



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 721

[EPA-HQ-OPPT-2018-0627; FRL-9983-82]

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 26 chemical substances which were the subject of premanufacture notices (PMNs). The chemical substances are subject to Orders issued by EPA pursuant to sections 5(e) and 5(f) of TSCA. This action requires persons who intend to manufacture (defined by statute to include import) or process any of these 26 chemical substances for an activity that is designated as a significant new use by this rule to notify EPA at least 90 days before commencing that activity. The required notification initiates EPA's evaluation of the intended use within the applicable review period. Persons may not commence manufacture or processing for the significant new use until EPA has conducted a review of the notice, made an appropriate determination on the notice, and has taken such actions as are required with that determination.

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

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

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

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2018-0627, by one of the following methods:

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

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

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

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

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

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

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

moss.kenneth@epa.gov.

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

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

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

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

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

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

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

II. Background

A. What Action is the Agency Taking?

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

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

2. *Proposed Rule.* In addition to this Direct Final Rule, elsewhere in this issue of the **Federal Register**, EPA is issuing a Notice of Proposed Rulemaking for this rule. If EPA receives no adverse comment, the Agency will not take further action on the proposed rule and the direct final rule will become effective as provided in this action. If EPA receives adverse comment on one or more of SNURs in this action by [*insert date 30 days after date of publication in the Federal Register*] (see Unit VI. of the **SUPPLEMENTARY INFORMATION**), the Agency will publish in the **Federal Register** a timely withdrawal of the specific SNURs that the adverse comments pertain to, informing the public that the actions will not take effect. EPA would then address all adverse public comments in a response to comments document in a subsequent final rule, based on the proposed rule.

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

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

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

C. Applicability of General Provisions

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

III. Significant New Use Determination

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

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

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

To determine what would constitute a significant new use for the 26 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 26 chemical substances in 40 CFR part 721, subpart E. In this unit, EPA provides the following information for each chemical substance:

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

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

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

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

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

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

These rules include 26 PMN substances that are subject to Orders under TSCA section 5(e)(1)(A) or section 5(f)(3)(A). Each Order is based on one or more of the findings in TSCA section 5(a)(3)(A) or section 5(a)(3)(B): there is insufficient information to permit a reasoned evaluation; in the absence of sufficient information to permit a reasoned evaluation, the activities associated with the PMN substances may present unreasonable risk to health or the environment; the substance is or will be produced in substantial quantities, and enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant (substantial) human exposure to the substance; presents an unreasonable risk of injury to health or 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(f)(4).

Where EPA determined that the PMN substance presents or may present an unreasonable risk of injury to human health via inhalation exposure, the underlying TSCA section 5(e) or 5(f) Order required, among other things, that potentially exposed employees wear specified respirators unless actual measurements of the workplace air show that air-borne concentrations of the PMN substance are below a New Chemical Exposure Limit (NCEL) that is established by EPA to provide adequate protection to

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

PMN Number: P-10-366

Chemical Name: Carbon nanomaterial (generic).

CAS Number: Not available.

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

Basis for TSCA section 5(e) Order: The PMN states that the generic (non-confidential) use of the substance will be in printing applications. EPA identified concerns for pulmonary toxicity and carcinogenicity based on analogy to carbon black. The Order was issued under TSCA sections 5(e)(1)(A)(i), based on a finding that the available information is insufficient to permit a reasoned evaluation of the human health and environmental effects of the PMN substance. The Order was also issued under TSCA

section 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

1. Submission to EPA of certain health testing and material characterization data before exceeding a specified confidential production volume;
2. Use of personal protective equipment where there is a potential for dermal exposure;
3. Use of a National Institute for Occupational Safety and Health (NIOSH) certified air purifying, tight-fitting full-face respirator equipped with N100, P-100, or R-100 filter with an Assigned Protection Factor (APF) of at least 50 where there is a potential for inhalation exposure;
4. No release of the PMN substance to surface waters;
5. Use of the PMN substance only for the confidential uses specified in the Order;
6. Limit the manufacture, processing and use of the PMN substance to industrial uses;
7. No processing or use of the powder form of the PMN substance outside of the site of manufacture/processing; and
8. No processing or use of the PMN substance in the liquid resin form using an application method that generates a vapor, mist, or aerosol.

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

Potentially useful information: EPA has determined that certain information about the health effects of the PMN substance may be potentially useful to characterize the effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. The submitter has agreed not to exceed certain time limits without performing specific physical-chemical property tests and characterization and pulmonary effects testing. EPA has also determined that the results of a carcinogenicity study would help characterize the potential health effects caused by the PMN substance. Although the Order does not require this test, the Order's restrictions will remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

CFR citation: 40 CFR 721.11149.

PMN Number: P-14-627

Chemical name: Cyclic amide (generic).

CAS Number: Not available.

Effective date of TSCA section 5(e) Order: November 16, 2017.

Basis for TSCA section 5(e) Order: The PMN states that the use of the substance will be in dispersions for industrial coatings (e.g., polyurethane, acrylic, epoxy), coating for consumer and professional use, adhesives and sealants, solvent-borne industrial coatings silicon wafer cleaning in microelectronics in clean rooms, photoresist stripping in microelectronics in clean rooms, coatings for microelectronics (e.g., casting of polymer films) in clean rooms, reaction medium for polymerization, polymer coatings for industrial and professional applications (e.g., wire enamel, non-stick and friction

reduction coating) membranes, solvent for chemical synthesis reactions (e.g., pharmaceuticals), formulation of inks, industrial cleaner (e.g., cleaner for wind turbine, oil rigs, large engines), solvent for cleaning industrial reactors, wax inhibitors (in hydrocarbon lines), petrochemical extraction processes, paint stripper, solvents for production and formulation of fertilizer, solvent for production and formulation of active ingredients for agriculture, and solvent for formulation of active ingredients for agriculture-end use pesticide products. Based on test data on the PMN substance, EPA identified concerns for developmental and reproductive toxicity, skin irritation, and systemic toxicity. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I) based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to health. The Order was also issued under TSCA sections 5(a)(3)(B)(ii)(II) and 5(e)(1)(A)(ii)(II), based on a finding that the substance either enters or may reasonably be anticipated to enter the environment in substantial quantities, or there is or may be significant (or substantial) human exposure to the substance. To protect against these risks, the Order requires:

1. Use of personal protective where there is a potential for dermal exposures;
2. Refraining from domestic manufacture of the PMN substance in the United States (i.e., import only);
3. Import the PMN substance only according to the terms specified in the Order;
4. Use of the PMN substance only for the uses and concentrations specified in the Order;

5. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the Safety Data Sheet (SDS);
6. Processing and use of the PMN substance only for uses specified in the Order; and
7. No use of the PMN substance in hand held spray applications that generate a vapor, mist, or aerosol.

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

Potentially useful information: EPA has determined that certain information about the fate 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. Although the Order does not require these tests, the Order’s restrictions will remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

CFR citations: 40 CFR 721.11150.

PMN Number: P-15-114

Chemical name: 2-Butanone 1,1,1,3,4,4,4-heptafluoro-3-(trifluoromethyl)-.

CAS Number: 756-12-7.

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

Basis for TSCA section 5(e) Order: The PMN states that the use of the substance will be as a dielectric medium for medium and high voltage power generation/distribution

equipment and heat transfer. Based on analysis of test data on the PMN substance, EPA identified concerns for irritation of eyes, skin, lungs, and mucous membranes. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I) of TSCA, based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to health and the environment. To protect against these risks, the Order requires:

1. Use of personal protective equipment where there is a potential for dermal exposure;
2. Establishment and use of a hazard communication program, label containers of the PMN substance with the statement: “contains a dielectric fluid which should not be mixed or used in conjunction with sulfur hexafluoride (SF6)” and provide SDS and worker training in accordance with the provisions of the Hazard Communication Program section;
3. No manufacture of the PMN substance beyond a confidential annual production volume (which includes import) specified in the Order;
4. No use other than as a dielectric medium for medium and high voltage power generation/distribution equipment and heat transfer as described in the Order; and
5. No release of the PMN substance resulting in surface water concentrations that exceed 180 parts per billion (ppb).

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

Potentially useful information: EPA has determined that certain information about the environmental and health effects of the PMN substance may be potentially useful to

characterize the effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of specific chronic aquatic toxicity and pulmonary effects testing would help characterize the potential environmental and health effects of the PMN substance. Although the Order does not require this information, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

CFR citation: 40 CFR 721.11151.

PMN Number: P-15-320

Chemical names: Propanenitrile, 2,3,3,3 tetrafluoro- 2-(trifluoromethyl)-.

CAS Number: 42532-60-5.

Effective date of TSCA section 5(e) Order: October 18, 2017.

Basis for TSCA section 5(e) Order: The PMN states that the use of the substance will be as a dielectric medium for medium and high voltage power generation and distribution equipment. Based on analysis of test data on the PMN substance, EPA identified concerns for neurotoxicity and irritation of eyes, skin, lungs, and mucous membranes.

The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I) of TSCA, based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to health.

To protect against these risks, the Order requires:

1. Establishment and use of a hazard communication program, label containers of the PMN substance with the statement: "contains a dielectric fluid which

should not be mixed or used in conjunction with sulfur hexafluoride (SF6)” and provide SDS and worker training in accordance with the provisions of the Hazard Communication Program section; and

2. Manufacturing, processing, or use as a dielectric medium for medium and high voltage power generation and distribution equipment as described in the PMN.

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

Potentially useful information: EPA has determined that certain information about the health effects of the PMN 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 pulmonary effects testing would help characterize the potential health effects of the PMN substance. Although the Order does not require this test, the Order’s restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

CFR citation: 40 CFR 721.11152.

PMN Number: P-15-734

Chemical name: Polymeric sulfide (generic).

CAS Number: Not available.

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

Basis for TSCA section 5(e) Order: The PMN states that the use of the substance will be for wastewater heavy metals removal. Based on physical/chemical properties of the PMN substance, EPA identified concerns for severe skin irritation, corrosion, neurotoxicity, developmental toxicity, and reproductive toxicity. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I) of TSCA, based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to health and the environment. The Order was also issued under TSCA sections 5(a)(3)(B)(ii)(II) and 5(e)(1)(A)(ii)(II), based on a finding that the substance is or will be produced in substantial quantities and that the substance either enters or may reasonable be anticipated to enter the environment in substantial quantities, or there is or may be significant (or substantial) human exposure to the chemical substance. To protect against these risks, the Order requires:

1. Submission of certain health testing on the PMN substance prior to exceeding the confidential production volume limit specified in the Order;
2. Use of personal protective equipment where there is a potential for dermal exposure;
3. No modification of the manufacturing, processing, or use activities of the PMN substance that result in inhalation exposure to workers;
4. Use of the PMN substance only for wastewater heavy metal removal as specified in the Order;
5. No release of the PMN substance resulting in surface water concentrations that exceed 2 ppb; and

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

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

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

CFR citation: 40 CFR 721.11153.

PMN Numbers: P-16-356 and P-16-357

Chemical name: Quaternary ammonium salts (generic).

CAS numbers: Not available.

Effective date of TSCA section 5(e) Order: February 27, 2018.

Basis for TSCA section 5(e) Order: The PMNs state that the generic (non-confidential) use of the substances will be as wellbore additives. EPA has identified concerns for irritation for the substances based on the pH and concerns for lung effects based on the surfactant properties. Based on analogy to cationic surfactants, EPA has identified ecotoxicity hazard concerns. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substances may present an unreasonable risk of injury

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

1. Use of personal protective equipment where there is 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. Refrain from manufacturing, processing or using the PMN substances in a manner that generates a vapor, mist, or aerosol; and
4. No use of the PMN substances other than the confidential use described in the Order.

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

Potentially useful information: EPA has determined that certain information about the health and environmental effects of the PMN substances may be potentially useful to characterize the effects of the PMN substances in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of specific pulmonary effects testing would help characterize the potential health effects of the PMN substances and results of acute aquatic toxicity testing would help characterize the potential environmental effects of the PMN

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

CFR citation: 40 CFR 721.11154.

PMN Number: P-16-375

Chemical name: Alkyl methacrylates, polymer with olefins (generic).

CAS Number: Not available.

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

Basis for TSCA section 5(e) Order: The PMN states that the generic (non-confidential) use of the substance will be as a binder for seal application. Based on physical/chemical properties of the PMN substance, EPA identified concerns for lung toxicity. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I) of TSCA, based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to health and the environment. To protect against these risks, the Order requires:

1. Refraining from domestic manufacture of the PMN substance in the United States (i.e., import only); and
2. Import of the PMN substance according to the confidential molecular weight parameters specified in the Order.

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

Potentially useful information: EPA has determined that certain information about the health and environmental effects of the PMN substance may be potentially useful to

characterize the effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of specific pulmonary effects testing and fate testing would help characterize the potential health effects of the PMN substance and results of acute aquatic toxicity testing would help characterize the potential environmental effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

CFR citation: 40 CFR 721.11155.

PMN Number: P-16-386

Chemical name: Hexanedioic acid, 1,6-bis(3,5,5-trimethylhexyl) ester.

CAS Number: 20270-50-2.

Effective date of TSCA section 5(e) Order: October 12, 2017.

Basis for TSCA section 5(e) Order: The PMN states that the substance will be used as a seal swell agent for motor formulations and gear oil lubricants. Based on analysis of an analogous compound, EPA has identified concerns for solvent neurotoxicity, liver and kidney effects, and concern for developmental toxicity based on analysis of testing for a potential degradant of the PMN substance. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to health. To protect against these risks, the Order requires:

1. Submit to EPA certain toxicity testing prior to manufacturing 1,545,000 kilograms of the PMN substance;
2. Use of personal protective equipment where there is a potential for dermal exposure;
3. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS; and
4. Use of the PMN substance only for the use specified in the Order.

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

Potentially useful information: EPA has determined that certain information about the health effects of the PMN substance may be potentially useful to characterize the effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. The submitter has agreed not to exceed the 1,545,000 kilogram production volume limit without performing specific target organ/reproductive/developmental toxicity testing.

CFR citation: 40 CFR 721.11156.

PMN Number: P-16-396

Chemical name: Alkylaminium hydroxide (generic).

CAS Number: Not available.

Effective date of TSCA section 5(e) Order: December 19, 2017.

Basis for TSCA section 5(e) Order: The PMN states that the generic (non-confidential) use of the PMN substance will be as a specialty chemical for processing additive. Based

on structural alerts and analysis of analogue data, EPA identified concerns for neurotoxicity, developmental and reproductive toxicity and irritation. EPA also identified concerns for lung effects based on surfactant properties and corrosivity and concern for reproductive and developmental toxicity based on analogue data from large quaternary ammonium compounds. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to health. To protect against these risks, the Order requires:

1. Submission of certain health 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 manufacturing, processing, or use of the PMN substance as a solid or powder;
5. Use of the PMN substance only for the confidential uses specified in the Order; and
6. No use of the PMN substance in application methods that generate a dust, vapor, mist, or aerosol.

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

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

CFR citation: 40 CFR 721.11157.

PMN Numbers: P-16-572 and P-16-573

Chemical name: Polyamine polyacid adducts (generic).

CAS Numbers: Not available.

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

Basis for TSCA section 5(e) Order: The PMNs state that the generic (non-confidential) use of the substances will be as adhesives for coatings. Based on physical chemical properties of the PMN substances, EPA identified potential concerns for lung toxicity and aquatic/terrestrial toxicity if the PMN substances are manufactured in such a manner that they are amine terminated. The Order was issued under TSCA sections 5(a)(3)(B)(i) and 5(e)(1)(A)(i), based on a finding that the available information is insufficient to permit a reasoned evaluation of the health and environmental effects for the PMN substances. The Order was also issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I) of TSCA, based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the 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 in a manner that they are not amine terminated in order to maintain water solubility levels below 1 ppb.

The SNUR designates as a “significant new use” the absence of this protective measure.

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

CFR citations: 40 CFR 721.11158.

PMN Numbers: P-17-24 and P-17-25

Chemical names: Aromatic isocyanate, polymer with alkyloxirane polymer with oxirane ether with alkyldiol (2:1), and alkyloxirane polymer with oxirane ether with alkyltriol (3:1) (generic) (P-17-24) and aromatic isocyanate polymer with alkyloxirane, alkyloxirane polymer with oxirane ether with alkanetriol and oxirane (generic) (P-17-25).

CAS Numbers: Not available.

Effective date of TSCA section 5(f) Order: October 31, 2017.

Basis for TSCA section 5(f) Order: The PMN states that the generic (non-confidential) use of the substances will be as urethane components. EPA identified concerns for

oncogenicity based on physical chemical properties of the PMN substances, mutagenicity based on data for analogous chemicals, and respiratory and dermal sensitization and lung and mucous membrane irritation based on the isocyanate moiety. The Order was issued under sections 5(a)(3)(A) and 5(f)(1) of TSCA, based on a finding that the substances present an unreasonable risk of injury to human health. To protect against these risks, the Order requires:

1. Use of personal protective equipment where there is a potential for dermal exposure;
2. No manufacturing, processing, or use of the PMN substances in application methods that generate a vapor, dust, mist, or aerosol;
3. No use of the PMN substances in a consumer product; and
4. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.

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

CFR citation: 40 CFR 721.11159 and 40 CFR 721.11160.

PMN Number: P-17-148

Chemical name: Oils, Hedychium Flavescens.

CAS Number: 1902936-65-5.

Effective date of TSCA section 5(e) Order: December 15, 2017.

Basis for TSCA section 5(e) Order: The PMN states that the substance will be used as an odoriferous component of fragrance compounds. Based on test data on PMN constituents, EPA has identified concerns for oncogenicity, developmental toxicity, liver, kidney, and

male reproductive effects. EPA also identified concern for sensitization based on submitted test data on the PMN mixture. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(II), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk on injury to health. To protect against these risks, the Order requires:

1. Use of personal protective equipment where there is a potential for dermal exposures;
2. Use of a NIOSH-certified respirator with an APF of at least 50 where there is a potential for inhalation exposures;
3. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS;
4. Refraining from domestic manufacture of the PMN substance in the United States (i.e., import only);
5. Not manufacture the PMN substance beyond an annual production volume of 70 kilograms;
6. Not manufacture, process, or use the PMN substance in any manner or method that generates mist or aerosol; and
7. Not use the PMN substance other than as an odoriferous component of fragrance compounds.

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

Potentially useful information: EPA has determined that certain information about the health effects of the PMN substance may be potentially useful to characterize the effects

of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of specific skin absorption, and chronic toxicity/carcinogenicity testing would help characterize the potential health effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

CFR citation: 40 CFR 721.11161.

PMN Number: P-17-174

Chemical name: Alkyltriethosilylpolysiloxane (generic)

CAS Number: Not available.

Effective date of TSCA section 5(e) Order: November 28, 2017.

Basis for TSCA section 5(e) Order: The PMN states that the generic (non-confidential) use of the substance will be as a plastic additive. Based on analysis of test data on analogous alkoxy silanes, EPA identified concerns for lung effects, irritation, developmental toxicity, and neurotoxicity. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I) of TSCA, based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to health. To protect against these risks, the Order requires:

1. Submission to EPA of certain health testing before manufacturing (including import) the aggregate confidential volume identified in the Order;
2. Use of personal protective equipment where there is a potential for dermal exposure;

3. No manufacturing or use of the PMN substance in application methods that generate a vapor, mist, or aerosol;
4. Refraining from domestic manufacture of the PMN substance in the United States (i.e., import only);
5. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.

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

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

CFR citation: 40 CFR 721.11162.

PMN Numbers: P-17-200 and P-17-204

Chemical names: 1,3-bis(substitutedbenzoyl)benzene (generic) (P-17-200) and 1,4-bis(substitutedbenzoyl)benzene (generic) (P-17-204)

CAS Numbers: Not available.

Effective date of TSCA section 5(e) Order: December 18, 2017.

Basis for TSCA section 5(e) Order: The PMNs state that the use of the substances will be as monomers for high performance polymers. Based on analysis of test data on

analogous chemical bisphenol A and predictions for polyphenols, EPA identified potential concerns for irritation to the eyes, lungs, and mucous membranes, liver and kidney effects, reproductive and developmental toxicity, sensitization, neurotoxicity, and aquatic/terrestrial toxicity. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I) of TSCA, based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substances may present an unreasonable risk of injury to the health and the environment. To protect against these risks, the Order requires:

1. Use of personal protective equipment 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;
3. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS;
4. Manufacture (including import) the PMN substances only in the form of a solid;
5. Refraining from domestic manufacture of the PMN substances in the United States (i.e., import only);
6. No manufacture (including import), processing, or use of the PMN substances with greater than 0.1% of the particle size distribution less than 10 microns;
7. No use other than as chemical intermediates;
8. No release of the PMN substances into the waters of the United States without application of an on-site wastewater treatment that reduces the concentration

of PMN substances in wastewater below the limit of detection of 0.03 ppm, using the on-site wastewater treatment system with activated carbon adsorption; and

9. Disposal of the PMN substances by incineration.

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

Potentially useful information: EPA has determined that certain information about the environmental and health effects of the PMN 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 these SNURs. EPA has also determined that the results of specific reproductive toxicity testing, skin sensitization, and chronic aquatic toxicity testing would help characterize the potential human and environmental effects of the PMN substances. Although the Order does not require these tests, the Order’s restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

CFR citation: 40 CFR 721.11163 and 40 CFR 721.11164.

PMN Number: P-17-205

Chemical name: Bis(fluorobenzoyl)benzene (generic).

CAS Number: Not available.

Effective date of TSCA section 5(e) Order: December 18, 2017.

Basis for TSCA section 5(e) Order: The PMN states that the generic (non-confidential) use of the substance will be as a monomer for high performance polymers. Based on

physical/chemical properties of the PMN substance (as described in the New Chemical Program's PBT category at 64 FR 60194; November 4, 1999) and test data on structurally similar substances, the PMN substance is a potentially persistent, bioaccumulative, and toxic (PBT) chemical. EPA has identified concern for eye irritation based on test data for an analogous chemical. Concerns for liver, kidney, blood effects and carcinogenicity were identified based on test data available for benzophenone. Based on experimental data of an analogous chemical, EPA has identified environmental hazard concerns. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the PMN substance may present an unreasonable risk of injury to health and the environment. To protect against these risks, the Order requires:

1. Use of personal protective equipment 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. Refraining from domestic manufacture of the PMN substance in the United States (i.e., import only);
4. Manufacture of the PMN substance only in the form of a solid;
5. No manufacture of the PMN substance with greater than 0.1% of the particle size distribution less than 10 microns;
6. No use other than as a chemical intermediate;
7. Disposal of the PMN substance by incineration; and

8. No release of the PMN without application of an on-site wastewater treatment that reduces the concentration of the PMN in wastewater below the limit of detection of 0.03 ppm.

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

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

CFR citation: 40 CFR 721.11165.

PMN Number: P-17-251

Chemical name: 1-H-Benz[DE] isoquinoline-1,3 (2H)-dione-2-(-alkyl)-(-alkyl-amino-)
(generic).

CAS Number: Not available.

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

Basis for TSCA section 5(e) Order: The PMN states that the specific (non-confidential) use of the substance will be as tracer dye. Based on the physical/chemical properties of the PMN substance and data for structurally analogous chemical substances, EPA has identified concerns for mutagenicity and ocular irritation. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(II), based on finding that in the absence of sufficient information to permit a reasoned evaluation, the PMN substance may present an unreasonable risk of injury to health. To protect against these risks, the Order requires:

1. Use of personal protective equipment where there is a potential for exposure;
2. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS;
3. Refraining from domestic manufacture of the PMN substance in the United States (i.e., import only); and
4. No import, processing, or use of the PMN substance at a concentration greater than 0.4%.

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

Potentially useful information: EPA has determined that certain information about the health effects of the PMN substance may be potentially useful to characterize the effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of specific skin absorption testing and genetic toxicology testing would help characterize the

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

CFR citation: 40 CFR 721.11166.

PMN Number: P-17-296

Chemical name: Siloxanes and Silicones, di-Me, hydrogen-terminated, reaction products with acrylic acid and 2-ethyl-2-[(2-propen-1-yloxy)methyl]-1,3-propanediol, polymers with chlorotrimethylsilane-iso-Pr alc.-sodium reaction products.

CAS Number: 2014386-23-1.

Effective date of TSCA section 5(e) Order: November 14, 2017.

Basis for TSCA section 5(e) Order: The PMN states that the use of the substance will be as a component of release coating mixture for paper and film. Based on analogy to acrylates, EPA identified concerns for dermal and respiratory sensitization, mutagenicity, oncogenicity, developmental toxicity, and irritation to all tissues. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I) of TSCA, based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to health. To protect against these risks, the Order requires:

1. Use of personal protective equipment where there is a potential for dermal exposure;
2. Use of a NIOSH certified respirator with an APF of at least 1,000 if used in a manner that generates a spray, mist, or aerosol and there is a potential for inhalation exposure;

3. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS; and
4. Refraining from domestic manufacture of the PMN substance in the United States (i.e., import only).

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

Potentially useful information: EPA has determined that certain information about the health effects of the PMN substance may be potentially useful to characterize the effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of specific reproductive/developmental toxicity testing, skin sensitization and genetic toxicology testing would help characterize the potential health effects of the PMN substance.

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

CFR citation: 40 CFR 721.11167.

PMN Numbers: P-17-308 and P-17-309

Chemical names: 2-Pentanone, 2,2',2''-[O,O',O''-(ethenylsilyldiylidene)trioxime] (P-17-308) and 2-Pentanone, 2,2',2''- [O,O',O''-(methylsilyldiylidene)trioxime] (P-17-309).

CAS numbers: 58190-62-8 (P-17-308) and 37859-55-5 (P-17-309).

Effective date of TSCA section 5(e) Order: October 30, 2017.

Basis for TSCA section 5(e) Order: The PMNs state that the use of the substances will be as crosslinkers for silicone sealants used in automotive and large appliance (white goods) manufacture and for silicone sealants used in auto repair shops. Based on hazard determination and available qualitative risk information, EPA has identified concerns for irritation, corrosion, sensitization; systemic effects to spleen, liver and bone marrow; developmental, reproductive, blood, and kidney toxicity; neurotoxicity, mutagenicity and oncogenicity. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substances may present an unreasonable risk of injury to health. To protect against these risks, the Order requires:

1. Submission to EPA of certain toxicity testing on P-17-308 before manufacturing the aggregate confidential production volume identified in the Order;
2. Provide 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. Refraining from domestic manufacture of the PMN substances in the United States (i.e., import only); and
5. Not process or use the PMN substances in any application that creates vapor, mist or aerosol.

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

Potentially useful information: EPA has determined that certain information about the health effects of the PMN substances may be potentially useful to characterize the effects of the PMN substances in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by these SNURs. The submitter has agreed not to exceed a confidential production volume limit without performing reproductive/developmental toxicity testing and skin sensitization testing on P-17-308.

CFR citation: 40 CFR 721.11168 and 40 CFR 721.11169.

PMN Number: P-17-321

Chemical name: Naphthalene trisulfonic acid sodium salt (generic).

CAS Number: Not available.

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

Basis for TSCA section 5(e) Order: The PMN states that the generic (non-confidential) use of the substance will be for monitoring of oil/gas well performance. Based on physical/chemical properties of the PMN substance and analysis of test data on analogous chemicals, EPA identified concerns for developmental toxicity and interference with blood clotting via chelation of nutrient metals, dermal and lung irritation, and sensitization. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I) of TSCA, based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to health. To protect against these risks, the Order requires:

1. Submission to EPA of certain toxicity testing before manufacturing (including import) the confidential aggregate volume identified in the Order;

2. Use of personal protective equipment where there is a potential for dermal exposure and a NIOSH certified respirator with an APF of at least 50 where there is a potential for inhalation exposure;
3. No manufacturing, processing, or use of the PMN substance in any manner that generates a vapor, mist, or aerosol;
4. No manufacture (including import) or processing of the PMN substance beyond the confidential annual production volume specified in the Order; and
5. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.

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

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

CFR citation: 40 CFR 721.11170.

PMN Number: P-17-327

Chemical name: Polymer of aliphatic dicarboxylic acid and dicyclo alkane amine (generic).

CAS Number: Not available.

Effective date of TSCA section 5(e) Order: October 18, 2017.

Basis for TSCA section 5(e) Order: The PMN states that the use of the PMN substance will be for injection molding of special applications and in compounding. Based on physical/chemical properties of the PMN substance, there are no significant concerns for the PMN substance as described in the PMN submission. However, if the PMN substance is made differently, there could be concern for lung toxicity. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I) of TSCA, based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to health. To protect against these risks, the Order requires:

1. Manufacture (which under TSCA includes importing) the PMN substance to have an average molecular weight of no greater than 10,000 Daltons.

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

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

CFR citation: 40 CFR 721.11171.

PMN Number: P-17-330

Chemical name: Hexanedioic acid, polymer with trifunctional polyol, 1,1'-methylenebis [isocyanatobenzene], and 2,2'-oxybis [ethanol] (generic).

CAS Number: Not available.

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

Basis for TSCA section 5(e) Order: The PMN states that the use of the substance will be as a polyurethane which is cured and used in a sprocket for water treatment. Based on physical/chemical properties of the PMN substance, EPA identified concerns for irritation to the eye, skin, respiratory tract, and gastrointestinal tract and for potential dermal and respiratory sensitization. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I) of TSCA, based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to health. To protect against these risks, the Order requires:

1. Use of personal protective equipment where there is a potential for dermal exposure;
2. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS;
3. No manufacture, processing, or use of the PMN substance in any manner that generates a dust, mist, or aerosol; and
4. No use of the PMN substance in a consumer product or for commercial uses when the sealable goods or service could introduce the PMN material into a consumer setting.

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

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

CFR citations: 40 CFR 721.11172.

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 26 chemical substances, regulation was warranted under TSCA section 5(e) or section 5(f), 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) or 5(f) 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, distribution in commerce, use, or disposal that does not conform to the restrictions imposed by the underlying Orders, consistent with TSCA section 5(f)(4).

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

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

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

VI. Direct Final Procedures

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

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

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

VII. Applicability of the Significant New Use Designation

To establish a significant new use, EPA must determine that the use is not ongoing. The chemical substances subject to this rule have undergone premanufacture review. In cases where EPA has not received 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) or 5(f) Orders have been issued for all of the chemical substances, and the PMN submitters

are prohibited by the TSCA section 5(e) and 5(f) Orders from undertaking activities which will be designated as significant new uses. The identities of 20 of the 26 chemical substances subject to this rule have been claimed as confidential and EPA has received no post-PMN *bona fide* submissions (per §§ 720.25 and 721.11) for a chemical substance covered by this action. Based on this, the Agency believes that it is highly unlikely that any of the significant new uses described in the regulatory text of this rule are ongoing.

Therefore, EPA designates [*insert date of publication in the **Federal Register***] as the cutoff date for determining whether the new use is ongoing. The objective of EPA's approach has been to ensure that a person could not defeat a SNUR by initiating a significant new use before the effective date of the direct final rule.

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

VIII. Development and Submission of Information

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

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

In certain of the TSCA section 5(e) Orders for the chemical substances regulated under this rule, EPA has established production or time limits in view of the lack of data on the potential health and environmental risks that may be posed by the significant new uses or increased exposure to the chemical substances. These limits cannot be exceeded unless the PMN submitter first submits the results of toxicity tests that would permit a reasoned evaluation of the potential risks posed by these chemical substances. The SNURs contain the same limits as the TSCA section 5(e) Orders. Exceeding these limits is defined as a significant new use. Persons who intend to exceed the limit must notify the Agency by submitting a SNUN at least 90 days in advance of commencement of non-exempt commercial manufacture or processing.

Any request by EPA for the triggered and pended testing described in the Orders was made based on EPA's consideration of available screening-level data, if any, as well as other available information on appropriate testing for the PMN substances. Further, any such testing request on the part of EPA that includes testing on vertebrates was made after consideration of available toxicity information, computational toxicology and bioinformatics, and high-throughput screening methods and their prediction models.

Potentially useful information identified in Unit IV. may not be the only means of addressing the potential risks of the chemical substance. However, submitting a SNUN without any test data may increase the likelihood that EPA will take action under TSCA section 5(e), particularly if satisfactory test results have not been obtained from a prior PMN or SNUN submitter. EPA recommends that potential SNUN submitters contact EPA early enough so that they will be able to conduct the appropriate tests.

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

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

IX. Procedural Determinations

By this rule, EPA is establishing certain significant new uses which have been claimed as CBI subject to Agency confidentiality regulations at 40 CFR part 2 and 40 CFR part 720, subpart E. Absent a final determination or other disposition of the confidentiality claim under 40 CFR part 2 procedures, EPA is required to keep this

information confidential. EPA promulgated a procedure to deal with the situation where a specific significant new use is CBI, at § 721.1725(b)(1).

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

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

X. SNUN Submissions

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

XI. Economic Analysis

EPA has evaluated the potential costs of establishing SNUN requirements for potential manufacturers and processors of the chemical substances subject to this rule. EPA's complete economic analysis is available in the docket under docket ID number EPA-HQ-OPPT-2018-0627.

XII. Statutory and Executive Order Reviews

A. Executive Order 12866

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

B. Paperwork Reduction Act (PRA)

According to PRA (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under PRA, unless it has been approved by OMB and displays a

currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable. EPA is amending the table in 40 CFR part 9 to list the OMB approval number for the information collection requirements contained in this action. This listing of the OMB control numbers and their subsequent codification in the CFR satisfies the display requirements of PRA and OMB's implementing regulations at 5 CFR part 1320. This Information Collection Request (ICR) was previously subject to public notice and comment prior to OMB approval, and given the technical nature of the table, EPA finds that further notice and comment to amend it is unnecessary. As a result, EPA finds that there is "good cause" under section 553(b)(3)(B) of the Administrative Procedure Act (5 U.S.C. 553(b)(3)(B)) to amend this table without further notice and comment.

The information collection requirements related to this action have already been approved by OMB pursuant to PRA under OMB control number 2070-0012 (EPA ICR No. 574). This action does not impose any burden requiring additional OMB approval. If an entity were to submit a SNUN to the Agency, the annual burden is estimated to average between 30 and 170 hours per response. This burden estimate includes the time needed to review instructions, search existing data sources, gather and maintain the data needed, and complete, review, and submit the required SNUN.

Send any comments about the accuracy of the burden estimate, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques, to the Director, Collection Strategies Division, Office of Environmental Information (2822T), Environmental Protection Agency, 1200

Pennsylvania Ave., NW., Washington, DC 20460-0001. Please remember to include the OMB control number in any correspondence, but do not submit any completed forms to this address.

C. Regulatory Flexibility Act (RFA)

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

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

2. The SNUR submitted by any small entity would not cost significantly more than \$8,300.

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

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

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

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

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

D. Unfunded Mandates Reform Act (UMRA)

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

E. Executive Order 13132

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

F. Executive Order 13175

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

G. Executive Order 13045

This action is not subject to Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997), because this is not an economically significant regulatory action as defined by

Executive Order 12866, and this action does not address environmental health or safety risks disproportionately affecting children.

H. Executive Order 13211

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

I. National Technology Transfer and Advancement Act (NTTAA)

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

J. Executive Order 12898

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

XIII. Congressional Review Act

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

List of Subjects

40 CFR Part 9

Environmental protection, Reporting and recordkeeping requirements.

40 CFR Part 721

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

Dated: September 14, 2018.

Jeffery T. Morris,

Director, Office of Pollution Prevention and Toxics.

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

PART 9--[AMENDED]

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

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

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

§ 9.1 OMB approvals under the Paperwork Reduction Act.

* * * * *

40 CFR citation	OMB control No.
* * * * *	* * * * *
Significant New Uses of Chemical Substances	
* * * * *	* * * * *
721.11149	2070-0012
721.11150	2070-0012
721.11151	2070-0012
721.11152	2070-0012
721.11153	2070-0012
721.11154	2070-0012

721.11155	2070-0012
721.11156	2070-0012
721.11157	2070-0012
721.11158	2070-0012
721.11159	2070-0012
721.11160	2070-0012
721.11161	2070-0012
721.11162	2070-0012
721.11163	2070-0012
721.11164	2070-0012
721.11165	2070-0012
721.11166	2070-0012
721.11167	2070-0012
721.11168	2070-0012
721.11169	2070-0012
721.11170	2070-0012
721.11171	2070-0012
721.11172	2070-0012
* * * * *	

* * * * *

PART 721--[AMENDED]

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

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

4. Add § 721.11149 to subpart E to read as follows:

§ 721.11149 Carbon nanomaterial (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as carbon nanomaterial (P-10-366) 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), incorporated or embedded into a polymer matrix that itself has been completely reacted (cured), embedded in a permanent solid polymer, metal, glass, or ceramic form, or completely embedded in an article as defined at 40 CFR 720.3(c).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i)(ii), (a)(3), (a)(4), (a)(5) (respirators must provide a National Institute for Occupational Safety and Health certified air purifying, tight-fitting full-face respirator equipped with N100, P-100, or R-100 filter with an Assigned Protection Factor of at least 50), (a)(6)(particulate), (when determining which persons are reasonable 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 exposures, where feasible), and (c).

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k), (l), (q), and (y)(1)(when the substance is in liquid resin form). It is a

significant new use to process or use the powder form of the substance outside of the site of manufacture or processing.

(iii) *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 (b).

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

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

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

5. Add § 721.11150 to subpart E to read as follows:

§ 721.11150 Cyclic amide (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as cyclic amide (P-14-627) 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)(butyl or silver shield gloves), (a)(2)(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 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), (ix), (g)(2)(i), (ii), (iii), (v), and (g)(5).

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

(iii) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(f) and (k)(dispersions for industrial coatings (e.g., polyurethane, acrylic, epoxy), coating for consumer and professional use, adhesives and sealants, solvent-borne industrial coatings silicon wafer cleaning in microelectronics in clean rooms, photoresist stripping in microelectronics in clean rooms, coatings for microelectronics (e.g., casting of polymer films) in clean rooms, reaction medium for polymerization, polymer coatings for industrial and professional applications (e.g., wire enamel, non-stick and friction reduction coating) membranes, solvent for chemical synthesis reactions (e.g., pharmaceuticals), formulation of inks, industrial cleaner (e.g., cleaner for wind turbine, oil rigs, large engines), solvent for cleaning industrial reactors, wax inhibitors (in hydrocarbon lines), petrochemical extraction processes, paint stripper, solvents for production and formulation of fertilizer, solvent for production and formulation of active ingredients for agriculture, and solvent for formulation of active ingredients for agriculture-end use pesticide product). It is a significant new use to import the substance other than in containers of 55 gallons or more when the concentration is greater than 5% by weight for any product either intended for sale or distribution for "consumer" use,

including for use in "consumer products", or both intended for "commercial use" and made available to consumers for retail purchase of any kind. It is a significant new use to use in hand held spray applications that generate a vapor, mist, or aerosol.

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

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

(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 § 721.11151 to subpart E to read as follows:

§ 721.11151 2-Butanone 1,1,1,3,4,4,4-heptafluoro-3-(trifluoromethyl)-.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 2-Butanone 1,1,1,3,4,4,4-heptafluoro-3-(trifluoromethyl)- (P-15-114, CAS No 756-12-7) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2), and (a)(3)(when determining which persons are reasonable likely to be exposed as required for § 721.63(a)(1), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g.,

workplace policies and procedures) shall be considered and implemented to prevent exposures, where feasible), (b)(concentration set at 1.0 %), and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (d), (f), (g)(1)(i), (g)(2)(i)(v), (g)(3)(ii)(harmful to fish), (g)(4)(iii), and (g)(5). It is a significant new use unless containers of the PMN substance are labeled with the statement: “contains a dielectric fluid which should not be mixed or used in conjunction with sulfur hexafluoride (SF6)”. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(t). It is a significant new use to use the substance other than as a dielectric medium for medium and high voltage power generation/distribution equipment and heat transfer.

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where N = 180.

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

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) and (k) are applicable to manufacturers, importers, 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 § 721.11152 to subpart E to read as follows:

§ 721.11152 Propanenitrile, 2,3,3,3 tetrafluoro- 2-(trifluoromethyl)-.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as propanenitrile, 2,3,3,3 tetrafluoro- 2-(trifluoromethyl)- (P-15-320, CAS No 42532-60-5) 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) *Hazard communication.* Requirements as specified in § 721.72(a) through (e)(concentration set at 1%), (f), and (g)(5). It is a significant new use unless containers of the PMN substance are labeled with the statement: “contains a dielectric fluid which should not be mixed or used in conjunction with sulfur hexafluoride (SF6)”. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80. It is a significant new use to use the substance other than as a dielectric medium for medium and high voltage power generation and distribution equipment.

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

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

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

8. Add § 721.11153 to subpart E to read as follows:

§ 721.11153 Polymeric sulfide (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as polymeric sulfide (P-15-734) 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), (when determining which persons are reasonable likely to be exposed as required for § 721.63(a)(1), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposures, where feasible), (b)(concentration set at 1%), and (c).

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

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k)(wastewater heavy metal removal) and (q). It is a significant new use to

manufacture, process, or use the substance in any manner that results in inhalation exposure to workers.

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

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

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

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

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

9. Add § 721.11154 to subpart E to read as follows:

§ 721.11154 Quaternary ammonium salts (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substances identified generically as quaternary ammonium salts (PMN P-16-356 and P-16-357) 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 § 721.63(a)(1), (a)(2)(i), (a)(3), (when determining which persons are reasonably likely to be exposed as

required for § 721.63(a)(1), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure where feasible), (b)(concentration set at 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), (neurotoxicity), (g)(2)(i), (iii), (v), (g)(3)(i), (ii), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

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

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

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

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

10. Add § 721.11155 to subpart E to read as follows:

§ 721.11155 Alkyl methacrylates, polymer with olefins (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as alkyl methacrylates, polymer with olefins (P-

16-375) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f). It is a significant new use to import the substance other than according to the confidential molecular weight parameters specified in the Order for the substance.

(ii) [Reserved]

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

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

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

(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.

11. Add § 721.11156 to subpart E to read as follows:

§ 721.11156 Hexanedioic acid, 1,6-bis(3,5,5-trimethylhexyl) ester.

(a) *Chemical substance and significant new uses subject to reporting.* (1) the chemical substance identified as hexanedioic acid, 1,6-bis(3,5,5-trimethylhexyl) ester (PMN P-16-386, CAS No 20270-50-2) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(3), (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 shall be considered and implemented to prevent exposure, where feasible), (a)(6)(v), (vi), (particulate), (b)(concentration set at 1%), and (c).

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

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k)(motor oil formulations and gear oil lubricants) and (p)(1,545,000 kilograms).

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

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

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

11. Add § 721.11157 to subpart E to read as follows:

§ 721.11157 Alkylaminium hydroxide (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as alkylaminium hydroxide (P-16-396) 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), (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 exposures, where feasible), (b)(concentration set at 1%), and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.71(a) through (e) (concentration set at 1.0%), (f), (g)(1)(i), (ii), (iii), (vi), (ix), (eye damage), (g)(2)(i), (ii), (iii), (v), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k), (q), (v)(1), (2), (w)(1), (2), (x)(1), (x)(2), (y)(1), and (y)(2).

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

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

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

(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.

12. Add § 721.11158 to subpart E to read as follows:

§ 721.11158 Polyamine polyacid adducts (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substances generically identified as polyamine polyacid adducts (P-16-572 and P-16-573) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80. It is a significant new use to manufacture the substances in any manner other than they are not amine terminated in order to maintain water solubility levels below 1 part per billion.

(ii) [Reserved]

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

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

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

13. Add § 721.11159 to subpart E to read as follows:

§ 721.11159 Aromatic isocyanate, polymer with alkyloxirane polymer with oxirane ether with alkyldiol (2:1) and alkyloxirane polymer with oxirane ether with alkyltriol (3:1) (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as aromatic isocyanate, polymer with alkyloxirane polymer with oxirane ether with alkyldiol (2:1) and alkyloxirane polymer with oxirane ether with alkyltriol (3:1) (P-17-24) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i), (iv), (a)(3), (a)(6)(v), (vi), (particulate), (when determining which persons are reasonable likely to be exposed as required for § 721.63(a)(1), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposures, where feasible), (b)(concentration set at 0.1%), and (c).

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

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

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

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

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

14. Add § 721.11160 to subpart E to read as follows:

§ 721.11160 Aromatic isocyanate polymer with alkyloxirane, alkyloxirane polymer with oxirane ether with alkanetriol and oxirane (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as aromatic isocyanate polymer with alkyloxirane, alkyloxirane polymer with oxirane ether with alkanetriol and oxirane (P-17-25) 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), (iv), (a)(3), (a)(6)(v), (vi), (particulate), (when determining which persons are reasonable likely to be exposed as required for § 721.63(a)(1), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be

considered and implemented to prevent exposures, where feasible), (b)(concentration set at 0.1%), and (c).

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

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

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

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

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

15. Add § 721.11161 to subpart E to read as follows:

§ 721.11161 Oils, Hedychium Flavescens.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as oils, hedychium flavescens, (PMN P-17-148, CAS No 1902936-65-5) 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), (iii), (iv), (a)(3), (a)(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)(v), (vi), (b)(concentration set at 1%), and (c).

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

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f), (k)(odoriferous component of fragrance compounds) and (s)(70 kilograms). It is a significant new use to manufacture, process, or use the substance in any manner that generates a mist or aerosol.

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

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

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

16. Add § 721.11162 to subpart E to read as follows:

§ 721.11162 Alkyltriethosilylpolysiloxane (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as alkyltriethosilylpolysiloxane (P-17-174) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been reacted (cured).

(2) The significant new uses are:

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

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

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

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

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

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

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

17. Add § 721.11163 to subpart E to read as follows:

§ 721.11163 1,3-Bis(substitutedbenzoyl)benzene.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as 1,3-bis(substitutedbenzoyl)benzene (P-17-200) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the PMN substance after they have been completely reacted (cured) or incorporated into a polymer matrix.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i), (iii), (iv), (a)(3), (a)(4), (a)(5)(respirators must provide a National Safety Institute for Occupational Safety and Health assigned protection factor of at least 50), (when determining which persons are reasonable 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 exposures, where feasible), (b)(concentration set at 1.0 %), and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e)(concentration set at 1.0 %), (f), (g)(1)(i), (iii), (iv), (vi), (ix), (sensitization), (irritation to the eyes, lungs, and mucous membranes), (g)(2)(i), (ii), (iii), (iv), (v), (g)(3)(i), (ii), (g)(4)(i), (water release restriction apply), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f), (g), (w)(3), and (w)(4). It is a significant new use to manufacture, process, or use of the PMN substance with greater than 0.1% of the particle size distribution less than 10 microns.

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

(v) *Release to water.* Requirements as specified in § 721.90(a)(2)(iv), (b)(2)(iv), and (c)(2)(iv). The concentration in released wastewater must be less than 0.03 ppm.

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

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

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

18. Add § 721.11164 to subpart E to read as follows:

§ 721.11164 1,4-Bis(substitutedbenzoyl)benzene (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 1,4-bis(substitutedbenzoyl)benzene (P-17-204) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the PMN substance after they have been completely reacted (cured) or incorporated into a polymer matrix.

(2) The significant new uses are:

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

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e)(concentration set at 1.0 %), (f), (g)(1)(i), (iii), (iv), (vi), (ix), (sensitization), (irritation to the eyes, lungs, and mucous membranes), (g)(2)(i), (ii), (iii), (iv), (v), (g)(3)(i), (ii), (g)(4)(i), (water release restriction apply), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f), (g), (w)(3) and (4). It is a significant new use to manufacture, process, or

use of the PMN substance with greater than 0.1% of the particle size distribution less than 10 microns.

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

(v) *Release to water.* Requirements as specified in § 721.90(a)(2)(iv), (b)(2)(iv), and (c)(2)(iv). The concentration in released wastewater must be less than 0.03 ppm.

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

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

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

19. Add § 721.11165 to subpart E to read as follows:

§ 721.11165 bis(fluorobenzoyl)benzene (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as bis(fluorobenzoyl)benzene (P-17-205) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the PMN substance after they have been completely reacted (cured) or incorporated into a polymer matrix.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(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 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%), (f), (g)(1)(iv), (vii), (eye irritation), (g)(2)(i), (ii), (iii), (g)(3)(i), (ii), (g)(4)(i), (water release restriction apply), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f), (g), (w)(3), and (w)(4). It is a significant new use to manufacture, process, or use of the PMN substance with greater than 0.1% of the particle size distribution less than 10 microns.

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

(v) *Release to water.* Requirements as specified in § 721.90(a)(2)(iv), (b)(2)(iv), and (c)(2)(iv). The concentration in released wastewater must be less than 0.03 ppm.

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

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

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

20. Add § 721.11166 to subpart E to read as follows:

**§ 721.11166 1-H-Benz[DE] isoquinoline-1,3 (2H)-dione-2-(-alkyl)-(-alkyl-amino-)
(generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as 1-H-Benz[DE] isoquinoline-1,3 (2H)-dione-2-(-alkyl)-(-alkyl-amino-) (P-17-251) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i), (iii), (iv), (a)(3), (when determining which persons are reasonably likely to be exposed as required as § 721.63(a)(1) engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation shall be considered and implemented to prevent exposure, where feasible), (a)(6)(v), (vi), (particulate), and (c).

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

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f). It is a significant new use to import, process, or use the PMN substance at a concentration greater than 0.4%.

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

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

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

21. Add § 721.11167 to subpart E to read as follows:

§ 721.11167 Siloxanes and Silicones, di-Me, hydrogen-terminated, reaction products with acrylic acid and 2-ethyl-2-[(2-propen-1-yloxy)methyl]-1,3-propanediol, polymers with chlorotrimethylsilane-iso-Pr alc.-sodium reaction products.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as siloxanes and silicones, di-Me, hydrogen-terminated, reaction products with acrylic acid and 2-ethyl-2-[(2-propen-1-yloxy)methyl]-1,3-propanediol, polymers with chlorotrimethylsilane-iso-Pr alc.-sodium reaction products (P-17-296, CAS No. 2014386-23-1) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the PMN substance after they have been completely reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i), (ii), (iii), (a)(3), (a)(4), (a)(5), (respirators must provide a National Institute for Occupational Safety and Health assigned protection factor of at least 1,000 and are required for any process generating a spray, mist, or aerosol), (when determining which persons are reasonable likely to be exposed as required for § 721.63(a)(1), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures)

shall be considered and implemented to prevent exposures, where feasible), (a)(6)(v), (vi), (particulate), (b)(concentration set at 1%), and (c).

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

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

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

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

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

22. Add § 721.11168 to subpart E to read as follows:

§ 721.11168 2-Pentanone, 2,2',2''-[O,O',O''-(ethenylsilyldyne)trioxime].

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance 2-pentanone, 2,2',2''-[O,O',O''-(ethenylsilyldyne)trioxime] (PMN P-17-308, CAS No. 58190-62-8) 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 completely reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i), (a)(3), (when determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible), (b)(concentration set at 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), (iii), (iv), (vi), (vii), (viii), (ix), (g)(2)(i), (iii), (v), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System, and OSHA Hazard Communication Standard may be used.

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

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

(1) *Recordkeeping.* Recordkeeping 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.

23. Add § 721.11169 to subpart E to read as follows:

§ 721.11169 2-Pentanone, 2,2',2''- [O,O',O''-(methylsilyldiylidene)trioxime].

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance 2-pentanone, 2,2',2''- [O,O',O''-(methylsilyldiylidene)trioxime] (PMN P-17-309, CAS No. 37859-55-5) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted (cured).

(2) The significant new uses are:

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

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

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

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

(1) *Recordkeeping*. Recordkeeping 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.

24. Add § 721.11170 to subpart E to read as follows:

§ 721.11170 Naphthalene trisulfonic acid sodium salt (generic).

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified generically as naphthalene trisulfonic acid sodium salt (P-17-321) 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), (iv), (a)(3), (a)(4), (a)(5)(respirators must provide a National Institute for Occupational Safety and Health assigned protection factor of at least 50), (when determining which persons are reasonable likely to be exposed as required for § 721.63(a)(1), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposures, where feasible), (b)(concentration set at 1.0 %), and (c).

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

and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

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

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

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

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

(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.

25. Add § 721.11171 to subpart E to read as follows:

§ 721.11171 Polymer of aliphatic dicarboxylic acid and dicyclo alkane amine (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as polymer of aliphatic dicarboxylic acid and dicyclo alkane amine (P-17-327) 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) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80. It is a significant new use to manufacture (includes import) the substance to have an average molecular weight of greater than 10,000 Daltons.

(ii) [Reserved]

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

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

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

26. Add § 721.11172 to subpart E to read as follows:

§ 721.11172 Hexanedioic acid, polymer with trifunctional polyol, 1,1'-methylenebis [isocyanatobenzene], and 2,2'-oxybis [ethanol] (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as hexanedioic acid, polymer with trifunctional polyol, 1,1'-methylenebis [isocyanatobenzene], and 2,2'-oxybis [ethanol] (P-17-330) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i), (ii), (iii), (iv), (a)(3), (when determining which persons are reasonable likely to

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

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (d), (f), (g)(1)(i), (eye and respiratory irritation), (g)(2)(i), (ii), (iii), (v), and (g)(5).

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

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80. It is a significant new use to manufacture, process, or use the substance for consumer use or for commercial uses that could introduce the substance into a consumer setting. It is a significant new use to manufacture, process, or use the substance in any manner 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 (b).

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

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