



## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Parts 721 and 725

[EPA-HQ-OPPT-2020-0588; FRL-10022-56]

RIN 2070-AB27

### Significant New Use Rules on Certain Chemical Substances (21-1.5e)

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

**ACTION:** Proposed rule.

**SUMMARY:** EPA is proposing significant new use rules (SNURs) under the Toxic Substances Control Act (TSCA) for chemical substances that were the subject of premanufacture notices (PMNs) and a Microbial Commercial Activity Notice (MCAN), and are also subject to Orders issued by EPA pursuant to TSCA. The SNURs require persons who intend to manufacture (defined by statute to include import) or process any of these chemical substances for an activity that is proposed as a significant new use by this rule 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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2020-0588, through the Federal eRulemaking Portal at <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit <https://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** *For technical information contact:* William Wysong, New Chemicals Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-4163; email address: [wysong.william@epa.gov](mailto:wysong.william@epa.gov).

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

## **SUPPLEMENTARY INFORMATION:**

### **I. 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 provisions 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, which would include the SNUR requirements

should these proposed rules be finalized. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, pursuant to 40 CFR 721.20 or 40 CFR 725.920 (for the microorganism), any persons who export or intend to export a chemical substance that is the subject of this proposed rule on or after [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)) (see 40 CFR 721.20), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

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

1. *Submitting CBI.* Do not submit this information to EPA through *regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

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

## **II. Background**

*A. What action is the Agency taking?*

EPA is proposing these SNURs under TSCA section 5(a)(2) (15 U.S.C. 2604(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 any of these chemical substances for an 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.

The docket for these proposed SNURs, identified as docket ID number EPA-HQ-OPPT-2020-0588, includes information considered by the Agency in developing these proposed SNURs.

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

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

*C. Applicability of General Provisions*

General provisions for SNURs appear in 40 CFR part 721, subpart A and (for microorganisms) 40 CFR part 725, subpart L. These provisions describe persons subject to the rule, recordkeeping requirements, exemptions to reporting requirements, and applicability of the rule to uses occurring before the effective date of the rule. Provisions relating to user fees appear at 40 CFR part 700. Pursuant to 40 CFR 721.1(c), persons subject to these SNURs must comply with the same significant new use notice (SNUN) requirements and EPA regulatory procedures as submitters of PMNs under TSCA section 5(a)(1)(A). These requirements include the information submission requirements of TSCA sections 5(b) and 5(d)(1), the exemptions authorized by TSCA sections 5(h)(1), (h)(2), (h)(3), and (h)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUN and before the manufacture or processing for the significant new use can commence, 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. 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 what would constitute a significant new use for the chemical substances that are the subject of these SNURs, EPA considered relevant information about the toxicity of the chemical substances, potential human exposures and environmental releases that may be associated with possible uses of these chemical substances, in the context of the four TSCA section 5(a)(2) factors listed in this unit.

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

Where EPA determined that the PMN substance may present an unreasonable risk of injury to human health via inhalation exposure, the underlying TSCA Order usually requires 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), and includes requirements addressing performance criteria for sampling and analytical methods, periodic monitoring, respiratory protection, and

recordkeeping. 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 Order for the same chemical substance.

#### **IV. Substances Subject to this Proposed Rule**

EPA is proposing significant new use and recordkeeping requirements for certain chemical substances in 40 CFR part 721, subpart E and in 40 CFR part 725, subpart M (for the microorganism). In this unit, EPA provides the following information for each chemical substance that is identified in this unit as subject to this proposed rule:

- PMN or MCAN 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).
- Effective date of and basis for the TSCA Order.
- Potentially Useful Information.
- CFR citation assigned in the regulatory text section of the proposed rule.

The chemicals subject to these proposed SNURs are as follows:

**PMN Number: P-16-167.**

*Chemical Name:* Hindered amine alkyl ester compounds (generic).

*CAS Number:* Not available.

*Effective Date of TSCA Order:* April 24, 2020.

*Basis for TSCA Order:* The PMN states that the use will be as a light stabilizer for plastic articles. Based on submitted test data, EPA has identified concerns for dermal irritation and

sensitization. Based on comparison to analogous aliphatic amines, EPA predicts that toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health or the environment. To protect against these risks, the Order requires:

- Use of personal protective equipment where there is a potential for dermal exposure;
- 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;
- Establishment of a hazard communication program, including human health precautionary statements on each label and in the SDS; and
- No release of the PMN substance resulting in surface water concentrations that exceed 1 ppb.

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

*Potentially Useful Information:* EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of chronic aquatic toxicity and reproduction/developmental toxicity screening testing may be potentially useful to characterize the human health and environmental effects of the PMN substance. Although the Order does not require these tests, the Order’s restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

*CFR Citation:* 40 CFR 721.11571.

**PMN Numbers: P-16-419, P-16-423, and P-16-424.**

*Chemical Names:* N-alkyl-dialkyl piperidine (generic) (P-16-419), Tetraalkylpiperidinium halide (generic) (P-16-423), and Tetraalkylpiperidinium hydroxide (generic) (P-16-424).

*CAS Numbers:* Not available.

*Effective Date of TSCA Order:* April 15, 2020.

*Basis for TSCA Order:* The PMNs state that the generic (non-confidential) uses will be as an intermediate (P-16-419 and P-16-423) and as a directing agent (P-16-424). Based on comparison to analogous chemical substances, EPA has identified concerns for acute toxicity, corrosion, systemic and respiratory effects (P-16-419). Based on comparison to analogous chemical substances and the high pH, EPA has identified concerns for acute oral toxicity, developmental/reproductive toxicity, neurotoxicity, renal effects, and corrosion to all tissues (P-16-423 and P-16-424). Based on comparison to analogous chemical substances, EPA predicts that toxicity to aquatic organisms may occur at concentrations that exceed 286 ppb for P-16-419 and 20 ppb for P-16-423 and P-16-424. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substances may present an unreasonable risk of injury to human health or the environment. 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 which was the subject of P-16-424 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 a significant (or substantial) human exposure to the substance. To protect against these risks, the Order requires:

- Use of personal protective equipment where there is a potential for dermal exposure;
- Use of a NIOSH-certified respirator with an APF of at least 10 where there is a potential for inhalation exposure (P-16-419);
- Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS;



- Use of P-16-419 only as a site-limited intermediate;
- Use of P-16-423 only as an intermediate;
- Use of P-16-424 only for the confidential use allowed in the Order; and
- No release of the PMN substances resulting in surface water concentrations that exceed 286 ppb (P-16-419) or 20 ppb (P-16-423 and P-16-424).

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

*Potentially Useful Information:* EPA as determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of aquatic toxicity and specific target organ toxicity testing may be potentially useful to characterize the human health and environmental effects of the PMN substances. Additionally, the results of reproductive toxicity testing may be potentially useful to characterize the human health effects of PMNs P-16-423 and P-16-424.

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 721.11572 (P-16-419), 40 CFR 721.11573 (P-16-423), and 40 CFR 721.11574 (P-16-424).

**PMN Numbers: P-17-235 and P-18-226.**

*Chemical Names:* Amidoamino quaternary ammonium salt (generic) (P-17-235), and Tri alkyl, mono alkoxy, fatty acid ester, ammonium salt (generic) (P-18-226).

*CAS Numbers:* Not available.

*Effective Date of TSCA Order:* April 22, 2020.

*Basis for TSCA Order:* The PMNs state that the generic (non-confidential) use of the PMN substances will be as an anti-agglomerant. Based on the surfactant properties of the compounds and comparison to analogous substances, EPA has identified concerns for surfactant effects on

the lungs, irritation and possible corrosion to the eyes, skin, and respiratory tract. Based on comparison to analogous substances, EPA has also identified concerns for developmental toxicity. Based on comparison to analogous polycationic polymers, EPA predicts that toxicity to aquatic organisms may occur at concentrations that exceed 60 ppb for P-17-235 and 44 ppb for P-18-226. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substances may present an unreasonable risk of injury to human health or the environment.

To protect against these risks, the Order requires:

- Use of the PMN substances only for the uses allowed in the Order; and
- No release of the PMN substances resulting in surface water concentrations that exceed 44 ppb.

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

*Potentially Useful Information:* EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of chronic aquatic toxicity, reproductive toxicity, and pulmonary effects testing may be potentially useful to characterize the human 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 721.11575 (P-17-235) and 40 CFR 721.11576 (P-18-226).

**PMN Number: P-17-259.**

*Chemical Name:* Halogenated aromatic amine (generic).

*CAS Number:* Not available.

*Effective Date of TSCA Order:* August 31, 2020.

*Basis for TSCA Order:* The PMN states that the generic (non-confidential) use of the substance will be as a curative for thermosetting resins. Based on comparison to structurally analogous chemical substances, EPA has identified concerns for skin sensitization and systemic effects (liver, blood, and spleen). Based on comparison to analogous anilines, EPA predicts that toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health or the environment. To protect against these risks, the Order requires:

- No release of the PMN substance resulting in surface water concentrations that exceed 1 ppb.

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

*Potentially Useful Information:* EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of skin sensitization, specific target organ toxicity, and aquatic toxicity testing may be potentially useful to characterize the human health and environmental effects of the PMN substance. Although the Order does not require these tests, the Order’s restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

*CFR Citation:* 40 CFR 721.11577.

**PMN Number: P-18-43.**

*Chemical Name:* 1,4-Benzenedicarboxylic acid, 1,4-dipentyl ester, branched and linear.

*CAS Number:* 2097734-13-7.

*Effective Date of TSCA Order:* September 16, 2020.

*Basis for TSCA Order:* The PMN states that the use will be as a plasticizer or fast fuser in PVC-plastisols for flooring, wall paper, coated fabrics, underbody coating; processing aid or fast fuser in PVC dry blends for flooring, coated fabrics, films & sheets, tubes & hoses; flexibilizing additive for paints and lacquers; use in formulation or re-packing; and as a laboratory agent. Based on the potential metabolite terephthalic acid, EPA has identified concerns for systemic toxicity. Based on comparison to analogous esters, EPA predicts that toxicity to aquatic organisms may occur at concentrations that exceed 2 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health or 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 expected to be produced in substantial quantities, and that there may be a significant or substantial human exposure to the substance, and that the substance may enter the environment in substantial quantities. To protect against these risks, the Order requires:

- No release of the PMN substance resulting in surface water concentrations that exceed 2 ppb.

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

*Potentially Useful Information:* EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of chronic aquatic toxicity testing may be potentially useful to characterize the environmental effects of the PMN substance. Although the Order does not require these tests, the Order’s restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

*CFR Citation:* 40 CFR 721.11578.

**PMN Numbers: P-18-178, P-18-217, and P-18-218.**

*Chemical Names:* Dialkyltin dialkylcarboxylate (generic) (P-18-178), Alkyltin dodecylthioester (generic) (P-18-217), and Alkyltin tetradecylthioester (generic) (P-18-218).

*CAS Numbers:* Not available.

*Effective Date of TSCA Order:* May 20, 2020.

*Basis for TSCA Order:* The PMNs state that the use of the substances will be as stabilizers for PVC compounds. Based on the physical/chemical properties of the PMN substances and test data on structurally similar substances, the PMN substances are potentially persistent, bioaccumulative, and toxic (PBT) chemicals (as described in the New Chemical Program's PBT category at 64 FR 60194; November 4, 1999; FRL-6097-7). EPA estimates that the PMN substances will persist in the environment for more than 2 months and estimates a bioaccumulation factor of greater than or equal to 1,000. Based on comparison to analogous chemical substances, EPA has identified concerns for immune, reproductive, developmental, and systemic effects. Based on comparison to analogous organotins, EPA predicts that toxicity to aquatic organisms may occur at concentrations that exceed 2 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substances may present an unreasonable risk of injury to human health or 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 a significant (or substantial) human exposure to the substances. To protect against these risks, the Order requires:

- Use of personal protective equipment where there is a potential for dermal exposure;
- Use of a NIOSH-certified respirator with an APF of at least 10 where there is a potential for inhalation exposure for P-18-178;

- No use of the PMN substances other than as stabilizers for PVC compounds; and
- No release of the PMN substances into the waters of the United States.

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

*Potentially Useful Information:* EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of persistence, bioaccumulation, aquatic toxicity, reproductive toxicity and specific target organ toxicity testing may be potentially useful to characterize the human 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 721.11579 (P-18-178), 40 CFR 721.11580 (P-18-217), and 40 CFR 721.11581 (P-18-218).

**PMN Number: P-18-256.**

*Chemical Name:* Undecanol, branched.

*CAS Number:* 203473-00-4.

*Effective Date of TSCA Order:* August 18, 2020.

*Basis for TSCA Order:* The PMN states that the generic (non-confidential) use will be as a chemical intermediate and a solvent. Based on submitted test data on the new chemical substance, EPA has identified concerns for skin and eye irritation and systemic toxicity. Based on test data for structurally analogous chemical substance, EPA has also identified concerns for developmental and systemic toxicity. Based on comparison to analogous neutral organics, EPA predicts that toxicity to aquatic organisms may occur at concentrations that exceed 4 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may

present an unreasonable risk of injury to human health or the environment. 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 expected to be produced in substantial quantities, and that there may be significant or substantial human exposure to the substance, and that the substance may enter the environment in substantial quantities. To protect against these risks, the Order requires:

- No use of the PMN substance other than as a chemical intermediate; and
- No release of the PMN substance resulting in surface water concentrations that exceed 4 ppb.

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

*Potentially Useful Information:* EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of specific organ toxicity, developmental toxicity, and aquatic toxicity testing may be potentially useful to characterize the human health and environmental effects of the PMN substance. Although the Order does not require these tests, the Order’s restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

*CFR Citation:* 40 CFR 721.11582.

**PMN Number: P-18-283.**

*Chemical Name:* Hydroxy alkanolic acid, compds. with aminoalkoxyalcohol-epoxy polymer-alkanolamine reaction products (generic).

*CAS Number:* Not available.

*Effective Date of TSCA Order:* March 31, 2020.

*Basis for TSCA Order:* The PMN states that the generic (non-confidential) use of the substance will be for open, non-dispersive use. Based on comparison to structurally analogous chemical

substances for the low molecular weight (LMW) fractions of the PMN substance, EPA has identified concerns for irritation and sensitization. Based on comparison to structurally analogous chemical substances, EPA has also identified concerns for reproductive toxicity and systemic effects. Based on comparison to analogous aliphatic amines and polycationic polymers, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 4 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

- Use of personal protective equipment where there is a potential for dermal exposure;
- Establishment of a hazard communication program, including human health

precautionary statements on each label and in the SDS; and

- No release of the PMN substance into the waters of the United States.

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

*Potentially Useful Information:* EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of aquatic toxicity, skin and eye irritation, skin sensitization, reproductive toxicity, and specific target organ toxicity testing may be potentially useful to characterize the human health and environmental effects of the PMN substance.

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

*CFR Citation:* 40 CFR 721.11583.

**PMN Number: P-18-298.**



*Chemical Name:* 1,3-Propanediol, 2-ethyl-2-(hydroxymethyl)-, polymer with ethyleneamine, 2-(chloromethyl)oxirane, 2-[[4-(1,1-dimethylethyl)phenoxy]methyl]oxirane, 2,2'-[1,6-hexanediylbis(oxymethylene)]bis[oxirane], 4,4'-(1-methylethylidene)bis[phenol], alkyl ether amine, and 2-[(2-methylphenoxy)methyl]oxirane (generic).

*CAS Number:* Not available.

*Effective Date of TSCA Order:* August 4, 2020.

*Basis for TSCA Order:* The PMN states that the generic (non-confidential) use will be as an epoxy curing agent. Based on comparison to structurally analogous amines and the LMW fractions, EPA has identified concerns for skin and eye irritation, dermal and respiratory sensitization, and lung effects. Based on the comparison to structurally analogous epoxide residuals, EPA has also identified concerns for reproductive toxicity and systemic effects. Based on comparison to analogous aliphatic amines and polycationic polymers, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 50 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health or the environment. To protect against these risks, the Order requires:

- No manufacturing, processing, or use of the PMN substance in an application method that results in inhalation exposure;
- No use of the PMN substance in a consumer product; and
- No release of the PMN substance resulting in surface water concentrations that exceed 50 ppb.

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

*Potentially Useful Information:* EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or

processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of absorption, eye damage, skin irritation, specific target organ toxicity, and aquatic toxicity testing may be potentially useful to characterize the human health and environmental effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

*CFR Citation:* 40 CFR 721.11584.

**PMN Number: P-18-310.**

*Chemical Name:* Benzenepropanoic acid, 3-(2H-benzotriazol-2-yl)-5-(1,1-dimethylethyl)-4-hydroxy-2,2-bis(hydroxymethyl)butyl ester.

*CAS Number:* 2101609-93-0.

*Effective Date of TSCA Order:* August 14, 2020.

*Basis for TSCA Order:* The PMN states that the generic (non-confidential) use will be as a polymer additive. Based on test data on structurally analogous chemical substances, EPA has identified concerns for blood, liver, thyroid and kidney effects, reproductive toxicity, and developmental toxicity. Based on comparison to analogous phenols and benzotriazoles, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health or the environment. To protect against these risks, the Order requires:

- Use of personal protective equipment where there is a potential for dermal exposure;
- Use of a NIOSH-certified respirator with an APF of at least 1,000 where there is a potential for inhalation exposure;
- Establishment of a hazard communication program, including human health precautionary statements on each label and in the SDS; and

- No release of the PMN substance resulting in surface water concentrations that exceed 1 ppb.

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

*Potentially Useful Information:* EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if the manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of developmental neurotoxicity and aquatic toxicity testing may be potentially useful to characterize the human health and environmental effects of the PMN substance. Although the Order does not require these tests, the Order’s restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

*CFR Citation:* 40 CFR 721.11585.

**PMN Number: P-18-318.**

*Chemical Name:* 1-Octadecanaminium, N,N-dimethyl-N- [3-(triethoxysilyl)propyl]-, chloride (1:1).

*CAS Number:* 62117-57-1.

*Effective Date of TSCA Order:* September 25, 2020.

*Basis for TSCA Order:* The PMN states that the use will be as a surface treatment for added lubricity and anti-static purposes. Based on comparison to structurally analogous chemical substances, EPA has identified concerns for irritation to the eyes, skin, and respiratory tract and liver effects. Based on comparison to structurally analogous chemical substances and structural alerts for cationic surfactants, EPA has also identified concerns for lung effects. Based on comparison to analogous polycationic polymers, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient

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

- Establishment of a hazard communication program, including human health precautionary statements on each label and in the SDS;
- Use of the PMN substance only as a surface treatment for added lubricity and anti-static properties;
- No use of the PMN substance in an application method that results in inhalation exposure; and
- No release of the PMN substance resulting in surface water concentrations that exceed 1 ppb.

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

*Potentially Useful Information:* EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of skin irritation, eye irritation, pulmonary effects, and aquatic toxicity testing may be potentially useful to characterize the human health and environmental effects of the PMN substance. Although the Order does not require these tests, the Order’s restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

*CFR Citation:* 40 CFR 721.11586.

**PMN Number: P-18-323.**

*Chemical Name:* 2-Propenoic acid, 2-methyl-, 3-methyl-3-buten-1-yl ester.

*CAS Number:* 156291-88-2.

*Effective Date of TSCA Order:* March 13, 2020.

*Basis for TSCA Order:* The PMN states that the generic (non-confidential) use of the PMN

substance will be as a raw material for polymer manufacturing. Based on submitted test data on the PMN substance and structural alerts, EPA has identified concerns for skin irritation and skin/respiratory sensitization. Based on comparison to structurally analogous chemical substances, EPA has also identified concerns for systemic, respiratory, and developmental effects. Based on comparison to analogous methacrylates, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 98 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health or the environment. To protect against these risks, the Order requires:

- Use of personal protective equipment where there is a potential for dermal exposure;
- Use of a NIOSH-certified respirator with an APF of at least 50 to prevent inhalation exposure where there is a potential for inhalation exposure;
- Establishment of a hazard communication program, including human health precautionary statements on each label and in the SDS;
- Use of the PMN substance only for the confidential use allowed in the Order; and
- No release of the PMN substance resulting in surface water concentrations that exceed 98 ppb.

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

*Potentially Useful Information:* EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this SNUR. EPA has determined that the results of chronic aquatic toxicity and specific target organ toxicity testing may be potentially useful to characterize the environmental and human 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 721.11587.

**PMN Number: P-18-327.**

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

*CAS Number:* Not available.

*Effective Date of TSCA Order:* August 21, 2020.

*Basis for TSCA Order:* The PMN states that the generic (non-confidential) use will be as a filler for non-dispersive resins. Based on comparison to structurally analogous chemical substances, EPA has identified concerns for dermal and respiratory sensitization. EPA has also identified concerns for lung effects (lung overload) if the particulate is respirable, based on information for other poorly soluble particulates, and carcinogenicity if the PMN substance is crystalline and respirable. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health or the environment. To protect against these risks, the Order requires:

- Use of personal protective equipment where there is a potential for dermal exposure;
- 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 0.1 mg/m<sup>3</sup> as an 8-hour time-weighted average (TWA) to prevent inhalation exposure; and
- Establishment of a hazard communication program, including human health precautionary statements on each label and in the SDS.

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

*Potentially Useful Information:* EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by

this SNUR. EPA has determined that the results of pulmonary toxicity, skin sensitization, and carcinogenicity testing may be potentially useful to characterize the human 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 721.11588.

**PMN Number: P-18-347.**

*Chemical Name:* Amines, polyethylenepoly-, triethylenetetramine fraction, polymers with guanidine hydrochloride (1:1).

*CAS Number:* 1902936-67-7.

*Effective Date of TSCA Order:* March 17, 2020.

*Basis for TSCA Order:* The PMN states that the use of the substance will be as an aldehyde scavenger for the manufacture of polyurethane foams. Based on comparison to structurally analogous chemical substances, EPA has identified concerns for skin sensitization. Based on available test data on the PMN substance, EPA has also identified concerns for acute toxicity. Based on structural alerts for polycationic binding, EPA has also identified concerns for lung effects. Based on comparison to structurally analogous polycationic polymers, EPA predicts that toxicity to aquatic organisms may occur at concentrations that exceed 2 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

- Use of personal protective equipment where there is a potential for dermal exposure;
- Establishment of a hazard communication program, including human health

precautionary statements on each label and in the SDS; and

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

ppb.

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

*Potentially Useful Information:* EPA has determined that certain information about 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 determined that the results of aquatic toxicity, pulmonary effects and skin sensitization testing may be potentially useful to characterize the human health and environmental effects of the PMN substance. Although the Order does not require these tests, the Order’s restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

*CFR Citation:* 40 CFR 721.11589.

**PMN Number: P-18-405.**

*Chemical Name:* Phenol, 4,4’-(1-methylethylidene)bis-, polymer with 3,6,9,12-tetraoxatetradeca-1, 13-diene, glycidyl ether.

*CAS Number:* 647028-24-8.

*Effective Date of TSCA Order:* August 7, 2020.

*Basis for TSCA Order:* The PMN states that the generic (non-confidential) use will be as an adhesive. Based on the epoxide moiety for the LMW fraction, EPA has identified concerns for skin and lung sensitization, carcinogenicity, developmental toxicity, male reproductive toxicity, liver, and kidney toxicity. Based on submitted test data, information in the SDS, and analogous epoxides, EPA has also identified concerns for skin irritation and genotoxicity. Based on comparison to analogous epoxides, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health or



the environment. To protect against such risks, the Order requires:

- No manufacturing, processing, or use of the PMN substance in a manner that results in inhalation exposure;
- No use of the PMN substance in a consumer product; and
- No release of the PMN substance resulting in surface water concentrations that exceed 1 ppb.

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

*Potentially Useful Information:* EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of pulmonary toxicity, skin sensitization, carcinogenicity, reproductive/developmental toxicity, skin and eye irritation, specific target organ toxicity and aquatic toxicity testing may be potentially useful to characterize the human health and environmental effects of the PMN substance. Although the Order does not require these tests, the Order’s restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

*CFR Citation:* 40 CFR 721.11590.

**PMN Number: P-19-36.**

*Chemical Name:* 1,4-Benzenedicarboxylic acid, 1,4-bis(2-phenoxyethyl) ester.

*CAS Number:* 25900-07-6.

*Effective Date of TSCA Order:* July 24, 2020.

*Basis for TSCA Order:* The PMN states that the use will be as an additive to polymers for improvement in gas barrier performance. Based on comparison to structurally analogous chemical substances, EPA has identified concerns for irritation to the skin, eyes, and respiratory tract. Based on test data for terephthalic acid, EPA has also identified concerns for bladder

effects and developmental effects. Based on test data for 2-phenoxyethanol, EPA has also identified concerns for blood effects, kidney effects, bladder effects, and respiratory tract effects. Based on comparison to analogous esters, EPA predicts that toxicity to aquatic organisms may occur at concentrations that exceed 3 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health or the environment. To protect against these risks, the Order requires:

- Use of personal protective equipment where there is a potential for dermal exposure;
- Use of a NIOSH-certified respirator with an APF of at least 1,000 where there is a potential for inhalation exposure; and
- No release of the PMN substance resulting in surface water concentrations that exceed 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 may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of skin irritation, reproductive/developmental toxicity, specific target organ toxicity, and aquatic toxicity testing may be potentially useful to characterize the human health and environmental effects of the PMN substance. Although the Order does not require these tests, the Order’s restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

*CFR Citation:* 40 CFR 721.11591.

**PMN Number: P-19-52.**

*Chemical Name:* Poly(oxy-1,2-ethanediyl), .alpha.-nonyl-.omega.-hydroxy-, branched and linear.

*CAS Number:* 2242406-13-7.

*Effective Date of TSCA Order:* February 14, 2020.

*Basis for TSCA Order:* The PMN states that the use of the PMN substance will be as a hard surface cleaner and as a component of laundry detergent. Based on repeating polyether units, EPA has identified concerns for surfactant effects on the lungs. Based on comparison to structurally analogous chemical substances, EPA has also identified concerns for eye corrosion and mild skin irritation. Based on alcohol ethoxylates, EPA has also identified liver, cardiac, and systemic effects. Based on comparison to analogous nonionic surfactants, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 34 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health or the environment. To protect against these risks, the Order requires:

- Use of personal protective equipment where there is a potential for dermal exposure;
- Use of a NIOSH-certified respirator with an APF of at least 1,000 where there is potential for inhalation exposure;
- Establishment of a hazard communication program, including human health precautionary statements on each label and in the SDS;
- No use of the PMN substance where the concentration of the PMN substance in the product formulation intended for distribution in commerce exceeds 1% by weight; and
- No release of the PMN substance resulting in surface water concentrations that exceed 34 ppb.

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

*Potentially Useful Information:* EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by

this SNUR. EPA has determined that the results of acute aquatic toxicity, chronic aquatic toxicity, pulmonary effects, specific target organ toxicity, eye damage, and skin irritation testing may be potentially useful to characterize the human health and environmental effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions still 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 721.11592.

**PMN Number: P-19-53.**

*Chemical Name:* 1-Butanamine, N-butyl-N-[(triethoxysilyl)methyl]-.

*CAS Number:* 35501-23-6.

*Effective Date of TSCA Order:* August 5, 2020.

*Basis for TSCA Order:* The PMN states that the use of the substance will be as a surface treatment, sealant, caulk, and coating for mineral building materials such as concrete, brick, limestone, and plaster, as well as on wood, metal, and other substrates. Based on the alkoxysilanes category and reactivity of the new chemical substance, EPA has identified concerns for lung effects. Based on submitted test data, EPA has also identified concerns for skin sensitization and developmental effects. Based on comparison to analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur in concentrations that exceed 150 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health or the environment. To protect against these risks, the Order requires:

- Use of dermal protective equipment where there is a potential for dermal exposure;
- No import, processing, or use of the PMN substance other than in liquid form;
- No domestic manufacture (i.e., import only); and
- No use of the PMN 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 may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of pulmonary effects and skin sensitization testing may be potentially useful to characterize the human 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 721.11593.

**PMN Number: P-19-77.**

*Chemical Name:* Alkenylamide (generic).

*CAS Number:* Not available.

*Effective Date of TSCA Order:* March 31, 2020.

*Basis for TSCA Order:* The PMN states that the generic (non-confidential) use of the substance will be for agricultural use. Based on available test data on a structurally analogous chemical substance, EPA has identified concerns for skin irritation, eye irritation, reproductive toxicity, and systemic toxicity. Based on information in the SDS, EPA has also identified concerns for respiratory tract irritation. Based on comparison to analogous amides, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 4 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

- Use of the PMN substance only for the confidential use allowed in the Order; and
- No release of the PMN substance resulting in surface water concentrations that exceed 4

ppb.

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

*Potentially Useful Information:* EPA has determined that certain information may be potentially useful 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 determined that the results of eye damage, skin irritation, specific target organ toxicity, and aquatic toxicity testing may be potentially useful to characterize the human health and environmental effects of the PMN substance. Although the Order does not require these tests, the Order’s restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

*CFR Citation:* 40 CFR 721.11594.

**PMN Number: P-19-131.**

*Chemical Name:* Isoalkylaminium, N-isoalkyl, -N, N-dimethyl chloride (generic).

*CAS Number:* Not available.

*Effective Date of TSCA Order:* July 24, 2020.

*Basis for TSCA Order:* The PMN states that the generic (non-confidential) use will be as an additive for horizontal oil drilling. Based on comparison to structurally analogous chemical substances, EPA has identified concerns for irritation to the eyes and skin, systemic effects, lung effects, and developmental effects. Based on comparison to analogous chemical substances, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health or the environment. To protect against these risks, the Order requires:

- Establishment of a hazard communication program, including human health

precautionary statements on each label and in the SDS;

- No manufacturing, processing, or use of the PMN substance in a manner that results in inhalation exposure;
- No use of the PMN substance in consumer products; and
- No release of the PMN substance resulting in surface water concentrations that exceed 1 ppb.

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

*Potentially Useful Information:* EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of skin irritation, eye irritation, specific target organ toxicity, and aquatic toxicity testing may be potentially useful to characterize the human health and environmental effects of the PMN substance. Although the Order does not require these tests, the Order’s restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

*CFR Citation:* 40 CFR 721.11595.

**PMN Numbers: P-19-143 and P-19-144.**

*Chemical Names:* Aldehyde, polymer with mixed alkane polyamines, 2,2’-[1,4-alkanediylbis(oxyalkylene)]bis[oxirane], 2-(alkoxyalkyloxirane, 4,4’-(1-alkylidene)bis[phenol], 2,2’-[(1-alkylidene)bis(4,1-alkyleneoxyalkylene)]bis[oxirane] and 2-(aryloxyalkyl)oxirane, acetate (salt) (generic) (P-19-143) and Alkanedioic acid, compds. with substituted arylalkylamine-arylalcohol disubstituted alkane-the diglycidyl ether of a arylalcohol disubstituted alkane-epichlorohydrin-aldehyde-2,2’[(1-alkylidene)bis[4,1-aryleneoxy(alkyl-2,1-alkanediyl)oxyalkylene]]bis[oxirane]-alkanepolyamine polymer-1-[[2-[(2-aminoalkyl)amino]alkyl]amino]-3-aryloxy-2-alcohol reaction products (generic) (P-19-144).

*CAS Numbers:* Not available.

*Effective Date of TSCA Order:* February 18, 2020.

*Basis for TSCA Order:* The PMNs state that the use of the substances will be as a crosslinking agent for use in epoxy resin for water-based coating for a variety of substrates and civil applications in commercial uses (P-19-143) and a crosslinking agent in epoxy based self-leveling floor coatings (P-19-144). EPA has identified concerns for lung effects (cationic binding) if respirable particles are inhaled. Based on structural alerts for polyamines, EPA has identified dermal and respiratory sensitization. Based on comparison to analogous chemical substances, EPA has identified concerns for skin and eye irritation. Based on the LMW species, EPA has also identified concerns for systemic, reproductive, and developmental effects. Based on comparison to analogous polycationic polymers, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substances may present an unreasonable risk of injury to human health or 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 which was the subject of PMN P-19-143 is expected to be produced in substantial quantities, and that there may be significant or substantial human exposure to the substance, and that the substance may enter the environment in substantial quantities. To protect against these risks, the Order requires:

- No manufacture, processing, or use of the PMN substances in a manner that results in inhalation exposure to either the PMN substances or to formaldehyde;
- No use of the PMN substances in consumer products; and
- No release of the PMN substances resulting in surface water concentrations that exceed 1 ppb.

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



*Potentially Useful Information:* EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of pulmonary effects, eye irritation, skin irritation, skin sensitization, specific target organ toxicity, reproductive and developmental toxicity, and aquatic toxicity testing may be potentially useful to characterize the human 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 721.11596 (P-19-143) and 40 CFR 721.11597 (P-19-144).

**PMN Number: P-19-145.**

*Chemical Name:* Polyazaalkane with oxirane and methyloxirane, haloalkane (generic).

*CAS Number:* Not available.

*Effective Date of TSCA Order:* July 6, 2020.

*Basis for TSCA Order:* The PMN states that the use of the substance will be as an oil field drilling fluid additive. Based on structure, EPA has identified concerns for lung effects (surfactancy). Based on comparison to structurally analogous chemical substances, EPA has also identified concerns for neurological, systemic, and reproductive/developmental effects. Based on comparison to analogous cationic polymers, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 26 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health or the environment. To protect against these risks, the Order requires:

- Establishment of a hazard communication program, including human health precautionary statements on each label and in the SDS;
- No manufacture, processing, or use of the PMN substance in a manner that results in

inhalation exposure; and

- No release of the PMN substance resulting in surface water concentrations that exceed 26 ppb.

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

*Potentially Useful Information:* EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of neurotoxicity, specific target organ toxicity, pulmonary effects, reproductive/developmental effects, and aquatic toxicity testing may be potentially useful to characterize the health and environmental effects of the PMN substance.

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

*CFR Citation:* 40 CFR 721.11598.

**PMN Number: P-19-153.**

*Chemical Name:* Dibromoalkyl ether tetrabromobisphenol A (generic).

*CAS Number:* None available.

*Effective Date of TSCA Order:* July 20, 2020.

*Basis for TSCA Order:* The PMN states that the use of the substance will be as a raw material in flame retardant products. Based on the physical/chemical properties of the PMN substance and of the photolysis product, the PMN substance and the photolysis product are potentially persistent, bioaccumulative, and toxic (PBT) chemicals (as described in the New Chemical Program's PBT category at 64 FR 60194; November 4, 1999; FRL-6097-7). EPA estimates that the PMN substance will persist in the environment for more than 6 months and estimates a bioaccumulation factor of greater than or equal to 1,000. EPA estimates that the photolysis product will persist in the environment for more than 2 months and estimates a bioaccumulation

factor of greater than or equal to 1,000. Based on available data on the PMN substance, EPA has identified concerns for eye irritation, systemic effects, and reproductive/developmental effects. Based on data for the photolysis product, EPA has also identified concerns for systemic effects and carcinogenicity. Based on comparison to analogous anionic surfactants, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health or the environment. To protect against these risks, the Order requires:

- Use of personal protective equipment where there is a potential for dermal exposure;
- Establishment of a hazard communication program, including human health

precautionary statements on each label and in the SDS; and

- No release of the PMN substance into surface waters of the United States.

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

*Potentially Useful Information:* EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of environmental fate, bioaccumulation, specific target organ toxicity and carcinogenicity testing may be potentially useful to characterize the human 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 721.11599.

**PMN Number: P-20-29.**

*Chemical Name:* Octonal, 7(or 8)-formyl-.

*CAS Number:* 1607842-40-9.

*Effective Date of TSCA Order:* August 5, 2020.

*Basis for TSCA Order:* The PMN states that the generic (non-confidential) use will be as an oil soluble additive. Based on submitted test data on the new chemical substance, EPA has identified concerns for skin and eye irritation, dermal sensitization, systemic toxicity, and neurotoxicity. Based on OECD Toolbox results, EPA has identified concerns for respiratory sensitization. Based on comparison to structurally analogous chemical substances, EPA has also identified concerns for respiratory effects. Based on comparison to analogous neutral organics, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 17 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health or the environment. To protect against these risks, the Order requires:

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

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

*Potentially Useful Information:* EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of aquatic toxicity testing may be potentially useful to characterize the environmental effects of the PMN substance. Although the Order does not require these tests, the Order’s restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

*CFR Citation:* 40 CFR 721.115600.

**PMN Number: P-20-42.**

*Chemical Name:* Sulfonium, trisaryl-, 7,7-dialkyl-2-heteropolycyclic-1-alkanesulfonate (1:1) (generic).

*CAS Number:* Not available.

*Effective Date of TSCA Order:* April 29, 2020.

*Basis for TSCA Order:* The PMN states that the generic (non-confidential) use of the PMN substance will be as a photoacid generator. Based on the physical/chemical properties of the PMN substances and test data on structurally similar substances, the PMN substances are potentially persistent, bioaccumulative, and toxic (PBT) chemicals (as described in the New Chemical Program's PBT category at 64 FR 60194; November 4, 1999; FRL-6097-7). EPA estimates that the PMN substances will persist in the environment for more than 2 months and estimates a bioaccumulation factor of greater than or equal to 1,000. Based on the photoreactivity of the PMN substance, EPA has identified concerns for photosensitization. Based on comparison to analogous substances, EPA has identified concerns for eye corrosion, irritation, acute toxicity, liver toxicity, neurotoxicity, and reproductive (developmental) toxicity. EPA has also identified concerns for lung overload by insoluble polymers for photoacid generators with polymeric anions that have a molecular weight over 10,000 g/mol. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health or the environment. To protect against these risks, the Order requires:

- No manufacture of the PMN substance beyond the time limits specified in the Order without submittal to EPA the results of certain testing described in the Testing section of the Order.

- Use of personal protective equipment where there is a potential for dermal exposure;
- Establishment of a hazard communication program, including human health precautionary statements on each label and in the SDS;

- No modification of the processing of the PMN substance in any way that generates a

vapor, dust, mist, or aerosol in a non-enclosed process;

- Use of the PMN substance only as described in the PMN;
- No domestic manufacture of the PMN substance (i.e., import only);
- Import of the PMN substance only in solution, or in any form in sealed containers

weighing 5 kilograms or less; and

- No exceedance of the confidential annual importation volume listed the Order.

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

*Potentially Useful Information:* EPA has determined that certain information about the physical/chemical properties, fate, bioaccumulation, environmental hazard, and human health effects of the PMN substance may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. The submitter has agreed not to exceed the time limits specified in the Order without performing the required Tier I and Tier II testing outlined in the Testing section of the Order.

*CFR Citation:* 40 CFR 721.11601.

**PMN Number: P-20-104.**

*Chemical Name:* Alkenoic acid, polymer with (alkyl alkenyl) polyether (generic).

*CAS Number:* None available.

*Effective Date of TSCA Order:* August 25, 2020.

*Basis for TSCA Order:* The PMN states that the generic (non-confidential) use will be as an additive. Based on structural alerts and comparison to structurally analogous chemical substances, EPA has identified concerns for lung effects (surfactancy) and irritation to the skin, eyes, and respiratory tract. Based on comparison to structurally analogous chemical substances, EPA has also identified concerns for systemic effects (i.e., neurotoxicity and cardiotoxicity) and aquatic toxicity. Based on a residual which is present in the substance, EPA has also identified

concerns for irritation/corrosion to the skin and eyes, skin sensitization, systemic effects, and developmental effects. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health. 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 expected to be produced in substantial quantities, and that there may be significant or substantial human exposure to the substance, and that the substance may enter the environment in substantial quantities. To protect against these risks, the Order requires:

- No manufacture, processing, or use of the PMN substance in a manner that results in inhalation exposure;
- No use of the PMN substance in a consumer product;
- No release of the PMN substance resulting in surface water concentrations that exceed 75 ppb.

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

*Potentially Useful Information:* EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of aquatic toxicity testing may be potentially useful to characterize the environmental effects of the PMN substance. Although the Order does not require these tests, the Order’s restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

*CFR Citation:* 40 CFR 721.11602.

**MCAN Number: J-16-26.**

*Microorganism name:* *Trichoderma reesei* modified (generic).

*CAS number:* Not applicable.

*Effective Date of TSCA Order:* April 10, 2017.

*Basis for TSCA Order:* The MCAN states that the generic (non-confidential) use of the microorganism will be for enzyme production. EPA determined that certain fermentation conditions, other than the typical submerged standard industrial fermentation process for enzyme production, could result in increased exposures. Specifically, EPA is concerned that where growth on plant material or on solid substrates occurs, *T. reesei* has been shown to produce a secondary metabolite known as paracelsin, which is associated with a variety of toxic effects to mammalian and bacterial cells. 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 microorganism may present an unreasonable risk of injury to human health or the environment. To protect against these risks, the Order requires:

- No manufacture, processing, or use of the microorganism other than in a fermentation system that meets all of the following conditions:

- (A) Enzyme production occurs by submerged fermentation (i.e., for enzyme production, growth of the microorganism occurs beneath the surface of the liquid growth medium); and

- (B) Any fermentation of solid plant material or insoluble substrate, to which *Trichoderma reesei* fermentation broth is added after the standard industrial fermentation is completed, is initiated only after the inactivation of the microorganism as delineated in 40 CFR 725.422(d).

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

*Potentially useful information:* EPA has determined that the results of the following studies would help characterize any potential human health and environmental effects of the MCAN substance if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this SNUR:

- Investigation of whether paracelsin will be produced, and at what levels if the genetically-modified *T. reesei* is grown on various plant biomass materials for different durations



under various fermentation conditions in cellulosic biomass facilities.

- If paracelsin is produced, a study of whether paracelsin would be denatured/inactivated during production and processing.

- If paracelsin is released from the facility, a study of whether paracelsin would be degraded/inactivated during wastewater treatment.

- If released to the environment, studies on the persistence, stability, dissemination, accumulation, and the potential resulting biological activity of paracelsin with exposure to aquatic and terrestrial organisms in the environment.

- Studies to determine the ability of the MCAN microorganism to survive in the environment relative to the survival of the unmodified parent or recipient strain, and to assess its competitiveness with other fungi in the environment. This study may require some supplementation with one or more carbon sources and the use of various soil types.

- A study to determine survival of the fungus during an anaerobic fermentation for production of ethanol by an ethanologen, and survival of the fungus during ethanol distillation or at the distillation temperature for ethanol.

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 725.1081.

## **V. Rationale and Objectives of the Proposed Rule**

### *A. Rationale*

During review of the PMNs and MCAN submitted for the chemical substances that are the subject to these proposed SNURs, EPA concluded that regulation was warranted under TSCA section 5(e), pending the development of information sufficient to make reasoned evaluations of the health or environmental effects of the chemical substances. 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 and MCAN submitters. As a general matter, EPA believes it is necessary to follow the TSCA Orders with a SNUR that identifies the absence of those protective measures as significant new uses to ensure that all manufacturers and processors – not just the original submitter – are held to the same standard.

### *B. Objectives*

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

- To identify as significant new uses any manufacturing, processing, use, distribution in commerce, or disposal that does not conform to the restrictions imposed by the underlying TSCA Orders, consistent with TSCA section 5(f)(4).

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

- To be able to either determine that the prospective manufacture or processing is not likely to present an unreasonable risk, or to take necessary regulatory action associated with any other determination, before the described significant new use of the chemical substance occurs.

## **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 (or MCAN, as applicable). Therefore, for chemical substances for which an NOC has not been submitted EPA concludes that the designated significant new uses are not ongoing.

When chemical substances identified in this proposed rule are added to the TSCA Inventory, EPA recognizes that, before the rule is effective, other persons might engage in a use

that has been identified as a significant new use. However, TSCA Orders have been issued for these chemical substances and the PMN and MCAN submitters are prohibited by the TSCA Orders from undertaking activities which would be designated as significant new uses. The identities of many of the chemical substances subject to this proposed rule have been claimed as confidential per 40 CFR 720.85 or 40 CFR 725.85 (for the microorganism). Based on this, the Agency believes that it is highly unlikely that any of the significant new uses described in the regulatory text of this proposed rule are ongoing.

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

In the unlikely event that a person began 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.

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 <https://www.epa.gov/tsca-inventory>.

## **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: If a person is required to submit information for a chemical substance pursuant to a rule, TSCA Order or consent agreement under TSCA section 4, then TSCA section 5(b)(1)(A) requires such

information to be submitted to EPA at the time of submission of the SNUN.

In the absence of a rule, TSCA Order, or consent agreement under TSCA section 4 covering the chemical substance, persons are required only to submit information in their possession or control and to describe any other information known or reasonably ascertainable (see 40 CFR 720.50 or 40 CFR 725.160 [for the microorganism]). However, upon review of PMNs and SNUNs, the Agency has the authority to require appropriate testing. Unit IV. lists potentially useful information for the SNURs listed in this document. Descriptions of this information is provided for informational purposes. The potentially useful information identified in Unit IV. will be useful to EPA's evaluation in the event that someone submits a SNUN for the significant new use.

EPA strongly encourages persons, before performing any testing, to consult with the Agency. Furthermore, pursuant to TSCA section 4(h), which pertains to reduction of testing in vertebrate animals, EPA encourages consultation with the Agency on the use of alternative test methods and strategies (also called New Approach Methodologies, or NAMs), if available, to generate the recommended test data. EPA encourages dialog with Agency representatives to help determine how best the submitter can meet both the data needs and the objective of TSCA section 4(h). For more information on alternative test methods and strategies to reduce vertebrate animal testing, visit <https://www.epa.gov/assessing-and-managing-chemicals-under-tsc/alternative-test-methods-and-strategies-reduce>.

In some of the TSCA Orders for the chemical substances identified in this rule, EPA has established time limits in view of the lack of data on the potential health and environmental risks that may be posed by the significant new uses or increased exposure to the chemical substances. These limits cannot be exceeded unless the PMN submitter first submits the results of specified tests that would permit a reasoned evaluation of the potential risks posed by these chemical substances. The SNURs contain the same time limits as the TSCA Orders. Exceeding these production limits is defined as a significant new use. Persons who intend to exceed the time limit

must notify the Agency by submitting a SNUN at least 90 days in advance of commencement of non-exempt commercial manufacture or processing.

Any request by EPA for the triggered and pended testing described in the TSCA Orders was made based on EPA's consideration of available screening-level data, if any, as well as other available information on appropriate testing for the PMN substances. Further, any such testing request on the part of EPA that includes testing on vertebrates was made after consideration of available toxicity information, computational toxicology and bioinformatics, and high-throughput screening methods and their prediction models.

The potentially useful information listed in Unit IV. may not be the only means of addressing the potential risks of the chemical substance. However, submitting a SNUN without any test data or other information may increase the likelihood that EPA will take action under TSCA section 5(e) or 5(f). EPA recommends that potential SNUN submitters contact EPA early enough so that they will be able to conduct the appropriate tests.

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

- Human exposure and environmental release that may result from the significant new use of the chemical substances.
- Information on risks posed by the chemical substances compared to risks posed by potential substitutes.

### **VIII. SNUN Submissions**

According to 40 CFR 721.1(c), persons submitting a SNUN must comply with the same notification requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in 40 CFR 720.50. SNUNs must be submitted on EPA Form No. 7710-25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in 40 CFR 720.40. According to 40 CFR 725.900, persons submitting an MCAN for a significant new use of a

microorganism must comply with the same notification requirements and EPA regulatory procedures as persons submitting an MCAN for a new microorganism, including submission of test data on health and environmental effects as described in 40 CFR 725.160. E-PMN software is available electronically at <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca>.

## **IX. Economic Analysis**

EPA has evaluated the potential costs of establishing SNUN requirements for potential manufacturers and processors of the chemical substances subject to this proposed rule. EPA's complete economic analysis is available in the docket for this rulemaking.

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

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

*A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulations and Regulatory Review*

This action proposes to establish SNURs for several new chemical substances that were the subject of PMNs and an MCAN. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011).

*B. Paperwork Reduction Act (PRA)*

According to the PRA (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the *Federal Register*, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable.

The information collection activities associated with SNURs have already been approved

by OMB under the PRA and assigned OMB control number 2070-0012 (EPA ICR No. 574). This proposed rule does not contain 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 using 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 the RFA section 605(b) (5 U.S.C. 601 *et seq.*), the Agency hereby certifies that promulgation of these SNURs 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. EPA’s experience to date is that, in response to the promulgation of SNURs covering over 1,000 chemicals, the Agency receives only a small number of notices per year. For example, the number of SNUNs received was seven in Federal fiscal year (FY) 2013, 13 in FY2014, six in FY2015, 10 in FY2016, 14 in FY2017, and 18 in FY2018 and only a fraction of these were from small businesses. In addition, the Agency currently offers relief to qualifying small businesses by reducing the SNUN submission fee from

\$16,000 to \$2,800. This lower fee reduces the total reporting and recordkeeping of cost of submitting a SNUN to about \$10,116 for qualifying small firms. Therefore, the potential economic impacts of complying with this proposed SNUR are not expected to be significant or adversely impact a substantial number of small entities. In a SNUR that published in the *Federal Register* of June 2, 1997 (62 FR 29684) (FRL-5597-1), the Agency presented its general determination that final SNURs are not expected to have a significant economic impact on a substantial number of small entities, which was provided to the Chief Counsel for Advocacy of the Small Business Administration.

*D. Unfunded Mandates Reform Act (UMRA)*

Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reasons to believe that any State, local, or Tribal government will be impacted by this action. As such, EPA has determined that this proposed rule would not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the requirements of UMRA sections 202, 203, 204, or 205 (2 U.S.C. 1501 *et seq.*).

*E. Executive Order 13132: Federalism*

This action would not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999).

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

This action would not have Tribal implications because it is not expected to have substantial direct effects on Indian Tribes. This action 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 (65 FR 67249, November 9, 2000), do not apply to this action.



*G. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks*

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because this is not an economically significant regulatory action as defined by Executive Order 12866, and this action does not address environmental health or safety risks disproportionately affecting children.

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

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

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

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

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

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

**List of Subjects**

*40 CFR Parts 721 and 725.*

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

Dated: June 4, 2021.

**Tala Henry,**

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

Therefore, for the reasons stated in the preamble, it is proposed that 40 CFR chapter I be amended as follows:

## **PARTS 721-SIGNIFICANT NEW USES OF CHEMICAL SUBSTANCES**

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

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

2. Add §§ 721.11571 through 721.11603 to subpart E to read as follows:

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

\* \* \* \* \*

#### **Sec.**

\* \* \* \* \*

- 721.11571 Hindered amine alkyl ester compounds (generic).
- 721.11572 N-alkyl-dialkyl piperidine (generic).
- 721.11573 Tetraalkylpiperidinium halide (generic).
- 721.11574 Tetraalkylpiperidinium hydroxide (generic).
- 721.11575 Amidoamino quaternary ammonium salt (generic).
- 721.11576 Tri alkyl, mono alkoxy, fatty acid ester, ammonium salt (generic).
- 721.11577 Halogenated aromatic amine (generic).
- 721.11578 1,4-Benzenedicarboxylic acid, 1,4-dipentyl ester, branched and linear.
- 721.11579 Dialkyltin dialkylcarboxylate (generic).
- 721.11580 Alkyltin dodecylthioester (generic).
- 721.11581 Alkyltin tetradecylthioester (generic).
- 721.11582 Undecanol, branched.
- 721.11583 Hydroxy alkanolic acid, compds. with aminoalkoxyalcohol-epoxy polymer-alkanolamine reaction products (generic).
- 721.11584 1,3-Propanediol, 2-ethyl-2-(hydroxymethyl)-, polymer with ethyleneamine, 2-(chloromethyl)oxirane, 2-[[4-(1,1-dimethylethyl)phenoxy]methyl]oxirane, 2,2'-[1,6-hexanediylbis(oxymethylene)]bis[oxirane], 4,4'-(1-methylethylidene)bis[phenol], alkyl ether amine, and 2-[(2-methylphenoxy)methyl]oxirane (generic).
- 721.11585 Benzenepropanoic acid, 3-(2H-benzotriazol-2-yl)-5-(1,1-dimethylethyl)-4-hydroxy-2,2-bis(hydroxymethyl)butyl ester.
- 721.11586 1-Octadecanaminium, N,N-dimethyl-N- [3-(triethoxysilyl)propyl]-, chloride (1:1).
- 721.11587 2-Propenoic acid, 2-methyl-, 3-methyl-3-buten-1-yl ester.
- 721.11588 Mixed metal oxide (generic).
- 721.11589 Amines, polyethylenepoly-, triethylenetetramine fraction, polymers with guanidine hydrochloride (1:1).
- 721.11590 Phenol, 4,4'-(1-methylethylidene)bis-, polymer with 3,6,9,12-tetraoxatetradeca-1, 13-diene, glycidyl ether.
- 721.11591 1,4-Benzenedicarboxylic acid, 1,4-bis(2-phenoxyethyl) ester.
- 721.11592 Poly(oxy-1,2-ethanediyl), .alpha.-nonyl-.omega.-hydroxy-, branched and linear.
- 721.11593 1-Butanamine, N-butyl-N-[(triethoxysilyl)methyl]-.
- 721.11594 Alkenylamide (generic).
- 721.11595 Isoalkylaminium, N-isoalkyl, -N, N-dimethyl chloride (generic).

721.11596 Aldehyde, polymer with mixed alkane polyamines, 2,2'-[1,4-alkanediylbis(oxyalkylene)]bis[oxirane], 2-(alkoxyalkyloxirane, 4,4'-(1-alkylidene)bis[phenol], 2,2'-[(1-alkylidene)bis(4,1-alkyleneoxyalkylene)]bis[oxirane] and 2-(aryloxyalkyl)oxirane, acetate (salt) (generic).

721.11597 Alkanedioic acid, compds. with substituted arylalkylamine-arylalcohol disubstituted alkane-the diglycidyl ether of a arylalcohol disubstituted alkane-epichlorohydrin-aldehyde-2,2'[(1-alkylidene)bis[4,1-aryleneoxy(alkyl-2,1-alkanediyl)oxyalkylene]]bis[oxirane]-alkanepolyamine polymer-1-[[2-[(2-aminoalkyl)amino]alkyl]amino]-3-aryloxy-2-alcohol reaction products (generic).

721.11598 Polyazaalkane with oxirane and methyloxirane, haloalkane (generic).

721.11599 Dibromoalkyl ether tetrabromobisphenol A (generic).

721.11600 Octonal, 7(or 8)-formyl-.

721.11601 Sulfonium, trisaryl-, 7,7-dialkyl-2-heteropolycyclic-1-alkanesulfonate (1:1) (generic).

721.11602 Alkenoic acid, polymer with (alkyl alkenyl) polyether (generic).

\* \* \* \* \*

### § 721.11571 Hindered amine alkyl ester compounds (generic).

(a) *Chemical substance and significant new uses subject to reporting.* The chemical substance generically identified as hindered amine alkyl ester compounds (PMN P-16-167) 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) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i) through (iv), (a)(3) through (6), and (c). 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 of confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible). For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 50. For purposes of § 721.63(a)(6), the airborne form(s) of the substance include particulate (including solids or liquid droplets), gas/vapor (all substances in gas form), and combination gas/vapor and particulate (gas and liquid/solid physical states are present).

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (d), (f), (g)(1), (g)(2)(i) through (v), (g)(3)(i) and (ii), (g)(4)(i) through (iii), and (g)(5). For purposes of §

721.72(g)(1), this substance may cause: skin irritation; respiratory complications; central nervous system effects; blood effects. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

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

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

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

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

#### **§ 721.11572 N-alkyl-dialkyl piperidine (generic).**

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance generically identified as N-alkyl-dialkyl piperidine (PMN P-16-419) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace*. Requirements as specified in § 721.63(a)(1), (a)(2)(i) through (iii), (a)(3) through (6), (b), and (c). When determining which persons are 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. For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 10. For purposes of § 721.63(a)(6), the airborne form(s) of the substance include

gas/vapor (all substances in the gas form). For purposes of § 721.63(b), the concentration is set at 1.0%.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(2)(i) through (v), (g)(3)(ii), (g)(4), and (g)(5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), this substance may cause: skin corrosion; serious eye damage; acute toxicity; specific target organ toxicity. For purposes of § 721.72(g)(4), notice to users: water release restrictions apply. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

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

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where  $N=286$ .

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

### **§ 721.11573 Tetraalkylpiperidinium halide (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as tetraalkylpiperidinium halide (PMN P-16-423) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted (cured).

(2) The significant new uses are:

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

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(2)(i) through (iii) and (v), (g)(3)(ii), (g)(4), and (g)(5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), the substance may cause: acute toxicity; specific target organ toxicity; reproductive toxicity. For purposes of § 721.72(g)(4), notice to users: water release restrictions apply. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

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

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where  $N=20$ .

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

#### **§ 721.11574 Tetraalkylpiperidinium hydroxide (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as tetraalkylpiperidinium hydroxide (PMN P-16-424) is subject

to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted (cured).

(2) The significant new uses are:

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

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(2)(i) through (v), (g)(3)(ii), (g)(4), and (g)(5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), this substance may cause: skin corrosion; serious eye damage; acute toxicity; specific target organ toxicity; reproductive toxicity. For purposes of § 721.72(g)(4), notice to users: water release restrictions apply. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

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

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where  $N=20$ .

(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) *Limitation or revocation of certain modification 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).

**§ 721.11575 Amidoamino quaternary ammonium salt (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as amidoamino quaternary ammonium salt (PMN P-17-235) 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.* Requirements as specified in § 721.80(k).

(ii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where N=44.

(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) *Limitation or revocation of certain modification 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.

**§ 721.11576 Tri alkyl, mono alkoxy, fatty acid ester, ammonium salt (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as tri alkyl, mono alkoxy, fatty acid ester, ammonium salt (PMN P-18-226) 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(k).

(ii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where N=44.

(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) *Limitation or revocation of certain modification 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.

#### **§ 721.11577 Halogenated aromatic amine (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as halogenated aromatic amine (PMN P-17-259) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the PMN substance after they have been completely reacted (cured).

(2) The significant new uses are:

(i) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where N=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 (k) are applicable to manufacturers and processors of this substance.

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

**§ 721.11578 1,4-Benzenedicarboxylic acid, 1,4-dipentyl ester, branched and linear.**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 1,4-benzenedicarboxylic acid, 1,4-dipentyl ester, branched and linear (PMN P-18-43; CAS No. 2097734-13-7) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the PMN substance after they have been completely reacted (cured).

(2) The significant new uses are:

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

(ii) [Reserved]

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

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

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

**§ 721.11579 Dialkyltin dialkylcarboxylate (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as dialkyltin dialkylcarboxylate (PMN P-18-178) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(3) through (6), and (c). When determining which persons are 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. For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 10. For purposes of § 721.63(a)(6), the airborne form(s) of the substance include particulate (including solids or liquid droplets).

(ii) *Industrial, commercial, and consumer activities.* It is a significant new use to use the substance other than as a stabilizer for PVC compounds.

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

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

**§ 721.11580 Alkyltin dodecylthioester (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as alkyltin dodecylthioester (PMN P-18-217) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted (cured).

(2) The significant new uses are:

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

(ii) *Industrial, commercial, and consumer activities.* It is a significant new use to use the substance other than as a stabilizer for PVC compounds.

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

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

#### **§ 721.11581 Alkyltin tetradecylthioester (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as alkyltin tetradecylthioester (PMN P-18-218) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted (cured).

(2) The significant new uses are:

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

(ii) *Industrial, commercial, and consumer activities.* It is a significant new use to use the substance other than as a stabilizer for PVC compounds.

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

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

**§ 721.11582 Undecanol, branched.**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as undecanol, branched (PMN P-18-256) is subject to reporting under this section for the significant new use described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the PMN substance after they have been completely reacted (cured).

(2) The significant new uses are:

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

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

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

**§ 721.11583 Hydroxy alkanolic acid, compds. with aminoalkoxyalcohol-epoxy polymer-alkanolamine reaction products (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as hydroxy alkanolic acid, compds. with aminoalkoxyalcohol-epoxy polymer-alkanolamine reaction products (PMN P-18-283) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

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

(ii) *Hazard communication.* Requirements as specified in §721.72 (a) through (f), (g)(1), (g)(2)(i) and (v), (g)(3)(ii), (g)(4)(iii), and (g)(5). For purposes of § 721.72(e), the concentration is set at 1%. For purposes of § 721.72(g)(1), this substance may cause: skin irritation; skin sensitization; eye irritation; specific target organ toxicity; reproductive toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

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

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

**§ 721.11584 1,3-Propanediol, 2-ethyl-2-(hydroxymethyl)-, polymer with ethyleneamine, 2-(chloromethyl)oxirane, 2-[[4-(1,1-dimethylethyl)phenoxy]methyl]oxirane, 2,2'-[1,6-hexanediylbis(oxyethylene)]bis[oxirane], 4,4'-(1-methylethylidene)bis[phenol], alkyl ether amine, and 2-[(2-methylphenoxyethyl)oxirane (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as 1,3-propanediol, 2-ethyl-2-(hydroxymethyl)-, polymer with ethyleneamine, 2-(chloromethyl)oxirane, 2-[[4-(1,1-dimethylethyl)phenoxy]methyl]oxirane, 2,2'-[1,6-hexanediylbis(oxyethylene)]bis[oxirane], 4,4'-(1-methylethylidene)bis[phenol], alkyl ether amine, and 2-[(2-methylphenoxyethyl)oxirane (PMN P-18-298) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the PMN substance after they have been completely reacted (cured).

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o). It is a significant new use to manufacture, process, or use the PMN substance for an application method that results in inhalation exposure.

(ii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where N=50.

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

**§ 721.11585 Benzenepropanoic acid, 3-(2H-benzotriazol-2-yl)-5-(1,1-dimethylethyl)-4-hydroxy-2,2-bis(hydroxymethyl)butyl ester.**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as benzenepropanoic acid, 3-(2H-benzotriazol-2-yl)-5-(1,1-dimethylethyl)-4-hydroxy-2,2-bis(hydroxymethyl)butyl ester (PMN P-18-310; CAS No. 2101609-93-0) is subject to reporting under this section for the significant new use described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the PMN substance after they have been completely reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i) through (iii), (a)(3) through (6), and (c). 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. For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 1,000. For purposes of § 721.63(a)(6), the airborne form(s) of the substance include gas/vapor and particulate.

(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 0.16 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 (f), (g)(1),



(g)(3)(ii), and (g)(5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), this substance may cause: specific target organ toxicity; reproductive toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

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

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

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

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

**§ 721.11586 1-Octadecanaminium, N,N-dimethyl-N- [3-(triethoxysilyl)propyl]-, chloride (1:1).**

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified as 1-octadecanaminium, N,N-dimethyl-N- [3-(triethoxysilyl)propyl]-, chloride (1:1) (PMN P-18-318; CAS No. 62117-57-1) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Hazard communication*. Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(3)(ii), and (g)(5). For purposes of § 721.72(g)(1), this substance may cause: skin irritation; eye irritation; specific target organ toxicity. For purposes of § 721.72(e), the concentration is set at 1.0%. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(ii) *Industrial, commercial, and consumer activities*. It is a significant new use to use the substance other than as a surface treatment for added lubricity and anti-static properties. It is a

significant new use to use the substance in an application method that results in inhalation exposure to workers.

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

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

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

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

**§ 721.11587 2-Propenoic acid, 2-methyl-, 3-methyl-3-buten-1-yl ester.**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 2-propenoic acid, 2-methyl-, 3-methyl-3-buten-1-yl ester (PMN P-18-323; CAS No. 156291-88-2) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the PMN substance after they have been completely reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i) through (iii), (a)(3) through (6), and (c). 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. For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 50. For purposes of § 721.63(a)(6), the airborne form(s) of the substance include particulate (including solids or liquid droplets) and gas/vapor (all substances in the gas form).

(ii) *Hazard communication*. Requirements as specified in § 721.72(a) through (d), (f), (g)(1), (g)(2)(i) through (v), (g)(3)(i) and (ii), (g)(4)(i) through (iii), and (g)(5). For purposes of § 721.72(g)(1), this substance may cause: skin irritation; developmental effects; systemic effects; respiratory effects; skin sensitization; respiratory sensitization. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and Hazard Communication Standard may be used.

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

(iv) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where N=98.

(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) *Limitation 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.

#### **§ 721.11588 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-18-327) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace*. Requirements as specified in § 721.63(a)(1), (a)(3) through (6), and (c). 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. For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 1,000. For purposes of § 721.63(a)(6), the airborne form(s) of the substance include particulate (including solids or liquid droplets).

(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 0.1 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 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), (g)(2), and (g)(5). For purposes of § 721.72(g)(1), this substance may cause: cancer; skin sensitization; respiratory sensitization; specific target organ toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used. For purposes of § 721.72(g)(2), when using this substance: avoid skin contact, avoid breathing substance, avoid ingestion, use respiratory protection or maintain workplace airborne concentrations at or below an 8-hour time-weighted average of 0.1 mg/m<sup>3</sup>, and use skin protection.

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

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

are applicable to manufacturers and processors of this substance.

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

**§ 721.11589 Amines, polyethylenepoly-, triethylenetetramine fraction, polymers with guanidine hydrochloride (1:1).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as amines, polyethylenepoly-, triethylenetetramine fraction, polymers with guanidine hydrochloride (1:1) (PMN P-18-347; CAS No. 1902936-67-7) 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) and (3), (b), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(b), the concentration is set at 1%.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(2)(i) and (v), (g)(3)(i) and (ii), (g)(4)(i), and (g)(5). For purposes of § 721.72(e), the concentration is set at 1%. For purposes of § 721.72(g)(1), this substance may cause: acute toxicity; skin sensitization; specific target organ toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

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

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

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

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

**§ 721.11590 Phenol, 4,4'-(1-methylethylidene)bis-, polymer with 3,6,9,12-tetraoxatetradeca-1, 13-diene, glycidyl ether.**

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified as phenol, 4,4'-(1-methylethylidene)bis-, polymer with 3,6,9,12-tetraoxatetradeca-1, 13-diene, glycidyl ether (PMN P-18-405; CAS No. 647028-24-8) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the PMN substance after they have been completely reacted (cured).

(2) The significant new uses are:

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

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

(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, importers, and processors of this substance.

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

**§ 721.11591 1,4-Benzenedicarboxylic acid, 1,4-bis(2-phenoxyethyl) ester.**

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

substance identified as 1,4-benzenedicarboxylic acid, 1,4-bis(2-phenoxyethyl) ester (PMN P-19-36; CAS No. 25900-07-6) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the PMN substance after they have been completely reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i), (a)(3) through (6), and (c). 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 of confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 1,000. For purposes of § 721.63(a)(6), the airborne form(s) of the substance include particulate (including solids or liquid droplets).

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

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

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

**§ 721.11592 Poly(oxy-1,2-ethanediyl), .alpha.-nonyl-.omega.-hydroxy-, branched and linear.**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as poly(oxy-1,2-ethanediyl), .alpha.-nonyl-.omega.-hydroxy-, branched and

linear (PMN P-19-52; CAS No. 2242406-13-7) 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), (a)(2)(i) through (iii), (a)(3) through (6), (b), and (c). 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. For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 1,000. For purposes of § 721.63(a)(6), the airborne form(s) of the substance include particulate (including solids or liquid droplets). For purposes of § 721.63(b), the concentration is set at 1%.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(2)(i) through (v), (g)(3)(i) and (ii), and (g)(5). For purposes of § 721.72(e), the concentration is set at 1%. For purposes of § 721.72(g)(1), this substance may cause: skin irritation; respiratory complications; internal organ effects; eye corrosion. 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 use.* It is a significant new use to use the substance where the concentration of the substance in the product formulation intended for distribution in commerce exceeds 1% by weight.

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where N=34.

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

**§ 721.11593 1-Butanamine, N-butyl-N-[(triethoxysilyl)methyl]-.**

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified as 1-Butanamine, N-butyl-N-[(triethoxysilyl)methyl]- (PMN P-19-53; CAS No. 35501-23-6) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted (cured).

(2) The significant new uses are:

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

(ii) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(f) and (o). It is a significant new use to process and use the substance other than in a liquid formulation.

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

**§ 721.11594 Alkenylamide (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as alkenylamide (PMN P-19-77) 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(k).

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

(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) *Limitation 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.

**§ 721.11595 Isoalkylaminium, N-isoalkyl, -N, N-dimethyl chloride (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as isoalkylaminium, N-isoalkyl, -N, N-dimethyl chloride (PMN P-19-131) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(3)(ii), and (g)(5). For purposes of § 721.72(e), the concentration is set at 1%. For purposes of § 721.72(g)(1), this substance may cause: skin irritation; eye irritation; specific target organ toxicity. Alternative hazard and warning statements that meet the criteria of the Globally

Harmonized System and OSHA Hazard Communication Standard may be used.

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

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

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

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

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

**§ 721.11596 Aldehyde, polymer with mixed alkane polyamines, 2,2'-[1,4-alkanediylbis(oxyalkylene)]bis[oxirane], 2-(alkoxyalkyloxirane, 4,4'-(1-alkylidene)bis[phenol], 2,2'-[(1-alkylidene)bis(4,1-alkyleneoxyalkylene)]bis[oxirane] and 2-(aryloxyalkyl)oxirane, acetate (salt) (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as aldehyde, polymer with mixed alkane polyamines, 2,2'-[1,4-alkanediylbis(oxyalkylene)]bis[oxirane], 2-(alkoxyalkyloxirane, 4,4'-(1-alkylidene)bis[phenol], 2,2'-[(1-alkylidene)bis(4,1-alkyleneoxyalkylene)]bis[oxirane] and 2-(aryloxyalkyl)oxirane, acetate (salt) (PMN P-19-143) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the PMN substance after they have been completely reacted (cured) or destroyed.

(2) The significant new uses are:

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

manner that results in inhalation exposure to either the PMN substance or to formaldehyde.

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

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

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

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

**§ 721.11597 Alkanedioic acid, compds. with substituted arylalkylamine-arylalcohol disubstituted alkane-the diglycidyl ether of a arylalcohol disubstituted alkane-epichlorohydrin-aldehyde-2,2'[(1-alkylidene)bis[4,1-aryleneoxy(alkyl-2,1-alkanediyl)oxyalkylene]]bis[oxirane]-alkanepolyamine polymer-1-[[2-[(2-aminoalkyl)amino]alkyl]amino]-3-aryloxy-2-alcohol reaction products (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as alkanedioic acid, compds. with substituted arylalkylamine-arylalcohol disubstituted alkane-the diglycidyl ether of a arylalcohol disubstituted alkane-epichlorohydrin-aldehyde-2,2'[(1-alkylidene)bis[4,1-aryleneoxy(alkyl-2,1-alkanediyl)oxyalkylene]]bis[oxirane]-alkanepolyamine polymer-1-[[2-[(2-aminoalkyl)amino]alkyl]amino]-3-aryloxy-2-alcohol reaction products (PMN P-19-144) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted (cured) or destroyed.

(2) The significant new uses are:

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

manner that results in inhalation exposure to either the PMN substance or to formaldehyde.

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

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

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

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

### **§ 721.11598 Polyazaalkane with oxirane and methyloxirane, haloalkane (generic).**

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance generically identified as polyazaalkane with oxirane and methyloxirane, haloalkane (PMN P-19-145) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted (cured).

(2) The significant new uses are:

(i) *Hazard communication*. Requirements as specified in § 721.72(a) through (f), (g)(1), and (g)(5). For purposes of § 721.72(e), the concentration is set at 1%. For purposes of § 721.72(g)(1), this substance may cause: reproductive toxicity; specific target organ toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

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

(iii) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where N=26.

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

except as modified by this paragraph (b).

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

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

**§ 721.11599 Dibromoalkyl ether tetrabromobisphenol A (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as dibromoalkyl ether tetrabromobisphenol A (PMN P-19-153) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

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

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(3)(ii), and (g)(5). For purposes of § 721.72(e), the concentration is set at 1%. For purposes of § 721.72(g)(1), this substance may cause: eye irritation; carcinogenicity; reproductive toxicity; specific target organ toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *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 (h),

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

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

**§ 721.11600 Octonal, 7(or 8)-formyl-**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as Octonal, 7(or 8)-formyl- (PMN P-20-29; CAS No. 1607842-40-9) 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) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where N=17.

(ii) [Reserved]

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

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

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

**§ 721.11601 Sulfonium, trisaryl-, 7,7-dialkyl-2-heteropolycyclic-1-alkanesulfonate (1:1) (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as sulfonium, trisaryl-, 7,7-dialkyl-2-heteropolycyclic-1-alkanesulfonate (1:1) (PMN P-20-42) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted or adhered (during the photolithographic process) onto a semiconductor wafer surface or similar manufactured

article used in the production of semiconductor technologies.

(2) The significant new uses are:

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

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e), (g)(1), (g)(2)(i) through (v), (g)(3)(i) and (ii), and (g)(5). For purposes of § 721.72(e), the concentration is set at 1%. For purposes of § 721.72(g)(1), this substance may cause: skin irritation; acute toxicity; skin sensitization; serious eye damage; specific target organ toxicity; neurotoxicity; genetic toxicity; reproductive toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f), (k), and (t). It is a significant new use to import the PMN substance other than in solution, unless in sealed containers weighing 5 kilograms or less. It is a significant new use to process the PMN substance in any way that generates a dust, mist, or aerosol in a non-enclosed process. It is a significant new use to manufacture the PMN substance longer than 18 months.

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

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

(2) *Limitation or revocation of certain modification 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.

**§ 721.11602 Alkenoic acid, polymer with (alkyl alkenyl) polyether (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as alkenoic acid, polymer with (alkyl alkenyl) polyether (PMN P-20-104) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted (cured).

(2) The significant new uses are:

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

(ii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where N=75.

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

\* \* \* \* \*

**PART 725-- REPORTING REQUIREMENTS AND REVIEW PROCESSES FOR MICROORGANISMS**

3. The authority citation for part 725 continues to read as follows:

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

4. Add § 725.1081 to read as follows:

**§ 725.1081 *Trichoderma reesei* (generic).**

(a) *Microorganism and significant new uses subject to reporting.* (1) The genetically-modified microorganism generically identified as *Trichoderma reesei* modified (MCAN J-16-26) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2)(i) It is a significant new use to manufacture, process, or use the microorganism other than in a fermentation system that meets all of the following conditions:

(A) Enzyme production occurs by submerged fermentation (i.e., for enzyme production, growth of the microorganism occurs beneath the surface of the liquid growth medium); and

(B) Any fermentation of solid plant material or insoluble substrate to which *Trichoderma reesei* fermentation broth is added after the standard industrial fermentation is completed is initiated only after the inactivation of the microorganism as delineated in § 725.422(d).

(ii) [Reserved]

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

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 725.950(b)(2) through (4) are applicable to manufacturers and processors of this microorganism.

(2) *Modification or revocation of certain notification requirements.* The provisions of § 725.984 apply to this section.

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