemical properties and on test data submitted with the PMN, EPA identified concerns for pulmonary effects, neurotoxicity, developmental toxicity, kidney toxicity, carcinogenicity, skin and respiratory sensitization, and irritation to the eye, skin, and respiratory tract. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(I)(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 section 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 where there is a potential for dermal exposure.
2. Use a NIOSH-certified respirator with an APF of at least 50 where there is potential for inhalation exposure or

compliance with a NCEL of 0.05 mg/m<sup>3</sup> as an 8-hour time-weighted average to prevent inhalation exposure.

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

4. Submit to EPA certain environmental and health hazard testing within six months and four years of the first manufacture (including import), respectively on P-18-124.

5. No release of the PMN substances resulting in surface water concentrations that exceed 32 ppb.

The SNUR 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 substances may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this SNUR. The submitter has agreed to submit an algal toxicity test 6 months after the date of first manufacture and a specific organ toxicity test 4 years after the date of first manufacture on PMN substance P-18-124. EPA has also determined that information on specific target organ toxicity and reproductive/developmental toxicity would help characterize the potential health effects of the PMN substances. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

*CFR Citations:* 40 CFR 721.11315 (P-18-123) and 40 CFR 721.11316 (P-18-124).

*PMN Number:* P-18-152

*Chemical Name:* Hydrolyzed functionalized di-amino silanol polymer (generic).

*CAS Number:* Not available.

*Basis for action:* The PMN states that the generic (non-confidential) use of the PMN substance will be as an intermediate. Based on the estimated physical chemical properties of the PMN substance, data on the PMN substance, comparison with structurally analogous chemical substances, and Structure Analysis Relationships (SAR) analysis of test data on analogous aliphatic amines, EPA has identified irritation and corrosion to all tissues, sensitization, lung toxicity, and aquatic toxicity at surface water concentrations exceeding 3 parts per billion (ppb) if the chemical substance is not used

following the limitations noted. The conditions of use of the PMN substance as described in the PMN include the following protective measures:

1. No manufacturing, processing, or use of the PMN substance in any manner that results in inhalation exposure; and
2. No release of a manufacturing, processing, or use stream associated with any use of the PMN substance exceeding a surface water concentration of 3 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 if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of skin toxicity, sensitization, and aquatic toxicity testing of would help characterize the potential health and environmental effects of the PMN substance.

*CFR Citation:* 40 CFR 721.11317.

*PMN Number:* P-18-169

*Chemical Name:* Propanoic acid, 3-hydroxy-2-(hydroxymethyl)-2-methyl-, polymer with dimethyl carbonate, 1,6-hexanediol, diamine and 1,1'-methylenebis[4-isocyanatocyclohexane], pentaerythritol, triacrylate-blocked, compds. with triethylamine (generic).

*CAS Number:* Not available.

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

1. Use of personal protective equipment including impervious gloves where there is a potential for dermal exposure;
2. Use of a NIOSH certified respirator with an APF of at least 1,000 for spray applications and 50 for non-spray applications; and
3. No manufacture (including import) of the PMN substance with triethylamine concentrations greater

than the confidential concentration described in the PMN.

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

*Potentially useful information:* EPA has determined that certain information about the health effects of the PMN substance may be potentially useful 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 composition of Low Molecular Weight (LMW) species and specific organ toxicity testing for the LMW species would help characterize the potential health effects of the PMN substance.

*CFR Citation:* 40 CFR 721.11318.

*PMN Numbers:* P-18-200 and P-18-201

*Chemical names:* Waste plastics, poly(ethylene terephthalate), polymers with diethylene glycol, glycerol, polyerythritol, triethylene glycol, trimethylolalkane and polypropylene glycol (P-18-200) (generic) and Waste plastics, poly(ethylene terephthalate), polymers with diethylene glycol, glycerol, polyerythritol glycol, trimethylolalkane and polypropylene glycol (P-18-201) (generic).

*CAS numbers:* Not available.

*Effective date of TSCA section 5(e) Order:* January 20, 2019.

*Basis for TSCA section 5(e) Order:* The PMNs state that the generic (non-confidential) use of the substances will be as insulation components. Based on analogue data for low molecular weight components and metabolites of high molecular weight components, EPA identified concerns for bladder and kidney effects. . Based on SAR predictions for nonionic polymers EPA also identified concerns for aquatic toxicity at concentrations that exceed 280 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 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 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 involving impervious gloves 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. Use of a NIOSH-certified respirator with an APF of at least 10 where there is a potential for inhalation exposure;

4. Refrain from using the PMN substances for consumer use; and

5. No release of the PMN substances resulting in surface water concentrations that exceed 280 ppb.

The 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 human and environmental health effects of the PMN substances may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this SNUR. A toxicokinetics test, a specific target organ toxicity test, and a chronic aquatic organism toxicity test would help EPA determine the potential health and environmental effects of the PMN substances. Although the Order does not require these tests, the Order’s restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

**CFR citations:** 40 CFR 721.11319 (P–18–200) and 40 CFR 721.11320 (P–18–201).

**PMN Number:** P–18–235

**Chemical Name:** Naphtha oils (generic).

**CAS Number:** Not Available.

**Effective date of TSCA section 5(e)**

**Order:** April 10, 2019.

**Basis for TSCA section 5(e) Order:** The PMN states that the generic use of the PMN substance will be as a component in automotive gasoline and transportation fuel for consumer use. EPA identified concerns for neurological, liver, kidney, developmental, immunological, carcinogenic, mutagenic and irritation effects based on estimated physical/chemical properties and analysis of test data on structurally analogous chemical substances. In addition, based on SAR analysis of test data on analogous neutral organics, EPA predicts acute and chronic toxicity to aquatic organisms may occur at concentrations greater than 88 ppb and 3 ppb respectively. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation the substance may

present an unreasonable risk of injury to human health and the environment. The 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. No domestic manufacture of the PMN substance (import only).

2. Processing and use of the PMN substance only for the confidential use specified in the PMN.

The SNUR 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 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 SNUR. EPA has also determined that specific product composition testing of the PMN substance would be useful in determining the health and environmental 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 other relevant information.

**CFR citation:** 40 CFR 721.11321.

**PMN Number:** P–18–238

**Chemical Name:** Saccharide reaction products with acid anhydride, etherified (generic).

**CAS Number:** Not available.

**Basis for action:** The PMN states that the use of the PMN substance will be as a binder for wood panels. Based on the estimated physical chemical properties of the PMN substance, structural alerts, data on an analogue of a potential metabolites, and test data on analogous esters, EPA has identified skin and respiratory sensitization, germ cell mutagenicity, carcinogenicity, reproductive/developmental, liver, and kidney toxicity if the chemical substance is not used following the limitations noted. The conditions of use of the PMN substance as described in the PMN include this protective measure:

• No manufacturing, processing, or use that results in inhalation exposures.

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

**CFR Citation:** 40 CFR 721.11322.

**PMN Number:** P–18–307

**Chemical Name:** Alkyl alkenoic acid, alkyl ester, telomer with alkyl alkenoate, substituted alkyl alkyl alkenoate, alkylthiol, substituted carbomonocycle, hydroxyalkyl alkyl alkenoate and alkyl alkyl alkenoate (generic).

**CAS Number:** Not available.

**Basis for action:** The PMN states that the generic (non-confidential) use of the PMN substance will be as a binder resin in coatings. Based on the estimated and measured physical chemical properties of the PMN substance, data submitted on the new chemical substance, and comparison with structurally analogous chemical substances, EPA has identified concerns for systemic effects if the chemical substance is not used following the limitations noted. The conditions of use of the PMN substance as described in the PMN include the following protective measure:

• No manufacture (including import) of the PMN substance with more than 5% of the molecular weight content less than 1,000 Daltons.

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 health effects of the PMN substance may be potentially useful to 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 toxicokinetic and specific target organ toxicity testing would help characterize the potential health effects of the PMN substance.

**CFR Citation:** 40 CFR 721.11323.

**PMN Number:** P–18–312

**Chemical Name:** Formaldehyde, polymer with 2-phenoxyalkanol and .alpha.-phenyl-.omega.



hydroxypoly(oxy-1,2-alkylenediyl), dihydrogen phosphate 2-phenoxyalkyl hydrogen phosphate, alkaline salt (generic).

*CAS Number:* Not available.

*Basis for action:* The PMN states that the generic (non-confidential) use of the PMN substance will be as a dispersing agent. Based on the estimated physical chemical properties of the PMN substance and hazard data on chemically analogous substances, EPA has identified concerns for lung effects, eye irritation, and systemic (blood/kidney) effects, if the chemical substance is not used following the limitations noted. The conditions of use of the PMN substance as described in the PMN include the following protective measures:

1. No manufacturing, processing, or use that results in inhalation exposures; and

2. No manufacture of the PMN substance with greater than 20% (weight percent) components with molecular weight below 500 Daltons.

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 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 composition of low molecular weight (LMW) species and specific organ toxicity testing for the LMW species would help characterize the potential health effects of the PMN substance.

*CFR Citation:* 40 CFR 721.11324.

*PMN Number:* P-19-8

*Chemical Name:* Substituted polyalkylenepolycarbomonocycle ester, polymer with dialkanolamine, [(hydroxyalkoxy)carbonyl] derivs., (alkoxyalkoxy) alkanol-blocked (generic).

*CAS Number:* Not available.

*Basis for action:* The PMN states that the use of the PMN substance will be as a component in coating resin products that are applied by cathodic electrodeposition and used as additives for corrosion protection. Based on the estimated physical chemical properties of the PMN substance and comparison with structurally analogous chemical substances, EPA has identified concerns for irritation, lung effects, immunotoxicity, and blood effects if the chemical substance is not used following the limitations noted. The conditions of use of the PMN substance

as described in the PMN include the following protective measures:

1. No manufacture (including import) or processing the PMN substance in the forms of a powder or solid; and

2. No use of the PMN substance involving application methods that generate inhalation exposures.

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

*CFR Citation:* 40 CFR 721.11325.

*PMN Number:* P-19-9

*Chemical Name:* Carbonmonocycles, polymer with haloalkyl substituted heteromonocycle and hydro-hydroxypoly[oxy(alkyl-alkanediyl)], dialkyl-alkanediamineterminated, hydroxyalkylated, acetates (salts) (generic).

*CAS Number:* Not available.

*Basis for action:* The PMN states that the use of the PMN substance will be as a corrosion protection additive in resin for cathodic electrodeposition dip coating for metal substrates. Based on the estimated physical chemical properties of the PMN substance and comparison with structurally analogous chemical substances, EPA has identified concerns for lung effects and irritation if the chemical substance is not used following the limitations noted. The conditions of use of the PMN substance as described in the PMN include the following protective measures:

1. No manufacturing (including import), processing, or use that results in inhalation exposures; and

2. No manufacture beyond an annual production volume of 85,000 kg.

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

potential health effects of the PMN substance.

*CFR Citation:* 40 CFR 721.11326.

*PMN Number:* P-19-26

*Chemical Name:* Alkanoic acid, compds. with substituted carbomonocycle-dialkyl-alkanediamine-halosubstituted heteromonocycle-polyalkylene glycol polymerdialkanolamine reaction products (generic).

*CAS Number:* Not available.

*Basis for action:* The PMN states that the use of the PMN substance will be as a component in coating resin products that are applied by cathodic electrodeposition and as an additive for corrosion protection. Based on the estimated physical chemical properties of the PMN substance, comparison with structurally analogous chemical substances, and Structure Analysis Relationships (SAR) analysis of test data on cationic polymers, EPA has identified concerns for irritation, lung effects, and aquatic toxicity at concentrations greater than 15 ppb if the chemical substance is not used following the limitation noted. The conditions of use of the PMN substance as described in the PMN include the following protective measures:

1. No manufacturing (including import), processing, or use that results in inhalation exposures to vapor, particulate, mist or aerosols; and

2. No release of a manufacturing, processing, or use stream associated with any use of the PMN substance exceeding a surface water concentration of 15 ppb.

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

*Potentially useful information:* EPA has determined that certain information about the human health and environmental effects of the PMN substance may be potentially useful 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, skin irritation, and aquatic toxicity testing would help characterize the potential health effects of the PMN substance.

*CFR Citation:* 40 CFR 721.11327.

*PMN Number:* P-19-27

*Chemical Name:* Substituted carbomonocycle, polymer with haloalkyl substituted heteromonocycle, dialkyl-alkanediamine and hydro-hydroxypoly[oxy(alkylalkanediyl)], reaction products with metal oxide and dialkanolamine, acetates (salt) (generic).

*CAS Number:* Not available.

*Basis for action:* The PMN states that the use of the PMN substance will be as an isolated intermediate incorporated as a component in coating resin products that are applied by cathodic electrodeposition and used as additives for corrosion protection. Based on the estimated physical chemical properties of the PMN substance, comparison with structurally analogous chemical substances, and Structure Analysis Relationships (SAR) analysis of test data on analogous cationic polymers, EPA has identified lung effects and aquatic toxicity if the chemical substance is not used following the limitations noted. The conditions of use of the PMN substance as described in the PMN include the following protective measures:

1. No manufacturing, processing, or use that results in inhalation exposures to vapor, particulate, mist or aerosols; and

2. No manufacture (including import) of an annual production volume of the PMN substance greater than 95,600 kg.

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

*CFR Citation:* 40 CFR 721.11328.

*PMN Number:* P-19-45

*Chemical Name:* Non-metal tetrakis (hydroxyalkyl)-, halide, polymer with amide oxidized (generic).

*CAS Number:* Not available.

*Basis for action:* The PMN states that the generic (non-confidential) use of the PMN substance will be as a component of a textile coating. Based on the estimated physical chemical properties of the PMN substance and comparison with structurally analogous chemical substances, EPA has identified effects concerns for irritation to the skin and eyes, skin sensitization, and reproductive and developmental toxicity if the chemical substance is not used following the limitations noted. The conditions of use of the PMN substance as described in the PMN include the following protective measures:

1. No manufacturing, processing, or use that results in inhalation exposures;

2. No manufacturing that results in unbound formaldehyde residuals greater than 0.1%; and

3. No manufacturing, processing, or use other than the confidential use described in the PMN.

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

*Potentially useful information:* EPA has determined that certain information about the human health toxicity of the PMN substance may be potentially useful if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of skin and eye irritation, skin sensitization, and developmental toxicity testing would help characterize the potential health effects of the PMN substance.

*CFR Citation:* 40 CFR 721.11329.

## 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 7 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/MCAN submitters. The 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).

During review of the other 24 chemical substances that are the subject of these SNURs and as further discussed in Unit IV, EPA identified circumstances different from the intended conditions of use identified in the PMNs that raised potential risk concerns. EPA determined that deviations from the protective measures identified in the submissions could result in changes in the type or form of exposure to the chemical substances and/or increased exposures to the chemical substances and/or changes in the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of the chemical substances, and

therefore warranted SNURs. The SNURs would identify as significant new uses any manufacturing, processing, use, distribution in commerce, or disposal that does not conform to the protection measures in the submission.

### B. Objectives

EPA is proposing these SNURs for specific chemical substances which have undergone premanufacture review because the Agency wants to achieve the following objectives with respect to the significant new uses that would be designated in this proposed 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 be required 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 required to either determine that the prospective manufacture or processing is not likely to present an unreasonable risk, or to take necessary regulatory action associated with any other determination, before the described significant new use of the chemical substance occurs.

Issuance of a SNUR for a chemical substance does not signify that the chemical substance is listed on the TSCA Chemical Substance Inventory (TSCA Inventory). Guidance on how to determine if a chemical substance is on the TSCA Inventory is available on the internet at <http://www.epa.gov/opptintr/existingchemicals/pubs/tscainventory/index.html>.

## VI. Applicability of the Proposed Significant New Use Designation

To establish a significant new use, EPA must determine that the use is not ongoing. The chemical substances subject to this proposed rule have undergone premanufacture review. In cases where EPA has not received a notice of commencement (NOC) and the chemical substance has not been added to the TSCA Inventory, no person may commence such activities without first submitting a PMN. Therefore, for chemical substances for which a 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 7 of the 31 chemical substances, and the PMN submitters are prohibited by the TSCA section 5(e) Orders from undertaking activities which would be designated as significant new uses. The identities of 25 of the 31 chemical substances subject to this proposed rule have been claimed as confidential (per §§ 720.85 and 725.85) for a chemical substance covered by this action. Based on this, the Agency believes that it is highly unlikely that any of the significant new uses described in the regulatory text of this proposed rule are ongoing.

Therefore, EPA designates August 6, 2019 as the cutoff date for determining whether the new use is ongoing. The objective of EPA's approach is to ensure that a person cannot defeat a SNUR by initiating a significant new use before the effective date of the final rule.

Persons who begin commercial manufacture or processing of the chemical substances for a significant new use identified as of that date would have to cease any such activity upon the effective date of the final rule. To resume their activities, these persons would have to first comply with all applicable SNUR notification requirements and wait until EPA has conducted a review of the notice, made an appropriate determination on the notice, and has taken such actions as are required with that determination.

## VII. Development and Submission of Information

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

In the absence of a TSCA section 4 test rule covering the chemical substance, persons are required only to submit information in their possession or control and to describe any other information known to or reasonably ascertainable by them (see 40 CFR 720.50 and 725.155). 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 test guidelines are available from the OECD Bookshop at <http://www.oecdbookshop.org> or SourceOECD at <http://www.sourceoecd.org>.

The potentially useful information listed in Unit IV. may not be the only means of addressing the potential risks of the chemical substance. EPA recommends that potential SNUN submitters contact EPA early enough so that they will be able to conduct the appropriate tests.

SNUN submitters should be aware that EPA will be better able to evaluate SNUNs which provide detailed information on the following:

- Human exposure and environmental release that may result from the significant new use of the chemical substances.

## VIII. SNUN Submissions

According to 40 CFR 721.1(c), persons submitting a SNUN must comply with the same notification requirements and EPA regulatory procedures as persons submitting a PMN or MCAN, including submission of test data on health and environmental effects as described in 40 CFR 720.50 or 725.160. SNUNs must be submitted on EPA Form No. 7710-25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in 40 CFR 720.40 and 721.25 (or 40 CFR 725.25 and § 725.27). E-PMN software is available electronically at <http://www.epa.gov/opptintr/newchems>.

## IX. Economic Analysis

EPA has evaluated the potential costs of establishing SNUN requirements for potential manufacturers and processors of the chemical substances subject to this proposed rule. EPA's complete economic analysis is available in the docket under docket ID number EPA-HQ-OPPT-2019-0359.

## 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, Regulatory Support Division, Office of Mission Support (2822T), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001. Please remember to include the OMB control number in any correspondence,

but do not submit any completed forms to this address.

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

Pursuant to section 605(b) of the 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, 14 in FY2017, and 18 in FY2018 and only a fraction of these were from small businesses. In addition, the Agency currently offers relief to qualifying small businesses by reducing the SNUN submission fee from \$16,000 to \$2,800. This lower fee reduces the total reporting and recordkeeping of cost of submitting a SNUN to about \$10,116 for qualifying small firms. Therefore, the potential economic impacts of complying with this proposed SNUR are not expected to be significant or adversely impact a substantial number of small entities. In a SNUR that published in the **Federal Register** of June 2, 1997 (62 FR 29684) (FRL–5597–1), the Agency presented its general determination that final SNURs are not expected to have a significant economic impact on a substantial number of small entities, which was provided to the Chief Counsel for Advocacy of the Small Business Administration.

#### D. Unfunded Mandates Reform Act (UMRA)

Based on EPA’s experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reasons to believe that any State, local, or Tribal

government will be impacted by this action. As such, EPA has determined that this proposed rule would not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the requirements of UMRA sections 202, 203, 204, or 205 (2 U.S.C. 1501 *et seq.*).

#### E. Executive Order 11632

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 in 40 CFR Parts 721

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

Dated: July 26, 2019.

**Tala Henry,**

*Deputy Director, Office of Pollution Prevention and Toxics.*

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

#### PARTS 721—[AMENDED]

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

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

■ 2. Add §§ 721.11300 through 721.11329 to subpart E to read as follows:

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

Sec.

- |           |  |   |   |   |
|-----------|--|---|---|---|
| *         | *  | * | * | * |
| 721.11300 | Alkanes, C11–16-branched and linear.   |   |   |   |
| 721.11301 | Alkyl alkenoic acid, alkoxyalkyl ester, polymer with alkyl alkenoate, alkyl alkyl alkenoate and tris alkyl silyl alkyl alkenoate (generic).  |   |   |   |
| 721.11302 | Alkyldiamine, aminoalkyl dimethylaminoalkyl dimethyl-, reaction products with propylene oxide (generic).   |   |   |   |
| 721.11303 | 2-Oxepanone, reaction products with alkylenediamine-alkyleneimine polymer, 2-[[[(2-alkyl)oxy]alkyl]oxirane and tetrahydro-2H-pyran-2-one (generic).  |   |   |   |
| 721.11304 | Dicarboxylic acids, polymers with alkanolic acid, alkanediol, substituted-alkylalkanoic acid, substituted alkyl carbomonocycle, alkanedioic acid, alkanolamine blocked compds with alkanolamine (generic). |   |   |   |
| 721.11305 | Unsaturated polycyclic hydrocarbon (generic).  |   |   |   |
| 721.11306 | Glycerides, soya mono- and di-, epoxidized, acetates.  |   |   |   |
| 721.11307 | Glycerides, C16-18 and C18-unsatd. mono- and di-, epoxidized, acetates.  |   |   |   |
| 721.11308 | Mixed metal oxide (generic).   |   |   |   |
| 721.11309 | Urea, reaction products with N-butylphosphorothioic triamide and formaldehyde.   |   |   |   |
| 721.11310 | Fatty acid reaction products with ethyleneamines and dialkyl ester (generic).  |   |   |   |

- 721.11311 Pentaerythritol, mixed esters with linear and branched fatty acids (generic).
- 721.11312 Alcohol capped polycarbodiimide from diethyldiisocyanatobenzene (generic).
- 721.11313 Oxirane, 2-methyl-, polymer with methoxirane homopolymer, 1,1'-methylenebis[4-isocyanatobenzene], and glycerol-propylene oxide polymer (generic).
- 721.11314 Oxirane, 2-methyl-, polymer with methoxirane homopolymer, 1,1'-methylenebis[isocyanatobenzene], and glycerol-propylene oxide polymer (generic).
- 721.11315 Lithium nickel hydride oxide.
- 721.11316 Lithium nickel potassium oxide.
- 721.11317 Hydrolyzed functionalized diamino silanol polymer (generic).
- 721.11318 Propanoic acid, 3-hydroxy-2-(hydroxymethyl)-2-methyl-, polymer with dimethyl carbonate, 1,6-hexanediol, diamine and 1,1'-methylenebis[4-isocyanatocyclohexane], pentaerythritol, triacrylate-blocked, compds. with triethylamine (generic).
- 721.11319 Waste plastics, poly(ethylene terephthalate), polymers with diethylene glycol, glycerol, polyerythritol, triethylene glycol, trimethylolalkane and polypropylene glycol (generic).
- 721.11320 Waste plastics, poly(ethylene terephthalate), polymers with diethylene glycol, glycerol, polyerythritol glycol, trimethylolalkane and polypropylene glycol (generic).
- 721.11321 Naphtha oils (generic).
- 721.11322 Saccharide reaction products with acid anhydride, etherified (generic).
- 721.11323 Alkyl alkenoic acid, alkyl ester, telomere with alkyl alkenoate, substituted alkyl alkyl alkenoate, alkylthiol, substituted carbomonocycle, hydroxyalkyl alkyl alkenoate and alkyl alkyl alkenoate (generic).
- 721.11324 Formaldehyde, polymer with 2-phenoxyalkanol and .alpha.-phenyl-.omega.hydroxypoly(oxy-1,2-alkylenediyl), dihydrogen phosphate 2-phenoxyalkyl hydrogen phosphate, alkaline salt (generic).
- 721.11325 Substituted polyalkylenepolycarbomonocycle ester, polymer with dialkanolamine, (hydroxyalkoxy)carbonyl] derivs., (alkoxyalkoxy) alkanol blocked (generic).
- 721.11326 Carbonmonocycles, polymer with haloalkyl substituted heteromonocycle and hydro-hydroxypoly[oxy(alkyl-alkanediyl)], dialkyl-alkanediamineterminated, hydroxyalkylated, acetates (salts) (generic).
- 721.11327 Alkanoic acid, compds. with substituted carbomonocycle-dialkyl-alkanediamine-halosubstituted heteromonocycle-polyalkylene glycol polymerdialkanolamine reaction products (generic).
- 721.11328 Substituted carbomonocycle, polymer with haloalkyl substituted heteromonocycle, dialkyl-alkanediamine and hydro-hydroxypoly[oxy(alkylalkanediyl)], reaction products with metal oxide and dialkanolamine, acetates (salt) (generic).

- 721.11329 Non-metal tetrakis (hydroxyalkyl)-, halide, polymer with amide oxidized (generic).

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

\* \* \* \* \*

#### § 721.11300 Alkanes, C11–16-branched and linear.

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

(1) The chemical substance identified as alkanes, C11–16-branched and linear (PMN P–16–400, CAS No. 1809170–78–2) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o). It is a significant new use to use the substance other than as a chemical intermediate, in cured coatings, cleaning fluids, metalworking fluids/rolling oils, and in agrochemicals.

(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.

#### § 721.11301 Alkyl alkenoic acid, alkoxyalkyl ester, polymer with alkyl alkenoate, alkyl alkyl alkenoate and tris alkyl silyl alkyl alkenoate (generic).

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

(1) The chemical substance generically identified as alkyl alkenoic acid, alkoxyalkyl ester, polymer with alkyl alkenoate, alkyl alkyl alkenoate and tris alkyl silyl alkyl alkenoate (PMN P–17–119) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

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

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part

apply to this section except as modified by this paragraph (b).

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

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

#### § 721.11302 Alkyldiamine, aminoalkyl dimethylaminoalkyl dimethyl-, reaction products with propylene oxide (generic).

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

(1) The chemical substance generically identified alkyldiamine, aminoalkyl dimethylaminoalkyl dimethyl-, reaction products with propylene oxide (PMN P–17–191) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture, process, or use the PMN substance in any manner that generates a spray, mist, or aerosol.

(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.

#### § 721.11303 2-Oxepanone, reaction products with alkylenediamine-alkyleneimine polymer, 2-[[[(2-alkyl)oxy]alkyl]oxirane and tetrahydro-2H-pyran-2-one (generic).

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

(1) The chemical substance generically identified as 2-oxepanone, reaction products with alkylenediamine-alkyleneimine polymer, 2-[[[(2-alkyl)oxy]alkyl]oxirane and tetrahydro-2H-pyran-2-one (PMN P–17–220) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f) and (j). It is a significant new use to manufacture or import the PMN substance other than in liquid form.

(ii) [Reserved]

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

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

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

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

**§ 721.11304 Dicarboxylic acids, polymers with alkanolic acid, alkanediol, substituted-alkylalkanoic acid, substituted alkyl carbomonocycle, alkanedioic acid, alkanolamine blocked compds with alkanolamine (generic).**

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

(1) The chemical substances generically identified as dicarboxylic acids, polymers with alkanolic acid, alkanediol, substituted-alkylalkanoic acid, substituted alkyl carbomonocycle, alkanedioic acid, alkanolamine blocked compds with alkanolamine (P-17-387 and P-17-388) are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture, process, or use the PMN substances resulting in amine counter ions greater than 4% by weight, isocyanate residuals greater than 0.1% by weight, or a proportion of the acid group greater than 20% by weight. It is a significant new use to manufacture, process, or use the PMN substances that results in the average molecular weight smaller than the molecular weight specified in the PMNs or proportion of the low molecular weight species greater than the values specified in the PMNs for the 500 and 1000 dalton species.

(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 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)(i) of this section.

**§ 721.11305 Unsaturated polycyclic hydrocarbon (generic).**

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

(1) The chemical substance generically identified as unsaturated polycyclic hydrocarbon (PMN P-17-419) 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), (3), (4), 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, (5) respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 50, (6)(v), (vi), (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), (vi), (ix), (skin sensitization), (specific target organ toxicity), (2)(i), (ii), (iv), (v), (3)(i), (ii), (4)(iii), and (5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(j) and (t). It is a significant new use to manufacture the substance for more than 9 months.

(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 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.

**§ 721.11306 Glycerides, soya mono- and di-, epoxidized, acetates.**

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

(1) The chemical substance identified as glycerides, soya mono- and di-, epoxidized, acetates (P-18-7, CAS No. 2097734-14-8) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

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

(ii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where N=9,000.

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

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

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

**§ 721.11307 Glycerides, C16-18 and C18-unsatd. mono- and di-, epoxidized, acetates.**

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

(1) The chemical substance identified as glycerides, C16-18 and C18-unsatd. mono- and di-, epoxidized, acetates (P-18-8, CAS No. 2097734-15-9) 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) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture, process, or use the substance in any manner that results in inhalation exposures.

(ii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where N=9,000.

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

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

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

**§ 721.11308 Mixed metal oxide (generic).**

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

(1) The chemical substance generically identified as mixed metal oxide (PMN P-18-55) 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), (3), (4) 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, (5)(respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 1,000), (6)(particulate), (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 is 0.04 mg/m<sup>3</sup> 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 the EPA will be required to follow NCELs provisions comparable to those contained in the corresponding TSCA section 5(e) Order.

(B) [Reserved]

(ii) [Reserved]

(ii) *Hazard communication.*

Requirements as specified in § 721.72(a) through (d) (e)(concentration set at 0.1%), (f), (g)(1)(ii), (vii), (allergic skin reaction), (respiratory sensitization), (germ cell mutagenicity), (2)(i), (ii), (iii), (iv) (use respiratory protection or maintain workplace airborne concentrations at or below an 8-hour time-weighted average of 0.04 mg/m<sup>3</sup>), (v), and (5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

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

(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.

**§ 721.11309 Urea, reaction products with N-butylphosphorothioic triamide and formaldehyde.**

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

(1) The chemical substance identified as urea, reaction products with N-butylphosphorothioic triamide and formaldehyde (P-18-77, CAS No. 2093385-47-6) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

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

(ii) [Reserved]

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

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

**§ 721.11310 Fatty acid reaction products with ethyleneamines and dialkyl ester (generic).**

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

(1) The chemical substance generically identified as fatty acid reaction products with ethyleneamines and dialkyl ester (P-18-85) is subject to reporting under this section for the significant new use described in paragraph (a)(2) of this section.

(2) The significant new uses are:

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

(ii) [Reserved]

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

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

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

**§ 721.11311 Pentaerythritol, mixed esters with linear and branched fatty acids (generic).**

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

(1) The chemical substance generically identified as pentaerythritol, mixed esters with linear and branched fatty acids (PMN P-18-101) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80 (y)(1).

(ii) [Reserved]

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

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

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

**§ 721.11312 Alcohol capped polycarbodiimide from diethyldiisocyanatobenzene (generic).**

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

(1) The chemical substance generically identified as alcohol capped polycarbodiimide from diethyldiisocyanatobenzene (PMN P-18-107) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture the substance with a residual isocyanate level greater than 0.1%.

(ii) [Reserved]

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



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

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

**§ 721.11313 Oxirane, 2-methyl-, polymer with methoxirane homopolymer, 1,1'-methylenebis[4-isocyanatobenzene], and glycerol-propylene oxide polymer (generic).**

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

(1) The chemical substance generically identified as oxirane, 2-methyl-, polymer with methoxirane homopolymer, 1,1'-methylenebis[4-isocyanatobenzene], and glycerol-propylene oxide polymer (P-18-118) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80 (o). It is a significant new use to manufacture, process, or use the substance in any manner that results in inhalation exposures. It is a significant new use to manufacture, process, or use the substance with isocyanate residuals greater than 0.1%.

(ii) [Reserved]

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

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

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

**§ 721.11314 Oxirane, 2-methyl-, polymer with methoxirane homopolymer, 1,1'-methylenebis[isocyanatobenzene], and glycerol-propylene oxide polymer (generic).**

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

(1) The chemical substance generically identified as oxirane, 2-methyl-, polymer with methoxirane homopolymer, 1,1'-methylenebis[isocyanatobenzene], and glycerol-propylene oxide polymer (P-18-119) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities*. Requirements as

specified in § 721.80 (o). It is a significant new use to manufacture, process, or use the substance in any manner that results in inhalation exposures. It is a significant new use to manufacture, process, or use the substance with isocyanate residuals greater than 0.1%.

(ii) [Reserved]

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

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

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

**§ 721.11315 Lithium nickel hydride oxide.**

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

(1) The chemical substance identified as lithium nickel hydride oxide (P-18-123, CAS No. 2081933-92-6) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace*.

Requirements as specified in § 721.63(a)(1), (2), (3), (4), (5) (respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) 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, (6) (particulate), 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) consent order for this substance. The NCEL is 0.05 mg/m<sup>3</sup> 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) consent order.

(B) [Reserved]

(ii) *Hazard communication*.

Requirements as specified in § 721.72(a) through (d), (f), (g)(1)(i), (ii), (iii), (iv), (vii), (viii), (ix), (eye irritation), (2)(i), (ii), (iii), (iv) (use respiratory protection or maintain workplace airborne concentrations at or below an 8-hour time-weighted average of 0.05 mg/m<sup>3</sup>), (v), (skin irritation), (3)(ii), (4)(i), (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 for more than six months.

(iv) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where N=32.

(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.

**§ 721.11316 Lithium nickel potassium oxide.**

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

(1) The chemical substance identified as lithium nickel potassium oxide (P-18-124, CAS No. 210352-95-7) 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), (3), (4), (5) (respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) 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, (6) (particulate), 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) consent order

for this substance. The NCEL is 0.05 mg/m<sup>3</sup> as an 8-hour time weighted average. Persons who wish to pursue NCEs as an alternative to § 721.63 respirator requirements may request to do so under § 721.30. Persons whose § 721.30 requests to use the NCEs approach are approved by EPA will be required to follow NCEs provisions comparable to those contained in the corresponding TSCA section 5(e) consent order.

(B) [Reserved]

(ii) *Hazard communication.*

Requirements as specified in § 721.72(a) through (d), (f), (g)(1)(i), (ii), (iii), (iv), (vii), (viii), (ix), (eye irritation), (2)(i), (ii), (iii), (iv) (use respiratory protection or maintain workplace airborne concentrations at or below an 8-hour time-weighted average of 0.05 mg/m<sup>3</sup>), (v), (skin irritation), (3)(ii), (4)(i), (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 for more than six months.

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where N=32.

(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.

**§ 721.11317 Hydrolyzed functionalized di-amino silanol polymer (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as hydrolyzed functionalized di-amino silanol polymer (PMN P-18-152) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

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

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

(b) *Specific requirements.* The provisions of subpart A of this part

apply to this section except as modified by this paragraph (b).

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

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

**§ 721.11318 Propanoic acid, 3-hydroxy-2-(hydroxymethyl)-2-methyl-, polymer with dimethyl carbonate, 1,6-hexanediol, diamine and 1,1'-methylenebis[4-isocyanatocyclohexane], pentaerythritol, triacrylate-blocked, compds. with triethylamine (generic).**

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

(1) The chemical substance generically identified as propanoic acid, 3-hydroxy-2-(hydroxymethyl)-2-methyl-, polymer with dimethyl carbonate, 1,6-hexanediol, diamine and 1,1'-methylenebis[4-isocyanatocyclohexane], pentaerythritol, triacrylate-blocked, compds. with triethylamine (PMN P-18-169) 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)(2)(i), (3), (4) and (5) (respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 1,000 for spray applications and of at least 50 for non-spray applications). When determining which persons are reasonably likely to be exposed as required for in § 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.

(ii) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture (including import) the PMN substance with triethylamine concentration no greater than the confidential concentration 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 (e) and (i) are applicable to manufacturers and processors of this substance.

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

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

**§ 721.11319 Waste plastics, poly(ethylene terephthalate), polymers with diethylene glycol, glycerol, polyerythritol, triethylene glycol, trimethylolalkane and polypropylene glycol (generic).**

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

(1) The chemical substance generically identified as waste plastics, poly(ethylene terephthalate), polymers with diethylene glycol, glycerol, polyerythritol, triethylene glycol, trimethylolalkane and polypropylene glycol. (PMN P-18-200) 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), (3), (4), (5) (respirators must provide a National Institute for Occupational Safety and Health assigned protection factor of at least 10), when determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), (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, (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)(iv), (2)(i), (iv), (v), (avoid eye contact), (use eye protection), (3)(i), (ii), (4)(water releases restrictions apply), and (5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System (GHS) and OSHA Hazard Communication Standard may be used.

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

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where N=280.

(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.

**§ 721.11320 Waste plastics, poly(ethylene terephthalate), polymers with diethylene glycol, glycerol, polyerythritol glycol, trimethylolalkane and polypropylene glycol (generic).**

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

(1) The chemical substance generically identified as waste plastics, poly(ethylene terephthalate), polymers with diethylene glycol, glycerol, polyerythritol glycol, trimethylolalkane and polypropylene glycol (P-18-201) 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), (3), (4), (5) (respirators must provide a National Institute for Occupational Safety and Health assigned protection factor of at least 10), when determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), (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, (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)(iv), (2)(i), (iv), (v), (avoid eye contact), (use eye protection), (3)(i), (ii), (4)(water releases restrictions apply), and (5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System (GHS) and OSHA Hazard Communication Standard may be used.

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

(iv) *Release to water.* Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) where N=280.

(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.

**§ 721.11321 Naphtha oils (generic).**

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

(1) The chemical substance generically identified as naphtha oils (PMN P-18-235) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

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

(ii) [Reserved]

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

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

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

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

**§ 721.11322 Saccharide reaction products with acid anhydride, etherified (generic).**

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

(1) The chemical substance generically identified as saccharide reaction products with acid anhydride, etherified (PMN P-18-238) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

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

(ii) [Reserved]

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

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

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

**§ 721.11323 Alkyl alkenoic acid, alkyl ester, telomere with alkyl alkenoate, substituted alkyl alkyl alkenoate, alkylthiol, substituted carbomonocycle, hydroxyalkyl alkyl alkenoate and alkyl alkyl alkenoate (generic).**

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

(1) The chemical substance generically identified as alkyl alkenoic acid, alkyl ester, telomere with alkyl alkenoate, substituted alkyl alkyl alkenoate, alkylthiol, substituted carbomonocycle, hydroxyalkyl alkyl alkenoate and alkyl alkyl alkenoate (PMN P-18-307) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture (including import) the PMN substance with more than 5% of the molecular weight content less than 1,000 Daltons.

(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.

**§ 721.11324 Formaldehyde, polymer with 2-phenoxyalkanol and .alpha.-phenyl-.omega. hydroxypoly(oxy-1,2-alkylenediyl), dihydrogen phosphate 2-phenoxyalkyl hydrogen phosphate, alkaline salt (generic).**

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

(1) The chemical substance generically identified as formaldehyde, polymer with 2-phenoxyalkanol and .alpha.-phenyl-.omega. hydroxypoly(oxy-1,2-alkylenediyl), dihydrogen phosphate 2-phenoxyalkyl hydrogen phosphate, alkaline salt (PMN P-18-312) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture, process, or use the substance in any manner that results in inhalation exposure. It is a significant new use to manufacture the PMN substance with greater than 20% (weight percent) components with molecular weight below 500 Daltons.

(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.

**§ 721.11325 Substituted polyalkylenepolycarbomonocycle ester, polymer with dialkanolamine, (hydroxyalkoxy)carbonyl derivs., (alkoxyalkoxy) alkanol blocked (generic).**

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

(1) The chemical substance generically identified as substituted polyalkylenepolycarbomonocycle ester, polymer with dialkanolamine, [(hydroxyalkoxy)carbonyl] derivs., (alkoxyalkoxy) alkanol-blocked (PMN P-19-8) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(w)(1)(2), (x)(1)(2), and (y)(1)(2).

(ii) [Reserved]

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

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

**§ 721.11326 Carbonmonocycles, polymer with haloalkyl substituted heteromonocycle and hydro-hydroxypoly[oxy(alkyl-alkanediyl)], dialkyl-alkanediamineterminated, hydroxyalkylated, acetates (salts) (generic).**

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

(1) The chemical substance generically identified as carbonmonocycles, polymer with haloalkyl substituted heteromonocycle and hydro-hydroxypoly[oxy(alkyl-alkanediyl)], dialkyl-alkanediamineterminated, hydroxyalkylated, acetates (salts) (PMN P-19-9) 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) *Industrial, commercial, and consumer activities.* It is a significant

new use to manufacture, process, or use the substance in any manner that results in inhalation exposure to vapor, particulate, mist or aerosols. It is a significant new use to manufacture the PMN substance beyond an annual production volume of 85,000 kg.

(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.

**§ 721.11327 Alkanoic acid, compds. with substituted carbomonocycle-dialkyl-alkanediamine-halosubstituted heteromonocycle-polyalkylene glycol polymerdialkanolamine reaction products (generic).**

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

(1) The chemical substance generically identified as alkanoic acid, compds. with substituted carbomonocycle-dialkyl-alkanediamine-halosubstituted heteromonocycle-polyalkylene glycol polymerdialkanolamine reaction products (PMN P-19-26) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

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

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

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

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

**§ 721.11328 Substituted carbomonocycle, polymer with haloalkyl substituted heteromonocycle, dialkyl-alkanediamine and hydro-hydroxypoly[oxy(alkylalkanediyl)], reaction products with metal oxide and dialkanolamine, acetates (salt) (generic).**

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

(1) The chemical substance generically identified as substituted carbomonocycle, polymer with haloalkyl substituted heteromonocycle, dialkyl-alkanediamine and hydro-hydroxypoly[oxy(alkylalkanediyl)], reaction products with metal oxide and dialkanolamine, acetates (salt) (PMN P-19-27) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture, process, or use the PMN substance in any manner that results in inhalation exposure to vapor, particulate, mist or aerosols. It is a significant new use to manufacture the PMN substance beyond an annual production volume of 95,600 kg.

(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.

**§ 721.11329 Non-metal tetrakis (hydroxyalkyl)-, halide, polymer with amide oxidized (generic).**

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

(1) The chemical substance generically identified as non-metal tetrakis (hydroxyalkyl)-, halide, polymer with amide oxidized (PMN P-19-45) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(j). It is a significant new use to manufacture, process, or use the substance in any manner that results in inhalation exposure. It is a significant new use to manufacture the substance that results in unbound formaldehyde residuals greater than 0.1%.

(ii) [Reserved]

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

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

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

(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.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### 42 CFR Part 88

[NIOH Docket 094]

#### World Trade Center Health Program; Petition 022—Monoclonal Gammopathy of Undetermined Significance; Finding of Insufficient Evidence

**AGENCY:** Centers for Disease Control and Prevention, HHS.

**ACTION:** Denial of petition for addition of a health condition.

**SUMMARY:** On March 11, 2019, the Administrator of the World Trade Center (WTC) Health Program received a petition (Petition 022) to add “monoclonal gammopathy of undetermined significance (MGUS)” to the List of WTC-Related Health Conditions (List). Upon reviewing the scientific and medical literature, including information provided by the petitioner, the Administrator has determined that the available evidence does not have the potential to provide a basis for a decision on whether to add MGUS to the List. The Administrator also finds that insufficient evidence exists to request a recommendation of the WTC Health Program Scientific/Technical Advisory Committee (STAC), to publish a proposed rule, or to publish a determination not to publish a proposed rule.

**DATES:** The Administrator of the WTC Health Program is denying this petition for the addition of a health condition as of August 6, 2019.

**ADDRESSES:** Visit the WTC Health Program website at [https://](https://www.cdc.gov/wtc/received.html)

[www.cdc.gov/wtc/received.html](https://www.cdc.gov/wtc/received.html) to review Petition 022.

**FOR FURTHER INFORMATION CONTACT:** Rachel Weiss, Program Analyst, 1090 Tusculum Avenue, MS: C-48, Cincinnati, OH 45226; telephone (855) 818-1629 (this is a toll-free number); email [NIOHregs@cdc.gov](mailto:NIOHregs@cdc.gov).

#### SUPPLEMENTARY INFORMATION:

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#### A. WTC Health Program Statutory Authority

Title I of the James Zadroga 9/11 Health and Compensation Act of 2010 (Pub. L. 111-347, as amended by Pub. L. 114-113), added Title XXXIII to the Public Health Service (PHS) Act,<sup>1</sup> establishing the WTC Health Program within the Department of Health and Human Services (HHS). The WTC Health Program provides medical monitoring and treatment benefits for health conditions on the List to eligible firefighters and related personnel, law enforcement officers, and rescue, recovery, and cleanup workers who responded to the September 11, 2001, terrorist attacks in New York City, at the Pentagon, and in Shanksville, Pennsylvania (responders), and to eligible persons who were present in the dust or dust cloud on September 11, 2001, or who worked, resided, or attended school, childcare, or adult daycare in the New York City disaster area (survivors).

All references to the Administrator of the WTC Health Program (Administrator) in this document mean the Director of the National Institute for Occupational Safety and Health (NIOSH) or his designee.

Pursuant to section 3312(a)(6)(B) of the PHS Act, interested parties may petition the Administrator to add a health condition to the List in 42 CFR 88.15. Within 90 days after receipt of a valid petition to add a condition to the List, the Administrator must take one of the following four actions described in

section 3312(a)(6)(B) of the PHS Act and § 88.16(a)(2) of the Program regulations: (1) Request a recommendation of the STAC; (2) publish a proposed rule in the **Federal Register** to add such health condition; (3) publish in the **Federal Register** the Administrator's determination not to publish such a proposed rule and the basis for such determination; or (4) publish in the **Federal Register** a determination that insufficient evidence exists to take action under (1) through (3) above.

#### B. Procedures for Evaluating a Petition

In addition to the regulatory provisions, the WTC Health Program has developed policies to guide the review of submissions and petitions,<sup>2</sup> as well as the analysis of evidence supporting the potential addition of a non-cancer health condition to the List.<sup>3</sup>

A valid petition must include sufficient medical basis for the association between the September 11, 2001, terrorist attacks and the health condition to be added; in accordance with WTC Health Program policy, reference to a peer-reviewed, published, epidemiologic study about the health condition among 9/11-exposed populations or to clinical case reports of health conditions in WTC responders or survivors may demonstrate the required medical basis.<sup>4</sup> Studies linking 9/11 agents or hazards<sup>5</sup> to the petitioned health condition may also provide sufficient medical basis for a valid petition.

After the Program has determined that a petition is valid, the Administrator must direct the Program to conduct a review of the scientific literature to determine if the available scientific information has the potential to provide

<sup>2</sup> See WTC Health Program [2014], *Policy and Procedures for Handling Submissions and Petitions to Add a Health Condition to the List of WTC-Related Health Conditions*, May 14, 2014, <http://www.cdc.gov/wtc/pdfs/WTCHPPPPetitionHandlingProcedures14May2014.pdf>.

<sup>3</sup> See WTC Health Program [2017], *Policy and Procedures for Adding Non-Cancer Conditions to the List of WTC-Related Health Conditions*, February 14, 2017, [https://www.cdc.gov/wtc/pdfs/policies/WTCHPP\\_Padding\\_NonCancers\\_14\\_February\\_2017-508.pdf](https://www.cdc.gov/wtc/pdfs/policies/WTCHPP_Padding_NonCancers_14_February_2017-508.pdf).

<sup>4</sup> See *supra* note 2.

<sup>5</sup> 9/11 agents are chemical, physical, biological, or other hazards reported in a published, peer-reviewed exposure assessment study of responders, recovery workers, or survivors who were present in the New York City disaster area, or at the Pentagon site, or the Shanksville, Pennsylvania site, as those locations are defined in 42 CFR 88.1, as well as those hazards not identified in a published, peer-reviewed exposure assessment study, but which are reasonably assumed to have been present at any of the three sites. See WTC Health Program [2018], *Development of the Inventory of 9/11 Agents*, July 17, 2018, [https://www.cdc.gov/ResearchGateway/Content/pdfs/Development\\_of\\_the\\_Inventory\\_of\\_9-11\\_Agents\\_20180717.pdf](https://www.cdc.gov/ResearchGateway/Content/pdfs/Development_of_the_Inventory_of_9-11_Agents_20180717.pdf).

<sup>1</sup> Title XXXIII of the PHS Act is codified at 42 U.S.C. 300mm to 300mm-61. Those portions of the James Zadroga 9/11 Health and Compensation Act of 2010 found in Titles II and III of Public Law 111-347 do not pertain to the WTC Health Program and are codified elsewhere.