



BILLING CODE 6560-50-P

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Parts 9 and 721**

**[EPA-HQ-OPPT-2016-0207; FRL-9953-41]**

**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 57 chemical substances which were the subject of premanufacture notices (PMNs). The applicable review periods for the PMNs submitted for these 57 chemical substances all ended prior to June 22, 2016 (i.e., the date on which President Obama signed into law the Frank R. Lautenberg Chemical Safety for the 21st Century Act which amends TSCA). Thirty-four of these chemical substances are subject to TSCA section 5(e) consent orders issued by EPA. This action requires persons who intend to manufacture (defined by statute to include import) or process any of these 57 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.

Manufacture and processing for the significant new use is unable to commence until EPA has conducted a review of the notice, made an appropriate determination on the notice, and take 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 or critical comments, or notice of intent to submit adverse or critical 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 or critical comments, or notice of intent to submit adverse or critical 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-2016-0207, by one of the following methods:

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

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

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

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

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

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

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

[moss.kenneth@epa.gov](mailto:moss.kenneth@epa.gov).

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

## **SUPPLEMENTARY INFORMATION:**

### **I. General Information**

#### *A. Does this Action Apply to Me?*

You may be potentially affected by this action if you manufacture, process, or use the chemical substances contained in this 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 the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

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

## **II. Background**

### *A. What Action is the Agency Taking?*

EPA is promulgating these SNURs using direct final 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 allows EPA to assess risks that may be presented by the intended uses and, if appropriate, to regulate the proposed use before it occurs. Additional rationale and background to these rules are more fully set out in the preamble to EPA's first direct final SNUR published in the **Federal Register** issue of April 24, 1990 (55 FR 17376). Consult that preamble for further information on the objectives, rationale, and procedures for SNURs and on the basis for significant new use designations, including provisions for developing test data.

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

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

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

### *C. Applicability of General Provisions*

General provisions for SNURs appear in 40 CFR part 721, subpart A. These provisions describe persons subject to the rule, recordkeeping requirements, 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 sections 5(h)(1), (h)(2), (h)(3), and (h)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUN, EPA must either determine that the 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 authorized EPA to consider any other relevant factors.

To determine what would constitute a significant new use for the 57 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 57 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) consent order or, for non-section 5(e) SNURs, the basis for the SNUR (i.e., SNURs without TSCA section 5(e) consent orders).
- Tests recommended by EPA to provide sufficient information to evaluate the chemical substance (see Unit VIII. for more information).
- CFR citation assigned in the regulatory text section of this rule.

The regulatory text section of this rule specifies the activities designated as significant new uses. Certain new uses, including 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.

This rule includes 34 PMN substances that are subject to “risk-based” consent orders under TSCA section 5(e)(1)(A)(ii)(I) where EPA determined that activities associated with the PMN substances may present unreasonable risk to human health or the environment. Those consent orders require protective measures to limit exposures or otherwise mitigate the potential unreasonable risk. The so-called “TSCA section 5(e) SNURs” on these PMN substances are promulgated pursuant to § 721.160, and are based on and consistent with the provisions in the underlying consent orders. The TSCA section 5(e) SNURs designate as a “significant new use” the absence of the protective measures required in the corresponding consent orders.

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)

consent order usually requires, among other things, that potentially exposed employees wear specified respirators unless actual measurements of the workplace air show that airborne 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) consent 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 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) consent order for the same chemical substance.

This rule also includes SNURs on 23 PMN substances that are not subject to consent orders under TSCA section 5(e). These cases completed Agency review prior to June 22, 2016. Under TSCA, prior to the enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act on June 22, 2016, EPA did not find that the use scenario described in the PMN triggered the determinations set forth under TSCA section 5(e). However, EPA does believe that certain changes from the use scenario described in the PMN could result in increased exposures, thereby constituting a “significant new use.”

These so-called “non-TSCA section 5(e) SNURs” are consistent with the determination made at the time and are promulgated pursuant to § 721.170. EPA has determined that every activity designated as a “significant new use” in all non-TSCA section 5(e) SNURs issued under § 721.170 satisfies the two requirements stipulated in § 721.170(c)(2), i.e., these significant new use activities, “(i) are different from those described in the premanufacture notice for the substance, including any amendments, deletions, and additions of activities to the premanufacture notice, and (ii) may be accompanied by changes in exposure or release levels that are significant in relation to the health or environmental concerns identified” for the PMN substance.

**PMN Number P-11-482**

*Chemical name:* Bimodal mixture consisting of multi-walled carbon nanotubes and other classes of carbon nanotubes (generic).

*CAS number:* Claimed confidential.

*Effective date of TSCA section 5(e) consent order:* September 30, 2015.

The PMN states that the generic use of the PMN substance will be as a specialty additive. Based on test data on analogous respirable, poorly soluble particulates and nanocarbon materials, EPA identified concerns for pulmonary toxicity and oncogenicity. Based on test data for other nanocarbon materials EPA identified concerns for environmental toxicity. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I), based on a finding that the substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the consent order requires:

1. Use of personal protective equipment involving impervious gloves and protective clothing (where there is a potential for dermal exposures) and a National Institute for Occupational Safety and Health (NIOSH)-certified air purifying, tight-fitting full-face respirator equipped with N-100, P-100, or R-100 cartridges, or power air purifying particulate respirator with an Assigned Protection Factor (APF) of at least 50 (where there is a potential for inhalation exposures).

2. Submission of a dustiness test within six months of notice of commencement of manufacture (NOC).

3. Submission of certain physical-chemical properties data within the time limits specified in the consent order.

4. Processing and use of the PMN substance only for the use specified in the consent order, including no application method that generates a vapor, mist or aerosol unless the application method occurs in an enclosed process.

5. No use of the PMN substance resulting in releases to surface waters and disposal of the PMN substance only by landfill or incineration.

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

*Recommended testing:* EPA has determined that the development of data on certain physical-chemical properties, as well as certain human health and environmental toxicity testing would help characterize possible effects of the substance. The submitter has agreed to provide a dustiness test (European Standard EU 15051) by six months from commencement of manufacture. In addition, the submitter has agreed to provide certain physical-chemical property testing as required in the consent order after the

commencement of manufacture. Although the order does not require a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465 or Organisation for Economic Co-operation and Development (OECD) Test Guideline 413) in rats with a post-exposure observation period of up to 9 months (including BALF analysis, a determination of cardiovascular toxicity (clinically-based blood/plasma protein analyses), and histopathology of the heart), a two-year inhalation bioassay (OPPTS Test Guideline 870.4200), a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300), a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400), or an algal toxicity test (OCSPP Test Guideline 850.4500), the Order's restrictions on manufacture, processing, distribution in commerce, and disposal will 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 721.10927.

**PMN Number P-12-292**

*Chemical name:* Coke (coal), secondary pitch.

*Definition:* A carbon-containing residue from the coking of air blown pitch coke oil and/or pitch distillate. Composed primarily of isotropic carbon, it contains small amounts of sulfur and ash constituents.

*CAS number:* 94113-91-4.

*Effective date of TSCA section 5(e) consent order:* July 1, 2015.

*Basis for TSCA section 5(e) consent order:* The PMN states that the generic (non-confidential) use of the substance will be in the carbon graphite industry. Based on SAR analysis of test data on analogous respirable, poorly soluble particulates, subcategory carbon black, EPA identified concerns for lung effects and cancer to workers exposed to

the PMN substance by the inhalation route. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) based on a finding that the substance may present an unreasonable risk of injury to human health. To protect against these risks, the consent order requires:

1. Use of personal protective equipment including a NIOSH-certified respirator with an APF of at least 50 or compliance with a NCEL of  $0.0025 \text{ mg/m}^3$  as an 8-hour time-weighted average, when there is a potential for inhalation exposures.

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

3. No domestic manufacture of the PMN substance.

4. Use of the PMN substances only for the confidential uses specified in the consent order.

5. Submission of certain toxicity testing on the PMN substance prior to exceeding the confidential production volume limit as specified in the consent order of the PMN substance.

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

*Recommended testing:* EPA has determined that the development of data on certain physical-chemical properties, as well as certain human health toxicity testing would help characterize possible effects of the substance. The submitter has agreed to provide the physical/chemical properties data and a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) in rats with a post-exposure observation period of 60 days

(including BALF analysis) before exceeding the production volume limits in the consent order. Although the order does not require a two-year inhalation bioassay (OPPTS Test Guideline 870.4200), the Order's restrictions on manufacture, processing, distribution in commerce, and disposal will 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 721.10928.

**PMN Numbers P-13-718, P-13-719, P-13-720, P-13-721, P-14-655, P-14-656, P-14-657, and P-14-658.**

*Chemical name:* Single-walled carbon nanotubes (generic).

*CAS number:* Claimed confidential.

*Effective date of TSCA section 5(e) consent order:* July 1, 2015.

*Basis for TSCA section 5(e) consent order:* The PMNs state that the use of the PMN substances will be as: a semi-conductor, conductive, or resistive element in electronic circuitry and devices; an electro-mechanical switch in electronic circuitry and devices; a film laminate to improve structural, electrical or electro-chemical properties of composite materials; a film laminate to improve conductivity in batteries, capacitors and fuels cells; with composite materials to improve their mechanical properties and electrical conductivities; catalyst support for use in fuel cells; in a nanoporous network in gas diffusion layers; for separation of chemicals; an additive to improve corrosion resistance of metals; an additive in lubricants and greases to improve wear resistance; an additive for transparency and conductivity in electronic devices; an additive for fibers in structural and electrical applications; an additive for fibers in fabrics and as a chemical intermediate. Based on test data on analogous respirable, poorly soluble particulates and

other carbon nanotubes, EPA identified concerns for pulmonary toxicity and oncogenicity. Based on test data for other carbon nanotubes, EPA identified concerns for environmental toxicity. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I), based on a finding that the substances may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the consent order requires:

1. Use of personal protective equipment involving impervious gloves and protective clothing (where there is a potential for dermal exposures) and a National Institute for Occupational Safety and Health (NIOSH)-certified air purifying, tight-fitting full-face respirator equipped with N-100, P-100, or R-100 cartridges, or power air purifying particulate respirator with an Assigned Protection Factor (APF) of at least 50 (where there is a potential for inhalation exposures).

2. Submission of certain physical-chemical data for the PMN substances within the time triggers specified in the consent order.

3. Submission of certain human health testing prior to exceeding the confidential production volume limit specified in the consent order.

4. Establishment of a medical surveillance program as specified in the consent order.

5. Processing and use of the PMN substances only for the uses specified in the consent order, including no application method that generates a vapor, mist or aerosol unless the application method occurs in an enclosed process.

6. No use of the PMN substances resulting in releases to surface waters and disposal of the PMN substances only by landfill or incineration.

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

*Recommended testing:* EPA has determined that the development of data on certain physical-chemical properties, as well as certain human health and environmental toxicity testing would help characterize possible effects of the substance. The submitter has agreed to provide the physical/chemical properties data within the specified time limits. In addition, the submitter has agreed not to exceed the confidential production limit without performing a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465 or OECD Test Guideline 413) in rats with a post-exposure observation period of up to 9 months (including BALF analysis, a determination of cardiovascular toxicity (clinically-based blood/plasma protein analyses), and histopathology of the heart). Although the order does not require a two-year inhalation bioassay (OPPTS Test Guideline 870.4200), a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300), a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400), or an algal toxicity test (OCSP Test Guideline 850.4500), the Order’s restrictions on manufacture, processing, distribution in commerce, and disposal will 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 721.10929.

**PMN Numbers P-14-150, P-14-151, P-14-152, P-14-165, and P-14-166**

*Chemical name:* Fatty acid amides (generic).

*CAS number:* Claimed confidential.

*Basis for Action:* The PMNs states that these substances will be used as chemical intermediates, additives for flotation products, and adhesion promoters for use in asphalt

applications. Based on SAR analysis of test data on analogous amides and aliphatic amines, EPA expects toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of PMNs P-14-150 and P-14-165, 2 ppb of PMN P-16-166, and 4 ppb of PMNs P-14-151 and P-14-152 in surface waters. For the uses described in the PMNs, releases of the substances are not expected to result in surface water concentrations that exceed their respective concern concentration levels. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substances may present an unreasonable risk. EPA has determined, however, that any use of the substances, excluding the uses described in the PMNs, resulting in releases to surface waters exceeding 1 ppb (P-15-150 and P-14-165), 2 ppb (P-16-166), or 4 ppb (P-15-151 and P-15-152) may result in significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(ii).

*Recommended testing:* EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substances P-14-150, P-14-151, and P-14-152. Further, EPA has determined results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); an algal toxicity test (OCSPP Test Guideline 850.4500); log Kow and water solubility measurements, as well as either the fish acute toxicity mitigated by humic acid test (OPPTS Test Guideline 850.1085) or the whole sediment acute toxicity invertebrates, freshwater test (OPPTS Test Guideline 850.1735) would help characterize the environmental effects of the PMN substances P-

14-165 and P-14-166. EPA also recommends that the guidance document on aquatic toxicity testing of difficult substances and mixtures (OECD Test Guideline 23) be followed to facilitate solubility in the test media, because of the low water solubility of the PMNs. EPA recommends conducting the water solubility and log Kow measurements testing first as the results may mitigate the need for further toxicity testing or change the testing recommendations.

*CFR citation:* 40 CFR 721.10930.

**PMN Number P-14-413**

*Chemical name:* Kaolin, reaction products with polysiloxane (generic).

*CAS number:* Claimed confidential.

*Effective date of TSCA section 5(e) consent order:* October 22, 2015.

*Basis for TSCA section 5(e) consent order:* The PMN states that the generic (non-confidential) use of the substance will be as an insulator. Based on SAR analysis of test data on analogous respirable, poorly soluble particulates, EPA identified concerns for lung effects to workers exposed to the PMN substance by the inhalation route. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) based on a finding that the substance may present an unreasonable risk of injury to human health. To protect against these risks, the consent order requires:

1. Use of personal protective equipment including a NIOSH-certified respirator with an APF of at least 1,000 or compliance with a NCEL of  $0.1 \text{ mg/m}^3$  as an 8-hour time-weighted average, when there is a potential for inhalation exposures.
2. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the MSDS.

3. Submission of a 90-day inhalation study on the PMN substance prior to exceeding the confidential production volume limit as specified in the consent order of the PMN substance.

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

*Recommended testing:* The submitter has agreed to provide a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) in rats with a post-exposure observation period of 60 days (including BALF analysis) before exceeding the production volume limit in the consent order. Although the order does not require a two-year inhalation bioassay (OPPTS Test Guideline 870.4200), the Order’s restrictions on manufacture, processing, distribution in commerce, and disposal will 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 721.10931.

**PMN Numbers P-14-428, P-14-429, P-14-430, and P-14-431**

*Chemical name:* Fatty acid amides (generic).

*CAS number:* Claimed confidential.

*Basis for Action:* The consolidated PMN states that the substances will be used as adhesion promoters and emulsifier intermediates for use in asphalt applications. Based on SAR analysis of test data on analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of P-14-428 and P-14-430, and 2 ppb of P-14-429 and P-14-431 in surface waters. For the uses described in the PMNs, releases of the substances are not expected to result in surface water concentrations that exceed their respective concentration values. Therefore, EPA has not determined that the

proposed manufacturing, processing, or use of the substances may present an unreasonable risk. EPA has determined, however, that any use of the substances, excluding the uses described in the PMNs, resulting in releases to surface waters exceeding 1 ppb of P-14-428 and P-14-430, and 2 ppb of P-14-429 and P-14-431, may cause significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(ii).

*Recommended testing:* EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substances.

*CFR citation:* 40 CFR 721.10932.

**PMN Numbers P-14-523, P-14-524, P-14-525, P-14-526, and P-14-527**

*Chemical name:* Copolymers of perfluorinated and alkyl methacrylates (generic).

*CAS number:* Claimed confidential.

*Effective date of TSCA section 5(e) consent order:* August 24, 2015.

*Basis for TSCA section 5(e) consent order:* The PMNs state that the generic (non-confidential) use of the substances will be as additives for textile finishing. Based on physical-chemical properties data, as well as test data on analogous perfluorinated chemicals and potential perfluorinated degradation products, EPA identified concerns for irritation to skin, eyes, lungs, mucous membranes, lung toxicity, liver toxicity, blood toxicity, male reproductive toxicity, immunosuppression, and oncogenicity. EPA has concerns that these degradation products will persist in the environment, could bioaccumulate or biomagnify, and could be toxic (PBT) to people, wild mammals, and

birds. The Order was issued under TSCA sections 5(e)(1)(A)(i), 5(e)(1)(A)(ii)(I), and 5(e)(1)(A)(ii)(II) based on a finding that the substances may present an unreasonable risk of injury to the environment and human health, the substances may be produced in substantial quantities and may reasonably be anticipated to enter the environment in substantial quantities, and there may be significant (or substantial) human exposure to the substances and their potential degradation products. To protect against these exposures and risks, the consent order requires:

1. Use of personal protective equipment including a NIOSH-certified respirator when there is a potential for inhalation exposures.
2. Risk notification. If as a result of the test data required, the company becomes aware that the PMN substances may present a risk of injury to human health or the environment, the company must incorporate this new information, and any information on methods for protecting against such risk into an MSDS, within 90 days.
3. Manufacture of the PMN substances: (a) According to the chemical composition section of the consent order, including analyzing and reporting certain starting raw material impurities to EPA; and (b) within the maximum established limits of certain fluorinated impurities of the PMN substance as stated in the consent order.
4. Submission of certain toxicity, physical-chemical property, and environmental fate testing on the PMN substance prior to exceeding the confidential production volume limits as specified in the consent order.
5. Use of the PMN substances only for water and oil repellent use on military protective clothing.
6. No distribution of the PMN substances for consumer use.

7. No manufacture of the PMN substances in the United States.

8. No water releases of the PMN substances exceeding 17 ppb.

*Recommended testing:* EPA has determined that the results of certain toxicity and environmental fate testing would help characterize the PMN substance. The submitter has agreed to complete the testing identified in the testing section of the consent order by the confidential limits specified. In addition, EPA has determined that the results of a 90-day inhalation toxicity test in rats (OPPTS Test Guideline 870.3465/OECD Test Guideline 413) with a 60-day holding period, and an avian reproduction test (OECD Test Guideline 206) in mallard ducks would help characterize potential human health and environmental effects of the PMN substances. The Order does not require this testing at any specified time or production volume. However, the Order's restrictions on manufacture, processing, distribution in commerce, use, and disposal of the PMN substances will remain in effect until the Order is modified or revoked by EPA based on submission of that or other relevant information.

*CFR citation:* 40 CFR 721.10933.

**PMN Number P-14-580**

*Chemical name:* Alkenoic acid, polymer with alkyl alkenoate, alkylalkylalkenoate, alkenoic acid and tridecafluoro alkylalkenoate, compds. with alkylaminoalcanol (generic).

*CAS number:* Claimed confidential.

*Effective date of TSCA section 5(e) consent order:* October 21, 2015.

*Basis for TSCA section 5(e) consent order:* The PMN states that the generic (non-confidential) use of the substance will be as a coating additive. Based on physical

chemical properties data, as well as test data on analogous perfluorinated chemicals and potential perfluorinated degradation products, EPA identified concerns for irritation to skin, eyes, lungs, mucous membranes, lung toxicity, liver toxicity, blood toxicity, male reproductive toxicity, immunosuppression, and oncogenicity. EPA has concerns that these degradation products will persist in the environment, could bioaccumulate or biomagnify, and could be toxic (PBT) to people, wild mammals, and birds. The Order was issued under TSCA sections 5(e)(1)(A)(i), 5(e)(1)(A)(ii)(I), and 5(e)(1)(A)(ii)(II) based on a finding that the substance may present an unreasonable risk of injury to the environment and human health, the substance may be produced in substantial quantities and may reasonably be anticipated to enter the environment in substantial quantities, and there may be significant (or substantial) human exposure to the substance and its potential degradation products. To protect against these exposures and risks, the consent order requires:

1. Use of a NIOSH-certified respirator when there is a potential for inhalation exposures.
2. Use of impervious gloves where there is a potential for dermal exposures.
3. Risk notification. If as a result of the test data required, the company becomes aware that the PMN substances may present a risk of injury to human health or the environment, the company must incorporate this new information, and any information on methods for protecting against such risk into an MSDS, within 90 days.
4. Manufacture of the PMN substance: (a) According to the chemical composition section of the consent order, including analyzing and reporting certain starting raw

material impurities to EPA; and (b) within the maximum established limits of certain fluorinated impurities of the PMN substance as stated in the consent order.

5. Submission of certain toxicity, physical-chemical property, and environmental fate testing on the PMN substance prior to exceeding the confidential production volume limits as specified in the consent order.

6. Use of the PMN substance only for the confidential uses specified in the consent order.

*Recommended testing:* EPA has determined that the results of certain toxicity and environmental fate testing would help characterize the PMN substance. The submitter has agreed to complete the testing identified in the testing section of the consent order by the confidential limits specified. In addition, EPA has determined that the results of a hydrolysis as a function of pH and temperature (OPPTS Test Guideline 835.2130); an indirect photolysis screening test (OPPTS Test Guideline 835.5270); a modified semi-continuous activated sludge (SCAS) test (OPPTS Test Guideline 835.5045 or OECD Test Guideline 302A) with analysis of degradation products; a simulation test-aerobic sewage treatment (activated sludge units) OECD Test Guideline OECD 303A); a phototransformation of chemicals in soils surfaces (Draft OECD Test Guideline Jan. 2002); an acute inhalation toxicity test (OPPTS Test Guideline 870.1300); and a fish short-term reproduction test (OPPTS Test Guideline 890.1350) would help characterize potential human health and environmental effects of the PMN substances. The Order does not require this testing at any specified time or production volume. However, the Order's restrictions on manufacture, processing, distribution in commerce, use, and

disposal of the PMN substances will remain in effect until the Order is modified or revoked by EPA based on submission of that or other relevant information.

*CFR citation:* 40 CFR 721.10934.

**PMN Number P-14-643**

*Chemical name:* Titanium oxide compound (generic).

*CAS number:* Claimed confidential.

*Effective date of TSCA section 5(e) consent order:* July 15, 2015.

*Basis for TSCA section 5(e) consent order:* The PMN states that the generic (non-confidential) use of the substance will be as a physical characteristics modifier for composite articles. Based on SAR analysis of test data on analogous respirable, poorly soluble particulates, EPA identified concerns for lung effects to workers exposed to the PMN substance by the inhalation route. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) based on a finding that the substance may present an unreasonable risk of injury to human health. To protect against these risks, the consent order requires:

1. Use of personal protective equipment including a NIOSH-certified respirator with an APF of at least 10 or compliance with a NCEL of  $2.4 \text{ mg/m}^3$  as an 8-hour time-weighted average, when there is a potential for inhalation exposures.
2. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the MSDS.
3. Submission of a 90-day inhalation study on the PMN substance prior to exceeding the production volume limit specified in the consent order of the PMN substance.

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

*Recommended testing:* The submitter has agreed to provide a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) in rats with a post-exposure observation period of 60 days (including BALF analysis) before exceeding the production volume limit in the consent order. Although the order does not require a two-year inhalation bioassay (OPPTS Test Guideline 870.4200), the Order’s restrictions on manufacture, processing, distribution in commerce, and disposal will 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 721.10935.

**PMN Numbers P-14-688, P-14-689, P-14-690, and P-14-691**

*Chemical name:* Fatty acid amide hydrochlorides (generic).

*CAS number:* Claimed confidential.

*Basis for Action:* The PMNs state that the substances will be used as surfactants for use in asphalt emulsions. Based on SAR analysis of test data on analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb for P-14-688, P-14-689, P-14-690, and 2 ppb for P-14-691 in surface waters. For the uses described in the PMNs, releases of the substances are not expected to result in surface water concentrations that exceed their respective concern concentration levels. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substances may present an unreasonable risk. EPA has determined, however, that any use of the substances, excluding the uses described in the PMNs, resulting in releases to surface waters exceeding 1 ppb for P-14-688, P-14-689, P-14-690, and 2 ppb for P-14-

691, may result in significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(ii).

*Recommended testing:* EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substances. EPA recommends that testing be conducted on P-14-688.

*CFR citation:* 40 CFR 721.10936.

**PMN Numbers P-14-712, P-14-713, P-14-714, and P-14-715**

*Chemical names:* Plastics, wastes, pyrolyzed, bulk pyrolysate (generic) (P-14-712); Plastics, wastes, pyrolyzed, light distillate (generic) (P-14-713); Plastics, wastes, pyrolyzed, middle distillate (generic) (P-14-714); and Plastics, wastes, pyrolyzed, heavy distillate (generic) (P-14-715).

*CAS numbers:* Claimed confidential.

*Effective date of TSCA section 5(e) consent order:* July 27, 2015.

*Basis for TSCA section 5(e) consent order:* The PMNs state that the generic (non-confidential) use of P-14-712 is a petroleum blend stock, of P-14-713 and P-14-714 is a fuel blend stock, and of P-14-715 is a component of grease or wax products. Based on the presence of benzene and naphthalene, EPA identified concerns for oncogenicity, immunotoxicity, liver toxicity, and blood toxicity. There is also a concern that polychlorinated dibenzo-p-dioxins and dibenzofurans could be present in the PMN substances. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I), based on a finding that the substances may present an unreasonable risk

of injury to human health and the environment. To protect against these risks, the consent order requires:

1. Use of a NIOSH-certified respirator with an APF of at least 10 (where there is a potential for inhalation exposures) or, as an alternative, maintaining workplace airborne concentrations of the chemical substances identified in the consent order at a level below the specified Exposure Limit (EL) of 0.1 ppm and 10 ppm respectively for an 8-hour time weighted average.

2. Use of the PMN substances only for the uses specified in the consent order.

3. Manufacture P-14-712 only as described in the PMN.

4. Provide personal protective equipment to workers to prevent dermal exposure, where there is a potential for dermal exposures.

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

6. Record and report on a quarterly basis polychlorinated dibenzo-p-dioxin and dibenzofuran levels for P-14-712.

*Recommended testing:* EPA has determined that quarterly testing of polychlorinated dibenzo-p-dioxin and dibenzofuran levels for P-14-712 will characterize potential health effects of the PMN substances.

*CFR citations:* 40 CFR 721.10937 (P-14-712); 40 CFR 721.10938 (P-14-713); 40 CFR 721.10939 (P-14-714); and 40 CFR 721.10940 (P-14-715).

**PMN Number P-15-28**

*Chemical name:* Carbon silicon oxide.

*CAS number:* 39345-87-4.

*Effective date of TSCA section 5(e) consent order:* September 22, 2015.

*Basis for TSCA section 5(e) consent order:* The PMN states that the generic (non-confidential) use of P-15-28 is a colorant for industrial, architecture, plastics, inks and automotive applications. Based on the presence on data on structurally analogous poorly soluble particulates, EPA identified concerns for lung overload. The Order was issued under TSCA sections 5(e)(1)(A)(i), 5(e)(1)(A)(ii)(I), and 5(e)(1)(A)(ii)(II), based on a finding that the substance may present an unreasonable risk of injury to human health, and that the substance will be produced in substantial quantities and may reasonably be anticipated to enter the environment in substantial quantities, and there may be significant (or substantial) human exposure to the substance. To protect against these risks, the consent order requires:

1. Use of personal protective equipment including a NIOSH-certified respirator with an APF of at least 10 or compliance with a NCEL of  $6 \text{ mg/m}^3$  as an 8-hour time-weighted average, when there is a potential for inhalation exposures.

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

3. Manufacture of the PMN substance only as described in the Consent Order.

4. Submission of certain toxicity testing on the PMN substance within two years of submission of the NOC, as specified in the consent order of the PMN substance.

*Recommended testing:* EPA has determined that the results of a 90-day inhalation toxicity study, with a 60-day holding period (OPPTS Test Guideline 870.3465), would help characterize human health and environmental effects of the PMN substance. The

submitter has agreed to conduct this test within two years of submission of the Notice of Commencement of Manufacture (NOC). EPA has also determined that the results of a Chronic Toxicity test (OPPTS Test Guideline 870.4100) via the inhalation route would further help characterize human health effects of the PMN substance. The Order does not require this testing at any specified time or production volume. However, the Order's restrictions on manufacture, processing, distribution in commerce, use, and disposal of the PMN substance will remain in effect until the Order is modified or revoked by EPA based on submission of that or other relevant information.

*CFR citation:* 40 CFR 721.10941.

**PMN Number P-15-54**

*Chemical name:* Carbon nanotubes (generic).

*CAS number:* Claimed confidential.

*Effective date of TSCA section 5(e) consent order:* August 31, 2015.

*Basis for TSCA section 5(e) consent order:* The PMN states that the generic (non-confidential) use of the PMN substance will be as a chemical intermediate. Based on test data on analogous respirable, poorly soluble particulates and carbon nanotubes, EPA identified concerns for pulmonary toxicity and oncogenicity. Based on test data for other nanocarbon materials EPA identified concerns for environmental toxicity. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I), based on a finding that the substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the consent order requires:

1. Use of personal protective equipment involving impervious gloves and protective clothing (where there is a potential for dermal exposures) and a National

Institute for Occupational Safety and Health (NIOSH)-certified air purifying, tight-fitting full-face respirator equipped with N-100, P-100, or R-100 cartridges, or power air purifying particulate respirator with an Assigned Protection Factor (APF) of at least 50 (where there is a potential for inhalation exposures).

2. Submission of certain physical chemical properties according to the time limits described in the order.

3. Submission of a 90-day inhalation study within one year of notice of commencement.

4. Use of the PMN substance only as a chemical intermediate.

5. No use of the PMN substance resulting in releases to surface waters and disposal of the PMN substance only by landfill or incineration.

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

*Recommended testing:* EPA has determined that the development of data on certain physical-chemical properties, as well as certain human health and environmental toxicity testing would help characterize possible effects of the substance. The submitter has agreed to provide the results of certain physical-chemical property testing annually for at least three years after the commencement of manufacture. The submitter has also agreed to provide the results of a 90-day inhalation toxicity study already being conducted.

Although the order does not require a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300), a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400), or an algal toxicity test (OCSPP Test Guideline 850.4500), the Order’s restrictions on manufacture, processing, distribution in commerce, and disposal will

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 721.10942.

**PMN Number P-15-149**

*Chemical name:* Sulfonated alkylbenzene salts (generic).

*CAS number:* Claimed confidential.

*Effective date of TSCA section 5(e) consent order:* September 15, 2015.

*Basis for TSCA section 5(e) consent order:* The PMN states that the generic (non-confidential) use of the substance will be for enhanced oil recovery. Based on test data on analogous surfactants, EPA identified concerns for surfactant effects on the lung and irritation to eyes and mucous membranes. Further, based on structural activity relationship (SAR) analysis of test data on analogous anionic surfactants, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 2 ppb of the PMN substance in surface waters. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) based on a finding that the substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the consent order requires:

1. Hazard communication. Establishment and use of a hazard communication program, including environmental and human health precautionary statements on each label and in the MSDS.

2. Submission of certain toxicity testing on the PMN substance prior to exceeding the confidential production volume limit as specified in the consent order of the PMN substance.

3. Use of the PMN substance only for the confidential use specified in the consent order.

4. Comply with the release to water provisions specified in the consent order.

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

*Recommended testing:* EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an acute invertebrate toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substance. The submitter has agreed to complete this testing by the confidential production volume identified in the consent order. In addition, EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); acute inhalation toxicity test (OPPTS Test Guideline 870.1300); acute eye irritation test (OPPTS Test Guideline 870.2400); and acute dermal irritation test (OPPTS Test Guideline OPPTS 870.2500) would help characterize the potential environmental and human health effects of the PMN substance. The Order does not require these tests at any specified time or production volume. However, the Order’s restrictions on manufacture, processing, distribution in commerce, use, and disposal of the PMN substance will remain in effect until the Order is modified or revoked by EPA based on submission of that or other relevant information.

*CFR citation:* 40 CFR 721.10943.

**PMN Number P-15-267**

*Chemical name:* Substituted quinoline derivative (generic).

*CAS number:* Claimed confidential.

*Basis for Action:* The PMN states that the generic (non-confidential) use of the substance will be as a pesticide additive. Based on test data on the PMN substance, EPA identified concerns for chronic toxicity including blood, kidney, and spleen toxicity. As described in the PMN, occupational exposures are expected to be minimal due to the use of adequate personal protective equipment. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that use of the substance without use of impervious dermal protection where there is potential for dermal exposures, use of a NIOSH-certified respirator with an APF of at least 10, where there is a potential for inhalation exposures, and use other than as a pesticide additive may result in serious health effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(3)(i).

*Recommended testing:* EPA has determined that the results of a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) would help characterize the human health effects of the PMN substance.

*CFR citation:* 40 CFR 721.10944.

**PMN Number P-15-470**

*Chemical name:* Algal oil amide (generic).

*CAS number:* Claimed confidential.

*Basis for Action:* The PMN states that the generic (non-confidential) use of the substance will be as a chemical intermediate. Based on SAR analysis of test data on analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations

that exceed 2 ppb of the PMN substance in surface waters for greater than 20 days per year. This 20-day criterion is derived from partial life cycle tests (daphnid chronic and fish early life stage tests) that typically range from 21 to 28 days in duration. EPA predicts toxicity to aquatic organisms may occur if releases of the substance to surface water, from uses other than as described in the PMN, exceed releases from the use described in the PMN. For the use described in the PMN, environmental releases did not exceed 2 ppb for more than 20 days per year. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance other than as listed in the PMN may result in significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(ii).

*Recommended testing:* EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an acute invertebrate toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substance.

*CFR citation:* 40 CFR 721.10945.

**PMN Number P-15-485**

*Chemical name:* Bismuth compound (generic).

*CAS number:* Claimed confidential.

*Effective date of TSCA section 5(e) consent order:* December 21, 2015.

*Basis for TSCA section 5(e) consent order:* The PMN states that the generic (non-confidential) use of the substance will be as an additive for industrial coatings. Based on

SAR analysis of test data on analogous respirable, poorly soluble particulates, EPA identified concerns for lung toxicity. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) based on a finding that the substance may present an unreasonable risk of injury to human health. To protect against these risks, the consent order requires:

1. Use of personal protective equipment including a NIOSH-certified respirator with an APF of at least 10 or compliance with a NCEL of 2.4 mg/m<sup>3</sup> as an 8-hour time-weighted average, when there is a potential for inhalation exposures.

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

3. Submission of certain toxicity testing on the PMN substance prior to exceeding the production volume limit as specified in the consent order.

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

*Recommended testing:* EPA has determined that the results of a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) with special attention to histopathology (inflammation and cell proliferation) of the lung tissues and various parameters of the bronchoalveolar lavage fluid (BALF) (e.g., marker enzyme activities, total protein content, total cell count, cell differential, and cell viability) would help to characterize the health effects of the PMN substance. The submitter has agreed to complete this testing by the aggregate production volume identified in the consent order. In addition, EPA has determined that the results of a 2-year inhalation bioassay (OCSPP Test Guideline 870.4200) would help characterize the potential human health effects of the PMN

substance. The Order does not require this test at any specified time or production volume. However, the Order's restrictions on manufacture, processing, distribution in commerce, use, and disposal of the PMN substance will remain in effect until the Order is modified or revoked by EPA based on submission of that or other relevant information.

*CFR citation:* 40 CFR 721.10946.

**PMN Numbers P-15-612, P-15-613, P-15-614, P-15-615, P-15-616, P-15-617, and P-15-618**

*Chemical names:* Sulfur thulium ytterbium yttrium oxide (P-15-612); Gadolinium sulfur ytterbium yttrium oxide, erbium- and thulium-doped (P-15-613); Neodymium sulfur yttrium oxide (P-15-614); Erbium gadolinium neodymium sulfur ytterbium yttrium oxide (P-15-615); Erbium gadolinium sulfur ytterbium yttrium oxide (P-15-616); Erbium gadolinium ytterbium oxide (P-15-617); and Erbium gadolinium sulfur ytterbium oxide (P-15-618).

*CAS numbers:* 180189-40-6 (P-15-612); 1651187-84-6 (P-15-613); 1651158-45-5 (P-15-614); 1651152-96-3 (P-15-615); 1622295-07-1 (P-15-616); 1651152-05-4 (P-15-617); and 934388-91-7 (P-15-618).

*Effective date of TSCA section 5(e) consent order:* December 21, 2015.

*Basis for TSCA section 5(e) consent order:* The PMNs state that the use of the substances will be as additives for brand protection and anti-counterfeiting inks and polymers. Based on SAR analysis of test data on analogous respirable, poorly soluble particulates, EPA identified concerns for lung toxicity. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) based on a finding that the substance may present an

unreasonable risk of injury to human health. To protect against these risks, the consent order requires:

1. Use of personal protective equipment including a NIOSH-certified respirator with an APF of at least 10 or compliance with a NCEL of  $0.07 \text{ mg/m}^3$  as an 8-hour time-weighted average, when there is a potential for inhalation exposures.

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

3. Submission of certain toxicity testing on the PMN substances prior to exceeding the production volume limit as specified in the consent order.

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

*Recommended testing:* EPA has determined that the results of a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) with special attention to histopathology (inflammation and cell proliferation) of the lung tissues and various parameters of the bronchoalveolar lavage fluid (BALF) (e.g., marker enzyme activities, total protein content, total cell count, cell differential, and cell viability) would help to characterize the health effects of the PMN substance. The submitter has agreed to complete this testing by the aggregate production volume identified in the consent order. In addition, EPA has determined that the results of a 2-year inhalation bioassay (OCSPP Test Guideline 870.4200) would help characterize the potential human health effects of the PMN substances. The Order does not require this test at any specified time or production volume. However, the Order’s restrictions on manufacture, processing, distribution in

commerce, use, and disposal of the PMN substances will remain in effect until the Order is modified or revoked by EPA based on submission of that or other relevant information.

*CFR citations:* 40 CFR 721.10947 (P-15-612); 40 CFR 721.10948 (P-15-613); 40 CFR 721.10949 (P-15-614); 40 CFR 721.10950 (P-15-615); 40 CFR 721.10951 (P-15-616); 40 CFR 721.10952 (P-15-617); and 40 CFR 721.10953 (P-15-618).

**PMN Number P-15-655**

*Chemical names:* 2-Ethylhexanoic acid, compound with alkyamino cyclohexane (generic) (P-15-0655, chemical A); and 2-Ethylhexanoic acid, compound with cyclohexylamine (generic) (P-15-0655, chemical B).

*CAS numbers:* Claimed confidential.

*Basis for Action:* The PMN states that the generic (non-confidential) use of the substances will be as an epoxy curing agent. Based on SAR analysis of test data on analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 34 ppb of the PMN substances in surface waters. As described in the PMN, releases of the substances are not expected to result in surface water concentrations that exceed 34 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substances that results in releases to surface water concentrations exceeding 34 ppb may cause significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(ii).

*Recommended testing:* EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an acute invertebrate toxicity

test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substances.

*CFR citation:* 40 CFR 721.10954.

**PMN Number P-15-680**

*Chemical name:* Propenoic acid, alkyl ester, polymer with 1,3-cyclohexanedialkylamine, reaction products with oxirane(alkoxyalkyl) (generic).

*CAS number:* Claimed confidential.

*Basis for Action:* The PMN states that the generic (non-confidential) use of the substance will be as an ingredient in liquid paint coating. Based on data on the PMN substance as well as SAR analysis of test data on analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PMN substance in surface waters. As described in the PMN, releases of the substance are not expected to result in surface water concentrations that exceed 1 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance that results in releases to surface water concentrations exceeding 1 ppb may result in significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170 (b)(4)(i) and (b)(4)(ii).

*Recommended testing:* EPA has determined that the results of an activated sludge sorption isotherm test (OPPTS Test Guideline 835.1110); a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); and a daphnid chronic toxicity test (OPPTS Test

Guideline 850.1300) would help characterize the environmental effects of the PMN substance.

*CFR citation:* 40 CFR 721.10955.

**PMN Number P-15-691**

*Chemical name:* Acrylic acid, polymer with polyalkylene polyamine (generic).

*CAS number:* Claimed confidential.

*Basis for Action:* The PMN states that the use of the substance will be as a chemical intermediate. Based on data on the PMN substance and SAR analysis of test data on analogous polycationic polymers, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 5 ppb of the PMN substance in surface waters for greater than 20 days per year. This 20-day criterion is derived from partial life cycle tests (daphnid chronic and fish early life stage tests) that typically range from 21 to 28 days in duration. EPA predicts toxicity to aquatic organisms may occur if releases of the substance to surface water, from uses other than as described in the PMN, exceed releases from the use described in the PMN. For the use described in the PMN, environmental releases did not exceed 5 ppb for more than 20 days per year. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance other than as listed in the PMN may result in significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170 (b)(4)(i) and (b)(4)(ii).

*Recommended testing:* EPA has determined that the results of a Zahn-Wellens/EMPA Test (OPPTS Test Guideline 835.3200); a fish early-life stage toxicity test (OPPTS Test

Guideline 850.1400); a fish acute-toxicity test (OPPTS Test Guideline 850.1085) mitigated by humic acid test; and a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); would help characterize the environmental effects of the PMN substance.

EPA recommends that the fate testing be performed first as the results may mitigate the need for further toxicity testing or change the testing recommendations.

*CFR citation:* 40 CFR 721.10956.

**PMN Number P-16-30**

*Chemical name:* 1,2-Cyclohexanedicarboxylic acid, 1-(2-phenylhydrazide).

*CAS number:* 1807977-72-5.

*Basis for Action:* The PMN states that the substance will be used as a curing agent in anaerobic adhesive and sealant formulations. Based on test data on analogous hydrazines, EPA identified concerns for blood toxicity, neurotoxicity, oncogenicity, and mutagenicity. Hydrazides are expected to be positive in the chromosome aberration test and positive for lung sensitization. Based on the presence of a free acid, irritation to moist tissue (eyes, lungs, and mucous membranes) is expected. As described in the PMN, occupational exposures are expected to be minimal due to the use of adequate personal protective equipment. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that use of the substance without use of impervious gloves and impervious clothing where there is a potential for dermal exposures, may result in serious health effects. Based on this information, the PMN substance meets the concern criteria at § 721.170 (b)(1)(i)(C) and (b)(3)(ii).

*Recommended testing:* EPA has determined that the results of a 90-day dermal toxicity test (OPPTS Test Guideline 870.3250) and a carcinogenicity test (OPPTS Test Guideline 870.4200) by the expected route of exposure in two species of rodents, would help characterize the human health effects of the PMN substance.

*CFR citation:* 40 CFR 721.10957.

**PMN Number P-16-52**

*Chemical name:* 2,5-Furandione, dihydro-, polymer with 1,1'-iminobis[2-propanol], benzoate (ester), N-benzoyl derivs.

*CAS number:* 592479-38-4.

*Basis for Action:* The PMN states that the generic (non-confidential) use of the substance will be as printing ink. Based on SAR analysis of test data on analogous esters and amides, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 5 ppb of the PMN substance in surface waters. As described in the PMN, releases of the substance are not expected to result in surface water concentrations that exceed 5 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 5 ppb may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(ii).

*Recommended testing:* EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an acute invertebrate toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test

(OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substance.

*CFR citation:* 40 CFR 721.10958.

**PMN Numbers P-16-56 and P-16-57**

*Chemical name:* Dialkyl fattyalkylamino propanamide alkylamine acetates (generic).

*CAS number:* Claimed confidential.

*Basis for Action:* The PMNs state that the generic (non-confidential) use of the substances is in oil production. Based on SAR analysis of test data on analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PMN substances in surface waters. As described in the PMNs, releases of the substances are not expected to result in surface water concentrations that exceed 1 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substances may present an unreasonable risk. EPA has determined, however, that any use of the substances that results in releases to surface water concentrations exceeding 1 ppb may cause significant adverse environmental effects. Based on this information, the PMN substances meets the concern criteria at § 721.170(b)(4)(i).

*Recommended testing:* EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a mysid chronic toxicity test (OPPTS Test Guideline 850.1350); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substances.

*CFR citation:* 40 CFR 721.10959

**PMN Number P-16-58**

*Chemical name:* Dialkylaminopropylaminopropanoate ester (generic).

*CAS number:* Claimed confidential.

*Basis for Action:* The PMN states that the substance will be used as a chemical intermediate. Based on SAR analysis of test data on analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 14 ppb of the PMN substance in surface waters. As described in the PMN, releases of the substance are not expected to result in surface water concentrations that exceed 14 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 14 ppb may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(ii).

*Recommended testing:* EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an acute invertebrate toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substance.

*CFR citation:* 40 CFR 721.10960.

## **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 34 of the 57 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) consent orders requiring the use of appropriate exposure controls were negotiated with the PMN submitters. The SNUR provisions for these chemical substances are consistent with the provisions of the TSCA section 5(e) consent orders. These SNURs are promulgated pursuant to § 721.160 (see Unit VI.).

In the other 23 cases, where the uses are not regulated under a TSCA section 5(e) consent order, EPA determined that one or more of the criteria of concern established at § 721.170 were met, as discussed in Unit IV.

#### *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 ensure that all manufacturers and processors of the same chemical substance that is subject to a TSCA section 5(e) consent order are subject to similar requirements.

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, as described in § 721.160(c)(3) and § 721.170(d)(4). In accordance with § 721.160(c)(3)(ii) and § 721.170(d)(4)(i)(B), 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 or critical comments, or notice of intent to submit adverse or critical comments before [*insert date 30 days after date of publication in the **Federal Register***].

If EPA receives written adverse or critical comments, or notice of intent to submit adverse or critical 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. EPA will then issue a proposed SNUR for the chemical substance(s) on which adverse or critical comments were received, providing a 30-day period for public comment.

This rule establishes SNURs for a number of chemical substances. Any person who submits adverse or critical comments, or notice of intent to submit adverse or critical

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 Rule to Uses Occurring Before Effective Date of the Final Rule**

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 a notice of commencement (NOC) and the chemical substance has not been added to the TSCA Inventory, no person may commence such activities without first submitting a PMN. Therefore, for chemical substances for which an NOC has not been submitted EPA concludes that the designated significant new uses are not ongoing.

When chemical substances identified in this 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) consent orders have been issued for 34 of the 57 chemical substances, and the PMN submitters are prohibited by the TSCA section 5(e) consent orders from undertaking activities which would be designated as significant new uses. The identities of 46 of the 57 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). 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 November 9, 2016 (the date of public release/web posting of this rule) as the cutoff date for determining whether the new use is ongoing.

This designation varies slightly from EPA's past practice of designating the date of **Federal Register** publication as the date for making this determination. 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. In developing this rule, EPA has recognized that, given EPA's practice of now posting rules on its website a week or more in advance of **Federal Register** publication, this objective could be thwarted even before that publication. Thus, EPA has slightly modified its approach in this rulemaking and plans to follow this modified approach in future significant new use rulemakings.

Persons who begin commercial manufacture or processing of the chemical substances for a significant new use identified as of that date would have to cease any such activity upon the effective date of the final rule. To resume their activities, these persons would have to first comply with all applicable SNUR notification requirements and wait until the notice review period, including any extensions, expires. If such a person met the conditions of advance compliance under § 721.45(h), the person would be considered exempt from the requirements of the SNUR. Consult the **Federal Register** document of April 24, 1990 for a more detailed discussion of the cutoff date for ongoing uses.

### **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. In cases where EPA issued a TSCA section 5(e) consent order that requires or recommends certain testing, Unit IV. lists those tests. Unit IV. also lists recommended testing for non-5(e) SNURs. Descriptions of tests are provided for informational purposes. EPA strongly encourages persons, before performing any testing, to consult with the Agency pertaining to protocol selection. To access the OCSPP test guidelines referenced in this document electronically, please go to <http://www.epa.gov/ocspp> and select “Test Methods and Guidelines.” The Organisation for Economic Co-operation and Development (OECD) test guidelines are available from the OECD Bookshop at <http://www.oecdbookshop.org> or SourceOECD at <http://www.sourceoecd.org>. ASTM International standards are available at <http://www.astm.org/Standard/index.shtml>.

In the TSCA section 5(e) consent orders for several of the chemical substances regulated under this rule, EPA has established production volume 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. Under recent TSCA section 5(e) consent orders, each PMN submitter is required to submit each study at least 14 weeks (earlier TSCA section 5(e) consent orders required submissions at least 12 weeks) before reaching the specified production limit. Listings of the tests specified in the TSCA section 5(e) consent orders are included in Unit IV. The SNURs contain the same production volume limits as the TSCA section 5(e) consent 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.

The recommended tests specified 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.
- Potential benefits 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 40 CFR 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-2016-0207.

## **XII. Scientific Standards, Evidence, and Available Information**

EPA has used scientific information, technical procedures, measures, methods, protocols, methodologies, and models consistent with the risk assessment documents included in the public docket. These information sources supply information relevant to whether a particular use would be a significant new use, based on relevant factors including those listed under TSCA section 5(a)(2).

The clarity and completeness of the data, assumptions, methods, quality assurance, and analyses employed in EPA's decision are documented, as applicable and to the extent necessary for purposes of this significant new use rule, in Unit II and in the documents noted above. EPA recognizes, based on the available information, that there is variability and uncertainty in whether any particular significant new use would actually present an unreasonable risk. For precisely this reason, it is appropriate to secure a future notice and review process for these uses, at such time as they are known more definitely. The extent to which the various information, procedures, measures, methods, protocols, methodologies or models used in EPA's decision have been subject to independent verification or peer review is adequate to justify their use, collectively, in the record for a significant new use rule.

### **XIII. 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) consent 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).

### **XIV. 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: November 3, 2016.

Maria J. Doa,

*Director, Chemical Control Division, 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>	
* * * * *	* * * * *
721.10927	2070-0012
721.10928	2070-0012
721.10929	2070-0012
721.10930	2070-0012
721.10931	2070-0012
721.10932	2070-0012

721.10933	2070-0012
721.10934	2070-0012
721.10935	2070-0012
721.10936	2070-0012
721.10937	2070-0012
721.10938	2070-0012
721.10939	2070-0012
721.10940	2070-0012
721.10941	2070-0012
721.10942	2070-0012
721.10943	2070-0012
721.10944	2070-0012
721.10945	2070-0012
721.10946	2070-0012
721.10947	2070-0012
721.10948	2070-0012
721.10949	2070-0012
721.10950	2070-0012
721.10951	2070-0012
721.10952	2070-0012
721.10953	2070-0012
721.10954	2070-0012
721.10955	2070-0012
721.10956	2070-0012

721.10957	2070-0012
721.10958	2070-0012
721.10959	2070-0012
721.10960	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 § 721.10927 to subpart E to read as follows:

**§ 721.10927 Bimodal mixture consisting of multi-walled carbon nanotubes and other classes of carbon nanotubes (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as a bimodal mixture consisting of multi-walled carbon nanotubes and other classes of carbon nanotubes (PMN P-11-482) 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), (a)(2)(ii), (a)(3), (a)(4), (a)(6)(particulate), 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. A National Institute for Occupational Safety and Health (NIOSH)-certified air purifying, tight-fitting full-face respirator equipped with N-100, P-100, or R-100 cartridges, or power air purifying particulate respirator with an Assigned Protection Factor (APF) of at least 50 meets the requirements of §721.63(a)(4).

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80 (k) and (q). A significant new use is any use involving an application method that generates a vapor, mist or aerosol.

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

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

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

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (e), (i), (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)(ii) of this section.

5. Add § 721.10928 to subpart E to read as follows:

**§ 721.10928 Coke (coal), secondary pitch; a carbon-containing residue from the coking of air blown pitch coke oil and/or pitch distillate; composed primarily of isotropic carbon, it contains small amounts of sulfur and ash constituents.**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as coke (coal), secondary pitch. Definition: A carbon-containing residue from the coking of air blown pitch coke oil and/or pitch distillate. Composed primarily of isotropic carbon, it contains small amounts of sulfur and ash constituents (PMN P-12-292; CAS No. 94113-91-4) 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)(4), (a)(6)(particulate), (b)(concentration set at 0.1 percent), 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. A National Institute for Occupational Safety and Health (NIOSH)-certified air purifying, tight-fitting full-face respirator equipped with N-100, P-100, or R-100 cartridges, or power air purifying particulate respirator with an Assigned Protection Factor (APF) of at least 50 meets the requirements of §721.63(a)(4).

(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 0.0025 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 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 program.* Requirements as specified in § 721.72(a) through (e)(concentration set at 0.1 percent), (f), (g)(1)(vii), (g)(2)(ii), (g)(2)(iv), (g)(1)(This substance may cause lung effects), and (g)(5).

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

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

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

(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 § 721.10929 to subpart E to read as follows:

**§ 721.10929 Single-walled carbon nanotubes (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substances identified generically as single walled carbon nanotubes (PMNs P-13-718, P-13-719, P-13-720, P-13-721, P-14-655, P-14-656, P-14-657, and P-14-658) are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this rule do not apply to the PMN substance when it is embedded or incorporated into a polymer matrix that itself has been reacted (cured), embedded in a permanent solid polymer form that is not intended to undergo further processing, except mechanical processing, or 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)(2)(ii), (a)(3), (a)(4), (a)(6)(particulate), (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. A National Institute for Occupational Safety and Health (NIOSH)-certified air purifying, tight-fitting full-face respirator equipped with N-100, P-100, or R-100 cartridges, or power air purifying particulate respirator with an Assigned Protection Factor (APF) of at least 50 meets the requirements of §721.63(a)(4).

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k)(A significant new use is use other than as: a semi-conductor, conductive, or resistive element in electronic circuitry and devices; an electro-mechanical switch in

electronic circuitry and devices; a film laminate to improve structural, electrical or electro-chemical properties of composite materials; a film laminate to improve conductivity in batteries, capacitors and fuels cells; with composite materials to improve their mechanical properties and electrical conductivities; catalyst support for use in fuel cells; in a nanoporous network in gas diffusion layers; for separation of chemicals; an additive to improve corrosion resistance of metals; an additive in lubricants and greases to improve wear resistance; an additive for transparency and conductivity in electronic devices; an additive for fibers in structural and electrical applications; an additive for fibers in fabrics and as a chemical intermediate) and (q). A significant new use is any use involving an application method that generates a vapor, mist or aerosol unless such application method occurs in an enclosed process. An enclosed process is defined as an operation that is designed and operated so that there is no release associated with normal or routine production processes into the environment of any substance present in the operation. An operation with inadvertent or emergency pressure relief releases remains an enclosed process so long as measures are taken to prevent worker exposure to and environmental contamination from the releases.

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

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

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

(1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (e), (i), (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)(ii) of this section.

7. Add § 721.10930 to subpart E to read as follows:

**§ 721.10930 Fatty acid amides (generic).**

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substances identified generically as fatty acid amides (PMNs P-14-150, P-14-151, P-14-152, P-14-165, and P-14-166) are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80. A significant new use of the substances is any use other than as chemical intermediates, additives for flotation products, or adhesion promoters for use in asphalt applications where the surface water concentrations described under paragraph (a)(3)(i) of this section are exceeded.

(ii) [Reserved]

(3) The significant new uses for any use other than as chemical intermediates, additives for flotation products, or adhesion promoters for use in asphalt applications are:

(i) *Release to water*. Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) where (N=1 for PMNs P-15-150 and P-14-165), (N=2 for PMN P-14-166), and (N=4 for PMNs P-14-151 and P-14-152).

(ii) [Reserved]

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

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

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

8. Add § 721.10931 to subpart E to read as follows:

**§ 721.10931 Kaolin, reaction products with polysiloxane (generic).**

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified generically as kaolin, reaction products with polysiloxane (PMN P-14-413) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(i) *Protection in the workplace*. Requirements as specified in § 721.63(a)(1), (a)(4), (a)(6)(particulate), (b)(concentration set at 1.0 percent), 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. A NIOSH-certified powered air purifying full facepiece

respirator with an Assigned Protection Factor (APF) of at least 1,000 equipped with an appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridge in combination with HEPA filters or a NIOSH-certified continuous flow supplied air respirator equipped with a full facepiece meet the requirements of §721.63(a)(4).

(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 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 program.* Requirements as specified in § 721.72(a), through (e)(concentration set at 1.0 percent), (f), (g)(1)(ii), (g)(2)(ii), (g)(2)(iii), (g)(2)(iv), and (g)(5).

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

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

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

(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.

9. Add § 721.10932 to subpart E to read as follows:

**§ 721.10932 Fatty acid amides (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substances identified generically as fatty acid amides (PMNs P-14-428, P-14-429, P-14-430, and P-14-431) are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80. A significant new use of the substances is any use other than as emulsifier intermediates or adhesion promoters for use in asphalt applications where the surface water concentrations described under paragraph (a)(3)(i) of this section are exceeded.

(ii) [Reserved]

(3) The significant new uses for any use other than as emulsifier intermediates or adhesion promoters for use in asphalt applications are:

(i) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where (N=1 for PMNs P-14-428 and P-14-429) and (N=2 for PMNs P-14-429 and P-14-431).

(ii) [Reserved]

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

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

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

10. Add § 721.10933 to subpart E to read as follows:

**§ 721.10933 Copolymers of perfluorinated and alkyl methacrylates (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substances identified generically as copolymers of perfluorinated and alkyl methacrylates (PMNs P-14-523, P-14-524, P-14-525, P-14-526, and P-14-527) are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(4), (a)(6)(particulate, gas/vapor or a combination gas/vapor and particulate)), 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), (k)(analysis and reporting and limitations of maximum impurity levels of

certain impurities), (o) and (q). It is a significant new use to use the PMN substance other than for water and oil repellent use on military protective clothing.

(iii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where N=17.

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

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

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

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

11. Add § 721.10934 to subpart E to read as follows:

**§ 721.10934 Alkenoic acid, polymer with alkyl alkenoate, alkylalkylalkenoate, alkenoic acid and tridecafluoro alkylalkenoate, compds. with alkylaminoalcanol (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as alkenoic acid, polymer with alkyl alkenoate, alkylalkylalkenoate, alkenoic acid and tridecafluoro alkylalkenoate, compds. with alkylaminoalcanol (PMN P-14-580) 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)(4), (a)(6)(particulate, gas/vapor or a combination gas/vapor and particulate)), 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(k) (analysis and reporting and limitations of maximum impurity levels of certain impurities; and use other described in the consent order) and (q).

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

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

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

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

12. Add § 721.10935 to subpart E to read as follows:

**§ 721.10935 Titanium oxide compound (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as titanium oxide compound (PMN P-14-643)

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)(4)(respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor of at least 10), (a)(6)(particulate), (b)(concentration set at 1.0 percent), 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.

(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 2.4 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 program.* Requirements as specified in § 721.72(a), through (e)(concentration set at 1.0 percent), (f), (g)(1)(ii), (g)(2)(ii), (g)(2)(iii), and (g)(2)(iv), and (g)(5).

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(p)(4,300,000 kilograms).

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

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

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

13. Add § 721.10936 to subpart E to read as follows:

**§ 721.10936 Fatty acid amide hydrochlorides (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substances identified generically as fatty acid amide hydrochlorides (PMNs P-14-688, P-14-689, P-14-690, and P-14-691) are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80. A significant new use of the substances is any use other than as surfactants for use in asphalt applications where the surface water concentrations described under paragraph (a)(3)(i) of this section are exceeded.

(ii) [Reserved]

(3) The significant new uses for any use other than as surfactants for use in asphalt applications are:

(i) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) (N=1 for PMNs P-14-688, P-14-689, and P-14-690) and (N=2 for PMN P-14-691).

(ii) [Reserved]

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

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

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

14. Add § 721.10937 to subpart E to read as follows:

**§ 721.10937 Plastics, wastes, pyrolyzed, bulk pyrolysate (generic).**

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified generically as plastics, wastes, pyrolyzed, bulk pyrolysate (PMN P-14-712) 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), (a)(3), (a)(4)(respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor of at least 10), (a)(6)(v), (a)(6)(vi), (a)(6)(particulate or a combination gas/vapor and particulate), (b)(concentration set at 0.1 percent), 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.

(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 exposure limit (EL) provision listed in the TSCA section 5(e) consent order for this substance. The EL is both 0.1 ppm for benzene and 10 ppm for naphthalene as an 8-hour time weighted average.

(B) [Reserved]

(ii) *Hazard communication program.* Requirements as specified in § 721.72(a) through (e)(concentration set at 1.0 percent), (f), (g)(1)(i), (g)(1)(ii), (g)(1)(iii), (g)(1)(iv), (g)(1)(v), (g)(1)(vi), (g)(1)(vii), (g)(1)(viii), (g)(1)(ix), (g)(2)(i), (g)(2)(ii), (g)(2)(iii), (g)(2)(v), (g)(3)(i), (g)(3)(i), and (g)(5).

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k). It is a significant new use to manufacture this substance other than as described in the PMN. It is a significant new use to manufacture this substance without testing the substance for polychlorinated dibenzo-p-dioxin and dibenzofuran impurities using EPA Method 8290A at each facility of manufacture, conducting the testing every quarter that the PMN substance is manufactured, submitting the results of any testing conducted, or providing test results more than 45 days after receiving them.

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

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

15. Add § 721.10938 to subpart E to read as follows:

**§ 721.10938 Plastics, wastes, pyrolyzed, light distillate (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as plastics, wastes, pyrolyzed, light distillate (PMN P-14-713) 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), (a)(3), (a)(4)(respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor of at least 10), (a)(6)(v), (a)(6)(vi), (a)(6)(particulate or a combination gas/vapor and particulate), (b)(concentration set at 0.1 percent), 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.

(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 exposure limit (EL)

provision listed in the TSCA section 5(e) consent order for this substance. The EL is both 0.1 ppm for benzene and 10 ppm for naphthalene as an 8-hour time weighted average.

(B) [Reserved]

(ii) *Hazard communication program.* Requirements as specified in § 721.72(a) through (e) (concentration set at 1.0 percent), (f), (g)(1)(i), (g)(1)(ii), (g)(1)(iii), (g)(1)(iv), (g)(1)(v), (g)(1)(vi), (g)(1)(vii), (g)(1)(viii), (g)(1)(ix), (g)(2)(i), (g)(2)(ii), (g)(2)(iii), (g)(2)(v), (g)(3)(i), (g)(3)(i), and (g)(5).

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

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

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

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

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

16. Add § 721.10939 to subpart E to read as follows:

**§ 721.10939 Plastics, wastes, pyrolyzed, middle distillate (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as plastics, wastes, pyrolyzed, middle distillate (PMN P-14-714) 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), (a)(3), (a)(4)(respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor of at least 10), (a)(6)(v), (a)(6)(vi), (a)(6)(particulate or a combination gas/vapor and particulate), (b)(concentration set at 0.1 percent), 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.

(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 exposure limit (EL) provision listed in the TSCA section 5(e) consent order for this substance. The EL is both 0.1 ppm for benzene and 10 ppm for naphthalene as an 8-hour time weighted average.

(B) [Reserved]

(ii) *Hazard communication program.* Requirements as specified in § 721.72(a) through (e) (concentration set at 1.0 percent), (f), (g)(1)(i), (g)(1)(ii), (g)(1)(iii), (g)(1)(iv), (g)(1)(v), (g)(1)(vi), (g)(1)(vii), (g)(1)(viii), (g)(1)(ix), (g)(2)(i), (g)(2)(ii), (g)(2)(iii), (g)(2)(v), (g)(3)(i), (g)(3)(i), and (g)(5).

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

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

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

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

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

17. Add § 721.10940 to subpart E to read as follows:

**§ 721.10940 Plastics, wastes, pyrolyzed, heavy distillate (generic).**

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified generically as plastics, wastes, pyrolyzed, heavy distillate (PMN P-14-715) 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), (a)(3), (a)(4)(respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor of at least 10), (a)(6)(v), (a)(6)(vi), (a)(6)(particulate or a combination gas/vapor and particulate), (b)(concentration set at 0.1 percent), 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.

(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 exposure limit (EL) provision listed in the TSCA section 5(e) consent order for this substance. The EL is both 0.1 ppm for benzene and 10 ppm for naphthalene as an 8-hour time weighted average.

(B) [Reserved]

(ii) *Hazard communication program.* Requirements as specified in § 721.72(a) through (e) (concentration set at 1.0 percent), (f), (g)(1)(i), through (g)(1)(ix), (g)(2)(i), through (g)(2)(iii), (g)(2)(v), (g)(3)(i), (g)(3)(ii), and (g)(5).

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

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

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

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

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

18. Add § 721.10941 to subpart E to read as follows:

**§ 721.10941 Carbon silicon oxide.**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as carbon silicon oxide (PMN P-15-28; CAS No. 39345-

87-4) 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), (a)(3), (a)(4)(respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor of at least 10), (a)(6)(v), (a)(6)(vi), (a)(6)(particulate or a combination gas/vapor and particulate), (b)(concentration set at 1.0 percent), 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.

(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 6 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 program.* Requirements as specified in § 721.72(a) through (e) (concentration set at 1.0 percent), (f), (g)(1)(i), (g)(1)(ii), (g)(2)(i), (g)(2)(ii), (g)(2)(iv), (g)(2)(v), and (g)(5).

(iii) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture the PMN substance other than specified in the TSCA section 5(e) consent order. Requirements as specified in § 721.80(p) (within 24 months of submission of a Notice of Commencement of Manufacture).

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

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

(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.

19. Add § 721.10942 to subpart E to read as follows:

**§ 721.10942 Carbon nanotubes (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as carbon nanotubes (PMN P-15-54) 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), (a)(2)(ii), (a)(3), (a)(4), (a)(6)(particulate), 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. A National Institute for Occupational Safety and Health (NIOSH)-certified respirator with an Assigned Protection Factor (APF) of at least 50 with an N-100, P-100, or R-100 cartridge meets the requirements of §721.63(a)(4).

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k)(chemical intermediate) and (p)(one year).

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

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

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

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

20. Add § 721.10943 to subpart E to read as follows:

**§ 721.10943 Sulfonated alkylbenzene salts (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as sulfonated alkylbenzene salts (PMN P-15-149) 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 program.* Requirements as specified in § 721.72(a) through (e)(concentration set at 1.0 percent), (f), (g)(1)(i), (g)(1)(ii), (g)(1)(serious eye damage), (g)(2)(i), (g)(2)(ii), (g)(2)(iii), (g)(2)(v), (g)(3)(i), (g)(3)(ii), (g)(4)(i) and (g)(5).

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

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

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

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a), (b), (c), (f), (g), (h), (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)(ii) of this section.

21. Add § 721.10944 to subpart E to read as follows:

**§ 721.10944 Substituted quinoline derivative (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as substituted quinoline derivative (PMN P-15-267) 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)(3), (a)(4)(respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor of at least 10), (a)(6)(particulate), (b)(concentration set at 1.0 percent), 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.

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

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

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

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

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

22. Add § 721.10945 to subpart E to read as follows:

**§ 721.10945 Algal oil amide (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as algal oil amide (PMN P-15-470) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

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

(ii) [Reserved]

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

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

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

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

23. Add § 721.10946 to subpart E to read as follows:

**§ 721.10946 Bismuth compound (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as bismuth compound (PMN P-15-485) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this order do not apply when the chemical substance has been completely reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(4)(respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor of at least 10), (a)(6)(particulate), (b)(concentration set at 1.0 percent), 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.

(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  $2.4 \text{ mg/m}^3$  as an 8-hour time weighted average. Persons who wish to pursue NCELs as an alternative to §721.63 respirator requirements may request to do so under §721.30. Persons whose §721.30 requests to use the NCELs approach are approved by EPA will be required to follow NCELs provisions comparable to those contained in the corresponding TSCA section 5(e) consent order.

(B) [Reserved]

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

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(p)(360,000 kilograms).

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

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

24. Add § 721.10947 to subpart E to read as follows:

**§ 721.10947 Sulfur thulium ytterbium yttrium oxide.**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as sulfur thulium ytterbium yttrium oxide (PMN P-15-612; CAS No. 180189-40-6) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(4)(respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor of at least 10), (a)(6)(particulate), (b)(concentration set at 1.0 percent), 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.

(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 0.07 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) consent order.

(B) [Reserved]

(ii) *Hazard communication program.* Requirements as specified in § 721.72(a), (b), (c), (d), (e) (concentration set at 1.0 percent), (f), (g)(1)(ii), (g)(2)(ii), (g)(2)(iii), and (g)(2)(iv), and (g)(5).

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(p)(6,000 kilograms, aggregate of PMNs P-15-612, P-15-613, P-15-614, P-15-615, P-15-616, P-15-617, P-15-618, combined).

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

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

25. Add § 721.10948 to subpart E to read as follows:

**§ 721.10948 Gadolinium sulfur yttrium oxide, erbium- and thulium-doped.**

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified as (PMN P-15-613; CAS No, 1651187-84-6) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace*. Requirements as specified in § 721.63(a)(1), (a)(4)(respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor of at least 10), (a)(6)(particulate), (b)(concentration set at 1.0 percent), 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.

(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 0.07 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) consent order.

(B) [Reserved]

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

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(p)(6,000 kilograms, aggregate of PMNs P-15-612, P-15-613, P-15-614, P-15-615, P-15-616, P-15-617, P-15-618, combined).

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

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

26. Add § 721.10949 to subpart E to read as follows:

**§ 721.10949 Neodymium sulfur yttrium oxide.**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as neodymium sulfur yttrium oxide (PMN P-15-614; CAS No. 1651158-45-5) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(4)(respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor of at least 10), (a)(6)(particulate), (b)(concentration set at 1.0 percent), 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.

(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 0.07 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) consent order.

(B) [Reserved]

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

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(p)(6,000 kilograms, aggregate of PMNs P-15-612, P-15-613, P-15-614, P-15-615, P-15-616, P-15-617, P-15-618, combined).

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

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

27. Add § 721.10950 to subpart E to read as follows:

**§ 721.10950 Erbium gadolinium neodymium sulfur ytterbium yttrium oxide (P-15-615).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as erbium gadolinium neodymium sulfur ytterbium yttrium oxide (PMN P-15-615; CAS No. 1651152-96-3) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(4)(respirators must provide a National Institute for Occupational Safety and Health

(NIOSH) assigned protection factor of at least 10), (a)(6)(particulate), (b)(concentration set at 1.0 percent), 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.

(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 0.07 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) consent order.

(B) [Reserved]

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

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(p)(6,000 kilograms, aggregate of PMNs P-15-612, P-15-613, P-15-614, P-15-615, P-15-616, P-15-617, P-15-618, combined).

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

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

28. Add § 721.10951 to subpart E to read as follows:

**§ 721.10951 Erbium gadolinium sulfur ytterbium yttrium oxide.**

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified as erbium gadolinium sulfur ytterbium yttrium oxide (P-15-616; CAS No. 1622295-07-1) 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) *Protection in the workplace*. Requirements as specified in § 721.63(a)(1), (a)(4)(respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor of at least 10), (a)(6)(particulate), (b)(concentration set at 1.0 percent), 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.

(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 0.07 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) consent order.

(B) [Reserved]

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

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(p)(6,000 kilograms, aggregate of PMNs P-15-612, P-15-613, P-15-614, P-15-615, P-15-616, P-15-617, P-15-618, combined).

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

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

29. Add § 721.10952 to subpart E to read as follows:

**§ 721.10952 Erbium gadolinium ytterbium oxide.**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as erbium gadolinium ytterbium oxide (PMN P-15-617;

CAS No. 1651152-05-4) 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)(4)(respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor of at least 10), (a)(6)(particulate), (b)(concentration set at 1.0 percent), 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.

(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 0.07 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) consent order.

(B) [Reserved]

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

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(p)(6,000 kilograms, aggregate of PMNs P-15-612, P-15-613, P-15-614, P-15-615, P-15-616, P-15-617, P-15-618, combined).

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

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

30. Add § 721.10953 to subpart E to read as follows:

**§ 721.10953 Erbium gadolinium sulfur ytterbium oxide.**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as erbium gadolinium sulfur ytterbium oxide (PMN P-15-618; CAS No. 934388-91-7) 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)(4)(respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor of at least 10), (a)(6)(particulate), (b)(concentration set at 1.0 percent), 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.

(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 0.07 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) consent order.

(B) [Reserved]

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

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(p)(6,000 kilograms, aggregate of PMNs P-15-612, P-15-613, P-15-614, P-15-615, P-15-616, P-15-617, P-15-618, combined).

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

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

31. Add § 721.10954 to subpart E to read as follows:

**§ 721.10954 2-Ethylhexanoic acid, compound with alkyamino cyclohexane (generic); and 2-Ethylhexanoic acid, compound with cyclohexylamine (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substances identified generically as 2-ethylhexanoic acid, compound with alkyamino cyclohexane (PMN P-15-0655, chemical A); and 2-ethylhexanoic acid, compound with cyclohexylamine (PMN P-15-0655, chemical B) are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

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

(ii) [Reserved]

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

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

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

32. Add § 721.10955 to subpart E to read as follows:

**§ 721.10955 Propenoic acid, alkyl ester, polymer with 1,3-cyclohexanedialkylamine, reaction products with oxirane(alkoxyalkyl) (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as propenoic acid, alkyl ester, polymer with 1,3-cyclohexanedialkylamine, reaction products with oxirane(alkoxyalkyl) (PMN P-15-680) 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=1.

(ii) [Reserved]

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

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

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

33. Add § 721.10956 to subpart E to read as follows:

**§ 721.10956 Acrylic acid, polymer with polyalkylene polyamine (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as acrylic acid, polymer with polyalkylene polyamine (PMN P-15-691) 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(g).

(ii) [Reserved]

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

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

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

34. Add § 721.10957 to subpart E to read as follows:

**§ 721.10957 1,2-Cyclohexanedicarboxylic acid, 1-(2-phenylhydrazide).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as (1,2-cyclohexanedicarboxylic acid, 1-(2-phenylhydrazide) (PMN P-16-30; CAS No. 1807977-72-5) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i), (a)(2)(ii), (a)(3), (a)(6)(particulate), (b)(concentration set at 1.0 percent), 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) [Reserved]

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

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

35. Add § 721.10958 to subpart E to read as follows:

**§ 721.10958 2,5-Furandione, dihydro-, polymer with 1,1'-iminobis[2-propanol], benzoate (ester), N-benzoyl derivs.**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 2,5-furandione, dihydro-, polymer with 1,1'-iminobis[2-propanol], benzoate (ester), N-benzoyl derivs. (PMN P-16-52; CAS No. 592479-38-4) 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=5.

(ii) [Reserved]

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

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

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

36. Add § 721.10959 to subpart E to read as follows:

**§ 721.10959 Dialkyl fattyalkylamino propanamide alkylamine acetates (generic).**

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substances identified generically as dialkyl fattyalkylamino propanamide alkylamine acetates (PMNs P-16-56 and P-16-57) are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *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.

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

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

37. Add § 721.10960 to subpart E to read as follows:

**§ 721.10960 Dialkylaminopropylaminopropanoate ester (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as dialkylaminopropylaminopropanoate ester (PMN P-16-58) 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=14.

(ii) [Reserved]

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

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

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

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