# **Prepublication Copy Notice:**

The Director of the Chemical Control Division in the Office of Pollution Prevention and Toxics signed the following Federal Register document on July 7, 2017:

Title: Significant New Use Rules on Certain Chemical Substances

Action: Direct Final Rule

RIN: 2070-AB27 FRL: 9964-42

Docket No.: **EPA-HQ-OPPT-2017-0166** 

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Once the official version of the document publishes in the Federal Register, the prepublication version of the document posted on the agency's internet will be replaced with a link to the document that appears in the Federal Register publication. At that time, you will also be able to access the on-line docket for this Federal Register document at <a href="http://www.regulations.gov">http://www.regulations.gov</a>.

For further information about the docket and, if applicable, instructions for commenting, please consult the ADDRESSES section in the front of the Federal Register document.

ENVIRONMENTAL PROTECTION AGENCY

**40 CFR Parts 9 and 721** 

[EPA-HQ-OPPT-2017-0166; FRL-9964-42]

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 29 chemical substances which were the subject of premanufacture notices (PMNs). The chemical substances are subject to consent orders issued by EPA pursuant to section 5(e) of TSCA. This action requires persons who intend to manufacture (defined by statute to include import) or process any of these 29 chemical substances for an activity that is designated as a significant new use by this rule to notify EPA at least 90 days before commencing that activity. The required notification initiates EPA's evaluation of the intended use within the applicable review period. Persons may not commence manufacture or processing for the significant new use until EPA has conducted a review of the notice, made an appropriate determination on the notice, and has taken such actions as are required with that determination.

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

Written adverse 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-2017-0166, 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 <a href="http://www.epa.gov/dockets/contacts.html">http://www.epa.gov/dockets/contacts.html</a>.

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

**FOR FURTHER INFORMATION CONTACT:** For technical information contact: Kenneth Moss, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-9232; email address: moss.kenneth @epa.gov.

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

#### SUPPLEMENTARY INFORMATION:

### I. General Information

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

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

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

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Chemical importers are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements promulgated at 19 CFR 12.118 through 12.127 and 19 CFR 127.28. Chemical importers must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA. Importers of chemicals subject to these SNURs must certify their compliance with the SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, pursuant to 40 CFR 721.20, 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)) 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 <a href="http://www.epa.gov/dockets/comments.html">http://www.epa.gov/dockets/comments.html</a>.

### 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)(i) (15 U.S.C. 2604(a)(1)(B)(i)) 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. TSCA 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. Pursuant 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) (15 U.S.C. 2604(a)(1)(A)). In particular, these requirements include the information submission requirements of TSCA sections 5(b) and 5(d)(1) (15 U.S.C. 2604(b) and 2604(d)(1), the exemptions authorized by TSCA sections 5(h)(1), 5(h)(2), 5(h)(3), and 5(h)(5) (15 U.S.C. 2604(h)(1), 2604(h)(2), 2604(h)(3), and 2604(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) (15 U.S.C. 2604(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 37 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 29 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 nonconfidential chemical identities).
  - Basis for the consent order under TSCA section 5(e) (15 U.S.C. 2604(e)).
- 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 29 PMN substances that are subject to "risk-based" consent orders under TSCA section 5(e)(1)(A)(ii)(I) (15 U.S.C. 2604(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 SNURs are promulgated pursuant to § 721.160, and are based on and consistent with the provisions in the underlying consent orders. The 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 air-

borne concentrations of the PMN substance are below a New Chemical Exposure Limit (NCEL) that is established by EPA to provide adequate protection to human health. In addition to the actual NCEL concentration, the comprehensive NCELs provisions in TSCA section 5(e) 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 requests under § 721.30 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.

## **PMN Number: P-15-310**

Chemical name: 1,2,4-Benzenetricarboxylic acid, mixed decyl and octyl triesters.

*CAS number*: Not available.

Effective date of TSCA section 5(e) consent order: January 31, 2017.

Basis for TSCA section 5(e) consent order: The PMN states that the PMN substance will be used as a lubricant in special chain oils for conveyor belts. Based on submitted test data, EPA predicts blood and adrenal gland effects to unprotected workers from repeated dermal exposures. EPA also predicts endocrine disruption based on Structure Activity

Relationship (SAR) analysis on analogous phthalates. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that the 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 to prevent dermal exposure.
- 2. Not use, formulate, or distribute for use other than as stated in the PMN.
- 3. No manufacture beyond an annual production volume of 150,000 kg.

Recommended testing: EPA has determined that the results of certain human health toxicity testing would help characterize the PMN substance. The submitter has agreed not to exceed the confidential production limit without performing an Extended One-Generation Reproductive Toxicity Study (OECD Test Guideline 443).

CFR citation: 40 CFR 721.10987.

PMN Numbers: P-15-487, P-15-488, P-15-489, P-15-490, and P-15-491

Chemical names: Multi-walled carbon nanotubes (generic).

*CAS numbers*: Not available.

Effective date of TSCA section 5(e) consent order: February 17, 2017.

Basis for TSCA section 5(e) consent order: The PMN states that the PMN substances will be used as additives for electro-static discharge (ESD) in electronic devices, electronics, and materials; additives for weight reduction in materials; additives to improve mechanical properties or electrical conductivities; heat-generating elements in heating devices and materials; additives for heat transfer and thermal emissions in electronic devices and materials; semi-conductor, conductive, or resistive elements in

electronic circuitry and devices; additives to improve conductivity in electronic circuitry, energy storage systems, and devices; electron emitters for lighting and x-ray sources; additive for electromagnetic interface shielding in electronic devices; additives for electrodes in electronic materials and electronic devices; catalyst support in chemical manufacturing; coating additives to improve corrosion resistance or conductive properties; additives for fibers in structural and electrical applications; additives for fibers in fabrics and textiles; filter additives to remove nanoscale materials; semi-conducting compounding additives far high-voltage cable; and additives for super-hydrophobicity. Based on SAR analysis on analogous carbon nanotubes (CNT), EPA predicts pulmonary toxicity and oncogenicity to unprotected workers from repeated inhalation exposures. No ecotoxicity studies on CNT are available in which a broad range of production methods, sources, purification, functionalization, etc. were investigated. EPA expects that some fraction of the PMN substances, if released into the environment, will eventually become suspended in water. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that the substances may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the consent order requires:

- Use of personal protective equipment to prevent dermal exposure and a NIOSH-certified respirator with N-100, P-100, or R-100 cartridges with an assigned protection factor (APF) of at least 50 (where there is a potential for inhalation exposure).
- 2. Use of the PMN substances only for the uses specified in the consent order.
- 3. No use in application methods that generate a dust, mist, or aerosol unless

such application method occurs in an enclosed process.

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

Recommended testing: EPA has determined that a subchronic 90-day inhalation toxicity study (OPPTS 870.3465 or OECD 413), a two-year inhalation bioassay (OPPTS 870.4200), a fish early-life stage toxicity test (OCSPP Test Guideline 850.1400), a daphnid chronic toxicity test (OCSPP Test Guideline 850.1300), and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize possible health and environmental effects of the substances. Although the Order does not require these tests, 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 721.10988.

**PMN Number: P-16-165** 

Chemical name: Propanoic acid, iron (2+) salt (2:1).

CAS number: 1952336-63-8.

Effective date of TSCA section 5(e) consent order: February 15, 2017.

Basis for TSCA section 5(e) consent order: The PMN states that the PMN substance will

be used as a component in a metal organic product that will be used in paint and ink

driers, unsaturated polyester resins promoters, lube/grease additives, fuel additives,

polymerization catalysts, and specialty petrochemical catalysts at less than 1 percent.

Based on submitted test data, EPA predicts liver and developmental toxicity to

unprotected workers from repeated inhalation exposures. The Order was issued under

TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that the

substance may present an unreasonable risk of injury to human health. 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).

2. Establishment and use of a hazard communication program, including human

health precautionary statements on each label and in the Safety Data Sheet

(SDS).

3. No manufacture beyond an annual production volume of 150,000 kg.

4. Not process or use the PMN substance for non-industrial applications.

5. Not process or use the PMN substance in formulations where the

concentration is greater than 1%.

Recommended testing: EPA has determined that the results of certain human health

toxicity testing would help characterize the PMN substance. The submitter has agreed not

to exceed the confidential production limit without performing the prenatal development

toxicity study (OECD 414). In addition, EPA has determined that the results of a

combined chronic toxicity and carcinogenicity toxicity test (OPPTS 870.4300) would

help characterize the health effects of the PMN substance. 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 721.10989.

### PMN Numbers: P-16-255, P-16-256, P-16-257, P-16-258, and P-16-259

Chemical names: 1-Butanaminium, N,N,N-tributyl-, carbonic acid (1:1) (P-16-255), 1-Butanaminium, N,N,N-tributyl-, methyl carbonate (1:1) (P-16-256), 1-Butanaminium, N,N,N-tributyl-, ethyl carbonate (1:1) (P-16-257), 1-Butanaminium, N,N,N-tributyl-, propyl carbonate (1:1) (P-16-258), 1-Butanaminium, N,N,N-tributyl-, and 1-methylethyl carbonate (1:1) (P-16-259)

CAS numbers: 17351-62-1(P-16-255), 56294-05-2(P-16-256), 478796-04-2(P-16-257), 1338579-13-7(P-16-258), and 1803407-49-9(P-16-259)

Effective date of TSCA section 5(e) consent order: March 7, 2017.

Basis for TSCA section 5(e) consent order: The PMN states that the PMN substances will be used as blocked catalysts for paints and coatings. Based on submitted test data, EPA predicts strong irritation to the skin, eyes, and mucous membranes as well as acute toxicity and corrosivity-related neurotoxicity from repeated dermal and inhalation exposures. Further, based on test data on the PMN substances, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 34 parts per billion (ppb) of the PMN substances in surface waters. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that the substances may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the consent order requires:

- 1. Use of personal protective equipment to prevent dermal exposures.
- 2. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in a safety data sheet (SDS).
- 3. Use of the PMN substances only for the use specified in the consent order.
- 4. Use of the PMN substances at a concentration no greater than 1.5% by weight in

the final product.

Recommended testing: EPA has determined that the results of certain environmental toxicity testing would help characterize the PMN substances. The submitter has agreed not to exceed the confidential production limit without performing a daphnid chronic toxicity test (OCSPP 850.1300).

CFR citations: 40 CFR 721.10990 (P-16-255), 40 CFR 721.10991 (P-16-256), 40 CFR 721.10992 (P-16-257), 40 CFR 721.10993 (P-16-258), and 40 CFR 721.10994 (P-16-259).

#### **PMN Number: P-16-284**

*Chemical name*: Anilino substituted bis-triazinyl derivative of 4,4'-diaminostilbene-2,2'-disulfonic acid, mixed amine sodium salt (generic).

*CAS number*: Not available.

Effective date of TSCA section 5(e) consent order: May 12, 2017.

Basis for TSCA section 5(e) consent order: The PMN states that the PMN substance will be used as an optical brightener for textiles, paper, and paperboard. Based on submitted test data, EPA predicts adrenal gland effects to unprotected workers from repeated dermal and inhalation exposures. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that the substance may present an unreasonable risk of injury to human health. To protect against these risks, the consent order requires:

- 1) Import only of the PMN substance as a solution.
- 2) Use only as an optical brightener for textiles, paper and paperboard.

3) No use of the PMN substance in application methods that generate a dust, mist, or

aerosol unless such application method occurs in an enclosed process.

4) Non industrial use only where the PMN substance is not sold for "consumer use"

or for "commercial uses" (as the term is defined in § 721.3) when the "saleable

goods or service" could introduce PMN material into a "consumer" setting (as that

term is defined in § 721.3).

Recommended testing: EPA has determined that the results of physical/chemistry testing

would help characterize the PMN substance. The submitter has agreed not to manufacture

beyond a certain time period without measuring the particle size distribution to

characterize the particle size distribution of fractions less than 10 microns of the dry

particle PMN substance. In addition, EPA has determined that the results of a 90-day

subchronic inhalation toxicity study (OPPTS 870.3465 or OECD 413) would help

characterize the health effects of the PMN substance. 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 721.10995.

PMN Numbers: P-16-309 and P-16-310

Chemical names: 12-Hydroxystearic acid, reaction products with alkylene diamine and

alkanoic acid (generic).

CAS numbers: Not available.

Effective date of TSCA section 5(e) consent order: February 17, 2017.

Basis for TSCA section 5(e) consent order: The PMN states that the PMN substances will be used as rheological or thixotropic agents used in the production of solvent based industrial coatings, high solid aromatic paints, adhesives, sealants, and other types of paints and topcoats. Based on submitted test data, EPA predicts blood and hematology effects. Further, based on SAR analysis of test data on analogous amides, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 2 ppb of the PMN substances in surface waters. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that the substances may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the consent order requires:

- 1) No domestic manufacture of the PMN substances.
- No manufacture beyond the annual production volume specified in the consent order.
- 3) Use of the PMN substances only for the use specified in the consent order.
- 4) Compliance with the release to water provisions.

Recommended testing: EPA has determined that the results of certain human health and environmental toxicity testing would help characterize the PMN substances. The submitter has agreed not to exceed the confidential production limit without performing a fish early-life stage toxicity test (OCSPP Test Guideline 850.1400), a daphnid chronic toxicity test (OCSPP Test Guideline 850.1300), and an algal toxicity test (OCSPP Test Guideline 850.1300). In addition, EPA has determined that the results of a repeated dose dermal toxicity test (OPPTS Test Guideline 870.3200) would help characterize the human health effects of the PMN substances. 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 721.10996.

**PMN Number: P-16-315** 

Chemical name: Alkyldiene, polymer, hydroxy terminated alkoxysilylalkylcarbamate

(generic).

CAS number: Not available

Effective date of TSCA section 5(e) consent order: January 17, 2017.

Basis for TSCA section 5(e) consent order: The PMN states that the PMN substance will be used as an additive to improve the compatibility of the dispersibility of inorganic fillers in industrial rubber formulation. Based on physical/chemical properties, EPA predicts irritation and lung effects to unprotected workers from repeated inhalation and dermal exposures. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that the substance may present an unreasonable risk

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

- 1) No domestic manufacture of the PMN substance.
- 2) Use of the PMN substance only for the use specified in the consent order. Recommended testing: EPA has determined that a 90-day subchronic inhalation test in rodents (OCSPP Harmonized Test Guideline 870.3465); would help characterize possible health effects of the substance. Although the Order does not require this test, 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 721.10997.

### **PMN Number: P-16-323**

Chemical name: Alkylaldehyde, reaction products with substituted carbomonocycle-substituted heteromonocycle-alkylene glycol bis[[[[substituted(oxoneoalkyl)oxy]alkyl] amino]alkyl] ether polymer and alkyl substituted alkanediamine, acetate salts (generic). CAS number: Not available.

*Effective date of TSCA section 5(e) consent order:* November 22, 2016.

Basis for TSCA section 5(e) consent order: The PMN states that the PMN substance will be used as a coating resin. Based on test data on formaldehyde and analogous cationic polymers, EPA predicts sensitization, carcinogenicity, and lung effects to unprotected workers from repeated dermal exposures. Further, based on SAR analysis of test data on analogous cationic polymers, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 32 ppb of the PMN substance in surface waters. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that the substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the consent order requires:

- 1) No manufacture of the PMN such that residual formaldehyde is more than 0.1 weight percent of the PMN substance.
- 2) Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.
- 3) Use of the PMN substance only for the use specified in the consent order.
- 4) No application method that generates a dust, mist, or aerosol.

Recommended testing: EPA has determined that a 28-day subacute inhalation toxicity

study (OECD 412), a fish acute toxicity test mitigated by humic acid (OCSPP Test

Guideline 850.1085), an aquatic invertebrate, acute toxicity test, freshwater daphnids

(OCSPP Test Guideline 850.1075), and an algal toxicity test (OCSPP Test Guideline

850.4500) would help characterize possible health and environmental effects of the

substance. Although the Order does not require these tests, 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 721.10998.

PMN Numbers: P-16-330 and P-16-331

Chemical names: Hydroxy functional triglyceride polymer with glycerol mono-ester and

1,1'-methylenebis[4-isocyanatobenzene] (P-16-330) and Hydroxy functional triglyceride

polymer with glycerol mono-ester and 1,1'-methylenebis[isocyanatobenzene] (P-16-331)

(generic)

CAS numbers: Not available

Effective date of TSCA section 5(e) consent order: February 14, 2017.

Basis for TSCA section 5(e) consent order: The PMN states that the PMN substances

will be used as industrial adhesives. Based on submitted test data, EPA predicts dermal

sensitization, respiratory sensitization, and lung effects to unprotected workers from

repeated inhalation and dermal exposures. The Order was issued under TSCA sections

5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that the substances may present

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

order requires:

(1) Manufacture of the PMN substances to contain no more than 0.1 % residual

isocyanate by weight.

(2) No sale of the PMN substances for "consumer use" or for "commercial uses"

(as the term is defined in § 721.3) when the "saleable goods or service" could

introduce PMNs material into a "consumer" setting (as that term is defined in

§ 721.3).

(3) Establishment and use of a hazard communication program, including human

health precautionary statements on each label and in the SDS.

Recommended testing: EPA has determined that a skin sensitization study (OPPTS

870.2600) and a 90-day inhalation study (OPPTS 870.3465) would help characterize

possible health effects of the substances. Although the Order does not require these tests,

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 citations: 40 CFR 721.10999 (P-16-330) and 40 CFR 721.11000 (P-16-331).

**PMN Number: P-16-360** 

Chemical name: Poly(oxy-1,2-ethanediyl),.alpha.-(1-oxodocosyl)-.omega.-[(1-

oxodocosyl)oxy]-.

CAS number: 36493-27-3.

Effective date of TSCA section 5(e) consent order: December 12, 2016.

Basis for TSCA section 5(e) consent order: The PMN states that the PMN substance will be used as a fuel additive. Based on physical/chemical properties, EPA estimates the PMN substance would have low environmental hazard due to its poor water solubility. However, if the number of repeating ethylene oxide units in the polymer is large (i.e. greater than 10), the polymer would become a dispersible surfactant. Based on SAR analysis of test data on an analogous nonionic polymer, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 350 ppb of the PMN substance in surface waters. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that the substance may present an unreasonable risk of injury to the environment. To protect against these risks, the consent order requires manufacture such that no more than 33% of the PMN substance contains 10 or more repeating ethylene oxide units.

Recommended testing: EPA has determined that an acute invertebrate toxicity test, freshwater daphnids (OCSPP Test Guideline 850.1010), a fish acute toxicity test, freshwater and marine (OCSPP Test Guideline 850.1075), a fish early-life stage toxicity test (OCSPP Test Guideline 850.1400), a daphnid chronic toxicity test (OCSPP Test Guideline 850.1300), and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize possible environmental effects of the substance. Although the Order does not require these tests, 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 721.11001.

**PMN Number: P-16-361** 

Chemical name: Pulp, cellulose, reaction products with lignin

*CAS number*: 1671062-70-6

Effective date of TSCA section 5(e) consent order: December 12, 2016

Basis for TSCA section 5(e) consent order: The PMN states that the PMN substance will

be used as plastic reinforcement. Based on SAR analysis on structurally similar

respirable poorly soluble particulates, EPA predicts pulmonary toxicity to unprotected

workers from repeated inhalational exposures. The Order was issued under TSCA

sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that the substance may

present an unreasonable risk of injury to human health. To protect against these risks, the

consent order requires:

1) Distribution of the PMN substance only in a liquid or gel formulation, unless

the solid particle form has a particle size distribution where less than 0.5% of

the particles are less than 10 microns.

2) No use in application methods that generate a dust, mist, or aerosol unless

such application method occurs in an enclosed process.

Recommended testing: EPA has determined that the results of physical/chemical

characteristics would help characterize the PMN substance. The submitter has agreed not

to manufacture beyond a certain time period without measuring the particle size

distribution to characterize the particle size distribution of fractions less than 10 microns

of the dry particle PMN substance

CFR citation: 40 CFR 721.11002.

### PMN Numbers: P-16-365 and P-16-367

Chemical names: Alkyl carbonate, polymer with, substituted alkanes and substituted heteromonocycle, substituted alkyl acrylate-blocked (generic) (P-16-365) and substituted heteromonocycle, polymer with substituted alkane and ethoxylated alkane, substituted heteromonocycle substituted alkyl ester-blocked (generic) (P-16-367).

CAS numbers: Not available.

Effective date of TSCA section 5(e) consent order: January 3, 2017.

Basis for TSCA section 5(e) consent order: The PMN states that the PMN substances will be used as a UV curable coating resin for industrial use. Based on SAR analysis on structurally similar diisocyanates and acrylates, EPA predicts eye and skin irritation, dermal sensitization, respiratory sensitization, lung effects, mutagenicity, cancer, developmental, liver, and kidney toxicity to unprotected workers from repeated inhalation and dermal exposures. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that the substances may present an unreasonable risk of injury to human health. To protect against these risks, the consent order requires:

- 1) Use of personal protective equipment involving impervious gloves (where there is a potential for dermal exposure).
- 2) Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.
- 3) No manufacture, process, or use of the substances as consumer products.
- 4) Manufacture of the PMN substances to contain no more than 0.1 residual isocyanate by weight.

Recommended testing: EPA has determined that the results of a local lymph node assay (OPPTS 870.2600), a 90-day inhalation toxicity test with 60-day holding period (OPPTS 870.3465), and a two-year oral bioassay (OPPTS 870.4200) would help characterize possible health effects of the substances. Although the Order does not require these tests, 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 citations: 40 CFR 721.11003 (P-16-365) and 40 CFR 721.11004 (P-16-367).

**PMN Number: P-16-369** 

Chemical name: Substituted heteromonocycle, telomer with substituted carbomonocycles, substituted alkyl ester (generic).

*CAS number*: Not available.

Effective date of TSCA section 5(e) consent order: January 23, 2017.

Basis for TSCA section 5(e) consent order: The PMN states that the PMN substance will be used as a UV curable coating resin for industrial use. Based on SAR analysis on structurally similar acrylates and other chemicals, EPA predicts eye and skin irritation, dermal sensitization, respiratory sensitization, lung effects, mutagenicity, cancer, developmental toxicity, liver, and kidney toxicity to unprotected workers from repeated inhalation and dermal exposures. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that the 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 involving impervious gloves and protective

clothing (where there is a potential for dermal exposure) and a NIOSH-certified

respirator with an APF of at least 50 (where there is a potential for inhalation

exposure).

2) No manufacture, process, or use of the substance for use in a consumer product.

3) Establishment and use of a hazard communication program, including human

health precautionary statements on each label and in the SDS.

4) Manufacture of the PMN substance to contain no more than 0.1 residual by

weight of chemicals described in the section 5(e) consent order.

Recommended testing: EPA has determined that the results of certain human health

toxicity testing would help characterize the PMN substance. 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

addition, EPA has determined that the results of a skin sensitization (OPPTS 870.2600), a

local lymph node assay (OECD 429), and two-year bioassay (oral) (OPPTS 870.4200)

would help characterize possible health effects of the substance. Although the Order does

not require these tests, 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 721.11005.

**PMN Number: P-16-387** 

Chemical name: Aliphatic polycarboxylic acid, polymer with alicyclic polyhydric alcohol

and polyoxyalkylene (generic).

CAS number: Not available.

*Effective date of TSCA section 5(e) consent order*: February 7, 2017.

Basis for TSCA section 5(e) consent order: The PMN states that the PMN substance will

be used as an additive for a polymer. Based on physical/chemical properties of the PMN

substance, EPA predicts lung effects to unprotected workers from repeated exposures.

The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based

on a finding that the substance may present an unreasonable risk of injury to human

health. To protect against these risks, the consent order requires:

1) Manufacture of the PMN substance such that the minimum average molecular weight

is 18,000 daltons.

2) No processing or use in any manner or method that generates a dust, mist, or aerosol.

3) Establishment and use of a hazard communication program, including human health

precautionary statements on each label and in the SDS.

Recommended testing: EPA has determined that the results of a 90-day inhalation

toxicity test with 30-day holding period (OPPTS 870.3465), a combined repeated dose

toxicity study with the reproduction/developmental toxicity screening test (OECD 422)

an acute fish toxicity test (OCSPP 850.1075), an acute daphnia toxicity test (OCSPP

850.1300), and an algal toxicity test (OCSPP 850.4500) would help characterize possible

health and environmental effects of the substance. Although the Order does not require

these tests, 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 721.11006.

**PMN Number: P-16-398** 

Chemical name: Di-ammonium di-carboxylate (generic).

CAS number: Not available.

*Effective date of TSCA section 5(e) consent order:* November 14, 2016.

Basis for TSCA section 5(e) consent order: The PMN states that the PMN substance will

be used as a corrosion inhibitor. Based on test data on analogous anionic surfactants, EPA

predicts eye and mucous membrane irritation and skin sensitization to unprotected

workers from repeated dermal exposures. The Order was issued under TSCA sections

5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that the 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 impervious gloves and

protective clothing to prevent dermal exposure.

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

3. Establishment and use of a hazard communication program, including human

health precautionary statements on each label and in the SDS.

Recommended testing: EPA has determined that the results of certain human health

toxicity testing would help characterize the effects of the PMN substance. The submitter

has agreed not to exceed the confidential production limit without performing three skin

sensitization studies (OECD 442B), (OECD 442C), and (OECD 442D).

*CFR citation:* 40 CFR 721.11007.

**PMN Number: P-16-455** 

*Chemical name*: Sodium tungsten oxide.

CAS number: Not available.

*Effective date of TSCA section 5(e) consent order*: November 2, 2016.

Basis for TSCA section 5(e) consent order: The PMN states that the PMN substance will be used as a component of infrared absorption material. Based on SAR analysis on structurally similar respirable poorly soluble particulates, EPA predicts pulmonary toxicity and carcinogenicity to unprotected workers from repeated inhalation exposures. Further, based on test data on analogous tungsten oxide, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PMN substance in surface waters. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that the 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 to prevent dermal exposure.
- 2. Use of a NIOSH-certified respirator with an APF of at least 1000 or compliance with a NCEL of 0.3 ppm as an 8-hour time-weighted average to prevent inhalation exposure.
- 3. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.
- 4. Use of the PMN substance only for the use specified in the consent order.
- 5. No use in application methods that generate a dust, mist, or aerosol unless such application method occurs in an enclosed process.
- 6. No use of the PMN substance resulting in releases to surface waters and disposal of the PMN substance only by landfill or incineration.

Recommended testing: EPA has determined that the results of certain human health toxicity testing would help characterize the PMN substance. 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) and a twoyear inhalation bioassay test (OPPTS 870.4200).

CFR citation: 40 CFR 721.11008.

**PMN Number: P-16-503** 

Chemical name: Fatty acids, tall-oil, polymers with alkanoic acid, substituted carbomonocycle, alkyl peroxide-initiated (generic).

CAS number: Not available.

Effective date of TSCA section 5(e) consent order: January 11, 2017.

Basis for TSCA section 5(e) consent order: The PMN states that the PMN substance will be used as a site-limited polymer intermediate for production of a deck stain coating resin additive. Based on physical/chemical properties, EPA predicts low health hazard for the PMN substance when it is manufactured as described in the PMN. However, if the chemical substance is manufactured with a lower molecular weight and a higher proportion of the acid component (i.e., greater than 24%), the PMN substance could cause developmental effects in unprotected workers from repeated dermal and inhalation exposures. Further, based on physical/chemical properties, EPA predicts low hazard for the PMN substance when it is manufactured as described in the PMN due to low water solubility. However, if the chemical substance is manufactured with a higher proportion of the acid component (i.e., greater than 24%), there is potential for aquatic toxicity. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a

finding that 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. Manufacture of the PMN substance to have an average molecular weight no

less than 1500 daltons.

2. Manufacture of the PMN substance to have no more than 24% by weight of

the acid component.

3. Use of the PMN substance only as intermediate.

Recommended testing: EPA has determined that a combined repeated dose toxicity study

with the reproduction/developmental toxicity screening test (OECD 422), water solubility

test, log Kow tests, a compositional/component analysis (certificate of analysis), a fish

early-life stage toxicity test (OCSPP Test Guideline 850.1400), a daphnid chronic

toxicity test (OCSPP Test Guideline 850.1300), fish acute toxicity mitigated by humic

acid (OCSPP Test Guideline 850.1085), an aquatic invertebrate, acute toxicity test,

freshwater daphnids (OCSPP Test Guideline 850.1075), and an algal toxicity test

(OCSPP Test Guideline 850.4500) would help characterize the physical-chemical

properties and possible health and environmental effects of the substance. Although the

Order does not require these tests, 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 721.11009.

**PMN Number: P-16-591** 

Chemical name: Alkyl bisphenol (generic).

*CAS number*: Not available.

Effective date of TSCA section 5(e) consent order: January 9, 2017.

Basis for TSCA section 5(e) consent order: The PMN states that the PMN substance will be used as a component of printing ink. Based on test data on bisphenol analogs, EPA predicts irritation to eyes, skin, lung, and mucous membranes; developmental, reproductive, liver and kidney toxicities; dermal sensitization; photosensitization; effects to the adrenals and other toxic effects associated with an endocrine disruption mode of action to unprotected workers from repeated dermal and inhalation exposures. Further, based on SAR analysis of test data on analogous phenols, 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(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that the substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the consent order requires:

- 1. Use of personal protective equipment including impervious gloves and protective clothing to prevent dermal exposure and a NIOSH-certified respirator with an APF of at least 10 to prevent inhalation exposure.
- 2. Use of the PMN substance only for the use specified in the consent order.
- 3. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.
- 4. No use of the PMN substance resulting in releases to surface waters.

  Recommended testing: EPA has determined that the results of certain human health and

environmental toxicity testing would help characterize the PMN substance. The submitter has agreed not to exceed the confidential production limit without performing

the reproduction/developmental toxicity screening test (OECD 422). In addition, EPA has determined that the results of a fish early-life stage toxicity test (OCSPP Test Guideline 850.1400) and a daphnid chronic toxicity test (OCSPP Test Guideline 850.1300) would help characterize the environmental effects of the PMN substance. Although the Order does not require these tests, 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 721.11010.

### V. Rationale and Objectives of the Rule

#### A. Rationale

During review of the PMNs submitted for the chemical substances that are subject to these SNURs, EPA concluded that for all 29 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.).

### 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

  TSCA Chemical Substance Inventory (TSCA Inventory) 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 Inventory. Guidance on how to determine if a chemical substance is on the TSCA Inventory is available on the Internet at <a href="http://www.epa.gov/opptintr/existingchemicals/pubs/tscainventory/index.html">http://www.epa.gov/opptintr/existingchemicals/pubs/tscainventory/index.html</a>.

### **VI. Direct Final Procedures**

EPA is issuing these SNURs as a direct final rule, as described in § 721.160(c)(3). In accordance with § 721.160(c)(3)(ii) 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 the Significant New Use Designation

To establish a significant new use, EPA must determine that the use is not ongoing. The chemical substances subject to this rule have undergone premanufacture review. In cases where EPA has not received 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 these 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 19 of the 29 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 July 10, 2017 (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: TSCA section 5(b)(1) requires development of test data where the chemical substance subject to the SNUR is also subject to a rule, order or consent agreement under TSCA section 4(15 U.S.C. 2603).

In the absence of a rule order, or consent agreement under TSCA section 4 covering the chemical substance, persons are required only to submit information in their possession or control and to describe any other information known to or reasonably ascertainable by them (see § 720.50). However, upon review of PMNs and SNUNs, the Agency has the authority to require appropriate testing. Unit IV. lists required or recommended testing for all of the listed 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 <a href="http://www.epa.gov/ocspp">http://www.epa.gov/ocspp</a> and select "Test Methods and Guidelines." The Organisation for Economic Co-operation and Development (OECD) test guidelines are available from the OECD Bookshop at <a href="http://www.oecdbookshop.org">http://www.oecdbookshop.org</a> or SourceOECD at <a href="http://www.sourceoecd.org">http://www.sourceoecd.org</a>.

In the TSCA section 5(e) consent orders for 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 tests specified in the order 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 § 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 § 720.50. SNUNs must be submitted on EPA Form No. 7710-25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in § 720.40 and § 721.25. E-PMN software is available electronically at <a href="https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca">https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca</a>.

## **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-2017-0166.

## XII. Statutory and Executive Order Reviews

## A. Executive Order 12866

This action establishes SNURs for several new chemical substances that were the subject of PMNs, or TSCA section 5(e) 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. 605(b)), 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. 1502, 1503, 1504, or 1505 *et seq.*).

#### E. Executive Order 13132

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

## F. Executive Order 13175

This action does not have Tribal implications because it is not expected to have substantial direct effects on Indian Tribes. This action does not significantly nor uniquely affect the communities of Indian Tribal governments, nor does it involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000), do not apply to this action.

## G. Executive Order 13045

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

#### H. Executive Order 13211

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

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

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

## J. Executive Order 12898

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

## **XIII. Congressional Review Act**

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

## **List of Subjects**

40 CFR Part 9

Environmental protection, Reporting and recordkeeping requirements.

40 CFR Part 721

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

Dated: July 7, 2017

/s/

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Maria J. Doa,

 $Director,\ Chemical\ Control\ Division,\ Office\ of\ Pollution\ Prevention\ and\ Toxics.$ 

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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.			
*	*	*	*	*	*	*
	Si	ignificant New	Uses of Chemical S	ubstance	S	
*	*	*	*	*	*	*
721.109	987		2070-0012			
721.109	988		2070-0012			
721.109	989		2070-0012			
721.109	990		2070-0012			
721.109	991		2070-0012			
721.109	992		2070-0012			

721.10993	2070-0012
721.10994	2070-0012
721.10995	2070-0012
721.10996	2070-0012
721.10997	2070-0012
721.10998	2070-0012
721.10999	2070-0012
721.11000	2070-0012
721.11001	2070-0012
721.11002	2070-0012
721.11003	2070-0012
721.11004	2070-0012
721.11005	2070-0012
721.11006	2070-0012
721.11007	2070-0012
721.11008	2070-0012
721.11009	2070-0012
721.11010	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 § 721.10987 to subpart E to read as follows:

## § 721.10987 1,2,4-Benzenetricarboxylic acid, mixed decyl and octyl triesters

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as 1,2,4-benzenetricarboxylic acid, mixed decyl and octyl triesters (PMN P-15-310) 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) and (b)(concentration set at 1.0 percent).
- (ii) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(k) (It is a significant new use to use the PMN substance other than as a lubricant in chain oils for conveyor belts.), (p)(2,440,000 kilograms), and (s)(150,000 kilograms).
- (iii) *Hazard communication program*. A significant new use of the substance is any manner or method of manufacture or processing associated with any use of the substance without providing risk notification as follows:
- (A) If as a result of the test data required under the TSCA section 5(e) consent order for the substance, the employer becomes aware that the substance may present a risk of injury to human health or the environment, the employer must incorporate this new information, and any information on methods for protecting against such risk, into a MSDS as described in §721.72(c) within 90 days from the time the employer becomes aware of the new information. If the substance is not being manufactured, processed, or used in the employer's workplace, the employer must add the new information to a MSDS before the substance is reintroduced into the workplace.

- (B) The employer must ensure that persons who will receive the PMN substance from the employer, or who have received the PMN substance from the employer within 5 years from the date the employer becomes aware of the new information described in paragraph (a)(2)(i)(A) of this section, are provided an MSDS containing the information required under paragraph (a)(2)(i)(A) of this section within 90 days from the time the employer becomes aware of the new information.
- (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 (f) and (i) are applicable to manufacturers and processors of this substance.
- (2) Limitations or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.
  - 5. Add § 721.10988 to subpart E to read as follows:

## § 721.10988 Multiwalled carbon nanotubes (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substances identified generically as multiwalled carbon nanotubes (PMN P-15-487/488/489/490/491) 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 when the PMN substances have been incorporated into a polymer matrix that has been reacted (cured) or embedded in a permanent solid polymer form that is not intended to undergo further processing except mechanical processing.
  - (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. The following National Institute for Occupational Safety and Health (NIOSH)-certified respirators with an APF of at least 50 meet the requirements of §721.63(a)(4): (A) a NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N-100, P-100, or R-100 cartridges. (B) Any NIOSH-certified powered air-purifying respirator equipped with a tight-fitting full facepiece and equipped with HEPA filters. (C) Any NIOSH-certified negative pressure (demand) supplied-air respirator equipped with a full facepiece.
- (ii) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80 (k)(additives for electro-static discharge in electronic devices, electronics, and materials; additives for weight reduction in materials; additives to improve mechanical properties or electrical conductivities; heat-generating elements in heating devices and materials; additives for heat transfer and thermal emissions in electronic devices and materials; semi-conductor, conductive, or resistive elements in electronic circuity and devices; additives to improve conductivity in electronic circuitry, energy storage systems, and devices; electron emitters for lighting and x-ray sources; additive for electromagnetic interface shielding in electronic devices; additives for electrodes in electronic materials and electronic devices; catalyst support in chemical manufacturing; coating additives to

improve corrosion resistance of conductive properties; additives for fibers in structural and electrical applications; additives for fibers in fabrics and textiles; filter additives to remove nanoscale materials; semi-conducting compounding additives for high-voltage cable; and additives for super-hydrophobicity). A significant new use is any use involving an application method that generates a dust, 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.
  - 6. Add § 721.10989 to subpart E to read as follows:

## § 721.10989 Propanoic acid, iron (2+) salt (2:1)

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as propanoic acid, iron (2+) salt (2:1) (CAS # 1952336-63-8) (PMN P-16-165) 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)(4), (a)(5)(particulate) and (b)(concentration set at 1.0 percent). When determining which persons are reasonably likely to be exposed as required for §721.63(a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. The following National Institute for Occupational Safety and Health (NIOSH)-certified respirators with an APF of at least 10 meet the requirements of §721.63(a)(4): (A) (NIOSH)-certified respirator with an N-100, P-100, or R-100 cartridge. (B) NIOSH-certified power air purifying respirator with a hood or helmet and with appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridges in combination with HEPA filters. (C) NIOSH-certified continuous flow supplied-air respirator equipped with a loose fitting facepiece, hood, or helmet.
- (ii) *Hazard communication*. Requirements as specified in § 721.72(a) through (e) (concentration set at 1.0 percent), (f), (g)(1)(iv), (g)(1)(ix), (g)(2)(ii), (g)(2)(iii), (g)(2)(iii), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System (GHS) and OSHA Hazard Communication Standard may be used.
- (iii) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(1), (p)(270,000 kilograms), and (s)(5,000 kilograms). It is a significant new use to use the substance in formulations where the concentration is greater than 1 percent.
- (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), (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.
  - 7. Add § 721.10990 to subpart E to read as follows:

## § 721.10990 1-Butanaminium, N,N,N-tributyl-, carbonic acid (1:1).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as 1-butanaminium, N,N,N-tributyl-, carbonic acid (1:1) (PMN P-16-255; CAS No. 17351-62-1) 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)(3), and (b)(concentration set at 1.0 percent).
- (ii) *Hazard communication*. 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)(iii), (g)(2)(iii), (g)(2)(v), (g)(3)(i), (g)(3)(ii), (g)(5) and Notice to users: minimize release to water.

  Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System (GHS) and OSHA Hazard Communication Standard may be used.
- (iii) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(k) (It is a significant new use to manufacture, process, or use the substance other than as a blocked catalyst for paints and coatings.) and (p)(64,000 kilograms aggregate of P-16-255, P-16-256, P-16-257, P-16-258, and P-16-259). It is a significant

new use to spray apply the PMN substance where the concentration of any combination of P-16-255, P-16-256, P-16-257, P-16-258, and P-16-259 in the final paint/coating formulation exceeds 1.5% by weight.

- (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.
  - 8. Add § 721.10991 to subpart E to read as follows:

## § 721.10991 1-Butanaminium, N,N,N-tributyl-, methyl carbonate (1:1).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as 1-Butanaminium, N,N,N-tributyl-, methyl carbonate (1:1) (PMN P-16-256; CAS No. 56294-05-2) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
  - (2) The significant new uses are:
- (i) *Protection in the workplace*. Requirements as specified in § 721.63(a)(1), (a)(3), and (b)(concentration set at 1.0 percent).
- (ii) *Hazard communication*. 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)(iii), (g)(2)(iii), (g)(2)(v), (g)(3)(i), (g)(3)(ii), (g)(5) and Notice to users: minimize release to water.

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

- (iii) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(k) (It is a significant new use to manufacture, process, or use the substance other than as a blocked catalyst for paints and coatings.) and (p)(64,000 kilograms aggregate of P-16-255, P-16-256, P-16-257, P-16-258, and P-16-259). It is a significant new use to spray apply the PMN substance where the concentration of any combination of P-16-255, P-16-256, P-16-257, P-16-258, and P-16-259 in the final paint/coating formulation exceeds 1.5% by weight.
- (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.
  - 9. Add § 721.10992 to subpart E to read as follows:

## § 721.10992 1-Butanaminium, N,N,N-tributyl-, ethyl carbonate (1:1).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as 1-butanaminium, N,N,N-tributyl-, ethyl carbonate (1:1) (PMN P-16-257; CAS No. 478796-04-2) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
  - (2) The significant new uses are:
- (i) Protection in the workplace. Requirements as specified in § 721.63(a)(1),(a)(3), and (b)(concentration set at 1.0 percent).

- (ii) *Hazard communication*. 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)(iii), (g)(2)(iii), (g)(2)(v), (g)(3)(i), (g)(3)(ii), (g)(5) and Notice to users: minimize release to water. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System (GHS) and OSHA Hazard Communication Standard may be used.
- (iii) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(k) (It is a significant new use to manufacture, process, or use the substance other than as a blocked catalyst for paints and coatings.) and (p)(64,000 kilograms aggregate of P-16-255, P-16-256, P-16-257, P-16-258, and P-16-259). It is a significant new use to spray apply the PMN substance where the concentration of any combination of P-16-255, P-16-256, P-16-257, P-16-258, and P-16-259 in the final paint/coating formulation exceeds 1.5% by weight.(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.
  - 10. Add § 721.10993 to subpart E to read as follows:

## § 721.10993 1-Butanaminium, N,N,N-tributyl-, propyl carbonate (1:1).

(a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as 1-butanaminium, N,N,N-tributyl-, propyl carbonate (1:1) (PMN P-16-258: CAS No. 1338579-13-7) 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)(3), and (b)(concentration set at 1.0 percent).
- (ii) *Hazard communication*. 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)(iii), (g)(2)(iii), (g)(2)(v), (g)(3)(i), (g)(3)(ii), (g)(5) and Notice to users: minimize release to water.

  Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System (GHS) and OSHA Hazard Communication Standard may be used.
- (iii) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(k) (It is a significant new use to manufacture, process, or use the substance other than as a blocked catalyst for paints and coatings.) and (p)(64,000 kilograms aggregate of P-16-255, P-16-256, P-16-257, P-16-258, and P-16-259). It is a significant new use to spray apply the PMN substance where the concentration of any combination of P-16-255, P-16-256, P-16-257, P-16-258, and P-16-259 in the final paint/coating formulation exceeds 1.5% by weight.(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.
  - 11. Add § 721.10994 to subpart E to read as follows:

## § 721.10994 1-Butanaminium, N,N,N-tributyl-, and 1-methylethyl carbonate.

(a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as 1-butanaminium, N,N,N-tributyl-, and 1-methylethyl

carbonate (PMN P-16-259; CAS No. 1803407-49-9) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

- (2) The significant new uses are:
- (i) *Protection in the workplace*. Requirements as specified in § 721.63(a)(1), (a)(3), and (b)(concentration set at 1.0 percent).
- (ii) *Hazard communication*. 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)(iii), (g)(2)(v), (g)(3)(i), (g)(3)(ii), (g)(4)( Notice to users: minimize release to water), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System (GHS) and OSHA Hazard Communication Standard may be used.
- (iii) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(k) (It is a significant new use to manufacture, process, or use the substance other than as a blocked catalyst for paints and coatings.) and (p)(64,000 kilograms aggregate of P-16-255, P-16-256, P-16-257, P-16-258, and P-16-259). It is a significant new use to spray apply the PMN substance where the concentration of any combination of P-16-255, P-16-256, P-16-257, P-16-258, and P-16-259 in the final paint/coating formulation exceeds 1.5% by weight.
- (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.

- 12. Add § 721.10995 to subpart E to read as follows:
- § 721.10995 Anilino substituted bis-triazinyl derivative of 4,4'-diaminostilbene-2,2'-disulfonic acid, mixed amine sodium salt (generic).
- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as anilino substituted bis-triazinyl derivative of 4,4'-diaminostilbene-2,2'-disulfonic acid, mixed amine sodium salt (PMN P-16-284) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
  - (2) The significant new uses are:
- (i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f). It is a significant new use to import or use the substance other than in a solution. It is a significant new use to use the substance other than as an optical brightener for textiles, paper, and paperboard. It is a significant new use to use the substance for non-industrial use or sell the substance for "consumer use" or for "commercial uses" (as the term is defined at 40 CFR 721.3) when the "saleable goods or service" could introduce the substance into a "consumer" setting (as that term is defined in 40 CFR 721.3). It is a significant new use to use the substance for an application method that generates a dust, mist, or aerosol unless the application method occurs in an enclosed process.
  - (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.
  - 13. Add § 721.10996 to subpart E to read as follows:

# § 721.10996 12-Hydroxystearic acid, reaction products with alkylene diamine and alkanoic acid (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substances identified generically as 12-Hydroxystearic acid, reaction products with alkylene diamine and alkanoic acid (PMNs P-16-309 and P-16-310) 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(f), (k) (It is a significant new use to use the PMN substance other than as a rheological or thixotropic agent used in the production of solvent based industrial coatings, high solid aromatic paints, adhesives, sealants, and other types of paints and topcoats.), (q), and (t).
- (ii) Releases to water. Requirements as specified in § 721.90(a)(4), (b)(4), (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) through (c), (i), and (k) are applicable to manufacturers and processors of this substance.
- (2) Limitations or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.
- (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.
  - 14. Add § 721.10997 to subpart E to read as follows:

## § 721.10997 Alkyldiene, polymer, hydroxy terminated alkoxysilylalkylcarbamate.

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as alkyldiene, polymer, hydroxy terminated alkoxysilylalkylcarbamate (PMN P-16-315) is subject to reporting under this section for 1the significant new uses described in paragraph (a)(2) of this section.
  - (2) The significant new uses are:
- (i) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(f). It is a significant new use to process the substance in a manner that results in inhalation exposure. It is a significant new use to use the PMN substance other than as an additive to improve the compatibility and dispersibility of inorganic filler in industrial rubber formulations.
  - (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.
  - 15. Add § 721.10998 to subpart E to read as follows:
- § 721.10998 Alkylaldehyde, reaction products with substituted carbomonocyclesubstituted heteromonocycle-alkylene glycol bis[[[[substituted(oxoneoalkyl)oxy]alkyl] amino]alkyl] ether polymer and alkyl substituted alkanediamine, acetate salts (generic).
- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as alkylaldehyde, reaction products with substituted carbomonocycle-substituted heteromonocycle-alkylene glycol bis[[[[substituted(oxoneoalkyl)oxy]alkyl] amino]alkyl] ether polymer and alkyl substituted alkanediamine, acetate salts (generic) (PMN P-16-323) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
  - (2) The significant new uses are:
- (i) *Hazard communication*. Requirements as specified in § 721.72(a) through (e) (concentration set at 0.1 percent), (f), (g)(1)(i), (g)(1)(vii), (g)(1)(respiratory tract irritation), (g)(2)(i), (g)(2)(ii), (g)(2)(iii), (g)(3)(i), (g)(3)(ii), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System (GHS) and OSHA Hazard Communication Standard may be used.
- (ii) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80. It is a significant new use to manufacture the PMN substance to contain a

residual of formaldehyde greater than 0.1 weight percent. It is a significant new use to manufacture the substance in a manner that results in inhalation exposure.

- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a), (b), (c), (f), (g), and (h) are applicable to manufacturers and processors of this substance.
- (2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.
- (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.
  - 16. Add § 721.10999 to subpart E to read as follows:

# § 721.10999 Hydroxy functional triglyceride polymer with glycerol mono-ester and 1,1'-methylenebis[4-isocyanatobenzene] (generic).

- (a) Chemical substances and significant new uses subject to reporting. (1) The chemical substance identified generically as hydroxy functional triglyceride polymer with glycerol mono-ester and 1,1'-methylenebis[4-isocyanatobenzene] (PMN P-16-330) 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)(iii), (a)(2)(iv), (a)(3), and (b)(concentration set at 0.1 percent)
- (ii) *Hazard communication*. 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)(iii),

- (g)(2)(v), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System (GHS) and OSHA Hazard Communication Standard may be used.
- (iii) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80. It is a significant new use to manufacture the PMN substance to contain a residual of isocyanate greater than 0.1 weight percent. It is a significant new use to sell the substance for "consumer use" or for "commercial uses" (as the term is defined at 40 CFR 721.3) when the "saleable goods or service" could introduce the substance into a "consumer" setting (as that term is defined in 40 CFR 721.3).
- (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.
  - 17. Add § 721.11000 to subpart E to read as follows:
- § 721.11000 Hydroxy functional triglyceride polymer with glycerol mono-ester and 1,1'-methylenebis[isocyanatobenzene] (generic).
- (a) Chemical substances and significant new uses subject to reporting. (1) The chemical substance identified generically as hydroxy functional triglyceride polymer with glycerol mono-ester and 1,1'-methylenebis[isocyanatobenzene] (PMN P-16-331) 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)(iii), (a)(2)(iv), (a)(3), and (b)(concentration set at 0.1 percent).
- (ii) *Hazard communication*. 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)(iii), (g)(2)(v), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System (GHS) and OSHA Hazard Communication Standard may be used.
- (iii) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80. It is a significant new use to manufacture the PMN substance to contain a residual of isocyanate greater than 0.1 weight percent. It is a significant new use to sell the substance for "consumer use" or for "commercial uses" (as the term is defined at 40 CFR 721.3) when the "saleable goods or service" could introduce the substance into a "consumer" setting (as that term is defined in 40 CFR 721.3).
- (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.
  - 18. Add  $\S$  721.11001 to subpart E to read as follows:

§ 721.11001 Poly(oxy-1,2-ethanediyl),.alpha.-(1-oxodocosyl)-.omega.-[(1-oxodocosyl)oxy]-

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as poly(oxy-1,2-ethanediyl),.alpha.-(1-oxodocosyl)-.omega.-[(1-oxodocosyl)oxy]- (PMN P-16-360; CAS No. 36493-27-3) 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) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80. It is a significant new use to manufacture the PMN substance such that more than 33% contains 10 or more repeating ethylene oxide units.
  - (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.
  - 19. Add § 721.11002 to subpart E to read as follows:

## § 721.11002 Pulp, cellulose, reaction products with lignin.

(a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as pulp, cellulose, reaction products with lignin (PMN P-16-361; CAS No. 167062-70-6) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of

this SNUR do not apply to quantities of the PMN substance after they have been incorporated into a polymer matrix.

- (2) The significant new uses are:
- (i) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(y)(1). It is a significant new use to manufacture, process, or use the PMN substance other than in a liquid or gel formulation, unless the solid particle form has a particle size distribution where less than 0.5% of the particles are less than 10 microns. It is a significant new use to manufacture the solid particle form more than six months without measuring the particle size distribution to characterize the particle size distribution of fractions less than 10 microns of the dry particle PMN substance and sending the results of the measurement to EPA.
  - (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.
  - 20. Add § 721.11003 to subpart E to read as follows:
- § 721.11003 Alkyl carbonate, polymer with, substituted alkanes and substituted heteromonocycle, substituted alkyl acrylate-blocked (generic).
- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as alkyl carbonate, polymer with, substituted

alkanes and substituted heteromonocycle, substituted alkyl acrylate-blocked (generic) (PMN P-16-365) 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), and (b)(concentration set at 0.1 percent).
- (ii) Hazard communication. Requirements as specified in § 721.72(a) through (e)
  (concentration set at 0.1 percent), (f), (g)(1)(vii), (g)(1)(lung effects),
  (g)(1)(sensitization), (g)(2)(i), (g)(2)(ii), (g)(2)(iii), (g)(2)(v), and (g)(5).
- (iii) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80. It is a significant new use to manufacture the substance to contain a residual of isocyanate greater than 0.1 weight percent. It is a significant new use to sell the substance for "consumer use" or for "commercial uses" (as the term is defined at 40 CFR 721.3) when the "saleable goods or service" could introduce the substance into a "consumer" setting (as that term is defined in 40 CFR 721.3).
- (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.
  - 21. Add § 721.11004 to subpart E to read as follows:

- § 721.11004 Substituted heteromonocycle, polymer with substituted alkane and ethoxylated alkane, substituted heteromonocycle substituted alkyl ester-blocked (generic).
- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as substituted heteromonocycle, polymer with substituted alkane and ethoxylated alkane, substituted heteromonocycle substituted alkyl ester-blocked (PMN P-16-367) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this SNUR do not apply to quantities of the PMN substance after they have been completely reacted (cured).
  - (2) The significant new uses are:
- (i) *Protection in the workplace*. Requirements as specified in § 721.63(a)(1), (a)(3), and (b)(concentration set at 0.1 percent).
- (ii) Hazard communication. Requirements as specified in § 721.72(a) through (e)
  (concentration set at 0.1 percent), (f), (g)(1)(vii), (g)(1)(lung effects),
  (g)(1)(sensitization), (g)(2)(i), (g)(2)(ii), (g)(2)(iii), (g)(2)(v), and (g)(5).
- (iii) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80. It is a significant new use to manufacture the substance to contain a residual of isocyanate greater than 0.1 weight percent. It is a significant new use to sell the substance for "consumer use" or for "commercial uses" (as the term is defined at 40 CFR 721.3) when the "saleable goods or service" could introduce the substance into a "consumer" setting (as that term is defined in 40 CFR 721.3).

- (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.
  - 22. Add § 721.11005 to subpart E to read as follows:

# § 721.11005 Substituted heteromonocycle, telomer with substituted carbomonocycles, substituted alkyl ester (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as substituted heteromonocycle, telomer with substituted carbomonocycles, substituted alkyl ester (PMN P-16-369) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this SNUR do not apply to quantities of the PMN substance after they have been completely reacted (cured).
  - (2) The significant new uses are:
- (i) *Protection in the workplace*. Requirements as specified in § 721.63(a)(1), (a)(3), (a)(4), (a)(6)(v), (a)(6)(vi), (a)(6)(particulate) and (b)(concentration set at 0.1 percent). The following National Institute for Occupational Safety and Health (NIOSH)-certified respirators with an APF of at least 50 meet the requirements of §721.63(a)(4): (A) Any NIOSH-certified air-purifying full facepiece respirator equipped with N100 (if oil aerosols absent), R-100, or P-100 filter(s). (B) Any NIOSH-certified powered air-purifying respirator equipped with a tight-fitting full facepiece and equipped with HEPA

- filters. (C) Any NIOSH-certified negative pressure (demand) supplied-air respirator equipped with a full facepiece. (D) Any NIOSH-certified continuous flow supplied-air respirator equipped with a tight-fitting full facepiece (half or full facepiece). (E) Any NIOSH-certified negative pressure (demand) self-contained breathing apparatus (SCBA) equipped with a hood or helmet or a full facepiece.
- (ii) Hazard communication. Requirements as specified in § 721.72(a), (b), (c), (d),
  (e) (concentration set at 0.1 percent), (f), (g)(1)(vii), (g)(1)(lung effects),
  (g)(1)(sensitization), (g)(2)(i), (g)(2)(ii), (g)(2)(iii), (g)(2)(v), and (g)(5).
- (iii) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(q). It is a significant new use to manufacture the substance to contain residuals greater than 0.1 weight percent of chemicals described in the section 5(e) consent order. It is a significant new use to sell the substance for "consumer use" or for "commercial uses" (as the term is defined at 40 CFR 721.3) when the "saleable goods or service" could introduce the substance into a "consumer" setting (as that term is defined in 40 CFR 721.3).
- (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)(ii) of this section.

- 23. Add § 721.11006 to subpart E to read as follows:
- § 721.11006 Aliphatic polycarboxylic acid, polymer with alicyclic polyhydric alcohol and polyoxyalkylene (generic).
- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as aliphatic polycarboxylic acid, polymer with alicyclic polyhydric alcohol and polyoxyalkylene (PMN P-16-387) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
  - (2) The significant new uses are:
- (i) *Hazard communication*. Requirements as specified in § 721.72 (a) through (e) (concentration set at 1.0 percent), (f), (g)(1)(ii), (g)(2)(ii), (g)(3)(i), (g)(3)(ii), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System (GHS) and OSHA Hazard Communication Standard may be used.
- (ii) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(y)(1) and (y)(2). It is a significant new use to manufacture the substance with a molecular weight less than 18,000 daltons.
- (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), 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.
  - 24. Add § 721.11007 to subpart E to read as follows:

## § 721.11007 Di-ammonium di-carboxylate (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as di-ammonium di-carboxylate (PMN P-16-398) 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)(iii), (a)(2)(iv), (a)(3), and (b)(concentration set at 1.0 percent).
- (ii) *Hazard communication*. Requirements as specified in § 721.72 (a) through (e) (concentration set at 1.0 percent), (f), (g)(1)(i), (g)(1)(skin sensitization), (g)(2)(i), (g)(2)(v), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System (GHS) and OSHA Hazard Communication Standard may be used.
- (iii) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(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 (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.

25. Add § 721.11008 to subpart E to read as follows:

## § 721.11008 Sodium tungsten oxide.

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as sodium tungsten oxide (PMN P-16-455) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance that have been incorporated into a polymer matrix.
  - (2) The significant new uses are:
- (i) *Protection in the workplace*. Requirements as specified in § 721.63(a)(1), (a)(3), (a)(4), and (a)(6)(particulate). The following National Institute for Occupational Safety and Health (NIOSH)-certified respirators with an APF of at least 1000 meet the requirements of §721.63(a)(4): (A) Any NIOSH-certified powered air purifying full facepiece respirator equipped with appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridges. (B) Any NIOSH-certified continuous flow supplied-air respirator equipped with a full facepiece (C) Any NIOSH-certified pressure-demand or other positive pressure mode supplied-air respirator equipped with a full facepiece. (D) Any NIOSH-certified continuous flow supplied-air respirator equipped with a full facepiece. (E) Any NIOSH-certified pressure-demand or other positive pressure mode supplied-air respirator equipped with a full facepiece.
- (1) As an alternative to the respiratory requirements listed here, a manufacturer or processor may choose to follow the New Chemical Exposure Limit (NCEL) provisions listed in the TSCA section 5(e) consent order for this substance. The NCEL is 0.3 mg/m<sup>3</sup> as an 8-hour time weighted average verified by actual monitoring data.

- (ii) *Hazard communication*. Requirements as specified in § 721.72(a), (b), (c), (d),
  (e) (concentration set at 0.1 percent), (f), (g)(1)(vii), (g)(1)(lung effects), (g)(2)(ii),
  (g)(2)(iii), (g)(2)(iv), (g)(3)(ii), (g)(4)(i), (g)(4)(iii), and (g)(5).
- (iii) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80. It is a significant new use to use the PMN substance other than as a component of infrared absorption material. It is a significant new use for any application method that generates a dust, mist, or aerosol, unless such application method occurs in an enclosed process.
- (iv) *Disposal*. Requirements as specified in § 721.85(a)(1), (a)(2), (b)(1), (b)(2), (c)(1), and (c)(2),
- (v) *Releases 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 (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.
  - 26. Add § 721.11009 to subpart E to read as follows:
- § 721.11009 Fatty acids, tall-oil, polymers with alkanoic acid, substituted carbomonocycle, alkyl peroxide-initiated (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as fatty acids, tall-oil, polymers with alkanoic acid, substituted carbomonocycle, alkyl peroxide-initiated (PMN P-16-503) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the PMN substance that have been completely reacted (cured).
  - (2) The significant new uses are:
- (i) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(g). It is a significant new use to manufacture the substance to have an average molecular weight less than 1500 daltons. It is a significant new use to manufacture the substance to have more than 24% by weight of the acid component identified in the section 5(e) consent order.
  - (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)(ii) of this section.
  - 27. Add § 721.11010 to subpart E to read as follows:

## § 721.11010 Alkyl bisphenol (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as alkyl bisphenol (PMN P-16-591) 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)(2)(iv), (a)(3), (a)(4), (a)(6)(v), (a)(6)(vi), (a)(6)(particulate), and (b)(concentration set at 1.0 percent). When determining which persons are reasonably likely to be exposed as required for §721.63 (a)(4), engineering control measures (e.g. enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g. workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. The following National Institute for Occupational Safety and Health (NIOSH)-certified respirators with an APF of at least 10 meet the requirements of §721.63(a)(4): (A) (NIOSH)-certified respirator with an N-100, P-100, or R-100 cartridge. (B) NIOSH-certified power air purifying respirator with a hood or helmet and with appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridges in combination with HEPA filters. (C) NIOSH-certified continuous flow supplied-air respirator equipped with a loose fitting facepiece, hood, or helmet.
- (ii) *Hazard communication*. Requirements as specified in § 721.72 (a) through (e) (concentration set at 0.1 percent), (f), (g)(1)(i), (g)(1)(ii), (g)(1)(iv), (g)(1)(ix), (g)(1)(dermal sensitization), (g)(1)(endocrine disruption), (g)(1)(reproductive effects), (g)(2)(i), (g)(2)(ii), (g)(2)(iii), (g)(2)(iv), (g)(2)(v), (g)(3)(i), (g)(3)(ii), (g)(4)(iii), and

- (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System (GHS) and OSHA Hazard Communication Standard may be used.
- (iii) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(k) (It is a significant new use to use the PMN substance in thermal paper printing.) and (q).
- (iv) *Releases 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 (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.