ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 721
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 145 chemical substances which were the subject of premanufacture notices (PMNs). The chemical substances are subject to consent orders issued by EPA pursuant to section 5(e) of TSCA. This action requires persons who intend to manufacture (defined by statute to include import) or process any of these 145 chemical substances for an activity that is designated as a significant new use by this rule to notify EPA at least 90 days before commencing that activity. The required notification initiates EPA’s evaluation of the intended use within the applicable review period. Persons may not commence manufacture or processing for the significant new use until EPA has conducted a review of the notice, made an appropriate determination on the notice, and has taken such actions as are required with that determination.

DATES: This rule is effective on October 1, 2018. For purposes of judicial review, this rule shall be promulgated at 1 p.m. (e.s.t.) on August 15, 2018.

Written adverse comments on one or more of these SNURs must be received on or before August 31, 2018 (see Unit VI. of the SUPPLEMENTARY INFORMATION). If EPA receives written adverse comments on one or more of these SNURs before August 31, 2018, EPA will withdraw the relevant sections of this direct final rule before its effective date.

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

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2017–0366, 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.
• 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, AVBI-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 August 31, 2018 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?

1. Direct Final Rule. 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 obligates EPA to assess risks that may be associated with the significant new uses under the conditions of use and, if appropriate, to regulate the proposed uses before they occur.

2. Proposed Rule. In addition to this Direct Final Rule, elsewhere in this issue of the Federal Register, EPA is issuing a Notice of Proposed Rulemaking for this rule. If EPA receives no adverse comment, the Agency will not take further action on the proposed rule and the direct final rule will become effective as provided in this action. If EPA receives adverse comment on one or more of SNURs in this action by August 31, 2018 (see Unit VI. of the SUPPLEMENTARY INFORMATION), the
Agency will publish in the Federal Register a timely withdrawal of the specific SNURs that the adverse comments pertain to, informing the public that the actions will not take effect. EPA would then address all adverse public comments in a response to comments document in a subsequent final rule, based on the proposed rule.

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

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a “significant new use.” EPA must make this determination by rule after considering all relevant factors, including the four bulleted TSCA section 5(a)(2) factors listed in Unit III. Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1)(B) requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture or process the chemical substance for that use (15 U.S.C. 2604(a)(1)(B)(ii)). 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 extent to which production, distribution in commerce, and disposal of a chemical substance.
• The extent to which a use increases the magnitude and duration of exposure to 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.
• 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 projective information identified by EPA was to provide adequate information, computational toxicology and bioinformatics, and high-throughput screening methods and their prediction models. EPA also recognizes that whether testing/further information is needed will depend on the specific exposure and use scenario in the SNUN. EPA encourages all SNUN submitters to contact EPA to discuss any potential future testing. See Unit VIII. for more information.

To determine what would constitute a significant new use for the chemical substances that are the subject of these SNURs, EPA considered relevant information about the toxicity of the chemical substances, 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 145 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 chemical name is claimed as CBI).
• Chemical Abstracts Service (CAS) Registry number (if assigned for non-confidential chemical identities).
• Basis for the TSCA section 5(e) order.
• Information identified by EPA that would help characterize the potential health and/or environmental effects of the chemical substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use designated by the SNUR. This information may include testing required in a TSCA section 5(e) Order to be conducted by the PMN submitter, as well as testing not required to be conducted but which would also help characterize the potential health and/or environmental effects of the chemical substance. Any recommendation for information identified by EPA was made based on EPA’s consideration of available screening-level data, if any, as well as other available information on appropriate testing for the chemical substance. Further, any such testing identified by EPA that includes testing on vertebrates was made after consideration of available toxicity information, computational toxicology and bioinformatics, and high-throughput screening methods and their prediction models. EPA also recognizes that whether testing/further information is needed will depend on the specific exposure and use scenario in the SNUN. EPA encourages all SNUN submitters to contact EPA to discuss any potential future testing. See Unit VIII. for more information.

Where EPA determined that the PMN substance may present an unreasonable risk to human health or the environment. Those Orders require protective measures to limit exposures or otherwise mitigate the potential unreasonable risk. The SNURs identify as significant new uses any manufacturing, processing, use, distribution in commerce, or disposal that does not conform to the restrictions imposed by the underlying Orders, consistent with TSCA section 5(e)(4).

Where EPA determined that the PMN substance may present an unreasonable risk of injury to human health via inhalation exposure, the underlying TSCA section 5(e) Order 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
evaluation of the human health effects of the PMN substances. Further, the Order was issued under TSCA sections 5(a)(3)(B)(i) and 5(e)(1)(A)(i), based on a finding that the substances may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

1. Submission of certain toxicity testing on the PMN substances prior to exceeding the confidential production volume limit as specified in the Order.

2. Use of personal protective equipment to prevent dermal exposure.

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

4. No release of the PMN substances resulting in surface water concentrations that exceed 3 ppb for P–14–472 and 4 ppb for P–14–496.

5. No modification of the manufacturing process that results in inhalation exposure and no use involving application methods that generate a dust, mist, or aerosol.

6. Use of the PMN substances only as a site-controlled intermediate (P–14–472) and the confidential use specified in the Order (P–14–496).

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

Potentially useful information: EPA has determined that certain information about the fate and human health toxicity of the PMN substances may be potentially useful to characterize the effects of the PMN substances in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. The submitter has agreed not to exceed the confidential production limit without performing a skin sensitization study and a biodegradation test on each substance. In addition, EPA has determined that the results of a pulmonary effects testing of the PMN substance may be potentially useful in characterizing the health effects of the PMN substances. Although the Order does not require this additional testing, 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 information that EPA determines is relevant and needed to evaluate a modification request.

PMN Numbers: P–14–472 and P–14–496


CAS numbers: Not available.

Effective date of TSCA section 5(e) Order: April 26, 2017.

Basis for TSCA section 5(e) Order: The PMN states that the generic (non-confidential) uses of the PMN substances are as a site-controlled intermediate (P–14–472) and a paper additive (P–14–496). Based on Structure Activity Relationship (SAR) analysis of test data on acrylates/methacrylates, and other structurally similar substances, there is potential for irritation and sensitization for P–14–472. For P–14–496 there is concern for sensitization for P–14–472. For P–14–

496 there is concern for sensitization for P–14–496.

4. No use of the substance in a consumer product that generates a dust, mist, or aerosol.

The SNUR will designate as a “significant new use” the absence of these protective measures, and any use to vary or alter, the manufacturing, processing, use, distribution/transportation, treatment and disposal processes, process equipment, engineering controls, and handling practices (including worker activities and cleaning procedures) described in the PMN.

4. No use of the substance in a consumer product that generates a dust, mist, or aerosol.

The SNUR will designate as a “significant new use” the absence of these protective measures, and any use to vary or alter, the manufacturing, processing, use, distribution/transportation, treatment and disposal processes, process equipment, engineering controls, and handling practices (including worker activities and cleaning procedures) described in the PMN.

4. No use of the substance in a consumer product that generates a dust, mist, or aerosol.

The SNUR will designate as a “significant new use” the absence of these protective measures, and any use to vary or alter, the manufacturing, processing, use, distribution/transportation, treatment and disposal processes, process equipment, engineering controls, and handling practices (including worker activities and cleaning procedures) described in the PMN.
Potentially useful information: EPA has determined that certain information about the human health toxicity of the PMN substance may be potentially useful to characterize the effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. The submitter has agreed not to exceed the confidential production limit without performing specific target organ toxicity testing. In addition, EPA has determined that the results of a chronic toxicity/carcinogenicity test of the PMN substance may be potentially useful in characterizing the health effects of the PMN substance. Although the Order does not require this additional testing, 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 information that EPA determines is relevant and needed to evaluate a modification request.


PMN Number: P–15–450

Chemical name: Aluminum cobalt lithium nickel oxide.

CAS number: 177997–13–6.

Effective date of TSCA section 5(e) Order: March 23, 2017.

Basis for TSCA section 5(e) Order: The PMN states that the substance will be used as a mixed metal oxide for batteries. Based on test data on the PMN substance, EPA identified concerns for spleen and kidney toxicity. Based on physical/chemical properties of the PMN substance, as well as SAR analysis of analogous respirable, poorly soluble particulates, EPA identified concerns for lung effects based on lung overload. Based on the crystalline structure of the PMN substance, EPA identified concern for lung carcinogenicity. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on insufficient information to make a reasoned evaluation and a finding that the substance may present an unreasonable risk of injury to human health. To protect against these risks, the Order requires:

1. Submission of certain toxicity testing on the PMN substance prior to exceeding the time limit as specified in the Order.
2. Use of personal protective equipment including impervious gloves and protective clothing (where there is a potential for dermal exposures).
3. Use of a NIOSH-certified respirator with an APF of at least 1,000 (where there is a potential for inhalation exposure) or compliance with a NCEL of 0.000092 ppm as an 8-hour time-weighted average.
4. Use of the chemical transfer processes and air ventilation processes described in the PMN and the exposure monitoring requirements described in the Order.
5. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.
6. Disposal of the PMN substance by landfill only. Air releases are limited by processes described in the PMN, including filtering through a high-efficiency particulate air filter with an efficiency rate of 99.99%.
7. No domestic manufacture of the PMN substance.

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

Potentially useful information: EPA has determined that certain information about the human health toxicity of the PMN substance may be potentially useful to characterize the effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. The submitter has agreed not to exceed the confidential production limit without performing specific target organ toxicity testing and carcinogenicity testing. In addition, EPA has determined that the results of medical monitoring of the workers exposed to the substance during manufacturing, processing, and use may be potentially useful in characterizing the health effects of the PMN substance. Although the Order does not require this medical monitoring, 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 information that EPA determines is relevant and needed to evaluate a modification request.


PMN Number: P–15–705

Chemical name: Alkylarylamine (generic).

CAS number: Not available.
SNUN for a significant new use that will be designated by this SNUR. The submitter has agreed not to exceed the confidential production limit without performing specific target organ toxicity testing and a chronic aquatic toxicity test.

**CFR citation:** 40 CFR 721.11028.

**PMN Numbers:** P–15–706 and P–15–707

**Chemical names:** Aliphatic N-alkyl urea polymer containing cyclohexyl groups and trimethoxy silanes (generic) (P–15–706) and Aliphatic N-alkyl urea polymer containing aspartic ester groups and trimethoxy silanes (generic) (P–15–707).

**CAS numbers:** Not available.

**Effective date of TSCA section 5(e) Order:** April 26, 2017.

**Basis for TSCA section 5(e) Order:** The PMNs state that the generic use of the substances will be as ingredients for multipurpose exterior coatings. Based on SAR analysis on reactive methoxy silane moieties, EPA has identified concerns for irritation to lungs, eyes, and mucus membranes. There are also concerns for acute toxicity, neurotoxicity, and developmental toxicity based on the presence of methanol, and for sensitization if there are residual isocyanates. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on insufficient information to make a reasoned evaluation and a finding that the substances may present an unreasonable risk of injury to human health. To protect against these risks, the Order requires:

1. Submission of certain toxicity testing on the PMN substance prior to exceeding the production limit as specified in the Order.
2. Use of personal protective equipment including impervious gloves (where there is a potential for dermal exposure).
3. Use of an APF of at least 10 (where there is a potential for dermal exposure).
4. No release of the PMN substances resulting in surface water concentrations that exceed 10 ppb.

**PMN Numbers:** P–16–273 and P–16–274

**Chemical names:** Aliphatic polymers containing cyclohexyl groups and trimethoxy silanes (generic) (P–16–273) and Aliphatic N-alkyl urea polymer containing cyclohexyl, carboxyalkyl alkyl ethers (generic).

**CAS numbers:** Not available.

**Effective date of TSCA section 5(e) Order:** April 25, 2017.

**Basis for TSCA section 5(e) Order:** The PMNs state that the generic (non-confidential) use of the substances will be as ingredients in metalworking fluids. Based on submitted test data for P–16–273 and structurally similar surfactants, EPA has identified concerns for dermal sensitization and irritation and lung effects. Based on submitted toxicity data for P–16–273, EPA estimates toxicity to aquatic organisms may occur for both PMNs at concentrations that exceed 10 ppb of the PMN substances in surface waters. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on insufficient information to make a reasoned evaluation and a finding that the substances may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

1. No domestic manufacture of the PMN substances.
2. Use of the PMN substances only: (i) For the confidential uses specified in the Order, (ii) at a concentration no greater than 3% of the metalworking fluid, and only in closed metalworking systems as specified in the PMNs with no modifications in the process that would result in worker inhalation exposure.
3. Use of personal protective equipment including impervious gloves (where there is a potential for dermal exposure).
4. No use of the substances other than allowed in the Order.
5. No use of the substances in a consumer product.
6. Manufacture of the PMN substances to contain no more than 0.1% residual isocyanate by weight.
7. No uses of the substances other than allowed in the Order.
8. No release of the PMN substances in surface waters. The SNUR for a significant new use that will be designated by this SNUR. The submitter has agreed not to exceed the confidential production limit without performing specific target organ toxicity testing and a chronic aquatic toxicity test.


**PMN Numbers:** P–16–289

**Chemical name:** Benzene dicarboxylic acid, polymer with alkane dioic acid and aliphatic diamine (generic).

**CAS number:** Not available.

**Effective date of TSCA section 5(e) Order:** March 24, 2017.

**Basis for TSCA section 5(e) Order:** The PMN states the substances may be potentially useful to characterize the effects of the PMN substances in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that certain information about the fate and toxicity of the PMN substances may be potentially useful to characterize the health and environmental effects of the PMN substances in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that certain information about the fate and toxicity of the PMN substances may be potentially useful to characterize the health and environmental effects of the PMN substances. Although the Order does not require these tests, the Order’s restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other information that EPA determines is relevant and needed to evaluate a modification request.

**CFR citation:** 40 CFR 721.11031.

**PMN Number:** P–16–289
2. Manufacture of the PMN substance such that the solid particle form has a particle size distribution where less than 1% of the particles are less than 10 microns.

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

Potentially useful information: EPA has determined that certain information about the physical/chemical characteristics of the PMN substance may be potentially useful to characterize the health effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. The submitter has agreed not to manufacture beyond a certain time period without measuring the particle size distribution to characterize the fraction of the dry particle PMN substance less than 10 microns. In addition, EPA has determined that the results of specific target organ toxicity testing of the PMN substance may be potentially useful in characterizing the health effects of the PMN substance. Although the Order does not require this additional testing, 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 information that EPA determines is relevant and needed to evaluate a modification request.


PMN Number: P–16–322

Chemical name: Manganese cyclic (tri)amine chloride complex (generic).

CAS number: Not available.

Effective date of TSCA section 5(e) Order: April 25, 2017.

Basis for TSCA section 5(e) Order: The PMN states that the generic (non-confidential) use of the substance will be as a pulp bleaching catalyst. Based on test data on an analog, EPA has identified concerns for kidney, blood, and thyroid effects, immunotoxicity, reproductive and developmental toxicity, and neurotoxicity. Based on test data on the PMN substance, EPA estimates that toxicity to aquatic organisms may occur at concentrations that exceed 2 ppb of the PMN substance in surface waters. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on insufficient information to make a reasoned evaluation and a finding that the substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:
1. Submission of certain toxicity testing on the PMN substance prior to exceeding the confidential production volume limit as specified in the Order.
2. Use of personal protective equipment to prevent dermal exposure (where there is a potential for dermal exposure).
3. Use of a NIOSH-certified respirator with an APT of at least 25 (where there is a potential for inhalation exposure) or compliance with a NCEL of 1.2 ppm as an 8-hour time-weighted average. (EPA’s estimates indicate that variations of the parameters (including batch size, number of processing sites, days per year of operation) of the uses identified below would not result in inhalation exposure that would indicate a different respirator.)
4. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.
5. No domestic manufacture of the PMN substance.
6. Process and use of the PMN substance only for the confidential uses and formulation percentage specified in the Order.
7. No release of the PMN substance resulting in surface water concentrations that exceed 18 ppb.

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

Potentially useful information: EPA has determined that certain information about the human health and aquatic toxicity of the PMN substance may be potentially useful to characterize the effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. The submitter has agreed not to exceed the confidential production limit without performing specific target organ toxicity testing, reproductive/developmental toxicity testing; and chronic aquatic toxicity testing.


Chemical names: Xanthylum, (sulfoaryl)-bis ((substituted aryl) amino)-, sulfo derivs., inner salts, metal salts (generic) (P–16–338); Substituted triazinyl metal salt, diazotized, coupled with substituted pyridobenzimidazolesulfonic acids, substituted pyridobenzimidazolesulfonic acids, diazotized substituted alkanesulfonic acid, diazotized substituted aromatic sulfonate, diazotized substituted aromatic sulfonate, metal salts (generic) (P–16–339); Carbon black, (organic acidic carbocyclic)-modified, inorganic salt (generic) (P–16–439); and Carbon black, (organic acidic carbocyclic)-modified, metal salt (generic) (P–16–440).

CAS numbers: Not available.

Effective date of TSCA section 5(e) Order: April 11, 2017.

Basis for TSCA section 5(e) Order: The PMN states that the generic (non-confidential) uses of the PMN substances will be as dyestuffs (P–16–0338 and P–16–0339) and as coloring agents (P–16–0439 and P–16–0440). Based on physical/chemical properties of the PMN substances and test data on analogously poorly respirable particles, EPA has identified concerns for irritation to the eyes, lungs, and mucous membranes, and lung effects. Further, based on SAR analysis of test data on analogously dyes, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 200 ppb of the PMN substances in surface waters. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on insufficient information to make a reasoned evaluation and a finding that the substances may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:
1. No manufacture of the PMN substances beyond the confidential annual production volume specified in the Order.
2. No domestic manufacture of the PMN substances.
3. Import the PMN substances only according to the terms specified and for the confidential uses specified in the Order.
4. No release of the PMN substances to surface waters.

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

Potentially useful information: EPA has determined that certain information about the fate, human health toxicity, and aquatic toxicity of the PMN substances may be potentially useful to characterize the effects of the PMN substances in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of a biodegradation test, specific target organ toxicity testing, and acute and chronic aquatic toxicity testing of the PMN...
substances may be potentially useful in characterizing the health and environmental effects of the PMN substances. Although the Order does not require these tests, the Order’s restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other information that EPA determines is relevant and needed to evaluate a modification request.


**PMN Number:** P–16–350

**Chemical name:** Polymethacrylic acid (generic).

**CAS number:** Not available.

**Effective date of TSCA section 5(e) Order:** March 31, 2017.

**Basis for TSCA section 5(e) Order:** The PMN states that the generic (non-confidential) use of the substance will be as a paint medium. Based on test data on methacrylate moieties, EPA has identified concerns for irritation and sensitization based on antigenic activity between methacrylates. Based on SAR analysis of test data on structurally similar respirable surfactants, EPA has identified concerns for lung effects. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on insufficient information to make a reasoned evaluation and a finding that the substance may present an unreasonable risk of injury to human health. To protect against these risks, the Order requires:

1. Use of personal protective equipment including impervious gloves (where there is a potential for dermal exposure).
2. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.
3. Manufacture of the PMN substance such that it is not less than the minimum average molecular weight identified in the Order and does not contain more than the maximum weight percent of low molecular weight species below 1,000 Daltons.
4. Use of the PMN substance only for the confidential use specified in the Order.

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

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

**CFR citation:** 40 CFR 721.11032.

**PMN Number:** P–16–352

**Chemical names:** Phenol, 2-[[3-(octyloxy)propyl]iminomethyl] (P–16–352, chemical A) and Phenol, 2-[[3-(decyloxy)propyl]iminomethyl] (P–16–352, chemical B).

**CAS numbers:** 1858221–49–4 (P–16–352, chemical A) and 1858221–50–7 (P–16–352, chemical B).

**Effective date of TSCA section 5(e) Order:** April 21, 2017.

**Basis for TSCA section 5(e) Order:** The PMN states that the PMN substances will be used as co-catalysts in the manufacturing of release coatings for producing papers and films at a concentration of 1% or less. Based on SAR analysis of test data on analogous phenols, EPA has identified concerns for respiratory and dermal irritation and developmental toxicity. In addition, EPA has identified concerns for liver toxicity and reproductive effects based on the hydrolysis product o-hydroxybenzaldehyde. Further, based on SAR analysis of test data on analogous phenols, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PMN substances in surface waters. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on insufficient information to make a reasoned evaluation and a finding that the substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

1. Submission of certain toxicity testing on the PMN substance prior to exceeding the confidential production volume limit as specified in the Order.
2. Use of personal protective equipment including impervious gloves (where there is a potential for dermal exposure).

**Potentially useful information:** EPA has determined that certain information about the health and aquatic toxicity of the PMN substance may be potentially useful to characterize the effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. The submitter has agreed not to exceed the confidential production limit without performing specific target organ toxicity, reproductive/developmental toxicity, and acute aquatic toxicity testing.

**CFR citations:** 40 CFR 721.11039 (P–16–352, chemical A) and 40 CFR 721.11040 (P–16–352, chemical B).

**PMN Number:** P–16–358

**Chemical name:** Alkyl phenol (generic).

**CAS number:** Not available.

**Effective date of TSCA section 5(e) Order:** April 24, 2017.

**Basis for TSCA section 5(e) Order:** The PMN states that the substance will be used as a chemical intermediate. Based on SAR analysis of test data on analogous phenols, EPA has identified concerns for developmental toxicity. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on insufficient information to make a reasoned evaluation and a finding that the substance may present an unreasonable risk of injury to human health. To protect against these risks, the Order requires:

1. Submission of certain toxicity testing on the PMN substance prior to exceeding the confidential production volume limit as specified in the Order.
2. Use of personal protective equipment including impervious gloves (where there is a potential for dermal exposure).
3. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.

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

5. No manufacture, process, or use of the PMN substance in any manner or method that generates a dust, mist, or aerosol in a non-enclosed process.

6. No release of the PMN substance to surface waters.

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

Potentially useful information: EPA has determined that certain information about the human health toxicity of the PMN substance may be potentially useful to characterize the effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. The submitter has agreed not to exceed the confidential production limit without performing specific target organ toxicity and reproductive/developmental toxicity tests.


PMN Number: P–16–364

Chemical name: Nitrile-butadiene-acrylate terpolymers (generic).

CAS number: Not available.

Effective date of TSCA section 5(e) Order: March 31, 2017.

Basis for TSCA section 5(e) Order:
The PMN states that the generic (non-confidential) use of the substance will be as a chemical intermediate. Based on SAR analysis of test data on structurally similar respirable particles, EPA has identified concerns for lung effects, including lung overload. The Order was issued under TSCA sections 5(a)(3)/(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on insufficient information to make a reasoned evaluation and a finding that the substance may present an unreasonable risk of injury to human health. To protect against these risks, the Order requires:

1. Use of the PMN substance only as a site-limited chemical intermediate.

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

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

Potentially useful information: EPA has determined that certain information about the toxicity of the PMN substance may be potentially useful to characterize the effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of specific target organ toxicity testing of the PMN substance may be potentially useful in characterizing the health effects of the PMN substance. Although the Order does not require this test, the Order’s restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other information that EPA determines is relevant and needed to evaluate a modification request.


PMN Number: P–16–399

Chemical name: Starch, polymer with 2-propenoic acid, potassium salt, oxidized.

CAS number: 1638117–09–5.

Effective date of TSCA section 5(e) Order: April 6, 2017.

Basis for TSCA section 5(e) Order:
The PMN states that the substance will be used as an agricultural soil amendment for field crops, agricultural soil amendment for turf applications and direct soil injection with fertilizers, and a compound to be used in preparation of advanced seed coatings. Based on SAR analysis of test data on structurally similar respirable particles, EPA has identified concerns for lung effects, including lung overload. The Order was issued under TSCA sections 5(a)(3)/(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on insufficient information to make a reasoned evaluation and a finding that the substance may present an unreasonable risk of injury to human health. To protect against these risks, the Order requires:

1. Submission of certain toxicity testing on the PMN substance prior to exceeding the time limit as specified in the Order.

2. Use of personal protective equipment including impervious gloves (where there is a potential for dermal exposure).

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

4. Manufacture of the substance with a particulate size greater than 30 microns.

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

Potentially useful information: EPA has determined that certain information about the toxicity of the PMN substance may be potentially useful to characterize the health and environmental effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. The submitter has agreed not to manufacture beyond a certain time limit without performing an acute aquatic toxicity test. In addition, EPA has determined that the results of specific target organ toxicity testing of the PMN substance may be potentially useful in characterizing the health effects of the PMN substance. Although the Order does not require this additional testing, 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 information that EPA determines is relevant and needed to evaluate a modification request.


PMN Number: P–16–430

Chemical name: Pentanedioic acid, 2-methyl-.


Effective date of TSCA section 5(e) Order: May 17, 2017.

Basis for TSCA section 5(e) Order:
The PMN states the generic (non-confidential) use of the substance will be as a filler. Based on test data on the PMN substance, EPA has identified concerns for systemic and reproductive toxicity. Based on structural analysis on the acid groups and test data, EPA has identified concerns for dermal and respiratory irritation. Further, based on test data on the PMN substance and test data on analogous neutral organics, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 14 ppb of the PMN substance in surface waters. The Order was issued under TSCA sections 5(a)(3)/(B)(ii)(II) and 5(e)(1)(A)(ii)(I), based on insufficient information to make a reasoned evaluation and a finding that the
substance may present an unreasonable risk of injury to human health and the environment. EPA assessed risks based on the specific processing, use, distribution/transportation, treatment and disposal processes, process equipment, engineering controls, and handling practices (including worker activities and cleaning procedures) described in the PMN. To protect against these risks, the Order requires:

1. Use of personal protective equipment including impervious gloves (where there is a potential for dermal exposure).
2. Use of a NIOSH-certified respirator with an APF of at least 10 (where there is a potential for inhalation exposure).

(EPA’s estimates indicate that variations of the parameters (including batch size, number of processing sites, days per year of operation) of the uses identified below would not result in inhalation exposure that would indicate a different respirator.)

3. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.
4. No domestic manufacture of the PMN substance.
5. Import of the PMN substance at or below the maximum concentration specified in the Order.
6. No release of the PMN substance resulting in surface water concentrations that exceed 14 ppb.

The SNUR will designate as a “significant new use” the absence of these protective measures, and use of the chemical substance to vary or alter the processing, use, distribution, engineering controls, and handling practices described in the Order in such a way as to change the magnitude of inhalation exposure.

Potentially useful information: EPA has determined that certain information about the human health toxicity of the PMN substance may be potentially useful to characterize the effects of the substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. The submitter has agreed not to exceed the confidential production limit without performing chronic aquatic toxicity tests. In addition, EPA has determined that the results of specific target organ toxicity testing of the PMN substance may be potentially useful in characterizing the health effects of the PMN substance. Although the Order does not require this additional testing, 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 information that EPA determines is relevant and needed to evaluate a modification request.


PMN Number: P–16–495

Chemical name: 2-Pentanol, 4-methyl-, reaction products with phosphorus oxide (P2O5), compounds with alkylamine (generic).

CAS number: Not available.

Effective date of TSCA section 5(e) Order: April 25, 2017.

Basis for TSCA section 5(e) Order:
The PMN states that the generic use (non-confidential) of the substance will be as a lubricant additive. Based on test data on the substance, EPA has identified concerns for systemic effects, sensitization and irritation to the eyes and skin. Based on physical/chemical properties, EPA has concerns for lung effects, including lung surfactancy. Further, based on test data on analogous aliphatic amines for the cation and neutral organics for the anion as well as test data on the PMN substance, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 200 ppb of the PMN substance in surface waters. The Order was issued under TSCA sections 5(a)(3)[B][ii][I] and 5(e)(1)[A][ii][I], based on insufficient information to make a reasoned evaluation and a finding that the substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

1. Submission of certain toxicity testing on the PMN substance prior to exceeding the confidential production volume limit as specified in the Order.
2. Use of personal protective equipment (where there is a potential for dermal exposure).
3. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.
4. No manufacture in any manner or method that results in inhalation exposure.
5. No use of the PMN substance in an application method that generates a vapor, mist, or aerosol.
6. No release of the PMN substance resulting in surface water concentrations that exceed 200 ppb.

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

Potentially useful information: EPA has determined that certain information about the human health and aquatic toxicity of the PMN substance may be potentially useful in characterizing the health effects of the PMN substance. Although the Order does not require this test, the Order’s restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other information.


PMN Number: P–16–513

Chemical name: Hydroxy alkylbiphenyl (generic).

CAS number: Not available.

Effective date of TSCA section 5(e) Order: May 2, 2017.

Basis for TSCA section 5(e) Order:
The PMN states that the substance will be used as a chemical intermediate. Based on test data on an analog, EPA has identified concerns for developmental toxicity, systemic toxicity, blood effects, and corrosion of the skin, eyes, and mucous membranes. Further, based on SAR analysis of test data on analogous amides, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 17 ppb of the PMN substances in surface waters. The Order was issued under TSCA sections 5(a)(3)[B][ii][I] and 5(e)(1)[A][ii][I], based on insufficient information to make a reasoned evaluation and a finding that the substances may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

1. Submission of certain toxicity testing on the PMN substance prior to exceeding the confidential production volume limit as specified in the Order.
2. Use of personal protective equipment (where there is a potential for dermal exposure).
3. Use of a NIOSH-certified respirator with an APF of at least 50 (where there is a potential for inhalation exposure).
4. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.
5. No manufacture in any manner or method that results in inhalation exposure.
6. No release of the PMN substance resulting in surface water concentrations that exceed 200 ppb.

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

Potentially useful information: EPA has determined that certain information about the human health and aquatic toxicity of the PMN substance may be potentially useful in characterizing the health effects of the PMN substance. Although the Order does not require this test, the Order’s restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other information.
5. No release of the PMN substance resulting in surface water concentrations that exceed 17 ppb.

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

Potentially useful information: EPA has determined that certain information about the human health and aquatic toxicity of the PMN substance may be potentially useful to characterize the effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. The submitter has agreed not to exceed the confidential production limit without performing specific target organ toxicity and reproductive/developmental toxicity testing. In addition, EPA has determined that the results of acute aquatic toxicity tests may be potentially useful in characterizing the environmental effects of the PMN substance. Although the Order does not require these additional 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 information that EPA determines is relevant and needed to evaluate a modification request.

**CFR citation:** 40 CFR 721.11046.


**Chemical names:** Alkyl alkenoic acid, polymer with alkenylcarbomonocycle telomer with substituted alkanolic acid hydroxyl alkyl substituted alkenyl substituted alkyl ester, polyalkylene glycol alkyl ether alkyl alkenoate, dialkylene glycol diheteromonocyclic ether and alkylcarbomonocyclic alkenoate, metal salt (generic) (P–16–534); Alkyl alkenoic acid, polymer with alkenylcarbomonocycle telomer with substituted alkanolic acid hydroxyl alkyl substituted alkenyl substituted alkyl ester, alkaneodi diheteromonocyclic ether, polyalkylene glycol alkyl ether alkyl alkenoate and alkylcarbomonocyclic alkenoate, metal salt (generic) (P–16–535); and Alkyl alkenoic acid, polymer with bis heteromonocyclic substituted alkyl carboxomonocycle, alkenylcarbomonocycle telomer with substituted alkanolic acid hydroxyl alkyl substituted alkenyl substituted alkyl ester, polyalkylene glycol alkyl ether alkyl alkenoate and alkylcarbomonocyclic alkenoate, metal salt (generic) (P–16–536).

**CAS numbers:** Not available.

**Effective date of TSCA section 5(e) Order:** April 4, 2017.

**Basis for TSCA section 5(e) Order:** The PMN states that the generic (non-confidential) use of the substances will be a component of ink. Based on test data on structurally similar respirable particles, EPA has identified concerns for lung effects if inhaled, based on lung overload. In addition, EPA has identified ecotoxicity concerns for the substances if made with an acid component exceeding 20% of the molecular weight due potential for increased absorption and solubility. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on insufficient information to make a reasoned evaluation and a finding that the substances may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

1. Manufacture of the PMN substances such that the minimum average molecular weight is 1,800 daltons and the carboxylic acid content does not exceed 20%.

2. No domestic manufacture of the PMN substances.

3. Process or use of the PMN substances only for the use specified in the Order.

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

**Potentially useful information:** EPA has determined that certain information about the human health and aquatic toxicity of the PMN substances may be potentially useful to characterize the effects of the substances in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of specific target organ toxicity testing and an acute aquatic toxicity test of the PMN substances may be potentially useful in characterizing the health and environmental effects of the PMN substances. Although the Order does not require these tests, the Order’s restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other information that EPA determines is relevant and needed to evaluate a modification request.


**CAS numbers:** Not available.

**Effective date of TSCA section 5(e) Order:** May 2, 2017.

**Basis for TSCA section 5(e) Order:** The PMN states the substances will be used as crosslinked resins for chromatographic separation of biomolecules and biocatalysts. Based on test data on structurally similar respirable particles, EPA has identified concerns for lung effects, including lung overload. EPA has also identified irritation concerns for skin and eyes. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on insufficient information to make a reasoned evaluation and a finding that the substances may present an unreasonable risk of injury to human health. To protect against these risks, the Order requires:

1. Use of personal protective equipment including impervious gloves (where there is a potential for dermal exposure).

2. Manufacture of the PMN substances only in the physical form of spherical beads and with less than 0.1% below a particle size of 10 microns.

3. No domestic manufacture of the PMN substances.

4. Process or use of the PMN substances only for the uses specified in the Order.

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

**Potentially useful information:** EPA has determined that certain information about the human health toxicity of the PMN substances may be potentially useful to characterize the effects of the substances in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of specific target organ toxicity testing and an acute aquatic toxicity test of the PMN substances may be potentially useful in characterizing the health and environmental effects of the PMN substances. Although the Order does not require these tests, the Order’s restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other information that EPA determines is relevant and needed to evaluate a modification request.
if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of specific target organ toxicity testing of the PMN substances may be potentially useful in characterizing the health effects of the PMN substances. Although the Order does not require this testing, 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 information that EPA determines is relevant and needed to evaluate a modification request.


PMN Number: P–16–579

Chemical name: Waste plastics, poly(ethylene terephthalate), depolyymd, with polypropylene glycol ether with glycerol (3:1), polymers with alkenoic and alkanic acids (generic).

CAS number: Not available.

Effective date of TSCA section 5(e) Order: March 13, 2017.

Basis for TSCA section 5(e) Order: The PMN states that the substance will be used as an ultraviolet curable coating resin. Based on test data on similar structural moieties, EPA has identified concerns for dermal and respiratory sensitization and irritation of mucous membranes. In addition, EPA has identified human health and environmental concerns for the substance if made with lower molecular weight due potential for increased absorption and solubility. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on insufficient information to make a reasoned evaluation and a finding that the substances may present an unreasonable health or environmental risk to human health and the environment. To protect against these risks, the Order requires:

1. Use of personal protective equipment including gloves and protective clothing (where there is a potential for dermal exposure). EPA’s estimates indicate that variations of the parameters (including batch size, number of processing sites, days per year of operation) of the uses identified below would not result in inhalation exposure that would indicate a different respirator.)

2. Use of a NIOSH-certified full face respirator with an APF of at least 50 (where there is a potential for inhalation exposure). EPA’s estimates indicate that variations of the parameters (including batch size, number of processing sites, days per year of operation) of the uses identified below would not result in inhalation exposure (including batch size, number of processing sites, days per year of operation) of the uses identified below would not result in inhalation exposure.

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

4. No manufacture of the PMN substance with an average molecular weight less than 1,100 Daltons.

5. Use of the PMN substance only as an ultraviolet curable coating resin.

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

Potentially useful information: EPA has determined that certain information about the physical-chemical properties and health and aquatic toxicity of the PMN substance may be potentially useful to characterize the effects of the substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that measurement of certain physical-chemical properties, the results of specific target organ toxicity, reproductive/developmental toxicity, sensitization, and acute and chronic aquatic toxicity testing may be potentially useful in characterizing the health and environmental effects of the PMN substances. Although the Order does not require these tests, the Order’s restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other information that EPA determines is relevant and needed to evaluate a modification request.


PMN Number: P–17–32

Chemical name: 1.3,5-Naphthalenetrisulfonic acid.


Effective date of TSCA section 5(e) Order: March 22, 2017.

Basis for TSCA section 5(e) Order: The PMN states that the generic (non-confidential) use of the substance is for performing specific target organ toxicity and reproductive/developmental toxicity testing. Based on test data on an analog and on the physical-chemical properties, the results of specific target organ toxicity, sensitization, and acute and chronic aquatic toxicity testing may be potentially useful in characterizing the health and environmental effects of the PMN substances. Although the Order does not require these tests, the Order’s restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other information that EPA determines is relevant and needed to evaluate a modification request.


against these risks, the Order requires:

1. Use of personal protective equipment including impervious gloves (where there is a potential for dermal exposure).
2. Use of a NIOSH-certified respirator with an APF of at least 50 (where there is a potential for inhalation exposure) or compliance with a NCEL of 0.0184 ppm as an 8-hour time-weighted average.
3. Use of processes, process equipment, engineering controls, and handling practices specified in the Order for manufacturing and processing.
4. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.
5. No manufacture or process of PMN substances in support of a request for a significant new use that will be designated by this SNUR. The submitter has agreed not to exceed the confidential production limit without performing specific target organ toxicity testing on P–17–0091.

**Chemical Names and CAS Numbers**

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<th>Chemical name</th>
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**Effective date of TSCA section 5(e) Order:** March 22, 2017.

**Basis for TSCA section 5(e) Order:** The PMNs state that the generic (non-confidential) use of the substances are for monitoring of oil/gas well performance. Based on test data on an analog, EPA has identified concerns for reproductive, developmental and neurological toxicity, as well as lung toxicity and dermal irritation. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on insufficient information to make a reasoned evaluation and a finding that the substances may present an unreasonable risk of injury to human health. EPA assessed risks based on the specific manufacturing, processing, use, process equipment, engineering controls, and handling practices (including worker activities and cleaning procedures) described in the PMN. To protect against these risks, the Order requires:

1. Submission of certain toxicity testing on the PMN substances prior to exceeding the production volume limit as specified in the Order.
2. Use of personal protective equipment including impervious gloves (where there is a potential for dermal exposure).
3. Use of a NIOSH-certified respirator with an APF of at least 50 (where there is a potential for inhalation exposure) or compliance with a NCEL of 0.0184 ppm as an 8-hour time-weighted average.
4. Use of processes, process equipment, engineering controls, and handling practices specified in the Order for manufacturing and processing.
5. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.
6. No manufacture or process of PMN substances beyond a confidential annual production volume specified in the Order.

The SNUR will designate as a significant new use that will be considered for a SNUN for a significant new use that will be designated by this SNUR. The submitter has agreed not to exceed the confidential production limit without performing specific target organ toxicity testing on P–17–0091.

**CFR citations:** 40 CFR 721.11053.

Effective date of TSCA section 5(e) Order: March 22, 2017.

Basis for TSCA section 5(e) Order: The PMNs state that the generic (non-confidential) use of the substances are for monitoring of oil/gas well performance. Based on test data on an analog, EPA has identified concerns for reproductive, developmental and neurotoxicity, as well as lung toxicity and dermal irritation. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on insufficient information to make a reasoned evaluation and a finding that the substances may present an unreasonable risk of injury to human health. EPA assessed risks based on the specific manufacturing, processing, use, process equipment, engineering controls, and handling practices (including worker activities and cleaning procedures) described in the PMN. To protect against these risks, the Order requires:

1. Submission of certain toxicity testing on the PMN substances prior to exceeding the production volume limit as specified in the Order.
2. Use of personal protective equipment including impervious gloves (where there is a potential for dermal exposure).
3. Use of a NIOSH-certified respirator with an APF of at least 50 (where there is a potential for inhalation exposure) or compliance with a NCEL of 0.0184 ppm as an 8-hour time-weighted average to prevent inhalation exposure.
4. Use of processes, process equipment, engineering controls, and handling practices specified in the Order for manufacturing and processing.
5. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.
6. No manufacture or process of the PMN substances beyond a confidential annual production volume specified in the Order.

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

Potentially useful information: EPA has determined that certain information about the human health toxicity of the PMN substances may be potentially useful to characterize the effects of the PMN substances in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. The submitter has agreed not to exceed the confidential production limit without performing specific target organ toxicity and reproductive/developmental toxicity testing on both P–17–35 and P–17–37.


Effective date of TSCA section 5(e) Order: March 22, 2017.

Basis for TSCA section 5(e) Order:
The PMNs state that the substances are for monitoring oil/gas well performance. Based on test data on an analog, EPA has identified concerns for reproductive, developmental and neurotoxicity, as well as lung toxicity and dermal irritation. Further, based on SAR analysis of test data on analogous neutral organics, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 15 ppb of the PMN substances in surface waters. The Order was issued under TSCA sections 5(a)(3)(B)(i)(I) and 5(e)(I)(A)(i)(I), based on insufficient information to make a reasoned evaluation and a finding that the substances may present an unreasonable risk of injury to human health and the environment. EPA assessed risks based on the specific manufacturing, processing, use, process equipment, engineering controls, and handling practices (including worker activities and cleaning procedures) described in the PMNs. To protect against these risks, the Order requires:

1. Submission of certain toxicity testing on the PMN substances prior to exceeding the production volume limit as specified in the Order.

2. Use of personal protective equipment including impervious gloves (where there is a potential for dermal exposure).

3. Use of a NIOSH-certified respirator with an APF of at least 1,000 (where there is a potential for inhalation exposure) or compliance with a NCEL of 0.0184 ppm as an 8-hour time-weighted average.

4. Use of processes, process equipment, engineering controls, and handling practices specified in the Order for manufacturing and processing.

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

6. No manufacture or process of the PMN substances beyond a confidential annual production volume specified in the Order.

7. No release of the PMN substances resulting in surface water concentrations that exceed 15 ppb.

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

Potentially useful information: EPA has determined that certain information about the human health and aquatic toxicity of the PMN substances may be potentially useful to characterize the effects of the PMN substances in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUR for a significant new use that will be designated by this SNUR. The submitter has agreed not to exceed the confidential production limit without performing specific target organ toxicity and reproductive/developmental toxicity testing on P–17–101; and acetate aquatic toxicity testing on both P–17–101 and P–17–127.


PMN Number: P–17–198

Chemical name: Neodymium aluminium alkyl polymer complexes (generic).

CAS number: Not available.

Effective date of TSCA section 5(e) Order: April 27, 2017.

Basis for TSCA section 5(e) Order:
The PMN states the generic (non-confidential) use of the substance will be as a catalyst in a closed process. Based on physical/chemical properties of the substance and test data on the PMN substance, EPA has identified concerns for dermal and respiratory irritation, corrosion, developmental toxicity, and lung effects. The Order was issued under TSCA sections 5(a)(3)(B)(i)(I) and 5(e)(I)(A)(ii)(I), based on insufficient information to make a reasoned evaluation and a finding that the substance may present an unreasonable risk of injury to human health. To protect against these risks, the Order requires:

1. Submission of glove permeation testing on the PMN substance prior to exceeding the production volume limit as specified in the Order.

2. Use of personal protective equipment including impervious gloves (where there is a potential for dermal exposure).

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

4. No domestic manufacture of the PMN substance.

5. No use in any manner or method where there is potential for inhalation exposure.
6. Use of the PMN substance in a closed system as specified in the PMN.

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

Potentially useful information: EPA has determined that the results of glove permeability testing will help characterize the effectiveness of protective measures to mitigate human health risk of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. The submitter has agreed not to manufacture beyond a certain time period without performing glove permeability testing.


Chemical name: Fatty acid amide alkyl amine salts (generic).

CAS numbers: Not available.

Effective date of TSCA section 5(e) Order: August 4, 2017.

Basis for TSCA section 5(e) Order: The PMNs state that the generic (non-confidential) use of the substances will be as a component in asphalt emulsion. Based on SAR analysis of test data on analogous substances, EPA has identified concerns for dermal and respiratory irritation, corrosion, developmental toxicity, systemic effect, sensitization and lung effects. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on insufficient information to make a reasoned evaluation and a finding that the substances may present an unreasonable risk of injury to human health and environment. To protect against these risks, the Order requires:

1. Use of the PMN substances only for the use specified in the Order.
2. Use of personal protective equipment for workers exposed dermally to the PMN substances (including impervious gloves, chemical goggles or equivalent eye protection and clothing which covers any other exposed areas of the arms and torso).
3. No modification of the manufacture, process or use of the PMN substances if it results in inhalation exposure to vapor, dust, mist or aerosol.
4. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.
5. No release of the PMN substances into the waters of the United States.

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

Potentially useful information: EPA has determined that certain information about the human health and aquatic toxicity of the PMN substances may be potentially useful to characterize the effects of the PMN substances in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of specific target organ toxicity testing of the PMN substances, and acute and chronic aquatic toxicity testing of the PMN substances may be potentially useful in characterizing the health and environmental effects of the PMN substances. Although the Order does not require these tests, the Order’s restrictions on manufacture, processing and distribution in commerce, will remain in effect until the Order is modified or revoked by EPA based on submission of this or other information that EPA determines is relevant and needed to evaluate a modification request.


Chemical name: Fatty acid amide alkyl amine salts (generic).

CAS numbers: Not available.

Effective date of TSCA section 5(e) Order: August 4, 2017.

Basis for TSCA section 5(e) Order: The PMNs state that the generic (non-confidential) use of the substances will be as a component in asphalt emulsion. Based on SAR analysis of test data on analogous substances, EPA has identified concerns for irritation, corrosion, developmental toxicity, systemic effect, sensitization and lung effects. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on insufficient information to make a reasoned evaluation and a finding that the substances may present an unreasonable risk of injury to human health and environment. To protect against these risks, the Order requires:

1. Use of the PMN substances only for the use specified in the Order.
2. Use of personal protective equipment for workers exposed dermally to the PMN substances (including impervious gloves, chemical goggles or equivalent eye protection and clothing which covers any other exposed areas of the arms and torso).
3. No modification of the manufacture, process or use of the PMN substances if it results in inhalation exposure to vapor, dust, mist or aerosol.
4. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.
5. No release of the PMN substances into the waters of the United States.

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

Potentially useful information: EPA has determined that certain information about the human health and aquatic toxicity of the PMN substances may be potentially useful to characterize the effects of the PMN substances in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of specific target organ toxicity testing of the PMN substances, and acute and chronic aquatic toxicity testing of the PMN substances may be potentially useful in characterizing the health and environmental effects of the PMN substances. Although the Order does not require these tests, the Order’s restrictions on manufacture, processing and distribution in commerce will remain in effect until the Order is modified or revoked by EPA based on submission of this or other information that EPA determines is relevant and needed to evaluate a modification request.


V. Rationale and Objectives of the Rule
A. Rationale

During review of the PMNs submitted for the chemical substances that are subject to these SNURs, EPA concluded that for all 145 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 SNURs identify as significant new uses any manufacturing, processing, use, distribution in commerce, or disposal that does not conform to the restrictions imposed by the underlying Orders, consistent with TSCA section 5(f)(4).
B. Objectives

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

- EPA will receive notice of any person’s intent to manufacture or process a listed chemical substance for the described significant new use before that activity begins.
- EPA will have an opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing or processing a listed chemical substance for the described significant new use.
- EPA will be able to either determine that the prospective manufacture or processing is not likely to present an unreasonable risk, or to take necessary regulatory action associated with any other determination, before the described significant new use of the chemical substance occurs.
- EPA will identify as significant new uses any manufacturing, processing, use, distribution in commerce, or disposal that does not conform to the restrictions imposed by the underlying Orders, consistent with TSCA section 5(f)(4).

Issuance of a SNUR for a chemical substance does not signify that the chemical substance is listed on the TSCA Chemical Substance Inventory (TSCA Inventory). Guidance on how to determine if a chemical substance is on the TSCA Inventory is available on the internet at http://www.epa.gov/opptint/chemicals/pubs/tscainventory/index.html.

VI. Direct Final Procedures

EPA is issuing these SNURs as a direct final rule. The effective date of this rule is October 1, 2018 without further notice, unless EPA receives written adverse comments before August 31, 2018.

If EPA receives written adverse comments on one or more of these SNURs before August 31, 2018, EPA will withdraw the relevant sections of this direct final rule before its effective date.

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

VII. Applicability of the Significant New Use Designation

To establish a significant new use, EPA must determine that the use is not ongoing. The chemical substances subject to this rule have undergone premanufacture review. In cases where EPA has not received 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 all of the chemical substances, and the PMN submitters are prohibited by the TSCA section 5(e) consent orders from undertaking activities which will be designated as significant new uses. The identities of 38 of the 145 chemical substances subject to this rule have been claimed as confidential and EPA has received one post-PMN bona fide submission (per §§ 720.25 and 721.11) for a chemical substance covered by this action. Based on this, the Agency believes that it is highly unlikely that any of the significant new uses described in the regulatory text of this rule are ongoing.

Therefore, EPA designates August 1, 2018 (the date of public release of this rule) as the cutoff date for determining whether the new use is ongoing. The objective of EPA’s approach has been to ensure that a person could not defeat a SNUR by initiating a significant new use before the effective date of the direct final rule. In developing this rule, EPA has recognized that, given EPA’s practice of on occasion posting rules on its website a week or more in advance of Federal Register publication, this objective could be thwarted even before that publication.

Persons who begin commercial manufacture or processing of the chemical substances for a significant new use identified as of that date will have to cease any such activity upon the effective date of the final rule. To resume their activities, these persons will have to first comply with all applicable SNUR notification requirements and wait until EPA has conducted a review of the notice, made an appropriate determination on the notice, and has taken such actions as are required with that determination.

VIII. Development and Submission of Information

EPA recognizes that TSCA section 5 does not require developing any particular new information (e.g., generating test data) before submission of a SNUN. There is an exception: Development of test data is required where the chemical substance subject to the SNUR is also subject to a rule, order or consent agreement under TSCA section 4 (see TSCA section 5(b)(1)). In the absence of a TSCA section 4 test rule covering the chemical substance, persons are required only to submit information in their possession or control and to describe any other information known to or reasonably ascertainable by them (see 40 CFR 720.50). However, upon review of PMNs and SNUNs, the Agency has the authority to require appropriate testing. Unit IV lists potentially useful information for all of the listed SNURs. Descriptions of this information is provided for informational purposes. EPA strongly encourages persons, before performing any testing, to consult with the Agency pertaining to protocol selection. Furthermore, pursuant to TSCA section 4(h), which pertains to reduction of testing in vertebrate animals, EPA encourages consultation with the Agency on the use of alternative test methods and strategies (also called New Approach Methodologies, or NAMs), if available, to generate the recommended test data. EPA encourages dialog with Agency representatives to help determine how best the submitter can meet both the data needs and the objective of TSCA section 4(h). 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.sourceoeecd.org.

In certain of the TSCA section 5(e) consent orders for the chemical substances regulated under this rule, EPA has established production volume limits in view of the lack of data on the potential health and environmental risks that may be posed by the significant new uses or increased exposure to the chemical substances. These limits cannot be exceeded unless the PMN submitter first submits the results of specified 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. 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. Any request by EPA for the triggered and pending testing described in the Consent Orders was made based on EPA’s consideration of available screening-level data, if any, as well as other available information on appropriate testing for the PMN substances. Further, any such testing request on the part of EPA that includes testing on vertebrates was made after consideration of available toxicity information, computational toxicology and bioinformatics, and high-throughput screening methods and their prediction models.

The potentially useful information identified in Unit IV. may not be the only means of addressing the potential risks of the chemical substance. However, submitting a SNUN without any test data or other information 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 generate useful information.

SNUN submitters should be aware that EPA will be better able to evaluate SNUNs which provide detailed information on the following:
- Human exposure and environmental release that may result from the significant new use of the chemical substances.
- Information on risks posed by the chemical substances compared to risks posed by potential substitutes.

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

Under these procedures a manufacturer or processor may request EPA to determine whether a proposed use would be a significant new use under the rule. The manufacturer or processor must show that it has a bona fide intent to manufacture or process the chemical substance and must identify the specific use for which it intends to manufacture or process the chemical substance. If EPA concludes that the person has shown a bona fide intent to manufacture or process the chemical substance, EPA will tell the person whether the use identified in the bona fide submission would be a significant new use under the rule. Since most of the chemical identitites of the chemical substances subject to these SNURs are also CBI, many 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–2017–0366.

XII. Statutory and Executive Order Reviews

A. Executive Order 12866
This action establishes SNUNs for several new chemical substances that were the subject of PMNs and 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 SNUR would not cost any small entity significantly more than $8,300.

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

D. Unfunded Mandates Reform Act (UMRA)

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

E. Executive Order 13132

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

F. Executive Order 13175

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

G. Executive Order 13045

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

H. Executive Order 13211

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

I. National Technology Transfer and Advancement Act (NTTAA)

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

J. Executive Order 12898

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

XIII. Congressional Review Act

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

List of Subjects

40 CFR Part 9

Environmental protection, Reporting and recordkeeping requirements.

40 CFR Part 721

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

Dated: July 19, 2018.

Jeffery T. Morris,
Director, Office of Pollution Prevention and Toxics.

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

PART 9—[AMENDED]

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


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

§ 9.1 OMB approvals under the Paperwork Reduction Act.

* * * * *

<table>
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<th>OMB control No.</th>
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<td>721.11024</td>
<td>2070–0012</td>
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Significant New Uses of Chemical Substances

* * * * *
PART 721—[AMENDED]

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


4. Add § 721.11024 to subpart E to read as follows:

§ 721.11024 Polyphosphoric acids, 2-[(alkyl-1-oxo-2-propen-1-yl)oxy]ethyl esters, compds. with N-(aminoiminomethyl)urea (generic).

(a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as polyphosphoric acids, 2-[(alkyl-1-oxo-2-propen-1-yl)oxy]ethyl esters, compds. with N-(aminoiminomethyl)urea (PMN P–14–472) 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), (3), and (c).

(ii) Hazard communication. Requirements as specified in § 721.72(a) through (f), (g)(1)(i), (ii), (sensitization), (g)(2)(i), (v), (g)(3)(i), (ii), (g)(4)(i), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System (GHS) and OSHA Hazard Communication Standard may be used.

(iii) Industrial, commercial, and consumer activities. Requirements as specified in § 721.80(h), (g), and (y)(1). It is a significant new use to have manufacturing activities that result in inhalation exposure.

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

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

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

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

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

5. Add § 721.11025 to subpart E to read as follows:

§ 721.11025 Polyphosphoric acids, 2-[(2-methyl-1-oxo-2-propen-1-yl)oxy]ethyl esters, compds. with N-(hydroxymethyl)propenamide and styrene (generic).

(a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as polyphosphoric acids, 2-[(2-methyl-1-oxo-2-propen-1-yl)oxy]ethyl esters, compds. with alkyl amino, polymers with Bu acrylate, N-(hydroxymethyl)propenamides and styrene (PMN P–14–496) 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), (3), and (c).

(ii) Hazard communication. Requirements as specified in § 721.72(a), through (f), (g)(1)(i), (ii), (sensitization), (g)(2)(i), (v), (g)(3)(i), (ii), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System (GHS) and OSHA Hazard Communication Standard may be used.

(iii) Industrial, commercial, and consumer activities. Requirements as specified in § 721.80(k), (q) and (y)(1). It is a significant new use to have manufacturing activities that result in inhalation exposure.

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

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

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

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

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

6. Add § 721.11026 to subpart E to read as follows:

§ 721.11026 Bismuth bromide iodide oxide.

(a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as bismuth bromide iodide oxide (PMN P–14–630, CAS No. 340181–06–8) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been reacted (cured).

(2) The significant new uses are:

(i) Protection in the workplace. Requirements as specified in § 721.63(a)(4), when determining which persons are reasonably likely to be exposed as required for § 721.63(a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. (a)(5) respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 10, (a)(6) particulate, (b) (concentration set at 1.0%), and (c).

(A) As an alternative to the respirator requirements in paragraph (a)(2)(i) of this section, a manufacturer or processor may choose to follow the new chemical exposure limit (NCSEL) provision listed in the TSCA section 5(e) Order for this substance. The NCSEL is 2.4 mg/m³ as an 8-hour time weighted average. Persons who wish to pursue NCSELS as an alternative to § 721.63 respirator requirements may request to do so.
under §721.30. Persons whose §721.30 requests to use the NCELS approach are approved by EPA will be required to follow NCELS provisions comparable to those contained in the corresponding TSCA section 5(e) Order. (B) [Reserved]  
(ii) Hazard communication. Requirements as specified in §721.72(a) through (e) [concentration set at 1.0%], (f), (g)(1)(ii), (g)(2)(ii), use respiratory protection or maintain workplace airborne concentrations at or below an 8-hour time-weighted average of 2.4 mg/m³, and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System (GHS) and OSHA Hazard Communication Standard may be used.  
(iii) Industrial, commercial, and consumer activities. Requirements as specified in §721.80(q). It is a significant new use to vary or alter, the manufacturing, processing, and use, distribution/transportation, treatment and disposal processes, process equipment, engineering controls, and handling practices (including worker activities and cleaning procedures) described in the PMN in such a way as to change the magnitude of inhalation exposure. It is a significant new use to use the substance for a consumer product that generates a dust, mist, or aerosol.  
(b) Specific requirements. The provisions of subpart A of this part apply to this section except as modified by this paragraph.  
(1) Recordkeeping. Recordkeeping requirements as specified in §721.125(a) through (d), and (f) through (i) are applicable to manufacturers and processors of this substance.  
(2) Limitations or revocation of certain notification requirements. The provisions of §721.185 apply to this section.  
(3) Determining whether a specific use is subject to this section. The provisions of §721.1725(b)(1) apply to paragraph (a)(2)(iii) of this section.  
7. Add §721.11027 to subpart E to read as follows:  
§721.11027 Aluminum cobalt lithium nickel oxide.  
(a) Chemical substance and significant new uses subject to reporting.  
(1) The chemical substance identified as aluminum cobalt lithium nickel oxide (PMN No. 15–450, CAS No. 177799–13–6) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.  
(2) The significant new uses are:  
(i) Protection in the workplace. Requirements as specified in §721.63(a)(1), (3), (4), when determining which persons are reasonably likely to be exposed as required for §721.63(a)(1) and (4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (a)(5) (respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 1,000), (a)(6) (particulate) (b) (concentration set at 0.1%), and (c). It is a significant new use to manufacture or process the substance without the chemical transfer processes and air ventilation processes described in the PMN and the exposure monitoring requirements described in the Order.  
(A) As an alternative to the respirator requirements in paragraph (a)(2)(i) of this section, a manufacturer or processor may choose to follow the new chemical exposure limit (NCEL) provision listed in the TSCA section 5(e) Order for this substance. The NCEL is 0.000092 mg/m³ as an 8-hour time weighted average. Persons who wish to pursue NCELS as an alternative to §721.63 respirator requirements may request to do so under §721.30. Persons whose §721.30 requests to use the NCELS approach are approved by EPA will be required to follow NCELS provisions comparable to those contained in the corresponding TSCA section 5(e) Order.  
(B) [Reserved]  
(ii) Hazard communication. Requirements as specified in §721.72(a) through (e) [concentration set 0.1%], (f), (g)(1)(ii), (g)(2)(ii), (This substance may cause damage to the lung, kidney, and spleen), (g)(4)(vii), (g)(2)(i), (ii), (iii), (When using this substance wear protective gloves/protective clothing/eye protection/face protection), the following human health precautionary statement must appear on the SDS as specified in paragraph (a)(2)(ii): (When using this substance wear respiratory protection or maintain workplace airborne concentrations at or below an 8-hour time-weighted average of 0.000092 mg/m³, (g)(2)(v), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System (GHS) and OSHA Hazard Communication Standard may be used.  
(iii) Industrial, commercial, and consumer activities. Requirements as specified in §721.80(p) (24 months and 6 years).  
(iii) Disposal. Requirements as specified in §721.85(a)(2), (b)(2), and (c)(2). It is a significant new use to release this chemical substance to air unless using the chemical transfer and air ventilation processes described in P-15–0450 including filtering through a high-efficiency particular air filter with an efficiency rate of 99.99% before release to air.  
(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 (j) 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.  
8. Add §721.11028 to subpart E to read as follows:  
§721.11028 Alkylarylamine (generic).  
(a) Chemical substance and significant new uses subject to reporting.  
(1) The chemical substance identified generically as alkylarylamine (PMN P–15–705) 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), (ii), (iii), (a)(3), and (4), when determining which persons are reasonably likely to be exposed as required for §721.63(a)(1) and (4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (a)(5) (respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 1,000), (a)(6)(particulate), (a)(6)(v), (vi), (b) (concentration set at 0.1%), and (c).  
(A) As an alternative to the respirator requirements in paragraph (a)(2)(i) of this section, a manufacturer or processor may choose to follow the new chemical exposure limit (NCEL) provision listed in the TSCA section 5(e) Order for this substance. The NCEL is 0.48 mg/m³ as an 8-hour time weighted average. Persons who wish to pursue NCELS as an alternative to §721.63 respirator requirements may request to do so under §721.30. Persons whose §721.30 requests to use the NCELS approach are
approved by EPA will be required to follow NCELS provisions comparable to those contained in the corresponding TSCA section 5(e) Order.

(B) [Reserved]

(ii) Hazard communication.

Requirements as specified in §721.72(a) through (e) (concentration set at 0.1%), (f), (g)(1)(i), (ii), (iv), (vi), (vii), (ix), (g)(2)(i), (ii), (iii), (use respiratory protection or maintain workplace airborne concentrations at or below an 8-hour time-weighted average of 0.48 mg/m³, (g)(2)(v), (g)(3)(ii), (g)(4)(i), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System (GHS) and OSHA Hazard Communication Standard may be used.

(iii) Industrial, commercial, and consumer activities. Requirements as specified in §721.80(o) and (q). It is a significant new use to use the substance other than as a chemical intermediate or as an additive and octane booster in aviation fuels.

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

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

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

(2) Limitations or revocation of certain notification requirements. The provisions of §721.165 apply to this section.

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

■ 9. Add §721.11030 to subpart E to read as follows:

§721.11030 Aliphatic N-alkyl urea polymer containing cyclohexyl groups and trimethoxy silanes (generic).

(a) Chemical substance and significant new uses subject to reporting.

(1) The chemical substance identified generically as aliphatic N-alkyl urea polymer containing cyclohexyl groups and trimethoxy silanes (PMN P—15–707) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been reacted (cured).

(2) The significant new uses are:

(i) Protection in the workplace.

Requirements as specified in §721.63(a)(1), (a)(2)(ii), (iii), (iv), (a)(3), and (4), when determining which persons are reasonably likely to be exposed as required for §721.63(a)(1) and (4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (a)(5) (respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 10), (a)(6) (particulate), (a)(6)(v), (vi), (b) (concentration set at 1.0%), and (c).

(A) As an alternative to the respirator requirements in paragraph (a)(2)(i) of this section, a manufacturer or processor may choose to follow the new chemical exposure limit (NCEL) provision listed in the TSCA section 5(e) Order for this substance. The NCEL is 0.9 mg/m³ as an 8-hour time-weighted average. Persons who wish to pursue NCELS as an alternative to §721.63 respirator requirements may request to do so under §721.30. Persons whose §721.30 requests to use the NCELS approach are approved by EPA will be required to follow NCELS provisions comparable to those contained in the corresponding TSCA section 5(e) Order.

(B) [Reserved]

(ii) Hazard communication.

Requirements as specified in §721.72(a) through (e) (concentration set at 1.0%), (f), (g)(1)(ii), (ix), (g)(2)(i), (ii), (iii), (use respiratory protection or maintain workplace airborne concentrations at or below an 8-hour time-weighted average of 0.9 mg/m³, (g)(2)(v), and (g)(5).
Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System (GHS) and OSHA Hazard Communication Standard may be used.

(iii) Industrial, commercial, and consumer activities. Requirements as specified in § 721.80(k), (a), (g), (l) (594,000 kilograms, P–15–706 and P–15–707 combined), and (t) (250,000 kilograms, P–15–706 and P–15–707 combined). A significant new use is any manufacture, processing, or use of the PMN substance with more than 1% residual isocyanate by weight.

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

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

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

(3) Determining whether a specific use is subject to this section. The provisions of § 721.127(b)(1) apply to paragraph (a)(2)(iii) of this section.

11. Add § 721.11031 to subpart E to read as follows:

§ 721.11031 Alkyl heteromonocycle, polymer with heteromonocycle, carboxyalkyl alkyl ether (generic).

(a) Chemical substances and significant new uses subject to reporting.

(1) The chemical substances identified generically as alkyl heteromonocycle, polymer with heteromonocycle, carboxyalkyl alkyl ether (PMNs P–16–273 and P–16–272) are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) Protection in the workplace.

Requirements as specified in § 721.63(a)(1), (3), (4), when determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) and (4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (a)(5) (respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 25), (a)(6)(i), (particulate), (b) (concentration set at 1.0%), and (c).

(A) As an alternative to the respirator requirements in paragraph (a)(2)(i) of this section, a manufacturer or processor may choose to follow the new chemical exposure limit (NCEL) provision listed in the TSCA section 5(e) Order for this substance. The NCEL is 1.2 mg/m³ as an 8-hour time weighted average. Persons who wish to pursue NCELS as an alternative to § 721.63 respirator requirements may request to do so under § 721.30. Persons whose § 721.30 requests to use the NCELS approach are approved by EPA will be required to follow NCELS provisions comparable to those contained in the corresponding TSCA section 5(e) Order.

(B) [Reserved]

(ii) Hazard communication.

Requirements as specified in § 721.72(a) through (e) (concentration set at 1.0%), (f), (g)(1)(iv), (vi), (viii), (ix), (g)(2)(i), (ii), (iii), (use respiratory protection or maintain workplace airborne concentrations at or below an 8-hour time-weighted average of 1.2 mg/m³), (v), (g)(3) (This substance may be toxic to algae. This substance may be harmful to invertebrates), (g)(4)(i), (ii), (do not release to water to yield surface water...
concentrations above 18 ppb., and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System (GHS) and OSHA Hazard Communication Standard may be used.

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

(iv) Release to water. Requirements as specified in §721.90(a)(4), (b)(4), and (c)(4) where N = 18.

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

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

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

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

14. Add §721.11034 to subpart E to read as follows:

§721.11034 Xanthylum, (sulfooaryl)-bis [([substituted aryl] amino)-, sulfo derivs., inner salts, metal salts (generic).

(a) Chemical substance and significant new uses subject to reporting.

(1) The chemical substance identified generically as xanthylum, (sulfooaryl)-bis [([substituted aryl] amino)-, sulfo derivs., inner salts, metal salts (PMN P–16–338) 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), (k), and (t).

(ii) 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), (b), (c), (l), (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.

15. Add §721.11035 to subpart E to read as follows:

§721.11035 Substituted triazinyl metal salt, diazotized, coupled with substituted pyridobenzimidazolesulfonic acids, substituted pyridobenzimidazolesulfonic acids, diazotized substituted alkanesulfonic acid, diazotized substituted aromatic sulfonate, diazotized substituted aromatic sulfonate, metal salts (generic).

(a) Chemical substance and significant new uses subject to reporting.

(1) The chemical substance identified generically as substituted triazinyl metal salt, diazotized, coupled with substituted pyridobenzimidazolesulfonic acids, substituted pyridobenzimidazolesulfonic acids, diazotized substituted alkanesulfonic acid, diazotized substituted aromatic sulfonate, diazotized substituted aromatic sulfonate, metal salts (generic).

(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.

16. Add §721.11036 to subpart E to read as follows:

§721.11036 Carbon black, (organic acidic carbocyclic)-modified, metal salt (generic).

(a) Chemical substance and significant new uses subject to reporting.

(1) The chemical substance identified generically as carbon black, (organic acidic carbocyclic)-modified, metal salt (PMN P–16–440) 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), (k), and (t).

(ii) 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 (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.

17. Add §721.11037 to subpart E to read as follows:

§721.11037 Carbon black, (organic acidic carbocyclic)-modified, metal salt (generic).

(a) Chemical substance and significant new uses subject to reporting.

(1) The chemical substance identified generically as carbon black, (organic acidic carbocyclic)-modified, metal salt (PMN P–16–440) 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), (k), and (t).

(ii) 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 (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.

18. Add §721.11038 to subpart E to read as follows:

§721.11038 Polyaralkyl aryl ester of methacrylic acid (generic).

(a) Chemical substance and significant new uses subject to reporting.

(1) The chemical substance identified as
generically as polyalkyl aryl ester of methacrylic acid (PMN P–16–350) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:
   (i) **Protection in the workplace.** Requirements as specified in §721.63(a)(1), (a)(2)(i), (a)(3), (a)(5), (vi), (particulate), (b) (concentration set at 1.0%), and (c). When determining which persons are reasonably likely to be exposed as required for §721.63(a)(1) engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, and (c).
   (ii) **Hazard communication.** Requirements as specified in §721.72(a) through (e) (concentration set at 1.0%), (f), (g)(1)(i), (iv), (vi), (ix), (g)(2)(i), (v), (g)(3)(i), (ii), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System (GHS) and OSHA Hazard Communication Standard may be used.
   (iii) **Industrial, commercial, and consumer activities.** Requirements as specified in §721.80(k). It is a significant new use to manufacture the substance lower than the minimum average molecular weight identified in the Order and to contain more than the maximum weight percent of low molecular weight species below 1,000 daltons identified in the Order.
   (b) **Specific requirements.** The provisions of subpart A of this part apply to this section except as modified by this paragraph.
   (1) **Recordkeeping.** Recordkeeping requirements as specified in §721.125(a) through (i) are applicable to manufacturers and processors of this substance.
   (2) **Limitations or revocation of certain notification requirements.** The provisions of §721.185 apply to this section.
   (3) **Determining whether a specific use is subject to this section.** The provisions of §721.1725(b)(1) apply to paragraph (a)(2)(iii) of this section.

■ 19. Add §721.11039 to subpart E to read as follows:

### §721.11039 Phenol, 2-[[3-(octyloxy)propyl]limino[methyl]].

(a) **Chemical substance and significant new uses subject to reporting.**
   (1) The chemical substance identified as phenol, 2-[[3-(octyloxy)propyl]limino[methyl]] (PMN P–16–352) chemical A; CAS No. 1858221–49–4 is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

   (2) The significant new uses are:
   (i) **Protection in the workplace.** Requirements as specified in §721.63(a)(1), (a)(2)(i), (a)(3), (a)(6)(v), (vi), (particulate), (b) (concentration set at 1.0%), and (c). When determining which persons are reasonably likely to be exposed as required for §721.63(a)(1) engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible.
   (ii) **Hazard communication.** Requirements as specified in §721.72(a) through (e) (concentration set at 1.0%), (f), (g)(1)(i), (iv), (vi), (ix), (g)(2)(i), (v), (g)(3)(i), (ii), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System (GHS) and OSHA Hazard Communication Standard may be used.
   (iii) **Industrial, commercial, and consumer activities.** Requirements as specified in §721.80(f), (p) (10,500 and 13,000 kilograms respectively for the total of this substance and the substance subject to §721.11039), (t) (250 kilograms for the total of this substance and the substance subject to §721.11039), and (y)(1).
   (iv) **Release to water.** Requirements as specified in §721.90(a)(4), (b)(4), and (c)(4) where \( N = 1 \).
   (b) **Specific requirements.** The provisions of subpart A of this part apply to this section except as modified by this paragraph.
   (1) **Recordkeeping.** Recordkeeping requirements as specified in §721.125(a) through (i), and (k) are applicable to manufacturers and processors of this substance.
   (2) **Limitations or revocation of certain notification requirements.** The provisions of §721.185 apply to this section.

■ 21. Add §721.11041 to subpart E to read as follows:

### §721.11041 Alkyl phenol (generic).

(a) **Chemical substance and significant new uses subject to reporting.**
   (1) The chemical substance identified generically as alkyl phenol (PMN P–16–358) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
   (2) The significant new uses are:

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

(ii) Hazard communication. Requirements as specified in §721.72(a) through (e) (concentration set at 1.0%), (f), (g)(1)(i)(x), (g)(2)(i), (ii), (iii), (iv), (g)(4)(iii), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System (GHS) and OSHA Hazard Communication Standard may be used.

(iii) Industrial, commercial, and consumer activities. Requirements as specified in §721.80(a) through (c), (g), (q), (y)(1), and (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 (l), 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.

■ 23. Add §721.11043 to subpart E to read as follows:

§721.11043 Starch, polymer with 2-propenoic acid, potassium salt, oxidized.

(a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as starch, polymer with 2-propenoic acid, potassium salt, oxidized (PMN P–16–399, CAS No. 1638117–09–5) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) Protection in the workplace. Requirements as specified in §721.63(a)(1), (a)(2)(i), (a)(3), (4), when determining which persons are reasonably likely to be exposed as required for §721.63(a)(1) and (4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (a)(5) (respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 10), (a)(6)(i), (v), (vi), (b) (concentration set at 1.0%), and (c).

(ii) Hazard communication. Requirements as specified in §721.72(a) through (e) (concentration set at 1.0%), (f), (g)(1)(i), (ii), (vi), (g)(2)(i), (ii), (iii), (iv), (g)(3)(i), (ii), (g)(4)(i), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System (GHS) and OSHA Hazard Communication Standard may be used.

(iii) Industrial, commercial, and consumer activities. Requirements as specified in §721.80(f) and (k) (import of the substance at or below the maximum concentration specified in the Order).

(iv) Release to water. Requirements as specified in §721.90(a)(4), [b](4), and (c)(4) where N = 14.

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

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

(2) Limitations or revocation of certain notification requirements. The provisions of §721.185 apply to this section.
26. Add § 721.11046 to subpart E to read as follows:

§ 721.11046 Hydroxy alkylbiphenyl (generic).

(a) Chemical substance and significant new uses subject to reporting.

(1) The chemical substance identified generically as hydroxy alkylbiphenyl (PMN P–16–513) 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), (3), (4), when determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (a)(6) [particulate], (b) [concentration set at 1.0%], and (c).

(ii) Hazard communication. Requirements as specified in § 721.72(a) through (e) [concentration set at 1.0%], (f), (g)(1)(i), (ii), (iv), (g)(2)(i), (ii), (v), (g)(3)(i), (ii), (g)(4)(i), and (g)(5).

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

(iii) Industrial, commercial, and consumer activities. Requirements as specified in § 721.80(q) and (y)(1). A significant new use is any manner or method of manufacturing that results in inhalation exposure.

(iv) Release to water. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where N = 200.

(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)(iii) of this section.

(1) The chemical substance identified generically as alkyl alkenoic acid, polymer with alkenylcarbomonocycle telomer with substituted alkanoic acid hydroxy alkyl substituted alkyl ester, alkanediol diheteromonocyclic ether, polyalkylene glycol alkyl ether alkylnaioate, dialkylene glycol diheteromonocyclic ether and alkylcarbomonocyclic alkenoate, metal salt (PMN P–16–534) 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(i) and (k). It is a significant new use to manufacture the substance such that the lowest number average molecular weight is less than 1,800 daltons and the carboxylic acid content exceeds 20 percent.

(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)(iii) of this section.

28. Add § 721.11048 to subpart E to read as follows:

§ 721.11048 Alkyl alkenoic acid, polymer with alkenylcarbomonocycle telomer with substituted alkanoic acid hydroxy alkyl substituted alkyl ester, alkanediol diheteromonocyclic ether, polyalkylene glycol alkyl ether alkynoate and alkylnaioate, metal salt (generic).

(a) Chemical substance and significant new uses subject to reporting.

(1) The chemical substance identified generically as alkyl alkenoic acid, polymer with alkenylcarbomonocycle telomer with substituted alkanoic acid hydroxy alkyl substituted alkyl ester, polyalkylene glycol alkyl ether alkylnaioate, dialkylene glycol diheteromonocyclic ether and alkylcarbomonocyclic alkenoate, metal salt (PMN P–16–535) 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) and (k). It is a significant new use to manufacture the substance such that the lowest number average molecular weight is less than 1,800 daltons and the carboxylic acid content exceeds 20 percent).

(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)(iii) of this section.

29. Add § 721.11049 to subpart E to read as follows:

§721.11049 Alkyl alkenoic acid, polymer with bis heteromonomocyclic substituted alkyl carbomonocycle, alkylcarbomonocycle telomer with substituted alkanoic acid hydroxyl alkyl substituted alkyl ester, polyalkylene glycol alkyl ether alkyl alkenoate and alkylcarbomonocyclic alkenoate, metal salt (generic).

(a) Chemical substance and significant new uses subject to reporting.

(1) The chemical substance identified generically as alkyl alkenoic acid, polymer with bis heteromonomocyclic substituted alkyl carbomonocycle, alkylcarbomonocycle telomer with substituted alkanoic acid hydroxyl alkyl substituted alkyl ester, polyalkylene glycol alkyl ether alkyl alkenoate and alkylcarbomonocyclic alkenoate, metal salt (PMN P–16–536) 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) and (k). It is a significant new use to manufacture the substance such that the lowest number average molecular weight is less than 1,800 daltons, and the carboxylic acid content exceeds 20 percent).

(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.

30. Add § 721.11050 to subpart E to read as follows:

§721.11050 Certain functionalized methacrylate-substituted polymers.

(a)(1) The chemical substances listed in the Table of this section is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substances after they have been reacted (cured).

Table—Functionalized Methacrylate-Substituted Polymers

<table>
<thead>
<tr>
<th>PMN No.</th>
<th>Chemical name</th>
</tr>
</thead>
<tbody>
<tr>
<td>P–16–549</td>
<td>Alkaline functionalized methacrylate-substituted polymer (generic).</td>
</tr>
<tr>
<td>P–16–550</td>
<td>Alkaline functionalized methacrylate-substituted polymer (generic).</td>
</tr>
<tr>
<td>P–16–551</td>
<td>Alkaline functionalized methacrylate-substituted polymer (generic).</td>
</tr>
<tr>
<td>P–16–553</td>
<td>Quaternary alkylamine functionalized methacrylate-substituted polymer (generic).</td>
</tr>
<tr>
<td>P–16–554</td>
<td>Neutral alcohol functionalized methacrylate-substituted polymer (generic).</td>
</tr>
<tr>
<td>P–16–555</td>
<td>Neutral alcohol functionalized methacrylate-substituted polymer (generic).</td>
</tr>
<tr>
<td>P–16–556</td>
<td>Neutral alcohol functionalized methacrylate-substituted polymer (generic).</td>
</tr>
<tr>
<td>P–16–557</td>
<td>Neutral alcohol functionalized methacrylate-substituted polymer (generic).</td>
</tr>
<tr>
<td>P–16–558</td>
<td>Neutral alcohol functionalized methacrylate-substituted polymer (generic).</td>
</tr>
<tr>
<td>P–16–559</td>
<td>Neutral alcohol functionalized methacrylate-substituted polymer (generic).</td>
</tr>
<tr>
<td>P–16–560</td>
<td>Neutral alcohol functionalized methacrylate-substituted polymer (generic).</td>
</tr>
<tr>
<td>P–16–561</td>
<td>Acid functionalized methacrylate-substituted polymer (generic).</td>
</tr>
<tr>
<td>P–16–562</td>
<td>Acid functionalized methacrylate-substituted polymer (generic).</td>
</tr>
<tr>
<td>P–16–563</td>
<td>Acid functionalized methacrylate-substituted polymer (generic).</td>
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<tr>
<td>P–16–564</td>
<td>Acid functionalized methacrylate-substituted polymer (generic).</td>
</tr>
<tr>
<td>P–16–565</td>
<td>Acid functionalized methacrylate-substituted polymer (generic).</td>
</tr>
<tr>
<td>P–16–567</td>
<td>Alkylamine functionalized methacrylate-substituted polymer (generic).</td>
</tr>
</tbody>
</table>

(2) The significant new uses are:

(i) Protection in the workplace. Requirements as specified in §721.63(a)(1), (a)(2)(i), (iii), (a)(3), when determining which persons are reasonably likely to be exposed as required for §721.63(a)(1) engineering control measures (e.g., enclosure or confinement of 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)(6) (particulate), (b) (concentration set at 1.0%), and (c).

(ii) Industrial, commercial, and consumer activities. Requirements as specified in §721.80(f) and (k) (crosslinked resin used for chromatographic separation of biomolecules and biocatalysts). It is a significant new use to import the substance in any form other than spherical beads with 0.1 percent less than 10 microns

(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.

31. Add § 721.11051 to subpart E to read as follows:
§ 721.11051 Waste plastics, poly(ethylene terephthalate), depolymd. with polypropylene glycol ether with glycerol (3:1), polymers with alkenoic and alkanoic acids (generic).

(a) Chemical substance and significant new uses subject to reporting.
(1) The chemical substance identified generically as waste plastics, poly(ethylene terephthalate), depolymd. with polypropylene glycol ether with glycerol (3:1), polymers with alkenoic and alkanoic acids (PMN P–16–579) 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), (4), when determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) and (4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (a)(5) (respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 50), (a)(6) (concentration set 1.0%), and (c).
(ii) Hazard communication.
Requirements as specified in § 721.72(a) through (e) (concentration set at 1.0%), (f), (g)(1) (This substance may cause respiratory and dermal irritation). This substance may cause irritation of the mucous membranes. (This substance may cause respiratory and dermal sensitization). (This substance may cause mutagenicity), (g)(2)(i), (ii), (iii), (iv), (v), (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System (GHS) and OSHA Hazard Communication Standard may be used. (iii) Industrial, commercial, and consumer activities. Requirements as specified in § 721.80(k) (an ultraviolet curable coating resin). It is a significant new use to manufacture the substance with an average molecular weight less than 1,100 Daltons.
(b) Specific requirements. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
(1) Recordkeeping. Recordkeeping requirements as specified in § 721.125(a) 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.

§ 721.11052 1,3,5-Naphthalenetrisulfonic acid.

(a) Chemical substance and significant new uses subject to reporting.
(1) The chemical substance identified as 1,3,5-naphthalenetrisulfonic acid (PMN P–17–32, CAS No. 6654–64–4) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
(2) The significant new uses are:
(i) Protection in the workplace.
Requirements as specified in § 721.63(a)(1), (a)(2)(i), (a)(3), (4), when determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) and (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)

TABLE—HALOGENATED SODIUM BENZOATE SALTS

<table>
<thead>
<tr>
<th>PMN No.</th>
<th>CAS No.</th>
<th>Chemical name</th>
</tr>
</thead>
<tbody>
<tr>
<td>P–17–32</td>
<td>6654–64–4</td>
<td>Benzoic acid, 2-fluoro-, sodium salt (1:1).</td>
</tr>
</tbody>
</table>
| P–17–34 | 499–90–1 | Benzoic acid, 4-fluoro-, sodium salt (1:1).
| P–17–36 | 67652–79–3 | Benzoic acid, 2,3,4,5-tetrafluoro-, sodium salt (1:1).
| P–17–38 | 25066–44–1 | Benzoic acid, tetrafluoro-, sodium salt (1:1).
| P–17–41 | 522651–42–9 | Benzoic acid, 2,5-difluoro-, sodium salt (1:1).
| P–17–42 | 499–57–0 | Benzoic acid, 3-fluoro-, sodium salt (1:1).
| P–17–43 | 6185–28–0 | Benzoic acid, 2,6-difluoro-, sodium salt (1:1).
| P–17–47 | 1765–08–8 | Benzoic acid, 4-fluoro-, sodium salt (1:1).
| P–17–50 | 522651–44–1 | Benzoic acid, 3,4-difluoro-, sodium salt (1:1).
| P–17–52 | 1180493–12–2 | Benzoic acid, 3,4,5-trifluoro-, sodium salt (1:1).
| P–17–55 | 402955–41–3 | Benzoic acid, 2,3,4-trifluoro-, sodium salt (1:1).
| P–17–57 | 522651–48–5 | Benzoic acid, 2,4,5-trifluoro-, sodium salt (1:1).
| P–17–59 | 1604819–08–0 | Benzoic acid, 2,3-difluoro-, sodium salt (1:1).
| P–17–61 | 69226–41–1 | Benzoic acid, 3,4,5-trifluoro-, sodium salt (1:1).
| P–17–63 | 3866–66–6 | Benzoic acid, 4-chloro-, sodium salt (1:1).
TABLE—HALOGENATED SODIUM BENZOATE SALTS—Continued

<table>
<thead>
<tr>
<th>PMN No.</th>
<th>CAS No.</th>
<th>Chemical name</th>
</tr>
</thead>
<tbody>
<tr>
<td>P–17–64</td>
<td>17264–88–9</td>
<td>Benzoic acid, 3-chloro-, sodium salt (1:1).</td>
</tr>
<tr>
<td>P–17–66</td>
<td>118537–84–1</td>
<td>Benzoic acid, 2,3-dichloro-, sodium salt (1:1).</td>
</tr>
<tr>
<td>P–17–67</td>
<td>63891–98–5</td>
<td>Benzoic acid, 2,5-dichloro-, sodium salt (1:1).</td>
</tr>
<tr>
<td>P–17–69</td>
<td>154662–40–5</td>
<td>Benzoic acid, 3,5-dichloro-, sodium salt (1:1).</td>
</tr>
<tr>
<td>P–17–71</td>
<td>10007–84–6</td>
<td>Benzoic acid, 6-chloro-, sodium salt (1:1).</td>
</tr>
<tr>
<td>P–17–72</td>
<td>17274–10–1</td>
<td>Benzoic acid, 3,4-dichloro-, sodium salt (1:1).</td>
</tr>
<tr>
<td>P–17–73</td>
<td>38402–11–8</td>
<td>Benzoic acid, 2,4-dichloro-, sodium salt (1:1).</td>
</tr>
<tr>
<td>P–17–75</td>
<td>855471–43–1</td>
<td>Benzoic acid, 2-chloro-4-fluoro-, sodium salt.</td>
</tr>
<tr>
<td>P–17–76</td>
<td>1421761–18–3</td>
<td>Benzoic acid, 3-chloro-4-fluoro-, sodium salt.</td>
</tr>
<tr>
<td>P–17–80</td>
<td>1421029–88–0</td>
<td>Benzoic acid, 4-chloro-3-fluoro-, sodium salt.</td>
</tr>
<tr>
<td>P–17–83</td>
<td>1382106–64–0</td>
<td>Benzoic acid, 4-chloro-2-fluoro-, sodium salt.</td>
</tr>
<tr>
<td>P–17–85</td>
<td>1938142–12–1</td>
<td>Benzoic acid, 5-bromo-2-chloro-, sodium salt.</td>
</tr>
<tr>
<td>P–17–87</td>
<td>938142–13–2</td>
<td>Benzoic acid, 3-bromo-4-fluoro-, sodium salt.</td>
</tr>
<tr>
<td>P–17–93</td>
<td>1535169–81–3</td>
<td>Benzoic acid, 4-bromo-3-fluoro-, sodium salt.</td>
</tr>
</tbody>
</table>

(2) The significant new uses are:

(i) Protection in the workplace. Requirements as specified in § 721.63(a)(1), (2)(i), (iv), (a)(3), when determining which persons are reasonably likely to be exposed as required for § 721.63(a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (a)(5) (respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor of at least 50). (a)(6) (particulate), (a)(6)(v), (vi), (b) (concentration set at 1.0%), and (c).

(A) As an alternative to the respirator requirements in paragraph (a)(2)(i) of this section, a manufacturer or processor may choose to follow the new chemical exposure limit (NCEL) provision listed in the TSCA section 5(e) Order for this substance. The NCEL is 0.0184 mg/m³ as an 8-hour time-weighted average. Persons who wish to pursue NCELs as an alternative to § 721.63 respirator requirements may request to do so under § 721.30. Persons whose § 721.30 requests to use the NCELs approach are approved by EPA will be required to follow NCELs provisions comparable to those contained in the corresponding TSCA section 5(e) Order.

(B) [Reserved]

(ii) Hazard communication. Requirements as specified in § 721.72(a) through (e) (concentration set at 1.0%), (f), (g)(1)(i), (ii), (iii), (iv), (v), (ix), (g)(2)(i), (ii), (iii), (use respiratory protection or maintain workplace airborne concentrations at or below an 8-hour time-weighted average of 0.0184 mg/m³), (g)(2)(v), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System (GHS) and OSHA Hazard Communication Standard may be used.

(iii) Industrial, commercial, and consumer activities. Requirements as specified in § 721.80(k), (g) and (t). It is a significant new use to manufacture or process the substances other than for the processes described in the Order.

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

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

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

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

§ 721.11054 Certain halogenated benzoic acids

(a) The chemical substances listed in the Table of this section is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

TABLE—HALOGENATED BENZOIC ACIDS

<table>
<thead>
<tr>
<th>PMN No.</th>
<th>CAS No.</th>
<th>Chemical name</th>
</tr>
</thead>
<tbody>
<tr>
<td>P–17–35</td>
<td>1201–31–6</td>
<td>Benzoic acid, 2,3,4,5-tetrafluoro-.</td>
</tr>
<tr>
<td>P–17–40</td>
<td>2991–28–8</td>
<td>Benzoic acid, 2,5-difluoro-.</td>
</tr>
<tr>
<td>P–17–44</td>
<td>385–00–2</td>
<td>Benzoic acid, 2,6-difluoro-.</td>
</tr>
<tr>
<td>P–17–46</td>
<td>455–40–3</td>
<td>Benzoic acid, 3,5-difluoro-.</td>
</tr>
<tr>
<td>P–17–48</td>
<td>1583–58–0</td>
<td>Benzoic acid, 2,4-difluoro-.</td>
</tr>
<tr>
<td>P–17–51</td>
<td>455–86–7</td>
<td>Benzoic acid, 3,4-difluoro-.</td>
</tr>
<tr>
<td>P–17–53</td>
<td>121602–93–5</td>
<td>Benzoic acid, 3,5-difluoro-.</td>
</tr>
<tr>
<td>P–17–54</td>
<td>61079–72–9</td>
<td>Benzoic acid, 2,3,4-trifluoro-.</td>
</tr>
<tr>
<td>P–17–56</td>
<td>446–17–3</td>
<td>Benzoic acid, 2,4,5-trifluoro-.</td>
</tr>
<tr>
<td>P–17–58</td>
<td>4519–39–5</td>
<td>Benzoic acid, 2,3-difluoro-.</td>
</tr>
<tr>
<td>P–17–65</td>
<td>50–45–3</td>
<td>Benzoic acid, 2,3-dichloro-.</td>
</tr>
<tr>
<td>P–17–68</td>
<td>51–36–6</td>
<td>Benzoic acid, 2,4-dichloro-.</td>
</tr>
<tr>
<td>P–17–70</td>
<td>50–30–6</td>
<td>Benzoic acid, 2,6-dichloro-.</td>
</tr>
</tbody>
</table>
(2) The significant new uses are:

(i) Protection in the workplace. Requirements as specified in § 721.63(a)(1), (a)(2)(i), (v), (a)(3), (4), when determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) and (4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (a)(5) (respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor of at least 50, (a)(6) (particulate), (a)(6)(v), (vi), (b) [concentration set at 1.0%], and (c).

(A) As an alternative to the respirator requirements in paragraph (a)(2)(i) of this section, a manufacturer or processor may choose to follow the new chemical exposure limit (NCEL) provision listed in the TSCA section 5(e) Order for this substance. The NCEL is 0.0184 mg/m³ as an 8-hour time weighted average.

Persons who wish to pursue NCELS as an alternative to § 721.63 respirator requirements may request to do so under § 721.30. Persons whose § 721.30 requests to use the NCELS approach are approved by EPA will be required to follow NCELS provisions comparable to those contained in the corresponding TSCA section 5(e) Order.

(B) [Reserved]

(ii) Hazard communication.

Requirements as specified in § 721.72(a) through (e) (concentration set at 1.0%), (f), (g)(1)(i), (ii), (iii), ( iv), (vi), (ix), (g)(2)(i), (ii), (iii), (use respiratory protection or maintain workplace airborne concentrations at or below an 8-hour time-weighted average of 0.0184 mg/m³), (g)(2)(v), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System (GHS) and OSHA Hazard Communication Standard may be used.

(iii) Industrial, commercial, and consumer activities. Requirements as specified in § 721.80(q) and (t). It is a significant new use to manufacture or process the substances other than for the processes described in the Order.

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

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

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

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

☐ 35. Add § 721.11055 to part E to read as follows:

§ 721.11055 Certain halogenated benzoic acids ethyl esters.

(a) The chemical substances listed in the Table of this section is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

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### Table—Halogenated Benzoic Acids—Continued

<table>
<thead>
<tr>
<th>PMN No.</th>
<th>CAS No.</th>
<th>Chemical name</th>
</tr>
</thead>
<tbody>
<tr>
<td>P–17–74</td>
<td>2252–51–9</td>
<td>Benzoic acid, 2-chloro-4-fluoro-ethy ester.</td>
</tr>
<tr>
<td>P–17–78</td>
<td>403–16–7</td>
<td>Benzoic acid, 3-chloro-4-fluoro-ethy ester.</td>
</tr>
<tr>
<td>P–17–81</td>
<td>403–17–8</td>
<td>Benzoic acid, 4-chloro-3-fluoro-ethy ester.</td>
</tr>
<tr>
<td>P–17–84</td>
<td>446–30–0</td>
<td>Benzoic acid, 4-chloro-2-fluoro-ethy ester.</td>
</tr>
<tr>
<td>P–17–89</td>
<td>11007–16–5</td>
<td>Benzoic acid, 3-bromo-4-fluoro-ethy ester.</td>
</tr>
<tr>
<td>P–17–97</td>
<td>153556–42–4</td>
<td>Benzoic acid, 4-bromo-3-fluoro-ethy ester.</td>
</tr>
<tr>
<td>P–17–98</td>
<td>112704–79–7</td>
<td>Benzoic acid, 4-bromo-2-fluoro-ethy ester.</td>
</tr>
</tbody>
</table>

---

### Table—Halogenated Benzoic Acid Ethyl Esters

<table>
<thead>
<tr>
<th>PMN No.</th>
<th>CAS No.</th>
<th>Chemical name</th>
</tr>
</thead>
<tbody>
<tr>
<td>P–17–94</td>
<td>122894–73–9</td>
<td>Benzoic acid, 2,3,4,5-tetrafluoro-, ethyl ester.</td>
</tr>
<tr>
<td>P–17–95</td>
<td>583–02–8</td>
<td>Benzoic acid, 4-(trifluoromethyl)-, ethyl ester.</td>
</tr>
<tr>
<td>P–17–100</td>
<td>351354–50–2</td>
<td>Benzoic acid, 2,3,4-trifluoro-, ethyl ester.</td>
</tr>
<tr>
<td>P–17–125</td>
<td>23233–33–2</td>
<td>Benzoic acid, 3-bromo-4-fluoro-, ethyl ester.</td>
</tr>
<tr>
<td>P–17–128</td>
<td>203573–08–4</td>
<td>Benzoic acid, 4-chloro-3-fluoro-, ethyl ester.</td>
</tr>
<tr>
<td>P–17–131</td>
<td>108928–00–3</td>
<td>Benzoic acid, 2,4-difluoro-, ethyl ester.</td>
</tr>
</tbody>
</table>
(2) The significant new uses are:
  (i) Protection in the workplace.
  Requirements as specified in §721.63(a)(1), (a)(2)(i), (v), (a)(3), (4), when determining which persons are reasonably likely to be exposed as required for §721.63(a)(1) and (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, (b) (A) As an alternative to the respirator requirements in paragraph (a)(2)(i) of this section, a manufacturer or processor may choose to follow the new chemical exposure limit (NCEL) provision listed in the TSCA section 5(e) Order for this substance. The NCEL is 0.0184 mg/m³ as an 8-hour time weighted average. Persons who wish to pursue NCELS as an alternative to §721.63 respiratory requirements may request to do so under §721.30. Persons whose §721.30 requests to use the NCELS approach are approved by EPA will be required to follow NCELS provisions comparable to those contained in the corresponding TSCA section 5(e) Order.
  (B) [Reserved] (ii) Hazard communication.
  Requirements as specified in §721.72(a) through (e) (concentration set 1.0%), (f), (g)(1)(ix), (The substance may react violently with water, (This substance may cause skin irritation and corrosion), (This substance may cause respiratory complications, irritation, and corrosion), (g)(2)(i), (ii), (iii), (When using this substance use in closed system to prevent any inhalation exposure), (When using this substance use skin and eye protection), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System (GHS) and OSHA Hazard Communication Standard may be used.
  (iii) Industrial, commercial, and consumer activities. Requirements as specified in §721.80(q) and (t). It is a significant new use to manufacture or process the substances other than for processes described in the Order.
  (iv) Release to water. Requirements as specified in §721.90(a)(4), (b)(4), and (c)(4) where N = 15 ppb.
  (b) Specific requirements. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
  (1) Recordkeeping. Recordkeeping requirements as specified in §721.125(a) through (i) and (k) are applicable to manufacturers and processors of this substance.
  (2) Limitations or revocation of certain notification requirements. The provisions of §721.185 apply to this section.
  (3) Determining whether a specific use is subject to this section. The provisions of §721.1725(b)(1) apply to paragraph (a)(2)(ii) of this section.
  ■ 36. Add §721.11056 to subpart E to read as follows:

§721.11056 Neodymium aluminium alkyl polymer complexes (generic).
(a) Chemical substance and significant new uses subject to reporting.
(1) The chemical substance identified generically as neodymium aluminium alkyl polymer complexes (PMN P–17–196) 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), (ii), (iii), (iv), (vi), (ix), (g)(2)(i), (ii), (iii), (use respiratory protection or maintain workplace airborne concentrations at or below an 8-hour time-weighted average of 0.0184 mg/m³), (g)(2)(v), (g)(3)(i), (ii), (g)(4)(i), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System (GHS) and OSHA Hazard Communication Standard may be used.
  (iii) Industrial, commercial, and consumer activities. Requirements as specified in §721.72(a) through (e) (concentration set 1.0%), (f), (g)(1)(ix), (The substance may react violently with water, (This substance may cause skin irritation and corrosion), (This substance may cause respiratory complications, irritation, and corrosion), (g)(2)(i), (ii), (iii), (When using this substance use in closed system to prevent any inhalation exposure), (When using this substance use skin and eye protection), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System (GHS) and OSHA Hazard Communication Standard may be used.

§721.11057 Fatty acid amide alkyl amine salts (generic).
(a) Chemical substance and significant new uses subject to reporting.
(1) The chemical substances identified generically as fatty acid amide alkyl amine salts (PMN P–17–272, P–17–273, P–17–274, P–17–275, P–17–276 and P–17–277) are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section

### TABLE—HALOGENATED BENZOIC ACID ETHYL ESTERS—Continued

<table>
<thead>
<tr>
<th>PMN No.</th>
<th>CAS No.</th>
<th>Chemical name</th>
</tr>
</thead>
<tbody>
<tr>
<td>P–17–132</td>
<td>144267–96–9</td>
<td>Benzoic acid, 3,4-difluoro-, ethyl ester.</td>
</tr>
<tr>
<td>P–17–133</td>
<td>495405–09–9</td>
<td>Benzoic acid, 3,4,5-trifluoro-, ethyl ester.</td>
</tr>
<tr>
<td>P–17–134</td>
<td>351354–41–1</td>
<td>Benzoic acid, 2,4,5-trifluoro-, ethyl ester.</td>
</tr>
<tr>
<td>P–17–135</td>
<td>76763–59–0</td>
<td>Benzoic acid, 3-(trifluoromethyl)-, ethyl ester.</td>
</tr>
<tr>
<td>P–17–137</td>
<td>81055–73–4</td>
<td>Benzoic acid, 2,6-dichloro-, ethyl ester.</td>
</tr>
<tr>
<td>P–17–139</td>
<td>56882–52–1</td>
<td>Benzoic acid, 2,4-dichloro-, ethyl ester.</td>
</tr>
<tr>
<td>P–17–140</td>
<td>28394–58–3</td>
<td>Benzoic acid, 3,4-dichloro-, ethyl ester.</td>
</tr>
</tbody>
</table>
do not apply to quantities of the substances after they have been reacted (cured).

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

(ii) Hazard communication.
Requirements as specified in §721.72(a) through (e) (concentration set at 1.0%), (f), (g)(1) (skin irritation), (respiratory complication), (internal organ effect), (systemic effect), (sensitization), (g)(2)(i), (ii), (iii), (v), (g)(3)(i), (ii), (g)(4)(i), (iii), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System (GHS) and OSHA Hazard Communication Standard may be used.

(iii) Industrial, commercial, and consumer activities.
Requirements as specified in §721.80(k), and (y)(1).

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

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

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

§721.11058 Fatty acid amide alkyl amine salts (generic).

(a) Chemical substance and significant new uses subject to reporting.
(1) The chemical substances identified generically as fatty acid amide alkyl amine salts (PMN P–17–278, P–17–279 and P–17–280) are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substances after they have been reacted (cured).

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

(ii) Hazard communication.
Requirements as specified in §721.72(a) through (e) (concentration set at 1.0%), (f), (g)(1) (skin irritation), (respiratory complication), (internal organ effect), (systemic effect), (sensitization), (g)(2)(i), (ii), (iii), (v), (g)(3)(i), (ii), (g)(4)(i), (iii), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System (GHS) and OSHA Hazard Communication Standard may be used.

(iii) Industrial, commercial, and consumer activities.
Requirements as specified in §721.80(k), and (y)(1).

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

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

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

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