



BILLING CODE 6560-50-P

## **ENVIRONMENTAL PROTECTION AGENCY**

### **40 CFR Parts 9 and 721**

**[EPA-HQ-OPPT-2018-0649; FRL-9984-65]**

**RIN 2070-AB27**

### **Significant New Use Rules on Certain Chemical Substances**

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

**ACTION:** Direct final rule.

**SUMMARY:** EPA is promulgating significant new use rules (SNURs) under the Toxic Substances Control Act (TSCA) for 28 chemical substances which were the subject of premanufacture notices (PMNs). The chemical substances are subject to Orders issued by EPA pursuant to section 5(e) of TSCA. This action requires persons who intend to manufacture (defined by statute to include import) or process any of these 28 chemical substances for an activity that is designated 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 intended use within the applicable review period. Persons may not commence manufacture or processing for the significant new use until EPA has conducted a review of the notice, made an appropriate determination on the notice, and has taken such actions as are required with that determination.

**DATES:** This rule is effective on *[insert date 60 days after date of publication in the Federal Register]*. For purposes of judicial review, this rule shall be promulgated at 1 p.m. (e.s.t.) on *[insert date 14 days after date of publication in the Federal Register]*.

Written adverse comments on one or more of these SNURs must be received on or before [*insert date 30 days after date of publication in the **Federal Register***] (see Unit VI. of the **SUPPLEMENTARY INFORMATION**). If EPA receives written adverse comments, on one or more of these SNURs before [*insert date 30 days after date of publication in the **Federal Register***], EPA will withdraw the relevant sections of this direct final rule before its effective date.

For additional information on related reporting requirement dates, see Units I.A., VI., and VII. of the **SUPPLEMENTARY INFORMATION**.

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2018-0649, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

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

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at

<http://www.epa.gov/dockets/contacts.html>.

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

**FOR FURTHER INFORMATION CONTACT:** *For technical information contact:*

Kenneth Moss, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-9232; email address:

*moss.kenneth@epa.gov.*

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

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this Action Apply to Me?*

You may be potentially affected by this action if you manufacture, process, or use the chemical substances contained in this rule. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

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

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Chemical importers are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements promulgated at 19 CFR 12.118 through 12.127 and 19 CFR 127.28. Chemical importers must certify that the shipment of the chemical substance complies with all applicable rules and orders

under TSCA. Importers of chemicals subject to these SNURs must certify their compliance with the SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export a chemical substance that is the subject of this rule on or after [*insert date 30 days after date of publication in the Federal Register*] are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)) (see § 721.20), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

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

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

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

## **II. Background**

*A. What Action is the Agency Taking?*

1. *Direct Final Rule.* EPA is promulgating these SNURs using direct final rule procedures. These SNURs will require persons to notify EPA at least 90 days before

commencing the manufacture or processing of a chemical substance for any activity designated by these SNURs as a significant new use. Receipt of such notices obligates EPA to assess risks that may be associated with the significant new uses under the conditions of use and, if appropriate, to regulate the proposed uses before they occur.

*2. Proposed Rule.* In addition to this Direct Final Rule, elsewhere in this issue of the **Federal Register**, EPA is issuing a Notice of Proposed Rulemaking for this rule. If EPA receives no adverse comment, the Agency will not take further action on the proposed rule and the direct final rule will become effective as provided in this action. If EPA receives adverse comment on one or more of SNURs in this action by [*insert date 15 days after date of publication in the Federal Register*] (see Unit VI. of the **SUPPLEMENTARY INFORMATION**), the Agency will publish in the **Federal Register** a timely withdrawal of the specific SNURs that the adverse comments pertain to, informing the public that the actions will not take effect. EPA would then address all adverse public comments in a response to comments document in a subsequent final rule, based on the proposed rule.

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

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a “significant new use.” EPA must make this determination by rule after considering all relevant factors, including the four bulleted TSCA section 5(a)(2) factors listed in Unit III. Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1)(B) requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture or process the chemical substance for that use (15 U.S.C. 2604(a)(1)(B)(i)).

TSCA furthermore prohibits such manufacturing or processing from commencing until EPA has conducted a review of the notice, made an appropriate determination on the notice, and taken such actions as are required in association with that determination (15 U.S.C. 2604(a)(1)(B)(ii)). As described in Unit V., the general SNUR provisions are found at 40 CFR part 721, subpart A.

### *C. Applicability of General Provisions*

General provisions for SNURs appear in 40 CFR part 721, subpart A. These provisions describe persons subject to the rule, recordkeeping requirements, 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. According to § 721.1(c), persons subject to these SNURs must comply with the same SNUN requirements and EPA regulatory procedures as submitters of PMNs under TSCA section 5(a)(1)(A). In particular, these requirements include the information submission requirements of TSCA section 5(b) and 5(d)(1), the exemptions authorized by TSCA section 5(h)(1), (h)(2), (h)(3), and (h)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUN, EPA must either determine that the significant new use is not likely to present an unreasonable risk of injury or take such regulatory action as is associated with an alternative determination before the manufacture or processing for the significant new use can commence. If EPA determines that the significant new use is not likely to present an unreasonable risk, EPA is required under TSCA section 5(g) to make public, and submit for publication in the **Federal Register**, a statement of EPA's findings.

### **III. Significant New Use Determination**

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

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

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

To determine what would constitute a significant new use for the 28 chemical substances that are the subject of these SNURs, EPA considered relevant information about the toxicity of the chemical substances, likely human exposures and environmental releases associated with possible uses, and the four bulleted TSCA section 5(a)(2) factors listed in this unit.

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

EPA is establishing significant new use and recordkeeping requirements for 28 chemical substances in 40 CFR part 721, subpart E. In this unit, EPA provides the following information for each chemical substance:

- PMN number.
- Chemical name (generic name, if the specific name is claimed as CBI).

- Chemical Abstracts Service (CAS) Registry number (if assigned for non-confidential chemical identities).
- Basis for the TSCA section 5(e) Order.
- Information identified by EPA that would help characterize the potential health and/or environmental effects of the chemical substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use designated by the SNUR.

This information may include testing required in a TSCA section 5(e) Order to be conducted by the PMN submitter, as well as testing not required to be conducted but which would also help characterize the potential health and/or environmental effects of the PMN substance. Any recommendation for information identified by EPA was made based on EPA's consideration of available screening-level data, if any, as well as other available information on appropriate testing for the chemical substance. Further, any such testing identified by EPA that includes testing on vertebrates was made after consideration of available toxicity information, computational toxicology and bioinformatics, and high-throughput screening methods and their prediction models. EPA also recognizes that whether testing/further information is needed will depend on the specific exposure and use scenario in the SNUN. EPA encourages all SNUN submitters to contact EPA to discuss any potential future testing. See Unit VIII. for more information.

- CFR citation assigned in the regulatory text section of this rule.

The regulatory text section of these rules specifies the activities designated as significant new uses. Certain new uses, including exceedance of production volume

limits (i.e., limits on manufacture volume) and other uses designated in this rule, may be claimed as CBI. Unit IX. discusses a procedure companies may use to ascertain whether a proposed use constitutes a significant new use.

These rules include 28 PMN substances that are subject to Orders under TSCA section 5(e)(1)(A). Each Order is based on one or more of the findings in TSCA section 5(a)(3)(B): there is insufficient information to permit a reasoned evaluation; in the absence of sufficient information to permit a reasoned evaluation, the activities associated with the PMN substances may present unreasonable risk to human health or the environment; the substance is or will be produced in substantial quantities, and enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant (substantial) human exposure to the substance. Those Orders require protective measures to limit exposures or otherwise mitigate the potential unreasonable risk. The SNURs identify as significant new uses any manufacturing, processing, use, distribution in commerce, or disposal that does not conform to the restrictions imposed by the underlying Orders, consistent with TSCA section 5(f)(4).

Where EPA determined that the PMN substance may present an unreasonable risk of injury to human health via inhalation exposure, the underlying TSCA section 5(e) Order required, among other things, that potentially exposed employees wear specified respirators unless actual measurements of the workplace air show that air-borne concentrations of the PMN substance are below a New Chemical Exposure Limit (NCEL) that is established by EPA to provide adequate protection to human health. In addition to the actual NCEL concentration, the comprehensive NCELS provisions in TSCA section 5(e) Orders, which are modeled after Occupational Safety and Health

Administration (OSHA) Permissible Exposure Limits (PELs) provisions, include requirements addressing performance criteria for sampling and analytical methods, periodic monitoring, respiratory protection, and recordkeeping. However, no comparable NCEL provisions currently exist in 40 CFR part 721, subpart B, for SNURs. Therefore, for these cases, the individual SNURs in 40 CFR part 721, subpart E, will state that persons subject to the SNUR who wish to pursue NCELS as an alternative to the § 721.63 respirator requirements may request to do so under § 721.30. EPA expects that persons whose § 721.30 requests to use the NCELS approach for SNURs that are approved by EPA will be required to comply with NCELS provisions that are comparable to those contained in the corresponding TSCA section 5(e) Order for the same chemical substance.

**PMN Numbers:** P-15-442, P-15-443, P-15-444, P-15-445, P-15-446, P-15-447, P-15-525, P-15-526, P-15-527, and P-15-528.

*Chemical names:* Rare earth doped zirconium oxide (generic).

*CAS numbers:* Not available.

*Effective date of TSCA section 5(e) Order:* January 25, 2018.

*Basis for TSCA section 5(e) Order:* The PMNs state that the generic (non-confidential) use of the substances will be as catalysts. EPA identified concern for lung toxicity and oncogenicity based on analogy to respirable poorly soluble particulates and the crystalline structure of the substances. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substances may present an unreasonable risk of injury to human health and the environment. The order was also issued under

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

1. Submit to EPA certain toxicity testing for both P-15-443 and P-15-445 within the 18 and 60-month time limits specified on the Order.
2. Use of a National Institute of Occupational Safety and Health (NIOSH)-certified respirator with an assigned protection factor (APF) of at least 1,000 where there is a potential for inhalation exposure or compliance with a NCEL of  $0.07 \text{ mg/m}^3$  as an 8-hour time-weighted average to prevent inhalation exposure;
3. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the safety data sheet (SDS).

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

*Potentially useful information:* EPA has determined that certain information about the health effects of the PMN substances may be potentially useful to characterize the effects of the PMN substances in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this SNUR. The submitter has agreed

not to exceed the time limits in the Order without performing specific pulmonary toxicity testing and carcinogenicity testing on PMN substances P-15-443 and P-15-445.

*CFR citation:* 40 CFR 721.11173.

**PMN Numbers:** P-16-194, P-16-195, P-16-196, P-16-197, P-16-198, P-16-199, P-16-460, P-16-461, P-16-462, P-16-463, and P-16-464.

*Chemical names:* Silane-treated aluminosilicate (generic).

*CAS numbers:* Not available.

*Effective date of TSCA section 5(e) Order:* January 22, 2018.

*Basis for TSCA section 5(e) Order:* The PMNs state that the generic (non-confidential) use of the substances will be as process aids. Based on analysis of test data on the PMN substances, EPA identified human health concerns for cancer and non-cancer chronic toxicity effects associated with the metal impurities found in the PMN substances.

Environmental effects were identified for the metal constituents in the PMN substances.

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

1. Submit to EPA metals content analysis of the material used to manufacture the PMN substances.
2. Provide personal protective equipment to its workers to prevent dermal exposure where there is potential for dermal exposure.
3. Use of a NIOSH-certified respirator with an APF of at least 50 where there is a potential for inhalation exposures.

4. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.
5. Not manufacture or process the PMN substances other than at facilities equipped with pollution controls, such as a bag house, that remove particulates from the air at 99% or greater efficiency.
6. Not use the PMN substances other than as described in the PMN.

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

*Potentially useful information:* EPA has determined that certain information about the health effects of the PMN substances may be potentially useful to characterize the effects of the PMN substances in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this SNUR. The submitter has agreed not to exceed the time limits in the Order without sampling and analyzing the immediate precursor used to manufacture the PMN substances via EPA Method 6010B for the following elements: arsenic, barium, beryllium, cadmium, chromium, cobalt, copper, lead, manganese, mercury, nickel, selenium, silver, vanadium, and zinc.

*CFR citations:* 40 CFR 721.11174.

**PMN Number:** P-16-307

*Chemical Name:* Heteropolycycliccarboxylic acid, 1,3-dihydro-disubstituted-, polymer with 1,1'-methylenebis, reaction products with silica (generic).

*CAS Number:* Not available.

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

*Basis for TSCA section 5(e) Order:* The PMN states that the generic (non-confidential) use of the substance will be an open, non-dispersive use. Based on physical/chemical properties of the PMN substance and structure activity relationship (SAR) analysis of test data on analogous poorly, soluble respirable particles and isocyanates, EPA identified concerns for lung effects and dermal and respiratory sensitization. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I) of TSCA, based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health. To protect against these risks, the Order requires:

1. Manufacture of the PMN substance to contain no more than 0.1% residual of free isocyanate by weight;
2. Use of personal protective equipment where there is a potential for dermal exposure;
3. No manufacturing, processing, or use of the PMN substance in any manner that generates a vapor, dust, mist, or aerosol;
4. Refraining from manufacture, processing or use for consumer use or in commercial use where there is use in a consumer setting;
5. Manufacture, process, or use the PMN substance only in liquid formulation;  
and
6. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.

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

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

*CFR citation:* 40 CFR 721.11175.

**PMN Number:** P-17-176

*Chemical name:* Carbonic acid, alkyl carbomonocyclic ester (generic).

*CAS number:* Not available.

*Effective date of TSCA section 5(e) Order:* February 21, 2018.

*Basis for TSCA section 5(e) Order:* The PMNs state that the generic (non-confidential) use of the substance will be as a battery ingredient. Based on toxicology data from an analogue, EPA has identified possible human health concerns for developmental toxicity and effects on the ovaries, adrenals and liver. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health. To protect against these risk, the Order requires:

1. Submit to EPA certain toxicity testing within 3 years of the notice of commencement of manufacturing (including import) of the PMN substance;

2. Use of personal protective equipment to its workers to prevent dermal exposure where there is a potential for dermal exposure;
3. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.
4. Refraining from domestic manufacture in the United States (i.e., import only);  
and
5. No release of the PMN substance into waters of the United States exceeding 45 parts per billion.

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

*Potentially useful information:* EPA has determined that certain information about the environmental and health effects of the PMN substance may be potentially useful to characterize the effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this SNUR. The submitter has agreed not to manufacture the PMN substance without performing specific reproductive/developmental toxicity testing 3 years from the notice of commencement. EPA has also determined that the results of specific chronic aquatic toxicity testing would help characterize the potential environmental effects of the PMN substance. Although the Order does not require these tests, the Order’s restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or relevant information.

*CFR citation:* 40 CFR 721.11176.

**PMN Number:** P-17-183

*Chemical name:* 1,3-Propanediol, 2-ethyl-2-(hydroxymethyl)-, polymer with 2-(chloromethyl)oxirane, reaction products with polyethylene-polypropylene glycol 2-aminopropyl Me ether.

*CAS number:* 1627528-04-4.

*Effective date of TSCA section 5(e) Order:* February 28, 2018.

*Basis for TSCA section 5(e) Order:* The PMNs state that the generic (non-confidential) use of the substance will be as a pigment wetting and dispersing additive. Based on the surfactant potential of the PMN compound, EPA has identified concerns for lung effects to workers if respirable particulates or droplets are inhaled. The Order was issued under TSCA sections 5(a)(3)(B)(i) and 5(e)(1)(A)(i), based on a finding that the available information is insufficient to permit a reasoned evaluation of the human health effects of the PMN substance. To protect against these risks, the Order requires:

1. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS;
2. Refraining from domestic manufacture in the United States (i.e., import only);
3. No manufacturing, processing, or using the PMN substance in any manner that results in inhalation exposure to vapors, mists, aerosols or dusts;
4. No use of the PMN substance other than the confidential uses allowed by the Order; and
5. No use of the PMN substance in consumer products.

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

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

*CFR citation:* 40 CFR 721.11177.

**PMN Number:** P-17-232

*Chemical name:* Copolyamide of an aromatic dicarboxylic acid and a mixture of diamines (generic).

*CAS number:* Not available.

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

*Basis for TSCA section 5(e) Order:* The PMN states that the generic (non-confidential) use of the substance is as an engineering thermoplastic. Based on SAR analysis on structurally similar poorly soluble particles, EPA identified concerns for lung effects to workers if respirable particles are present. The Order was issued under TSCA section 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient

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

Manufacture the PMN substance with a particle size of greater than 10 microns. The SNUR designates as a “significant new use” the absence of these protective measures.

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

*CFR citation:* 40 CFR 721.11178.

**PMN Number:** P-17-257

*Chemical name:* Single-walled carbon nanotubes.

*CAS number:* Not available.

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

*Basis for TSCA section 5(e) Order:* The PMN states that the generic (non-confidential) use of the substance will be as an additive in composite materials for mechanical, thermal, and conductivity improvements. Based on analysis of analogous carbon nanotubes, EPA identified concerns for pulmonary toxicity. Based on analogous carbon

nanotubes, EPA also identified potential toxicity to aquatic organisms if the PMN substance is released to water. The order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the PMN substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

1. Submit to EPA certain toxicity testing before manufacturing (including import) by the times specified in the Order.
2. Provide personal protective equipment to its workers to prevent dermal exposure where there is a potential for dermal exposure.
3. Provide NIOSH certified respirators with an APF of at least 50 to its workers to prevent inhalation exposure.
4. No use of the PMN substance in application methods that generate a dust, vapor, mist or aerosol.
5. Use the PMN substance for industrial uses only.
6. Use the PMN substance only for the confidential uses allowed in the Order.
7. No release of the PMN substance to water.
8. Disposal of the PMN substance only via landfill or incineration.

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

*Potentially useful information:* EPA has determined that certain information about the environmental and health effects of the PMN substance may be potentially useful to characterize the effects of the PMN substance in support of a request by the PMN

submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this SNUR. The submitter has agreed not to manufacture the PMN substance without performing specific physical property and pulmonary toxicity testing. EPA has also determined that the results of specific chronic aquatic toxicity testing would help characterize the potential environmental effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or relevant information.

*CFR citation:* 40 CFR 721.11179

**PMN Number:** P-17-283

*Chemical name:* Arenesulfonic acid, alkyl derivatives, metal salts (generic).

*CAS number:* Not available.

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

*Basis for TSCA section 5(e) Order:* The PMN states that the generic (non-confidential) use of the substance will be as a lubricating oil additive for automotive engine oils. Based on analysis of test data on the PMN substance, EPA identified concern for corrosion to skin, eyes, mucous membranes, and lungs. There is also concern for surfactant effects on the lung based on surfactant properties of the compounds. There is also concern for acute toxicity, mutagenicity, irritation, and sensitization based on submitted analogue test data. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health and the environment. The Order was also issued under TSCA sections 5(a)(3)(B)(ii)(II) and

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

1. Submit to EPA certain toxicity testing within six months of filing a notice of commencement (NOC) to EPA;
2. Use of personal protective equipment where there is a potential for dermal exposure;
3. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS; and
4. Refrain from manufacturing, processing, or using the PMN substance in any manner that produces vapor, mist, spray or aerosol.

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

*Potentially useful information:* EPA has determined that certain information about the health effects of the PMN substance may be potentially useful to characterize the effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this SNUR. The submitter has agreed not to manufacture the PMN substance without performing sensitization testing. EPA has also determined that the results of specific physical-chemical properties and acute and chronic pulmonary toxicity testing would help characterize the potential health effects of the

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

*CFR citation:* 40 CFR 721.11180.

**PMN Number:** P-17-353

*Chemical name:* Heteromonocycle, 2-[(bicarbomonocycle-2-substituted)alkyl]- (generic).

*CAS number:* Not available.

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

*Basis for TSCA section 5(e) Order:* The PMN states that the generic (non-confidential) use of the substance will be as an additive in resin manufacture. Based on information on analogous substances, EPA has identified concerns for irritation to the eye, lung, and mucous membranes, skin and lung sensitization, oncogenicity, developmental toxicity, male reproductive toxicity, liver toxicity, and kidney toxicity. Ecotoxicity hazard concerns were high based on EcoSAR analysis of analogous chemical. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the PMN substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

1. Refraining from domestic manufacture in the United States (i.e., import only);
2. Use of the PMN substance only for the confidential use allowed in the Order;
3. No processing and use of the PMN substance using methods that may generate a spray, mist or aerosol.

4. Use of personal protective equipment where there is a potential for dermal exposure.
5. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.
6. No release of the PMN substance into the waters of the United States.

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

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

*CFR citation:* 40 CFR 721.11181.

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

### *A. Rationale*

During review of the PMNs submitted for the chemical substances that are subject to these SNURs, EPA concluded that for all 28 chemical substances, regulation was warranted under TSCA section 5(e), pending the development of information sufficient to

make reasoned evaluations of the health or environmental effects of the chemical substances. The basis for such findings is outlined in Unit IV. Based on these findings, TSCA section 5(e) Orders requiring the use of appropriate exposure controls were negotiated with the PMN submitters.

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

#### *B. Objectives*

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

- EPA will receive notice of any person's intent to manufacture or process a listed chemical substance for the described significant new use before that activity begins.

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

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

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

Issuance of a SNUR for a chemical substance does not signify that the chemical substance is listed on the TSCA Chemical Substance Inventory (TSCA Inventory).

Guidance on how to determine if a chemical substance is on the TSCA Inventory is available on the Internet at

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

## **VI. Direct Final Procedures**

EPA is issuing these SNURs as a direct final rule. The effective date of this rule is [*insert date 60 days after date of publication in the **Federal Register***] without further notice, unless EPA receives written adverse comments before [*insert date 30 days after date of publication in the **Federal Register***].

If EPA receives written adverse comments on one or more of these SNURs before [*insert date 30 days after date of publication in the **Federal Register***], EPA will withdraw the relevant sections of this direct final rule before its effective date.

This rule establishes SNURs for a number of chemical substances. Any person who submits adverse comments must identify the chemical substance and the new use to which it applies. EPA will not withdraw a SNUR for a chemical substance not identified in the comment.

## **VII. Applicability of the 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 rule have undergone premanufacture review. In cases where EPA has not received an NOC and the chemical substance has not been added to the TSCA Inventory, no person may commence such activities without

first submitting a PMN. Therefore, for chemical substances for which an NOC has not been submitted EPA concludes that the designated significant new uses are not ongoing.

When chemical substances identified in this rule are added to the TSCA Inventory, EPA recognizes that, before the rule is effective, other persons might engage in a use that has been identified as a significant new use. However, TSCA section 5(e) Orders have been issued for all of the chemical substances, and the PMN submitters are prohibited by the TSCA section 5(e) Orders from undertaking activities which will be designated as significant new uses. The identities of 26 of the 28 chemical substances subject to this rule have been claimed as confidential and EPA has received no post-PMN *bona fide* submissions (per §§ 720.25 and 721.11) for a chemical substance covered by this action. Based on this, the Agency believes that it is highly unlikely that any of the significant new uses described in the regulatory text of this 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 has been to ensure that a person could not defeat a SNUR by initiating a significant new use before the effective date of the direct final rule.

Persons who begin commercial manufacture or processing of the chemical substances for a significant new use identified as of that date will have to cease any such activity upon the effective date of the final rule. To resume their activities, these persons will 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.

## **VIII. Development and Submission of Information**

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

In the absence of a TSCA section 4 test rule covering the chemical substance, persons are required only to submit information in their possession or control and to describe any other information known to or reasonably ascertainable by them (see 40 CFR 720.50). However, upon review of PMNs and SNUNs, the Agency has the authority to require appropriate testing. Unit IV. lists potentially useful information for all of the listed SNURs. Descriptions of the information are provided for informational purposes. EPA strongly encourages persons, before performing any testing, to consult with the Agency pertaining to protocol selection. Furthermore, pursuant to TSCA section 4(h), which pertains to reduction of testing in vertebrate animals, EPA encourages consultation with the Agency on the use of alternative test methods and strategies (also called New Approach Methodologies, or NAMs), if available, to generate the recommended test data. EPA encourages dialog with Agency representatives to help determine how best the submitter can meet both the data needs and the objective of TSCA section 4(h).

In certain of the TSCA section 5(e) Orders for the chemical substances regulated under this rule, EPA has established production volume or 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 toxicity tests

that would permit a reasoned evaluation of the potential risks posed by these chemical substances. Listings of the information required in the TSCA section 5(e) Orders are included in Unit IV. The SNURs contain the same production volume limits as the TSCA section 5(e) Orders. Exceeding these production limits is defined as a significant new use. Persons who intend to exceed the production limit must notify the Agency by submitting a SNUN at least 90 days in advance of commencement of non-exempt commercial manufacture or processing.

Any request by EPA for the triggered and pended testing described in the Orders was made based on EPA's consideration of available screening-level data, if any, as well as other available information on appropriate testing for the PMN substances. Further, any such testing 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.

Potentially useful information identified 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 may increase the likelihood that EPA will take action under TSCA section 5(e), particularly if satisfactory test results have not been obtained from a prior PMN or SNUN submitter. 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.

## **IX. Procedural Determinations**

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

Under these procedures a manufacturer or processor may request EPA to determine whether a proposed use would be a significant new use under the rule. The manufacturer or processor must show that it has a *bona fide* intent to manufacture or process the chemical substance and must identify the specific use for which it intends to manufacture or process the chemical substance. If EPA concludes that the person has shown a *bona fide* intent to manufacture or process the chemical substance, EPA will tell the person whether the use identified in the *bona fide* submission would be a significant new use under the rule. Since most of the chemical identities of the chemical substances subject to these SNURs are also CBI, manufacturers and processors can combine the *bona fide* submission under the procedure in § 721.1725(b)(1) with that under § 721.11 into a single step.

If EPA determines that the use identified in the *bona fide* submission would not be a significant new use, i.e., the use does not meet the criteria specified in the rule for a significant new use, that person can manufacture or process the chemical substance so

long as the significant new use trigger is not met. In the case of a production volume trigger, this means that the aggregate annual production volume does not exceed that identified in the *bona fide* submission to EPA. Because of confidentiality concerns, EPA does not typically disclose the actual production volume that constitutes the use trigger. Thus, if the person later intends to exceed that volume, a new *bona fide* submission would be necessary to determine whether that higher volume would be a significant new use.

## **X. SNUN Submissions**

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

## **XI. Economic Analysis**

EPA has evaluated the potential costs of establishing SNUN requirements for potential manufacturers and processors of the chemical substances subject to this rule. EPA's complete economic analysis is available in the docket under docket ID number EPA-HQ-OPPT-2018-0649.

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

### *A. Executive Order 12866*

This action establishes SNURs for several new chemical substances that were the subject of PMNs, or TSCA section 5(e) Orders. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993).

*B. Paperwork Reduction Act (PRA)*

According to PRA (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable. EPA is amending the table in 40 CFR part 9 to list the OMB approval number for the information collection requirements contained in this action. This listing of the OMB control numbers and their subsequent codification in the CFR satisfies the display requirements of PRA and OMB's implementing regulations at 5 CFR part 1320. This Information Collection Request (ICR) was previously subject to public notice and comment prior to OMB approval, and given the technical nature of the table, EPA finds that further notice and comment to amend it is unnecessary. As a result, EPA finds that there is “good cause” under section 553(b)(3)(B) of the Administrative Procedure Act (5 U.S.C. 553(b)(3)(B)) to amend this table without further notice and comment.

The information collection requirements related to this action have already been approved by OMB pursuant to PRA under OMB control number 2070-0012 (EPA ICR No. 574). This action does not impose any burden requiring additional OMB approval. If

an entity were to submit a SNUN to the Agency, the annual burden is estimated to average between 30 and 170 hours per response. This burden estimate includes the time needed to review instructions, search existing data sources, gather and maintain the data needed, and complete, review, and submit the required SNUN.

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

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

On February 18, 2012, EPA certified pursuant to RFA section 605(b) (5 U.S.C. 601 *et seq.*), that promulgation of a SNUR does not have a significant economic impact on a substantial number of small entities where the following are true:

1. A significant number of SNUNs would not be submitted by small entities in response to the SNUR.
2. The SNUR submitted by any small entity would not cost significantly more than \$8,300.

A copy of that certification is available in the docket for this action.

This action is within the scope of the February 18, 2012 certification. Based on the Economic Analysis discussed in Unit XI. and EPA's experience promulgating SNURs (discussed in the certification), EPA believes that the following are true:

- A significant number of SNUNs would not be submitted by small entities in response to the SNUR.

- Submission of the SNUN would not cost any small entity significantly more than \$8,300.

Therefore, the promulgation of the SNUR would not have a significant economic impact on a substantial number of small entities.

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

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

#### *E. Executive Order 13132*

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

#### *F. Executive Order 13175*

This action does not have Tribal implications because it is not expected to have substantial direct effects on Indian Tribes. This action does not significantly nor uniquely affect the communities of Indian Tribal governments, nor does it involve or impose any

requirements that affect Indian Tribes. Accordingly, the requirements of Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000), do not apply to this action.

*G. Executive Order 13045*

This action is not subject to Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997), because this is not an economically significant regulatory action as defined by Executive Order 12866, and this action does not address environmental health or safety risks disproportionately affecting children.

*H. Executive Order 13211*

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

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

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

*J. Executive Order 12898*

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

### **XIII. Congressional Review Act**

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

#### **List of Subjects**

##### *40 CFR Part 9*

Environmental protection, Reporting and recordkeeping requirements.

##### *40 CFR Part 721*

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

Dated: October 1, 2018.

Jeffery T. Morris,

*Director, Office of Pollution Prevention and Toxics.*

Therefore, 40 CFR parts 9 and 721 are amended as follows:

**PART 9--[AMENDED]**

1. The authority citation for part 9 continues to read as follows:

**Authority:** 7 U.S.C. 135 *et seq.*, 136-136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601-2671; 21 U.S.C. 331j, 346a, 348; 31 U.S.C. 9701; 33 U.S.C. 1251 *et seq.*, 1311, 1313d, 1314, 1318, 1321, 1326, 1330, 1342, 1344, 1345 (d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971-1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g-1, 300g-2, 300g-3, 300g-4, 300g-5, 300g-6, 300j-1, 300j-2, 300j-3, 300j-4, 300j-9, 1857 *et seq.*, 6901-6992k, 7401-7671q, 7542, 9601-9657, 11023, 11048.

2. In § 9.1, add the following sections in numerical order under the undesignated center heading “Significant New Uses of Chemical Substances” to read as follows:

**§ 9.1 OMB approvals under the Paperwork Reduction Act.**

\* \* \* \* \*

40 CFR citation	OMB control No.
* * * * *	* * * * *
<b>Significant New Uses of Chemical Substances</b>	
* * * * *	* * * * *
721.11173	2070-0012
721.11174	2070-0012
721.11175	2070-0012
721.11176	2070-0012
721.11177	2070-0012
721.11178	2070-0012

721.11179	2070-0012
721.11180	2070-0012
721.11181	2070-0012
* * * * *	* * * * *

\* \* \* \* \*

**PART 721--[AMENDED]**

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

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

4. Add § 721.11173 to subpart E to read as follows:

**§ 721.11173 Rare earth doped zirconium oxide (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substances identified generically as rare earth doped zirconium oxide (P-15-442, P-15-443, P-15-444, P-15-445, P-15-446, P-15-447, P-15-525, P-15-526, P-15-527, and P-15-528) are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been reacted (cured).

(2) The significant new uses are:

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

Occupational Safety and Health (NIOSH) assigned protection factor of at least 1000), (a)(6)(particulate), (b)(concentration set at 1.0%), and (c).

(A) As an alternative to the respirator requirements in paragraph (a)(2)(i) of this section, a manufacturer or processor may choose to follow the new chemical exposure limit (NCEL) provision listed in the TSCA section 5(e) Order for this substance. The NCEL is 0.07 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) Order.

(B) [Reserved]

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e)(concentration set at 1.0%), (f), (g)(1)(ii), (g)(2)(ii), (iii), (iv)(use respiratory protection or maintain workplace airborne concentrations at or below an 8-hour time-weighted average of 0.07 mg/m<sup>3</sup>), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(p)(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 (d) and (f) through (i) are applicable to manufacturers and processors of the substances.

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

5. Add § 721.11174 to subpart E to read as follows:

**§ 721.11174 Silane-treated aluminosilicate (generic).**

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substances identified generically as silane-treated aluminosilicate (PMNs P-16-194, P-16-195, P-16-196, P-16-197, P-16-198, P-16-199, P-16-460, P-16-461, P-16-462, P-16-463, and P-16-464) are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substances after they have been completely incorporated into a polymer matrix.

(2) The significant new uses are:

(i) *Protection in the workplace*. Requirements as specified in § 721.63(a)(4), (when determining which persons are reasonably likely to be exposed as required for §721.63(a)(4), engineering control measures (e.g. enclosure or confinement of operation, general and local ventilation) or administrative control measures (e.g. workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible), (a)(5)(respirators must provide a National Institute for Occupational Safety and Health assigned protection factor of at least 50), (a)(6)(particulate), (b)(concentration set at 0.1%), and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e) (concentration set at 0.1%), (f), (g)(1)(ii), (iii), (iv), (v), (vi), (vii), (viii), (ix), (g)(2)(i), (ii), (iii), (iv), (v), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80. It is a significant new use to manufacture the substances without sampling and analyzing the immediate precursor used to manufacture the substances according to the terms specified in the 5(e) Order for the following elements: arsenic, barium, beryllium, cadmium, chromium, cobalt, copper, lead, manganese, mercury, nickel, selenium, silver, vanadium, and zinc. It is a significant new use to manufacture the substances at facilities other than those equipped with pollution controls, such as a bag house, that remove particulates from the air at 99% or greater efficiency. It is a significant new use to process the substances other than in an enclosed system that does not allow for the release of particulates or at facilities equipped with pollution controls, such as a bag house, that remove particulates from the air at 99% or greater efficiency.

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

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

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

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

6. Add § 721.11175 to subpart E to read as follows:

**§ 721.11175 Heteropolycycliccarboxylic acid, 1,3-dihydro-disubstituted-, polymer with 1,1'-methylenebis, reaction products with silica (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as heteropolycycliccarboxylic acid, 1,3-dihydro-disubstituted-, polymer with 1,1'-methylenebis, reaction products with silica (P-16-307) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been reacted (cured).

(2) The significant new uses are:

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

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e)(concentration set at 1.0%), (f), (g)(1)(i), (ii), (g)(2)(i), (ii), (iii), (v), and (g)(5).

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

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80. It is a significant new use to manufacture, process, or use the substance for consumer use or for commercial uses that could introduce the substance into a consumer setting. It is a significant new use to manufacture, process, or use the substance other than in a liquid formulation. It is a significant new use to manufacture the PMN substance to contain more than 0.1% residual isocyanate by weight. It is a significant new use to manufacture, process, or use the substance in any manner that results in generation of a vapor, dust, mist or aerosol.

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

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

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

7. Add § 721.11176 to subpart E to read as follows:

**§ 721.11176 Carbonic acid, alkyl carbomonocyclic ester (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as carbonic acid, alkyl carbomonocyclic ester (PMN P-17-176) 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), (a)(2)(i), (iv), (a)(3), (a)(6) (particulate), (a)(6)(v), (vi), (when determining which

persons are reasonable likely to be exposed as required for § 721.63(a)(1), engineering control measures (e.g. enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g. workplace policies and procedures) shall be considered and implemented to prevent exposures, where feasible),

(b)(concentration set at 1.0%), and (c).

(ii) *Hazard communication*. Requirements as specified in § 721.72(a) through (e)(concentration set at 1.0%), (f), (g)(1)(iv), (v), (vi), (ix), (g)(2)(i), (v), (g)(3)(i), (ii), (g)(4)(do not release to water above 45 parts per billion), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(f) and (p)(3 years).

(iv) *Release to water*. Release to water requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where N = 45 ppb.

(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), (k).

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

8. Add § 721.11177 to subpart E to read as follows:

**§ 721.11177 1,3-Propanediol, 2-ethyl-2-(hydroxymethyl)-, polymer with 2-(chloromethyl)oxirane, reaction products with polyethylene-polypropylene glycol 2-aminopropyl Me ether.**

(a) *Chemical substance and significant new used subject to reporting.* (1) The chemical substance identified as 1,3-propanediol, 2-ethyl-2-(hydroxymethyl)-, polymer with 2-(chloromethyl)oxirane, reaction products with polyethylene-polypropylene glycol 2-aminopropyl Me ether (PMN P-17-183, CAS No 1627528-04-4) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been reacted (cured).

(2) The significant new uses are:

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

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f), (k), (o). It is a significant new use to process or use the substance in any manner way that results in generation of a vapor, dust, mist or aerosol.

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

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

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

9. Add § 721.11178 to subpart E to read as follows:

**§ 721.11178 Copolyamide of an aromatic dicarboxylic acid and a mixture of diamines (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as copolyamide of an aromatic dicarboxylic acid and a mixture of diamines (PMN P-17-232) 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. It is a significant new use to manufacture the substance with a particle size less than 10 microns.

(ii) [Reserved]

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

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

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

10. Add § 721.11179 to subpart E to read as follows:

**§ 721.11179 Single-walled carbon nanotubes.**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as single-walled carbon nanotubes (PMN P-17-257) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substances that have been:

(i) Embedded or incorporated into a polymer matrix that itself has been reacted (cured);

(ii) Embedded in a permanent solid polymer form that is not intended to undergo further processing, except mechanical processing; or

(iii) Incorporated into an article as defined at 40 CFR 720.3(c).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i), (a)(3), (a)(4), (when determining which persons are reasonable likely to be exposed as required for § 721.63(a)(1), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measure (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible), (a)(5)(respirators must provide a National Institute for Occupational Safety and Health assigned protection factor of at least 50), (a)(6)(particulate), and (c).

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f), (k), (p)(6 months), (y)(1), and (y)(2). (It is a significant new use to process or use the substance for non-industrial use except for the confidential non-industrial use described in the 5(e) Order).

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

(iv) *Release to water*. Requirements as specified in § 721.90(a)(1), (b)(1), (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), (j), and (k) are applicable to manufacturers and processors of this substance.

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

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

11. Add § 721.11180 to subpart E to read as follows:

**§ 721.11180 Arenesulfonic acid, alkyl derivatives, metal salts (generic).**

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified generically as arenesulfonic acid, alkyl derivatives, metal salts (PMN P-17-283) 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), (iii), (a)(3), (when determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (e.g. enclosure or confinement of 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), (b)(concentration set at 1.0%), and (c).

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

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(p)(6 months). It is a significant new use to manufacture, process or use the substance in any manner way that results in generation of a vapor, mist, spray, or aerosol.,

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

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

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

12. Add § 721.11181 to subpart E to read as follows:

**§ 721.11181 Heteromonocycle, 2-[(bicarbo monocycle-2-substituted)alkyl]- (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as heteromonocycle, 2-[(bicarbo monocycle-2-substituted)alkyl]- (PMN P-17-353) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of

this section do not apply to quantities of the substance after they have been reacted (cured).

(2) The significant new uses are:

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

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e) (concentration set at 0.1%), (f), (g)(1), (g)(1)(iv), (vi), (vii), (ix), (mutagenicity), (eye, skin, lung, and mucous membrane irritation), (skin and lung sensitization), (g)(2)(i), (ii), (iii), (v), (avoid workplace airborne concentrations), (g)(3)(i), (ii), (g)(4)(iii), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities:* Requirements as specified in § 721.80(f) and (k). It is a significant new use to process or use the substance in any manner that generates a vapor, spray, mist, or aerosol.

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

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

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

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

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

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