ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 721

[EPA-HQ-OPPT-2016-0331; FRL-9959-81]

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 37 chemical substances which were the subject of premanufacture notices (PMNs). The applicable review periods for the PMNs submitted for these 37 chemical substances all ended prior to June 22, 2016 (i.e., the date on which President Obama signed into law the Frank R. Lautenberg Chemical Safety for the 21st Century Act which amends TSCA). Six of these chemical substances are subject to TSCA section 5(e) consent orders issued by EPA. This action requires persons who intend to manufacture (defined by statute to include import) or process any of these 37 chemical substances for an activity that is designated as a significant new use by this rule to notify EPA at least 90 days before commencing that activity. The required notification initiates EPA's evaluation of the intended use within the applicable review period. Manufacture and processing for the significant new use is unable to commence until EPA has conducted a review of the notice, made an appropriate determination on the notice, and take such actions as are required with that determination.

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

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

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

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2016-0331, by one of the following methods:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- Mail: Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

 Hand Delivery: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at http://www.epa.gov/dockets/contacts.html.

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

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

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

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Chemical importers are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements promulgated at 19 CFR 12.118 through 12.127 and 19 CFR 127.28. Chemical importers must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA. Importers of chemicals subject to these SNURs must certify their compliance with the SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export a chemical substance that is the subject of this rule on or after [insert date 30 days after date of publication in the Federal Register] are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)) (see § 721.20), and must comply with the export notification requirements in 40 CFR part 707, subpart D. B. What Should I Consider as I Prepare My Comments for EPA?

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

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

II. Background

A. What Action is the Agency Taking?

EPA is promulgating these SNURs using direct final procedures. These SNURs will require persons to notify EPA at least 90 days before commencing the manufacture or processing of a chemical substance for any activity designated by these SNURs as a significant new use. Receipt of such notices allows EPA to assess risks that may be presented by the intended uses and, if appropriate, to regulate the proposed use before it occurs. Additional rationale and background to these rules are more fully set out in the preamble to EPA's first direct final SNUR published in the **Federal Register** issue of April 24, 1990 (55 FR 17376). Consult that preamble for further information on the objectives, rationale, and procedures for SNURs and on the basis for significant new use designations, including provisions for developing test data.

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

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

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

C. Applicability of General Provisions

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

III. Significant New Use Determination

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

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

In addition to these factors enumerated in TSCA section 5(a)(2), the statute 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 37 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 TSCA section 5(e) consent order or, for non-TSCA section 5(e) SNURs, the basis for the SNUR (i.e., SNURs without TSCA section 5(e) consent orders).
- Tests recommended by EPA to provide sufficient information to evaluate the chemical substance (see Unit VIII. for more information).
 - CFR citation assigned in the regulatory text section of this rule.

The regulatory text section of this rule specifies the activities designated as significant new uses. Certain new uses, including production volume limits (i.e., limits on manufacture volume) and other uses designated in this rule, may be claimed as CBI. Unit IX. discusses a procedure companies may use to ascertain whether a proposed use constitutes a significant new use.

This rule includes 6 PMN substances that are subject to "risk-based" consent orders under TSCA section 5(e)(1)(A)(ii)(I) where EPA determined that activities associated with the PMN substances may present unreasonable risk to human health or the environment. Those consent orders require protective measures to limit exposures or otherwise mitigate the potential unreasonable risk. The so-called "TSCA section 5(e) SNURs" on these PMN substances are promulgated pursuant to § 721.160, and are based on and consistent with the provisions in the underlying consent orders. The TSCA section 5(e) SNURs designate as a "significant new use" the absence of the protective measures required in the corresponding consent orders.

Where EPA determined that the PMN substance may present an unreasonable risk of injury to human health via inhalation exposure, the underlying TSCA section 5(e)

consent order usually requires, among other things, that potentially exposed employees wear specified respirators unless actual measurements of the workplace air show that airborne concentrations of the PMN substance are below a New Chemical Exposure Limit (NCEL) that is established by EPA to provide adequate protection to human health. In addition to the actual NCEL concentration, the comprehensive NCELs provisions in TSCA section 5(e) consent orders, which are modeled after Occupational Safety and Health Administration (OSHA) Permissible Exposure Limits (PELs) provisions, include requirements addressing performance criteria for sampling and analytical methods, periodic monitoring, respiratory protection, and recordkeeping. However, no comparable NCEL provisions currently exist in 40 CFR part 721, subpart B, for SNURs. Therefore, for these cases, the individual SNURs in 40 CFR part 721, subpart E, will state that persons subject to the SNUR who wish to pursue NCELs as an alternative to the § 721.63 respirator requirements may request to do so under § 721.30. EPA expects that persons whose § 721.30 requests to use the NCELs approach for SNURs are approved by EPA will be required to comply with NCELs provisions that are comparable to those contained in the corresponding TSCA section 5(e) consent order for the same chemical substance.

This rule also includes SNURs on 31 PMN substances that are not subject to consent orders under TSCA section 5(e). These cases completed Agency review prior to June 22, 2016. Under TSCA, prior to the enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act on June 22, 2016, EPA did not find that the use scenario described in the PMN triggered the determinations set forth under TSCA section 5(e). However, EPA does believe that certain changes from the use scenario described in the PMN could result in increased exposures, thereby constituting a "significant new use."

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

PMN Number P-05-436

Chemical name: Ethylene glycol ester of an aromatic substituted propenoic acid (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as a modifier for polyester polymer. Based on structure activity relationship (SAR) analysis of test data on structurally similar substances, EPA predicts toxicity to aquatic organisms at concentrations that exceed 10 parts per billion (ppb) of the PMN substance in surface waters. As described in the PMN, releases to surface waters of the PMN substance are not expected to exceed 10 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 10 ppb may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(ii).

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

CFR citation: 40 CFR 721.10961.

PMN Number P-10-504

Chemical name: Phosphoric acid, metal salt (generic).

CAS number: Not available.

Basis for action: The PMN states that the substance will be used as a flame retardant for textiles. Based on SAR analysis of test data on analogous substances, EPA identified eye and dermal irritation as well as immunotoxicity concerns to workers from exposure to the PMN substance via the inhalation route. Additionally, based on SAR analysis of test data on analogous inorganic phosphates, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 5 ppb of the PMN substance in surface waters. For the use described in the PMN, significant releases of the substance are not expected, and worker dermal and inhalation will be minimal. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that substantial production volume increases, or use of the PMN substance other than as described in the PMN, could change exposure potential, which may cause significant adverse health and environmental

effects. Based on this information, the PMN substance meets the concern criteria at § 721.170 (b)(3)(ii) and (b)(4)(ii).

Recommended testing: EPA has determined that the results of a 90-day oral toxicity test (OPPTS Test Guideline 870.3100); a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an acute invertebrate toxicity test, freshwater daphnids (OCSPP Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the human health and environmental effects of the PMN substance. EPA also recommends that the guidance document on aquatic toxicity testing of difficult substances and mixtures (Organisation for Economic Cooperation and Development (OECD) Test Guideline 23) be followed to facilitate solubility in the test media.

CFR citation: 40 CFR 721.10962.

PMN Number P-13-289

Chemical name: Alkanoic acid, tetramethylheteromonocycle ester (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance is as an additive component to engine lubricants. Based on test data on the PMN substance, as well as SAR analysis of test data on analogous aliphatic amines and esters, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 2 ppb of the PMN substance in surface waters. As described in the PMN, releases of the substance are not expected to result in surface water concentrations that exceed 2 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that

any use of the substance resulting in surface water concentrations exceeding 2 ppb may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170 (b)(4)(i) and (b)(4)(ii).

Recommended testing: EPA has determined that the results of a 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.

CFR citation: 40 CFR 721.10963.

PMN Number P-13-908

Chemical name: Polyether polyester urethane phosphate (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance is as an additive. Based on SAR analysis of test data on analogous inorganic phosphates, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 5 ppb of the substance in surface waters for greater than 20 days per year. This 20-day criterion is derived from partial life cycle tests (daphnid chronic and fish early life stage tests) that typically range from 21 to 28 days in duration. EPA predicts toxicity to aquatic organisms may occur if releases of the substance to surface water exceed releases from manufacturing, processing, and use levels described in the PMN. For the manufacturing, processing, and use operations described in the PMN, environmental releases did not exceed 5 ppb for more than 20 days per year. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. However, EPA has determined that, if in the future there is domestic manufacture,

the use changes from that described in the PMN, or if the production volume increases substantially, the potential for release to the environment may change correspondingly and can result in significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(ii).

Recommended testing: EPA has determined that the results of an algal toxicity test (OCSPP Test Guideline 850.4500), with the PMN substance substituted for the phosphate nutrient in the algal growth medium, would help characterize the environmental effects of the PMN substance.

CFR citation: 40 CFR 721.10964.

PMN Number P-14-129

Chemical name: Propanamide, 2-hydroxy-N,N-dimethyl-.

CAS number: 35123-06-9.

Basis for action: The PMN states that the generic (non-confidential) use of the substance is as a solvent in pesticide formulations and solvent for fertilizers. Based on test data on the PMN substance, EPA identified concerns for solvent neurotoxicity, blood and liver toxicity, kidney effects, and developmental toxicity. For the uses described in the PMN, EPA does not expect significant dermal or inhalation occupational exposures, nor does it expect consumer exposures. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however that any use of the substance other than as described in the PMN, any use of the PMN substance without the use of dermal protection, where there is a potential for dermal exposures; or any use of the PMN substance in consumer products

may cause serious human health effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(3)(i).

Recommended testing: EPA has determined that the results of a dermal penetration test (OPPTS Test Guideline 870.7600) would help characterize the human health effects of the PMN substance.

CFR citation: 40 CFR 721.10965.

PMN Number P-14-260

Chemical name: 1-Propene, 2-bromo-3,3,3-trifluoro-.

CAS number: 1514-82-5.

these risks, the consent order requires:

Effective date of TSCA section 5(e) consent order: March 7, 2016.

Basis for TSCA section 5(e) consent order: The PMN states that the PMN substance will be used as a fire extinguishing agent for: portable extinguishers (onboard aviation and all nonresidential); niche systems (aircraft, normally unoccupied systems, self-contained automatic fire extinguishing systems); and streaming systems for aircraft rescue fire fighting vehicles. Based on test data on the PMN substance, EPA predicts reproductive effects to unprotected workers from repeated inhalation exposures. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I), based on a finding that the substance may present an unreasonable risk of injury to human health. To protect against

1. Use of personal protective equipment including a NIOSH-certified respirator with an APF of at least 10 or compliance with a NCEL of 1.0 parts per million (ppm) as an 8-hour time-weighted average, when there is a potential for inhalation exposures.

2. Hazard communication. Establishment and use of a hazard communication

program, including human health precautionary statements on each label and in the

Safety Data Sheet (SDS).

3. No domestic manufacture of the PMN substance.

4. Processing (including filling of hand-held fire extinguishers or fire

extinguishing systems) of the PMN substance in an enclosed process.

5. Use only as either 1) total flooding agent in unoccupied spaces, specifically

engine nacelles and auxiliary power units (APUs) in aircraft; or 2) streaming fire

extinguishing agent for use only in handheld extinguishers in aircraft.

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

measures.

Recommended testing: EPA has determined that inhalation monitoring data, collected

according to the EPA draft Inhalation Monitoring Data Collection Guidelines (located in

the docket under docket ID number EPA-HQ-OPPT-2016-0331 would help characterize

the human 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 721.10966.

PMN Number P-14-759

Chemical name: Pyrolysis oil product (generic).

CAS number: Not available.

Effective date of TSCA section 5(e) consent order: May 4, 2016.

Basis for TSCA section 5(e) consent order: The PMN states that the generic (non-confidential) use of the substance is as an on-site coolant and petroleum feed-stock.

Based on SAR analysis of test data on analogous benzene and alkyl benzenes, EPA identified concerns for oncogenicity, neurological effect, and blood toxicity to unprotected workers from repeated inhalation exposures. Further, based on SAR analysis of test data on analogous neutral organic chemicals, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 20 ppb of the PMN substance in surface waters. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I), based on a finding that the substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the consent order requires:

- 1. Use of personal protective equipment including impervious gloves (where there is a potential for dermal exposures) and a NIOSH-certified respirator with an APF of at least 10 (where there is a potential for dermal or inhalation exposures) or compliance with a NCEL of 0.5 ppm as an 8-hour time-weighted average.
- 2. Manufacture, processing, or use of the PMN substance only for the use specified in the consent order.
- 3. No use of the PMN substance resulting in releases to surface waters concentrations that exceed 20 ppb.

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

Recommended testing: EPA has determined that the results of a developmental neurotoxicity test (OPPTS Test Guideline 870.6300) with a complete blood count and

differential for white blood cells; inhalation monitoring data, collected according to the EPA draft Inhalation Monitoring Data Collection Guidelines (located in the docket under docket ID number EPA-HQ-OPPT-2016-0331; a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an acute invertebrate toxicity test, freshwater daphnids (OCSPP Test Guideline 850.1010) and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the human health and environmental 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 721.10967.

PMN Number P-15-279

Chemical name: 1-Octanamine, 7 (or 8)-(aminomethyl)-.

CAS number: 1613320-81-2.

Basis for action: The PMN states that the substance is used as a raw material for highly heat resistant plastic. Based on test data on the PMN substance, as well as SAR analysis of test data on analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 123 parts per billion of the PMN substance in surface waters. As described in the PMN, releases of the substance during the use described in the PMN are not expected to result in surface water concentrations that exceed 123 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance for the use described in the PMN may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 123 ppb may cause significant adverse

environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170 (b)(4)(i) and (b)(4)(ii).

Recommended testing: EPA has determined that the results of a 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.

CFR citation: 40 CFR 721.10968.

PMN Number P-15-409

Chemical name: Substituted alkanolamine ether (generic).

CAS number: Not available.

Effective date of TSCA section 5(e) consent order: March 3, 2016.

Basis for TSCA section 5(e) consent order: The PMN states that the substance will be used as a hydrogen sulfide scavenger. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(II) based on a finding that the substance may be produced in substantial quantities and may reasonably be anticipated to enter the environment in substantial quantities, and there may be significant (or substantial) human exposure to the substance. Based on this finding, the consent order requires:

1. Risk notification. If as a result of the test data required, the company becomes aware that the PMN substances may present a risk of injury to human health or the environment, the company must incorporate this new information, and any information on methods for protecting against such risk into an SDS, within 90 days.

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

The SNUR would designate as a "significant new use" the absence of these measures. Recommended testing: EPA has determined that the results of certain toxicity and environmental fate testing would help characterize the PMN substance. The submitter has agreed to complete the testing identified in the testing section of the consent order by the confidential limits specified.

CFR citation: 40 CFR 721.10969.

PMN Number P-15-583

Chemical name: Butanedioic acid, alkyl amine, dimethylbutyl ester (generic).

CAS number: Not available.

Effective date of TSCA section 5(e) consent order: February 8, 2016.

Basis for TSCA section 5(e) consent order: The PMN states that the substance will be used as an additive to engine motor oil. Based on physical-chemical properties data, EPA predicts that the PMN substance will persist in the environment, could bioaccumulate or biomagnify, and could be toxic (PBT) to people, wild mammals, and birds. Further, based on test data on the PMN, as well as SAR analysis of analogous aliphatic amines, 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(e)(1)(A)(i), 5(e)(1)(A)(ii)(I), and 5(e)(1)(A)(ii)(II) based on a finding that the substance may present an unreasonable risk of injury to the environment and human health, the substance may be produced in substantial quantities and may reasonably be anticipated to

enter the environment in substantial quantities, and there may be significant (or substantial) human exposure to the substance. To protect against these exposures and risks, the consent order requires:

- 1. Risk notification. If as a result of the test data required, the company becomes aware that the PMN substances may present a risk of injury to human health or the environment, the company must incorporate this new information, and any information on methods for protecting against such risk into an SDS, within 90 days.
- 2. Submission of certain toxicity, physical-chemical property, and environmental fate testing on the PMN substance prior to exceeding the confidential production volume limits as specified in the consent order.
- 3. No releases of the PMN substance into the waters of the United States.

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

Recommended testing: EPA has determined that the results of certain toxicity and environmental fate testing would help characterize the PMN substance. The submitter has agreed to complete the testing identified in the testing section of the consent order by the confidential limits specified. In addition, EPA has determined that the results of a 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. 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 721,10970.

PMN Number P-15-672

Chemical name: Carbon nanotube (generic).

CAS number: Not available.

Effective date of TSCA section 5(e) consent order: January 15, 2016.

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

- 1. Use of personal protective equipment involving impervious gloves and protective clothing (where there is a potential for dermal exposure) and a NIOSH-certified respirator with N-100, P-100, or R-100 cartridges (where there is a potential for inhalation exposure).
- Processing and use of the PMN substance only for the use specified in the consent order.
- 3. Processing and use of the PMN substance only as an aqueous slurry, wet form, or a contained dry form as described in the PMN.
- 4. No use of the PMN substance resulting in releases to surface waters and disposal of the PMN substance only by landfill or incineration.

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

Recommended testing: EPA has determined that 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 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 721.10971.

PMN Number P-15-678

Chemical name: Metal salt of mineral acid, reaction products with alumina, aluminum hydroxide, aluminum hydroxide oxide (Al(OH)O), silica, titanium oxide (TiO2) and 3-(triethoxysilyl)-1-propanamine (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance is as an industrial paper additive. Based on SAR analysis of test data on analogous respirable, poorly soluble particulates, EPA identified concerns for lung toxicity if inhaled based on lung overload. As described in the PMN, inhalation is expected to be minimal for this use. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance other than as identified in

the PMN may result in serious health effects. Based on this information, the PMN meets the concern criteria at § 721.170(b)(3)(ii).

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

CFR citation: 40 CFR 721.10972.

CAS numbers: Not available.

PMN Numbers P-15-766 and P-15-767

Chemical names: Halogenated bisphenol A, polymer with epichlorohydrin, alkenoate (generic) (P-15-766) and Halogenated bisphenol A, polymer with bisphenol A diglycidyl ether and epoxidized phenol-formaldehyde resin, alkenoate (generic) (P-15-767).

Basis for action: The PMNs state that the generic (non-confidential) use of the substances will be as resins for flame retardant polyester. Based on test data on the confidential impurity of the PMN substance, EPA identified concerns for chronic toxicity effects to workers and the general population exposed to the PMN substances. Further, based on the confidential impurity, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 20 ppb of the impurity in surface waters. As described in the PMNs, EPA does not expect significant occupational exposures, general population exposures, nor releases of the substance to result in surface water concentrations that exceed 20 ppb of the impurity in surface waters. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substances may present an unreasonable risk. EPA has determined, however, that any consumer use, any use other than as described in the PMNs, or any increase in production volume over 10,000 kg/yr

may result in serious human health and significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(5)(ii). *Recommended testing*: EPA has determined that the results of a combined repeated dose toxicity test (OECD Test Guideline 422) with the reproduction/developmental toxicity screening test; 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 the human health and environmental effects of the PMN substances.

CFR citations: 40 CFR 721.10973 (P-15-766) and 40 CFR 721.10974 (P-15-767).

PMN Number P-16-14

Chemical name: Silicon, tris[dialkyl phenyl]-dialkyl-dioxoalkane-naphthalene disulfonate (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance is as an ink additive. Based on test data on the PMN substance, as well as SAR analysis of test data on analogous diketones, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 6 ppb of the PMN substance in surface waters. As described in the PMN, releases of the substance during the use described in the PMN are not expected to result in surface water concentrations that exceed 6 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance for the use described in the PMN may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 6 ppb may cause significant adverse environmental effects. Based on this

information, the PMN substance meets the concern criteria at § 721.170 (b)(4)(i) and (b)(4)(ii).

Recommended testing: EPA has determined that the results of a ready biodegradability test (OECD Test Guideline 301); a fish early-life state 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.

CFR citation: 40 CFR 721.10975.

PMN Number P-16-40

Chemical name: Tar acids fraction (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance is as a polymer. Based on test data on the PMN substance, as well as SAR analysis of test data on analogous phenols, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 45 ppb of the PMN substance in surface waters. As described in the PMN, releases of the substance during the use described in the PMN are not expected to result in surface water concentrations that exceed 45 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance for the use described in the PMN may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 45 ppb may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170 (b)(4)(i) and (b)(4)(ii).

Recommended testing: EPA has determined that the results of a fish early-life state 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 the environmental effects of the PMN substance.

CFR citation: 40 CFR 721.10976.

PMN Numbers P-16-59 and P-16-60

Chemical names: Dialkyl fattyalkylamino propanamide alkylamine (generic) (P-16-59) and Fattyalkylaminopropanoate ester (generic) (P-16-60).

CAS numbers: Not available.

Basis for action: The PMNs state that the substances will be used as chemical intermediates. Based on data on the PMN substances, as well as SAR analysis of test data on analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PMN substances in surface waters. As described in the PMNs, releases of the substance are not expected to result in surface water concentrations that exceed 1 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substances resulting in surface water concentrations exceeding 1 ppb may cause significant adverse environmental effects. Based on this information, the PMN substances meets the concern criteria at § 721.170(b)(4)(i).

Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (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 the environmental effects of the PMN substances.

CFR citations: 40 CFR 721.10977 (P-16-59) and 40 CFR 721.10978 (P-16-60).

PMN Number P-16-70

Chemical Name: Boron sodium oxide (B5NaO8), labeled with boron-10.

CAS Number: 200443-98-7.

Basis for Action: The PMN states that this substance is to be used as an emergency shutdown coolant in boiling water reactors. Based on test data for boron compounds, the EPA identified potential human health concerns regarding reproductive effects, developmental toxicity, neurotoxicity, and blood effects from exposure to the PMN substance via inhalation exposure. Further, based on SAR analysis of test data on boron compounds, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1,240 ppb of the PMN substance in surface waters for greater than 20 days per year. This 20-day criterion is derived from partial life cycle tests (daphnid chronic and fish early life stage tests) that typically range from 21 to 28 days in duration. EPA predicts toxicity to aquatic organisms may occur if releases of the substance to surface water, from uses other than as described in the PMN, exceed releases from the use described in the PMN. For the use described in the PMN, inhalation and dermal exposures are expected to be minimal and environmental releases did not exceed 1,240 ppb for more than 20 days per year. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance other than as listed in the PMN may result in serious human health and significant adverse environmental effects.

Based on this information, the PMN substance meet the concern criteria at § 721.170 (b)(3)(ii) and (b)(4)(ii).

Recommended Testing: EPA has determined that the results of a reproductive/developmental toxicity screening test (OPPTS 870.3550/OECD Test Guideline 421); a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an acute invertebrate toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the human health and environmental effects of the PMN substance.

CFR Citation: 40 CFR 721.10979.

PMN Number P-16-94

Chemical name: Perfluoropolyether modified organosilane (generic).

CAS number: Not available.

Basis for action: The PMN states that the substance will be used as a stain-proof coating agent for touch panel. Based on physical-chemical properties data on the PMN substance, as well as SAR analysis of test data on analogous perfluorinated chemicals and potential perfluorinated degradation products, EPA identified concerns for irritation to skin, eyes, lungs, mucous membranes, lung toxicity, liver toxicity, blood toxicity, male reproductive toxicity, immunosupression, and oncogenicity. EPA has concerns that these degradation products will persist in the environment, could bioaccumulate or biomagnify, and could be toxic (PBT) to people, wild mammals, and birds. EPA predicts adverse effects to human health and the environment may occur if releases of the PMN substance to surface water at production volumes higher than described in the PMN exceed the releases expected from the production volume described in the PMN. For the described production volume in the PMN, significant environmental releases are not expected.

Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any substantial combined production volume increase could result in exposures which may cause serious human health and significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at $\S721.170$ (b)(1)(i)(D), (b)(3)(iii), and (b)(4)(iv).

Recommended testing: EPA has determined that the results of an indirect photolysis screening test: sunlight photolysis in waters containing dissolved humic substances (OPPTS Test Guideline 835.5270), and simulation tests to assess the primary and ultimate biodegradability of chemicals discharged to wastewater (OPPTS Test Guideline 835.3280/OECD Test Guideline 314) would help characterize the environmental effects of the PMN substance.

CFR citation: 40 CFR 721.10980.

PMN Number P-16-95

Chemical name: Modified phenol-formaldehyde resin (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance is as a flame retardant additive. Based on SAR analysis of test data on analogous neutral organics, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 96 ppb of the PMN substance in surface waters. Further, based on the alcohol groups, EPA has concern for irritation to eyes, lungs, and mucous membranes. As described in the PMN, releases of the substance are not expected to result in surface water concentrations that exceed 96 ppb and exposures to workers and general population

are minimal due to the use as a flame retardant additive. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that use of the substance other than as stated in the PMN or any use of the substance resulting in surface water concentrations exceeding 96 ppb may result in serious human health and significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170 (b)(3)(ii) and (b)(4)(ii).

Recommended testing: EPA has determined that the results of an acute toxicity test (OPPTS Test Guideline 870.1000); a repeated dose 28-day oral toxicity study (OPPTS Test Guideline 870.3050) in rodents; a bacterial reverse mutation test (OPPTS Test Guideline 870.5100); a mammalian erythrocyte micronucleus test (OPPTS Test Guideline 870.5395); a fish early-life stage toxicity test (OCSPP Test Guideline 850.1300); and an algal toxicity test (OCSPP Test Guideline 850.1300) would help characterize the human health and environmental effects of the PMN substance.

CFR citation: 40 CFR 721.10981.

PMN Number P-16-101

Chemical name: Disubstituted benzene alkanal (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as a component for household products, including cleaning, fabric and air care.

Based on SAR analysis of test data on analogous structurally similar substances, EPA identified concerns for developmental toxicity from dermal exposures of the PMN

substance to workers and consumers. For the use described in the PMN, dermal exposures are not expected based on the use of impervious gloves, and consumer dermal exposures are expected to be minimal. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substances may present an unreasonable risk. EPA has determined, however, that any use of the PMN substance without the use of dermal protection, where there is a potential for dermal exposures, or any use of the PMN substance other than for the use specified in the PMN may result in serious human health effects. Based on this information, the PMN substance meet the concern criteria at § 721.170(b)(3)(ii).

Recommended testing: EPA has determined that results of a 90-day oral toxicity test (OPPTS Test Guideline 870.3100) in rats via the gavage route, and a developmental toxicity test OPPTS Test Guideline 870.3650) in rats via the gavage route would help characterize the effects of the PMN substance.

CFR citation: 40 CFR 721.10982.

PMN Number P-16-102

Chemical name: Phthalic anhydride, polymer with alkylene glycol and alkanepolyol, acrylate (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance is as a coating component. Based on SAR analysis of test data on analogous acrylates, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PMN substance in surface waters. As described in the PMN, releases of the substance during the use described in the PMN are not expected to result in surface water

concentrations that exceed 1 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance for the use described in the PMN may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 1 ppb may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(ii).

Recommended testing: EPA has determined that the results of a water solubility test (OPPTS Test Guideline 830.7840, a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an acute invertebrate toxicity test, freshwater daphnids (OCSPP Test Guideline 850.1010); and algal toxicity test (OCSPP Test Guideline 850.4500); would help characterize the environmental effects of the PMN substance.

CFR citation: 40 CFR 721.10983.

PMN Number P-16-104

Chemical name: 2-Pyridinecarboxylic acid, 4,5-dichloro-6-(4-chloro-2-fluoro-3-

methoxyphenyl)-.

CAS number: 1546765-39-2.

Basis for action: The PMN states that the generic (non-confidential) use of the substance is as a feed stock for an intermediate. Based on SAR analysis of test data on analogous halopyridines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 8 ppb of the PMN substance in surface waters. Further, based on the acid moiety, EPA has concern for irritation to eyes, lungs, and mucous membranes. As described in the PMN, releases of the substance are not expected to result in surface

water concentrations that exceed 8 ppb and exposures to workers and general population are minimal due to the use as an intermediate. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that use of the substance other than as an intermediate or any use of the substance resulting in surface water concentrations exceeding 8 ppb may result in serious human health and significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170 (b)(3)(ii) and (b)(4)(ii).

Recommended testing: EPA has determined that the results of an acute toxicity test (OPPTS Test Guideline 870.1000); a repeated dose 28-day oral toxicity study (OPPTS Test Guideline 870.3050) in rodents; a bacterial reverse mutation test (OPPTS Test Guideline 870.5100); a mammalian erythrocyte micronucleus test (OPPTS Test Guideline 870.5395); a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an acute invertebrate toxicity test, freshwater daphnids (OCSPP Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the human health and environmental effects of the PMN substance.

CFR citation: 40 CFR 721.10984.

PMN Numbers P-16-136, P-16-139, and P-16-140

Chemical names: Dialkylamino alkylamide inner salt (generic).

CAS numbers: Not available.

Basis for action: The PMNs state that the generic (non-confidential) use of these substances is in oil production. Based on SAR analysis of test data on analogous aliphatic

amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PMN substances in surface waters. As described in the PMNs, releases of these substances are not expected to result in surface water concentrations that exceed 1 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substances may present an unreasonable risk. EPA has determined, however, that any use of the substances resulting in surface water concentrations exceeding 1 ppb may cause significant adverse environmental effects.

Based on this information, the PMN substances meets the concern criteria at § 721.170(b)(4)(ii).

Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OCSPP Test Guideline 850.1400); a mysid chronic toxicity test (OCSPP Test Guideline 850.1350); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substances. Testing should be conducted on PMN substance P-16-139.

CFR citation: 40 CFR 721.10985.

PMN Number P-16-170

Chemical name: Nanocarbon (generic).

CAS number: Not available.

Effective date of TSCA section 5(e) consent order: June 21, 2016.

Basis for TSCA section 5(e) consent order: The PMN states that the substance will be used as an additive to composite materials. Based on test data on analogous respirable, poorly soluble particulates and nanocarbon materials, EPA identified concerns for pulmonary toxicity and oncogenicity. Based on test data for other nanocarbon materials

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

- 1. Use of personal protective equipment involving impervious gloves and protective clothing (where there is a potential for dermal exposure) and a NIOSH-certified respirator with N-100, P-100, or R-100 cartridges (where there is a potential for inhalation exposure).
 - 2. Submission of a dustiness test within six months of notice of commencement.
- 3. Submission of a 90-day chronic inhalation study prior to exceeding the confidential production volume limit specified in the consent order.
- 4. Processing and use of the PMN substance only for the use specified in the consent order including no application method that generates a vapor, mist or aerosol unless the application method occurs in an enclosed process.
- 5. No use of the PMN substance resulting in releases to surface waters and disposal of the PMN substance only by landfill or incineration.

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

Recommended testing: EPA has determined that the development of data on certain physical-chemical properties, as well as certain human health and environmental toxicity testing would help characterize possible effects of the substance. The submitter has agreed to provide a dustiness test (European Standard EU 15051) by six months from commencement of manufacture. In addition, the submitter has agreed not to exceed the

confidential production limit without performing a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465 or OECD Test Guideline 413) in rats with a postexposure observation period of up to 9 months (including BALF analysis, a determination of cardiovascular toxicity (clinically-based blood/plasma protein analyses), and histopathology of the heart). Although the order does not require a two-year inhalation bioassay (OPPTS Test Guideline 870.4200), a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300), a fish early-life stage toxicity test (OCSPP Test Guideline 850.1400), or an algal toxicity test (OCSPP Test Guideline 850.4500), the Order's restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

CFR citation: 40 CFR 721.10986.

PMN Number P-16-177

Chemical name: Barium molybdenum niobium tantalum tellurium vanadium zinc oxide.

CAS number: 1440529-21-4.

Basis for action: The PMN states that the generic (non-confidential) use of the substance is as a glass coating. Based on SAR analysis of test data on the analogous respirable, poorly soluble particulates, EPA identified concerns for lung effects to workers exposed to the PMN substance. As described in the PMN, worker exposure will be minimal due to the use of adequate respiratory protection. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that use of the substance without a National Institute for Occupational Safety and Health (NIOSH)-certified respirators with an assigned

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protection factor (APF) of at least 10, where there is potential respiratory exposure, any use other than in the PMN, or domestic manufacture may result in serious human health effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(3)(ii).

Recommended testing: EPA has determined that the results of a 90-day subchronic toxicity test (OPPTS Test Guideline 870.3465) via the inhalation route with a 60-day holding period would help characterize the human health effects of the PMN substance. *CFR citation:* 40 CFR 721.10987.

PMN Number P-16-179

Chemical name: Alkanoic acids, esters with alkanetriol (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance is as a grease. Based on SAR analysis of test data on analogous esters, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PMN substance in surface waters. As described in the PMN, releases of the substance are not expected to result in surface water concentrations that exceed 1 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 1 ppb may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(ii).

Recommended testing: EPA has determined that the results of a fish 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 the environmental effects of the PMN substance.

CFR citation: 40 CFR 721.10988.

PMN Number P-16-182

Chemical names: Manganese, tris[.mu.-(2-ethylhexanoato-

.kappa.O:.kappa.O')]bis(octahydro-1,4,7-trimethyl-1H-1,4,7-triazonine-

.kappa.N1,.kappa.N4,.kappa.N7)di- (P-16-182, chemical A); Manganese, [.mu.-(acetato-

.kappa.O:.kappa.O')]bis[.mu.-(2-ethylhexanoato-.kappa.O:.kappa.O')]bis(octahydro-

1,4,7-trimethyl-1H-1,4,7-triazonine-.kappa.N1,.kappa.N4,.kappa.N7)di- (P-16-182,

chemical B); Manganese, bis[.mu.-(acetato-.kappa.O:.kappa.O')][.mu.-(2-

ethylhexanoato-.kappa.O:.kappa.O')]bis(octahydro-1,4,7-trimethyl-1H-1,4,7-triazonine-

.kappa.N1,.kappa.N4,.kappa.N7)di- (P-16-182, chemical C); and Manganese, tris[.mu.-

(acetato-.kappa.O:.kappa.O')]bis(octahydro-1,4,7-trimethyl-1H-1,4,7-triazonine-

.kappa.N1,.kappa.N4,.kappa.N7)di- (P-16-182, chemical D).

CAS numbers: 2020407-62-7 (P-16-182, chemical A); 2020407-63-8 (P-16-182,

chemical B); 2020407-64-9 (P-16-182, chemical C); and 2020407-65-0 (P-16-182,

chemical D).

Basis for action: The PMN states that the generic (non-confidential) use of the substances will be as resins. Based on SAR analysis of test data on analogous compounds, EPA identified concerns for systemic effects to the thyroid and pituitary gland, liver toxicity, developmental and reproductive toxicity, and mutagenicity. There are also concerns for immunotoxicity, reproductive and developmental toxicity, neurotoxicity, blood effects, and kidney toxicity, and uncertain concerns for asthma and

oncogenicity, based on manganese, and concerns for developmental toxicity for branched acid hydrolysis products, by analogy to valproic acid and other acids that are branched on the carbon adjacent to the acid group, all based on exposure to the PMN substances via inhalation or dermal exposure. As described in the PMN, exposure is expected to be minimal due to negligible inhalation exposures and use of adequate dermal personal protection equipment. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substances may present an unreasonable risk. EPA has determined, however, that any domestic manufacture; any manufacture of the PMN substances at a concentration greater than 10% in any formulation; or any use of the PMN substances without the use of chemical impervious gloves, where there is a potential for dermal exposures may result in serious human health effects. Based on this information, the PMN substances meet the concern criteria at 40 CFR 721.170(b)(3)(ii). Recommended testing: EPA has determined that the results of a combined repeated dose toxicity reproduction/development toxicity screening test (OECD Test Guideline 422) would help characterize the human health effects of the PMN substances. CFR citations: 40 CFR 721.10989 (P-16-182, chemical A), 40 CFR 721.10990 (P-16-182, chemical B), 40 CFR 721.10991 (P-16-182, chemical C), and 40 CFR 721.10992 (P-16-182, chemical D).

PMN Number P-16-190

Chemical name: Aryl polyolefin (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as a lubricant. Based on analogy to C10-13 alkyl derivatives of benzene, EPA

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identified concerns for reproductive and developmental toxicity to workers exposed to the PMN substance based on exposure to the PMN substance via dermal exposure. As described in the PMN, exposure is expected to be minimal due to use of adequate dermal personal protection equipment. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that use of the substance other than as described in the PMN, or any use without the use of dermal protection where there is a potential for dermal exposures may cause serious human health effects. Based on this information, the PMN substance meets the concern criteria at 40 CFR 721.170(b)(3)(ii).

Recommended testing: EPA has determined that the results of a two-generation reproduction toxicity test (OECD Test Guideline 416) would help characterize the human health effects of the PMN substance.

CFR citation: 40 CFR 721.10993.

PMN Number P-16-260

Chemical name: Melamine nitrate (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance is as a gas generant for automobile air bag inflators. Based on test data on the PMN substance, as well as SAR analysis of test data on analogous melamines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 14 ppb of the PMN substance in surface waters. As described in the PMN, releases of the substance during the use described in the PMN are not expected to result in surface water concentrations that exceed 14 ppb. Therefore, EPA has not determined that the proposed manufacturing,

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processing, or use of the substance for the use described in the PMN may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 14 ppb may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170 (b)(4)(i) and (b)(4)(ii).

Recommended testing: 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.

CFR citation: 40 CFR 721.10994.

PMN Number P-16-272

Chemical name: Lecithins, soya, hydrogenated.

CAS number: 308068-11-3.

Basis for action: The PMN states that the generic (non-confidential) use of the substance is an ingredient in a formulated product. Based on SAR analysis of test data on analogous amphoteric surfactants, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PMN substance in surface waters. As described in the PMN, releases of the substance during the use described in the PMN are not expected to result in surface water concentrations that exceed 1 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance for the use described in the PMN may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations

exceeding 1 ppb may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(ii). *Recommended testing*: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test, freshwater daphnids (OCSPP Test Guideline 850.1010); an algal toxicity test (OCSPP Test Guideline 850.4500); 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. *CFR citation:* 40 CFR 721.10995.

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 6 of the 37 chemical substances, regulation was warranted under TSCA section 5(e), pending the development of information sufficient to make reasoned evaluations of the health or environmental effects of the chemical substances. The basis for such findings is outlined in Unit IV. Based on these findings, TSCA section 5(e) consent orders requiring the use of appropriate exposure controls were negotiated with the PMN submitters. The SNUR provisions for these chemical substances are consistent with the provisions of the TSCA section 5(e) consent orders. These SNURs are promulgated pursuant to § 721.160 (see Unit VI.).

In the other 31 cases, where the uses are not regulated under a TSCA section 5(e) consent order, EPA determined that one or more of the criteria of concern established at § 721.170 were met, as discussed in Unit IV.

B. Objectives

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

- EPA will receive notice of any person's intent to manufacture or process a listed chemical substance for the described significant new use before that activity begins.
- EPA will have an opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing or processing a listed chemical substance for the described significant new use.
- EPA will be able to either determine that the prospective manufacture or processing is not likely to present an unreasonable risk, or to take necessary regulatory action associated with any other determination, before the described significant new use of the chemical substance occurs.
- EPA will ensure that all manufacturers and processors of the same chemical substance that is subject to a TSCA section 5(e) consent order are subject to similar requirements.

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

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

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

VI. Direct Final Procedures

EPA is issuing these SNURs as a direct final rule, as described in § 721.160(c)(3) and § 721.170(d)(4). In accordance with § 721.160(c)(3)(ii) and § 721.170(d)(4)(i)(B), the effective date of this rule is [insert date 60 days after date of publication in the Federal Register] without further notice, unless EPA receives written adverse or critical comments, or notice of intent to submit adverse or critical comments before [insert date 30 days after date of publication in the Federal Register].

If EPA receives written adverse or critical comments, or notice of intent to submit adverse or critical comments, on one or more of these SNURs before [insert date 30 days after date of publication in the **Federal Register**], EPA will withdraw the relevant sections of this direct final rule before its effective date. EPA will then issue a proposed SNUR for the chemical substance(s) on which adverse or critical comments were received, providing a 30-day period for public comment.

This rule establishes SNURs for a number of chemical substances. Any person who submits adverse or critical comments, or notice of intent to submit adverse or critical comments, must identify the chemical substance and the new use to which it applies.

EPA will not withdraw a SNUR for a chemical substance not identified in the comment.

VII. Applicability of 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 6 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 26 of the 37 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 June 1, 2017 which is the date of public release by posting on EPA's website, as the cutoff date for determining whether the new use is ongoing. This designation varies slightly from EPA's past practice of designating the date of **Federal Register** publication as the date for making this determination. The objective of EPA's approach has been to ensure that a person could not defeat a SNUR by initiating a significant new use before the effective date of the direct final rule. In developing this rule, EPA has recognized that, given EPA's practice of now posting rules on its website a week or more in advance of **Federal Register** publication, this objective could be thwarted even before that publication. Thus, EPA has slightly modified its approach in this rulemaking and plans to follow this modified approach in future significant new use rulemakings.

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

VIII. Development and Submission of Information

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

In the absence of a TSCA section 4 test rule covering the chemical substance, persons are required only to submit information in their possession or control and to describe any other information known to or reasonably ascertainable by them (see 40 CFR 720.50). However, upon review of PMNs and SNUNs, the Agency has the authority to require appropriate testing. In cases where EPA issued a TSCA section 5(e) consent order that requires or recommends certain testing, Unit IV. lists those tests. Unit IV. also lists recommended testing for non-TSCA section 5(e) SNURs. Descriptions of tests are provided for informational purposes. EPA strongly encourages persons, before

performing any testing, to consult with the Agency pertaining to protocol selection. To access the OCSPP test guidelines referenced in this document electronically, please go to http://www.epa.gov/ocspp and select "Test Methods and Guidelines." The Organisation for Economic Co-operation and Development (OECD) test guidelines are available from the OECD Bookshop at http://www.oecdbookshop.org or SourceOECD at http://www.sourceoecd.org.

In the TSCA section 5(e) consent orders for several of the chemical substances regulated under this rule, EPA has established production volume limits in view of the lack of data on the potential health and environmental risks that may be posed by the significant new uses or increased exposure to the chemical substances. These limits cannot be exceeded unless the PMN submitter first submits the results of toxicity tests that would permit a reasoned evaluation of the potential risks posed by these chemical substances. Under recent TSCA section 5(e) consent orders, each PMN submitter is required to submit each study at least 14 weeks (earlier TSCA section 5(e) consent orders required submissions at least 12 weeks) before reaching the specified production limit. Listings of the tests specified in the TSCA section 5(e) consent orders are included in Unit IV. The SNURs contain the same production volume limits as the TSCA section 5(e) consent orders. Exceeding these production limits is defined as a significant new use. Persons who intend to exceed the production limit must notify the Agency by submitting a SNUN at least 90 days in advance of commencement of non-exempt commercial manufacture or processing.

The recommended tests specified in Unit IV. may not be the only means of addressing the potential risks of the chemical substance. However, submitting a SNUN

without any test data may increase the likelihood that EPA will take action under TSCA section 5(e), particularly if satisfactory test results have not been obtained from a prior PMN or SNUN submitter. EPA recommends that potential SNUN submitters contact EPA early enough so that they will be able to conduct the appropriate tests.

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

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

IX. Procedural Determinations

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

Under these procedures a manufacturer or processor may request EPA to determine whether a proposed use would be a significant new use under the rule. The manufacturer or processor must show that it has a *bona fide* intent to manufacture or process the chemical substance and must identify the specific use for which it intends to manufacture or process the chemical substance. If EPA concludes that the person has

shown a *bona fide* intent to manufacture or process the chemical substance, EPA will tell the person whether the use identified in the *bona fide* submission would be a significant new use under the rule. Since most of the chemical identities of the chemical substances subject to these SNURs are also CBI, manufacturers and processors can combine the *bona fide* submission under the procedure in § 721.1725(b)(1) with that under § 721.11 into a single step.

If EPA determines that the use identified in the *bona fide* submission would not be a significant new use, i.e., the use does not meet the criteria specified in the rule for a significant new use, that person can manufacture or process the chemical substance so long as the significant new use trigger is not met. In the case of a production volume trigger, this means that the aggregate annual production volume does not exceed that identified in the *bona fide* submission to EPA. Because of confidentiality concerns, EPA does not typically disclose the actual production volume that constitutes the use trigger. Thus, if the person later intends to exceed that volume, a new *bona fide* submission would be necessary to determine whether that higher volume would be a significant new use.

X. SNUN Submissions

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

in 40 CFR 720.40 and § 721.25. E-PMN software is available electronically at http://www.epa.gov/opptintr/newchems.

XI. Economic Analysis

EPA has evaluated the potential costs of establishing SNUN requirements for potential manufacturers and processors of the chemical substances subject to this rule. EPA's complete economic analysis is available in the docket under docket ID number EPA-HQ-OPPT-2016-0331.

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. 601 *et seq.*), that promulgation of a SNUR does not have a significant economic impact on a substantial number of small entities where the following are true:

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

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

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

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

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

D. Unfunded Mandates Reform Act (UMRA)

Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reasons to believe that any State, local, or Tribal government will be impacted by this action. As such, EPA has determined that this action does not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small

governments subject to the requirements of UMRA sections 202, 203, 204, or 205 (2 U.S.C. 1501 *et seq.*).

E. Executive Order 13132

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

F. Executive Order 13175

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

G. Executive Order 13045

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

H. Executive Order 13211

This action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR

28355, May 22, 2001), because this action is not expected to affect energy supply, distribution, or use and because this action is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

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

J. Executive Order 12898

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

XIII. Congressional Review Act

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

| List | of | Su | bi | ects |
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40 CFR Part 9

Environmental protection, Reporting and recordkeeping requirements.

40 CFR Part 721

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

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Maria J. Doa, Ph.D.

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

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

PART 9--[AMENDED]

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

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

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

§ 9.1 OMB approvals under the Paperwork Reduction Act.

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| 40 CFR citation | | | OMB control No. | | |
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| Significant New Uses of Chemical Substances | | | | | |
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| 721.10 | 961 | | 2070-0012 | | |
| 721. 10 | 962 | | 2070-0012 | | |
| 721. 10 |)963 | | 2070-0012 | | |
| 721. 10 |)964 | | 2070-0012 | | |
| 721. 10 |)965 | | 2070-0012 | | |
| 721. 10 |)966 | | 2070-0012 | | |

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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 § 721.10961 to subpart E to read as follows:

§ 721.10961 Ethylene glycol ester of an aromatic substituted propenoic acid (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as ethylene glycol ester of an aromatic substituted propenoic acid (PMN P-05-436) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) (N=10).
 - (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.

- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (c) and (k) are applicable to manufacturers and processors of this substance.
- (2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.
 - 5. Add § 721.10962 to subpart E to read as follows:

§ 721.10962 Phosphoric acid, metal salt (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as phosphoric acid, metal salt (PMN P-10-504) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(j) and (s) (100,000 kilograms).
 - (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (c) and (i) are applicable to manufacturers and processors of this substance.
- (2) Limitations or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.
- (3) Determining whether a specific use is subject to this section. The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.
 - 6. Add § 721.10963 to subpart E to read as follows:

§ 721.10963 Alkanoic acid, tetramethylheteromonocycle ester (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as alkanoic acid, tetramethylheteromonocycle ester (PMN P-13-289) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) (N=2).
 - (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (c) and (k) are applicable to manufacturers and processors of this substance.
- (2) Limitations or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.
 - 7. Add § 721.10964 to subpart E to read as follows:

§ 721.10964 Polyether polyester urethane phosphate (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as polyether polyester urethane phosphate (PMN P-13-908) 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), (j) and (s) (1,000 kilograms).
 - (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (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.
 - 8. Add § 721.10965 to subpart E to read as follows:

§ 721.10965 Propanamide, 2-hydroxy-N,N-dimethyl-.

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as propanamide, 2-hydroxy-N,N-dimethyl- (PMN P-14-129, CAS No. 35123-06-9) 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)(2)(i), (a)(3), and (b) (concentration set at 1.0 percent).
- (ii) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(j) and (o).

- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (e) and (i) are applicable to manufacturers and processors of this substance.
- (2) Limitations or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.
- (3) Determining whether a specific use is subject to this section. The provisions of \$721.1725(b)(1) apply to paragraph (a)(2)(ii) of this section.
 - 9. Add § 721.10966 to subpart E to read as follows:

§ 721.10966 1-Propene, 2-bromo-3,3,3-trifluoro-.

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as 1-propene, 2-bromo-3,3,3-trifluoro- (PMN P-14-260, CAS No. 1514-82-5) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this rule do not apply to quantities of the PMN substance after they have been charged into a fire extinguisher or fire extinguishing system.
 - (2) The significant new uses are:
- (i) *Protection in the workplace*. (A) Requirements as specified in § 721.63(a)(1), (a)(3), (a)(4), (a)(6)(v), (a)(6)(vi), (b) (concentration set at 1.0 percent), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) and (a)(4), engineering control measures (*e.g.*, enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.*, workplace policies and procedures) shall be considered and implemented to prevent

exposure, where feasible. The following National Institute for Occupational Safety and Health (NIOSH)-certified respirator with an Applied Protection Factor (APF) of at least 10 meet the requirements of § 721.63(a)(4):

- (1) NIOSH-certified air-purifying half mask respirator equipped with a gas/vapor (organic vapor) cartridge.
- (2) NIOSH-certified powered air-purifying respirator with a hood or helmet and with a gas/vapor (organic vapor) cartridge.
- (3) NIOSH-certified negative pressure (demand) supplied-air respirator with a half-mask.
- (4) NIOSH-certified continuous flow supplied-air respirator with a loose fitting facepiece, hood, or helmet.
- (5) NIOSH-certified negative pressure (demand) self-contained breathing apparatus (SCBA) with a half-mask.
- (B) As an alternative to the respirator requirements in paragraph (a)(2)(i) of this section, a manufacturer or processor may choose to follow the new chemical exposure limit (NCEL) provision listed in the TSCA section 5(e) consent order for this substance. The NCEL is 1.0 parts per million (ppm) as an 8-hour time weighted average. Persons who wish to pursue NCELs as an alternative to § 721.63 respirator requirements may request to do so under § 721.30. Persons whose § 721.30 requests to use the NCELs approach are approved by EPA will be required to follow NCELs provisions comparable to those contained in the corresponding TSCA section 5(e) consent order.

- (ii) *Hazard communication program*. Requirements as specified in § 721.72(a) through (e) (concentration set at 1.0 percent), (f), (g)(1) (cardiac sensitization and reproductive effects), (g)(2)(i), (g)(2)(ii), (g)(2)(iv), (g)(2)(v), and (g)(5).
- (iii) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(c), (f), and (k) (A significant new use is any use other than as either a total flooding agent in unoccupied spaces, specifically engine nacelles and auxiliary power units (APUs) in aircraft; or as a streaming fire extinguishing agent for use only in handheld extinguishers in aircraft).
- (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 § 721.10967 to subpart E to read as follows:

§ 721.10967 Pyrolysis oil product (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as pyrolysis oil product (PMN P-14-759) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) *Protection in the workplace*. Requirements as specified in § 721.63(a)(1), (a)(3), (a)(4), (a)(6) (particulate and gas/vapor), (b) (concentration set at 0.1 percent), and

- (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) and (a)(4), engineering control measures (*e.g.*, enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.*, workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. The following National Institute for Occupational Safety and Health (NIOSH)-certified respirator with an Applied Protection Factor (APF) of at least 10 meet the requirements of § 721.63(a)(4):
- (A) NIOSH-certified air-purifying half mask respirator equipped with an organic vapor cartridge.
- (*B*) NIOSH-certified powered air-purifying respirator with a hood or helmet and with an organic vapor cartridge.
- (C) NIOSH-certified negative pressure (demand) supplied-air respirator with a half-mask.
- (D) NIOSH-certified continuous flow supplied-air respirator with a loose fitting facepiece, hood, or helmet.
- (E) NIOSH-certified negative pressure (demand) self-contained breathing apparatus (SCBA) with a half-mask.

As an alternative to the respirator requirements in paragraph (a)(2)(i) of this section, a manufacturer or processor may choose to follow the new chemical exposure limit (NCEL) provision listed in the TSCA section 5(e) consent order for this substance. The NCEL is 0.5 parts per million (ppm) as an 8-hour time weighted average. Persons who wish to pursue NCELs as an alternative to § 721.63 respirator requirements may request to do so under § 721.30. Persons whose § 721.30 requests to use the NCELs

approach are approved by EPA will be required to follow NCELs provisions comparable to those contained in the corresponding TSCA section 5(e) consent order.

- (ii) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(k).
- (iii) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) (N=20).
- (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) 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.
 - 11. Add § 721.10968 to subpart E to read as follows:

§ 721.10968 1-Octanamine, 7 (or 8)-(aminomethyl)-.

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as 1-octanamine, 7 (or 8)-(aminomethyl)- (PMN P-15-279, CAS No. 1613320-81-2) 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) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) (N=123).

- (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (c) and (k) are applicable to manufacturers and processors of this substance.
- (2) Limitations or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.
 - 12. Add § 721.10969 to subpart E to read as follows:

§ 721.10969 Substituted alkanolamine ether (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as substituted alkanolamine ether (PMN P-15-409) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) *Hazard communication program*. 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 TSCA section 5(e) consent order for the substance, the employer becomes aware that the substances 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 an SDS 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 an SDS 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 SDS 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.
- (ii) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(q).
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (c), (h) and (i) are applicable to manufacturers and processors of this substance.
- (2) Limitations or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.
- (3) Determining whether a specific use is subject to this section. The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(ii) of this section.
 - 13. Add § 721.10970 to subpart E to read as follows:

§ 721.10970 Butanedioic acid, alkyl amine, dimethylbutyl ester (generic).

(a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as butanedioic acid, alkyl amine, dimethylbutyl ester (PMN P-15-583) is subject to reporting under this section for the significant new

uses described in paragraph (a)(2) of this section. The requirements of this rule do not apply to quantities of the PMN substance after they have been added to engine oil.

- (i) *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 TSCA section 5(e) consent order for the substance, the employer becomes aware that the substances 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 an SDS 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 an SDS 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 SDS 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.
- (ii) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(q).
- (iii) *Release to water*. Requirements as specified in § 721.90(a)(1), (b)(1), and (c)(1).

- (2) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (c), (h), (i) and (k) are applicable to manufacturers and processors of this substance.
- (2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.
- (3) Determining whether a specific use is subject to this section. The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(ii) of this section.
 - 14. Add § 721.10971 to subpart E to read as follows:

§ 721.10971 Carbon nanotube (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as carbon nanotube (PMN P-15-672) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) *Protection in the workplace*. Requirements as specified in § 721.63(a)(1), (a)(2)(i), (a)(2)(ii), (a)(3), (a)(4), (a)(6) (particulate), and (c). When determining which persons are reasonably likely to be exposed as required for §721.63(a)(1) and (a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. A

National Institute for Occupational Safety and Health (NIOSH)-certified respirators with an N-100, P-100, or R-100 cartridge meet the requirements of §721.63(a)(4).

- (ii) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80. It is a significant new use to process or use the chemical substance other than as an aqueous slurry, wet form, or a contained dry form as described in the PMN.
- (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) and (i) 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)(iii) of this section.
 - 15. Add § 721.10972 to subpart E to read as follows:
- § 721.10972 Metal salt of mineral acid, reaction products with alumina, aluminum hydroxide, aluminum hydroxide oxide (Al(OH)O), silica, titanium oxide (TiO2) and 3-(triethoxysilyl)-1-propanamine (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as metal salt of mineral acid, reaction products with alumina, aluminum hydroxide, aluminum hydroxide oxide (Al(OH)O), silica, titanium oxide (TiO2) and 3-(triethoxysilyl)-1-propanamine (PMN P-15-678) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(j).
 - (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (c) and (i) are applicable to manufacturers and processors of this substance.
- (2) Limitations or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.
- (3) Determining whether a specific use is subject to this section. The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.
 - 16. Add § 721.10973 to subpart E to read as follows:
- § 721.10973 Halogenated bisphenol A, polymer with epichlorohydrin, alkenoate (generic).
- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as halogenated bisphenol A, polymer with

epichlorohydrin, alkenoate (PMN P-15-766) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

- (2) The significant new uses are:
- (i) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(j), (o) and (s) (10,000 kilograms).
 - (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (c) and (i) are applicable to manufacturers and processors of this substance.
- (2) Limitations or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.
- (3) Determining whether a specific use is subject to this section. The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.
 - 17. Add § 721.10974 to subpart E to read as follows:

§ 721.10974 Halogenated bisphenol A, polymer with bisphenol A diglycidyl ether and epoxidized phenol-formaldehyde resin, alkenoate (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substances identified generically as halogenated bisphenol A, polymer with bisphenol A diglycidyl ether and epoxidized phenol-formaldehyde resin, alkenoate (PMN P-15-767) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:

- (i) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(j), (o) and (s) (10,000 kilograms).
 - (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (c) and (i) are applicable to manufacturers and processors of this substance.
- (2) Limitations or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.
- (3) Determining whether a specific use is subject to this section. The provisions of \$721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.
 - 18. Add § 721.10975 to subpart E to read as follows:

§ 721.10975 Silicon, tris[dialkyl phenyl]-dialkyl-dioxoalkane-naphthalene disulfonate (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as silicon, tris[dialkyl phenyl]-dialkyl-dioxoalkane-naphthalene disulfonate (PMN P-16-14) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(j). The significant new use is use other than as described in PMN-16-14 where the surface water concentrations described in paragraph (a)(3)(i) are exceeded.
 - (ii) [Reserved]

- (3) The significant new uses for any use other than as described in PMN-16-14:
- (i) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) (N=6).
 - (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (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.
 - 19. Add § 721.10976 to subpart E to read as follows:

§ 721.10976 Tar acids fraction (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as tar acids fraction (PMN P-16-40) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) (N=45).
 - (ii) [Reserved]

- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (c) and (k) are applicable to manufacturers and processors of this substance.
- (2) Limitations or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.
 - 20. Add § 721.10977 to subpart E to read as follows:

§ 721.10977 Dialkyl fattyalkylamino propanamide alkylamine (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as dialkyl fattyalkylamino propanamide alkylamine (PMN P-16-59) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) (N=1).
 - (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (c) and (k) are applicable to manufacturers and processors of this substance.
- (2) *Limitations or revocation of certain notification requirements*. The provisions of § 721.185 apply to this section.
 - 21. Add § 721.10978 to subpart E to read as follows:

§ 721.10978 Fattyalkylaminopropanoate ester (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as fattyalkylaminopropanoate ester (PMN P-16-60) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) (N=1).
 - (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (c) and (k) are applicable to manufacturers and processors of this substance.
- (2) Limitations or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.
 - 22. Add § 721.10979 to subpart E to read as follows:

§ 721.10979 Boron sodium oxide (B5NaO8), labeled with boron-10.

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as boron sodium oxide (B5NaO8), labeled with boron-10 (PMN P-16-70, CAS No. 200443-98-7) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:

- (i) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80. A significant new use is any use of the substance other than as an emergency shutdown coolant in boiler water reactors.
 - (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (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.
 - 23. Add § 721.10980 to subpart E to read as follows:

§ 721.10980 Perfluoropolyether modified organosilane (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as perfluoropolyether modified organosilane (PMN P-16-94) 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(s) (500 kilograms).
 - (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.

- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (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.
 - 24. Add § 721.10981 to subpart E to read as follows:

§ 721.10981 Modified phenol-formaldehyde resin (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as modified phenol-formaldehyde resin (PMN P-16-95) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(j).
- (ii) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) (N=96).
- (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)(i) of this section.

25. Add § 721.10982 to subpart E to read as follows:

§ 721.10982 Disubstituted benzene alkanal (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as disubstituted benzene alkanal (PMN P-16-101) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) Protection in the workplace. Requirements as specified in §721.63(a)(2)(i),(a)(3), (b) (concentration set at 1.0 percent), and (c).
- (ii) *Industrial commercial, and consumer activities*. Requirements as specified in § 721.80 (j).
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125 (a) through (e) and (i) are applicable to manufacturers and processors of this substance.
- (2) *Limitations or revocation of certain notification requirements*. The provisions of § 721.185 apply to this section.
- (3) Determining whether a specific use is subject to this section. The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(ii) of this section.
 - 26. Add § 721.10983 to subpart E to read as follows:
- § 721.10983 Phthalic anhydride, polymer with alkylene glycol and alkanepolyol, acrylate (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as phthalic anhydride, polymer with alkylene glycol and alkanepolyol, acrylate (PMN P-16-102) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) (N=1).
 - (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (c) and (k) are applicable to manufacturers and processors of this substance.
- (2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.
 - 27. Add § 721.10984 to subpart E to read as follows:

§ 721.10984 2-Pyridinecarboxylic acid, 4,5-dichloro-6-(4-chloro-2-fluoro-3-methoxyphenyl)-.

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as 2-pyridinecarboxylic acid, 4,5-dichloro-6-(4-chloro-2-fluoro-3-methoxyphenyl)- (PMN P-16-104, CAS No. 1546765-39-2) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:

- (i) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(g).
- (ii) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) (N=8).
- (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.
 - 28. Add § 721.10985 to subpart E to read as follows:

§ 721.10985 Dialkylamino alkylamide inner salt (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substances identified generically as dialkylamino alkylamide inner salt (PMNs P-16-136, P-16-139 and P-16-140) are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) (N=1).
 - (ii) [Reserved]
- (b) Specific requirements. The provisions of subpart A of this part apply to this section except as modified by this paragraph.

- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (c) and (k) are applicable to manufacturers and processors of these substances.
- (2) *Limitations or revocation of certain notification requirements*. The provisions of § 721.185 apply to this section.
 - 29. Add § 721.10986 to subpart E to read as follows:

§ 721.10986 Nanocarbon (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as nanocarbon (PMN P-16-170) is 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 substance is incorporated into the composite material allowed by the section 5(e) consent order.
 - (2) The significant new uses are:
- (i) *Protection in the workplace*. Requirements as specified in § 721.63(a)(1), (a)(2)(i), (a)(2)(ii), (a)(3), (a)(4), (a)(6) (particulate), and (c). When determining which persons are reasonably likely to be exposed as required for §721.63(a)(1) and (a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. A National Institute for Occupational Safety and Health (NIOSH)-certified respirators with an N-100, P-100, or R-100 cartridge meet the requirements of §721.63(a)(4).
- (ii) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(k) and (q). A significant new use is any use involving an application method that generates a vapor, mist or aerosol.

- (iii) *Disposal*. Requirements as specified in § 721.85(a)(1), (a)(2), (b)(1), (b)(2), (c)(1), and (c)(2).
- (iv) *Release to water*. Requirements as specified in § 721.90(a)(1), (b)(1), and (c)(1).
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (e) and (i) 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)(iii) of this section.
 - 30. Add § 721.10987 to subpart E to read as follows:

§ 721.10987 Barium molybdenum niobium tantalum tellurium vanadium zinc oxide.

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as barium molybdenum niobium tantalum tellurium vanadium zinc oxide (PMN P-16-177, CAS No. 1440529-21-4) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) *Protection in the workplace*. Requirements as specified in § 721.63(a)(4), (a)(6)(i), (a)(6)(ii), (b) (concentration set at 1.0 percent) and (c). When determining which

persons are reasonably likely to be exposed as required for § 721.63(a)(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 assigned protection factor (APF) of at least 10 meet the requirements of § 721.63(a)(4).

- (ii) *Industrial, commercial, and consumer activities*. Requirements as specified in 721.80(f) and (j).
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (d) and (i) are applicable to manufacturers and processors of this substance.
- (2) Limitations or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.
- (3) Determining whether a specific use is subject to this section. The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.
 - 31. Add § 721.10988 to subpart E to read as follows:

§ 721.10988 Alkanoic acids, esters with alkanetriol (generic).

(a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as alkanoic acids, esters with alkanetriol (PMN P-16-179) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

- (2) The significant new uses are:
- (i) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) (N=1).
 - (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (c) and (k) are applicable to manufacturers and processors of this substance.
- (2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.
 - 32. Add § 721.10989 to subpart E to read as follows:
- § 721.10989 Manganese, tris[.mu.-(2-ethylhexanoato-
- .kappa.O:.kappa.O')]bis(octahydro-1,4,7-trimethyl-1H-1,4,7-triazonine-.kappa.N1,.kappa.N4,.kappa.N7)di- (P-16-182, chemical A).
- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as manganese, tris[.mu.-(2-ethylhexanoato-.kappa.O:.kappa.O')]bis(octahydro-1,4,7-trimethyl-1H-1,4,7-triazonine-.kappa.N1,.kappa.N4,.kappa.N7)di- (PMN P-16-182, chemical A; CAS No. 2020407-62-7) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) Protection in the workplace. Requirements as specified in § 721.63(a)(1),(a)(3), and (b) (concentration set at 1.0 percent).

- (ii) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(f) and (j) (a significant new use is any manufacture at a concentration of greater than 10% of the PMN substance in any formulation).
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (e) and (i) are applicable to manufacturers and processors of this substance.
- (2) Limitations or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.
 - 33. Add § 721.10990 to subpart E to read as follows:
- § 721.10990 Manganese, [.mu.-(acetato-.kappa.O:.kappa.O')]bis[.mu.-(2-ethylhexanoato-.kappa.O:.kappa.O')]bis(octahydro-1,4,7-trimethyl-1H-1,4,7-triazonine-.kappa.N1,.kappa.N4,.kappa.N7)di- (P-16-182, chemical B).
- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as manganese, [.mu.-(acetato-.kappa.O:.kappa.O')]bis[.mu.-(2-ethylhexanoato-.kappa.O:.kappa.O')]bis(octahydro-1,4,7-trimethyl-1H-1,4,7-triazonine-.kappa.N1,.kappa.N4,.kappa.N7)di- (PMN P-16-182, chemical B; CAS No. 2020407-63-8) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) 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(f) and (j) (a significant new use is any manufacture at a concentration of greater than 10% of the PMN substance in any formulation).
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (e) and (i) are applicable to manufacturers and processors of this substance.
- (2) Limitations or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.
 - 34. Add § 721.10991 to subpart E to read as follows:
- § 721.10991 Manganese, bis[.mu.-(acetato-.kappa.O:.kappa.O')][.mu.-(2-ethylhexanoato-.kappa.O:.kappa.O')]bis(octahydro-1,4,7-trimethyl-1H-1,4,7-triazonine-.kappa.N1,.kappa.N4,.kappa.N7)di- (P-16-182, chemical C).
- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as manganese, bis[.mu.-(acetato-.kappa.O:.kappa.O')][.mu.-(2-ethylhexanoato-.kappa.O:.kappa.O')]bis(octahydro-1,4,7-trimethyl-1H-1,4,7-triazonine-.kappa.N1,.kappa.N4,.kappa.N7)di- (PMN P-16-182, chemical C; CAS No. 2020407-64-9) 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) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(f) and (j) (a significant new use is any manufacture at a concentration of greater than 10% of the PMN substance in any formulation).
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (e) and (i) are applicable to manufacturers and processors of this substance.
- (2) Limitations or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.
 - 35. Add § 721.10992 to subpart E to read as follows:
- § 721.10992 Manganese, tris[.mu.-(acetato-.kappa.O:.kappa.O')]bis(octahydro-1,4,7-trimethyl-1H-1,4,7-triazonine-.kappa.N1,.kappa.N4,.kappa.N7)di- (P-16-182, chemical D).
- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as manganese, tris[.mu.-(acetato-.kappa.O:.kappa.O')]bis(octahydro-1,4,7-trimethyl-1H-1,4,7-triazonine-.kappa.N1,.kappa.N4,.kappa.N7)di- (PMN P-16-182, chemical D; CAS No. 2020407-65-0) 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(f) and (j) (a significant new use is any manufacture at a concentration of greater than 10% of the PMN substance in any formulation).
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (e) and (i) are applicable to manufacturers and processors of this substance.
- (2) Limitations or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.
 - 36. Add § 721.10993 to subpart E to read as follows:

§ 721.10993 Aryl polyolefin (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as aryl polyolefin (PMN P-16-190) 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(j).
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.

- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (d) 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.
 - 37. Add § 721.10994 to subpart E to read as follows:

§ 721.10994 Melamine nitrate (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as melamine nitrate (PMN P-16-260) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) (N=14).
 - (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (c) and (k) are applicable to manufacturers and processors of this substance.
- (2) *Limitations or revocation of certain notification requirements*. The provisions of § 721.185 apply to this section.
 - 38. Add § 721.10995 to subpart E to read as follows:

§ 721.10995 Lecithins, soya, hydrogenated.

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as lecithins, soya, hydrogenated (PMN P-16-272, CAS No. 308068-11-3) 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) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) (N=1).
 - (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (c) and (k) are applicable to manufacturers and processors of this substance.
- (2) Limitations or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.