



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 721

[EPA-HQ-OPPT-2017-0560; FRL-9982-77]

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 10 chemical substances which were the subject of premanufacture notices (PMNs). The chemical substances are subject to Orders issued by EPA pursuant to section 5(e) of TSCA. This action requires persons who intend to manufacture (defined by statute to include import) or process any of these 10 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-2017-0560, 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 15 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 10 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 10 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) 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 sections of these rules specify 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 10 PMN substances that are subject to Orders under TSCA section 5(e)(1)(A). Each Order is based on one or more of the findings in TSCA 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 human 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. 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 determines that the PMN substance may present an unreasonable risk of injury to human health via inhalation exposure, the underlying TSCA section 5(e) Order requires, among other things, that potentially exposed employees wear specified respirators unless actual measurements of the workplace air show that air-borne concentrations of the PMN substance are below a New Chemical Exposure Limit (NCEL) that is established by EPA to provide adequate protection to human health. In

addition to the actual NCEL concentration, the comprehensive NCELS provisions in TSCA section 5(e) 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-13-307

Chemical name: Substituted carbocycle, N-[[[4-[[[4-substituted carbocyclic)amino]sulfonyl]carbocyclic]amino]carbonyl]-4-methyl- (generic).

CAS number: Not available.

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

Basis for TSCA section 5(e) Order: The PMN states that the generic (non-confidential) use of the substance will be as a component of manufactured consumer article - contained use. Based on SAR analysis of test data on analogous substances, EPA has identified concerns for systemic toxicity on the spleen, liver and thymus, blood effects, developmental toxicity and immunotoxicity. Based on SAR analysis for amides, EPA

predicts toxicity to aquatic organisms may occur at concentrations that exceed 5 parts per billion (ppb) in surface waters. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that 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. Submission of certain toxicity testing prior to exceeding the confidential production volume limit specified in the Order;
2. Use of personal protective equipment, including impervious gloves, to prevent dermal exposure;
3. Use of NIOSH certified respirators with Assigned Protection Factor (APF) of 10 to prevent inhalation exposures or compliance with a NCEL of 4 mg/m^3 as an 8-hour time-weighted average to prevent inhalation exposure;
4. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the Safety Data Sheet (SDS);
5. Refraining from manufacturing the PMN substance in the United States (i.e., import only);
6. Use of the PMN substance only for the confidential use specified in the Order;
and
7. No release of the PMN substances resulting in surface water concentrations that exceed 30 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 human health toxicity of the PMN substances may be potentially useful to characterize the effects of the PMN substances in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. The submitter has agreed not to exceed a certain production volume limit without performing specific organ toxicity testing.

CFR citation: 40 CFR 721.11116.

PMN Numbers: P-16-316 and P-16-317

Chemical name: Aliphatic polyester (generic).

CAS numbers: Not available.

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

Basis for TSCA section 5(e) Order: The PMNs state that the generic (non-confidential) use of the substances will be as drilling chemicals. Based on SAR analysis of test data on analogous substances, EPA has identified concerns for kidney 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 substances may present an unreasonable risk of injury to health and the environment. To protect against these risks, the Order requires:

1. Use of the PMN substances only for the confidential use specified in the Order; and

2. Manufacture (which under TSCA includes import) the PMN substances with a average molecular weight no lower than 22,000 for P-16-0316 and no lower than 14,000 for P-16-0317 and species with a molecular weight less than 500 present at a maximum of 2% by weight.

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, environmental toxicity and human health toxicity of the PMN substances may be potentially useful to characterize the effects of the PMN substances in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of water solubility and log Kow testing, acute and chronic aquatic toxicity testing and developmental toxicity testing may be potentially useful in characterizing the health and environmental effects of the PMN substances. Although the Order does not require these tests, the Order’s restrictions 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 721.11117.

PMN Number: P-16-342

Chemical name: Modified acrylic polymer (generic).

CAS number: Not available

Effective date of TSCA section 5(e) Order: August 7, 2017.

Basis for TSCA section 5(e) Order: The PMN states that the generic (non-confidential) use of the substance will be as a dispersant for deflocculation of pigments in industrial paints and coatings. Based on SAR analysis of test data on analogous substances, EPA has 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), 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. Refrain from manufacturing the PMN substance in the United States (i.e., import only);
2. Use of the PMN substance only as a dispersant for deflocculation of pigments in industrial paints and coatings;
3. Use the PMN substance in the paint/coating formulation at a concentration not greater than 1 percent by weight or volume;
4. No modification of the processing method or use activities of the PMN substance that would allow inhalation exposure to the PMN substance by vapor, dust, mist or aerosols at concentrations greater than 1 percent by weight or volume; 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 human health toxicity of the PMN substances may be potentially useful to characterize the effects of the PMN substances in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of pulmonary toxicity testing may be potentially useful in characterizing the health effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions 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 721.11118.

PMN Numbers: P-16-406 and P-16-407

Chemical names: Functionalized polyimide (generic).

CAS numbers: Not available.

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

Basis for TSCA section 5(e) Order: The PMNs state that the generic (non-confidential) use of the substances will be as coating for solid substrates. Based on SAR analysis of test data on analogous substances, EPA has identified concerns for lung toxicity. The Order was issued under TSCA sections 5(a)(3)(B)(i) and 5(e)(1)(A)(i), based on a finding that the information available to the Agency is insufficient to permit a reasoned evaluation of the human health effects. To protect against any potential risks the Order requires:

1. Use of the PMN substances only as a coating for solid substrates;

2. No use of the PMN substances involving application methods that generate inhalation exposures to the PMN substance by vapor, dust, mist or aerosols; and
3. No modification of manufacturing process of the PMN substances such that workers would be exposed through inhalation.

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 human health toxicity of the PMN substances may be potentially useful to characterize the effects of the PMN substances in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of pulmonary toxicity testing may be potentially useful in characterizing the health effects of the PMN substances. 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 citation: 40 CFR 721.11119.

PMN Number: P-16-413

Chemical name: Siloxanes and Silicones, di-Me, 3-hydroxypropyl Me, Me
3,3,4,4,5,5,6,6,6-nonafluorohexyl

CAS number: 1610862-54-8

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

Basis for TSCA section 5(e) Order: The PMN states that the use of the PMN substance is as an anti-fingerprint material for a metal coating application. Based on SAR analysis of test data on analogous substances, EPA has identified concerns for lung toxicity based on waterproofing of the lung if inhaled. 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 and the environment. To protect against these risks, the Order requires:

1. Submission of certain fate testing on the PMN substance prior to exceeding the production volume limits specified in the Order;
2. No processing or use of the PMN substance in a manner that results in inhalation exposure due to spray, mist or aerosol;
3. Refraining from manufacturing the PMN substance in the United States (i.e., import only); and
4. No release of the PMN substance into the waters of the United States.

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 and human health toxicity of the PMN substance may be potentially useful to characterize the effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. The submitter has agreed not to exceed the confidential production limit without performing a

UV/visible absorption test, a direct and indirect photolysis test, aerobic and anaerobic transformation in soil test and aerobic and anaerobic transformation in sediment test. In addition, EPA has determined that the results of pulmonary toxicity testing may be potentially useful in characterizing the human health effects of the PMN substance. 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 citation: 40 CFR 721.11120.

PMN Number: P-16-455

Chemical name: Sodium Tungsten Oxide

CAS number: 11120-01-7.

Effective date of TSCA section 5(e) Order: November 2, 2016.

Basis for TSCA section 5(e) Order: The PMN states that the use of the PMN substance will be as a component of infrared absorption material. Based on test data on an analog, EPA has identified concerns for lung toxicity and carcinogenicity. 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 and the environment. EPA assessed risks based on the disposal processes and engineering controls described in the PMN. To protect against these risks, the Order requires:

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

2. Use of personal protective equipment, including impervious gloves, to prevent dermal exposure;
3. Use of NIOSH certified respirators with a minimum (APF) of 1000 to prevent inhalation exposure or compliance with a NCEL of 0.3 mg/m^3 as an 8-hour time-weighted average to prevent inhalation exposure;
4. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the (SDS);
5. Use of the PMN substance only as a component of infrared absorption material;
6. No use of the PMN substance involving application methods that generate dust, mist or aerosol unless such application method occurs within an enclosed process;
7. No release of the PMN substance into the waters of the United States; and
8. The PMN substance and any waste streams from manufacture, processing, and use containing the PMN substance must be disposed of only by incineration or landfill.

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 human health and environmental toxicity of the PMN substance may be potentially useful to characterize the effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. The submitter has agreed not to exceed the confidential production limit without performing specific pulmonary toxicity and carcinogenicity testing. In addition, EPA has determined that the

results of certain chronic aquatic toxicity testing may be potentially useful in characterizing the environmental effects of the PMN substance. 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 citation: 40 CFR 721.11121.

PMN Number: P-16-503

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

CAS number: Not available.

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

Basis for TSCA section 5(e) Order: The PMN states that the non-confidential use of the PMN substance will be as a site-limited polymer intermediate for production of a deck stain coating resin additive. Based on physical-chemical properties of the PMN substance, EPA identified low concerns for human health and environmental effects. However if the PMN substance were manufactured differently, EPA identified concerns for developmental toxicity and aquatic toxicity. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that 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. Manufacture (including import) the PMN substance with a number average molecular weight no lower than 1500, and no more than 24% by weight of acid monomer in the polymer; and

2. Use of the PMN substance only as an intermediate

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, human health and environmental toxicity of the PMN substance may be potentially useful to characterize the effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of physical-chemical property testing, chronic aquatic toxicity testing, and developmental toxicity testing may be potentially useful in characterizing the health and environmental effects of the PMN substance. 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 citation: 40 CFR 721.11122.

PMN Number: P-16-570

Chemical name: Carboxylic acids, C6-18 and C8-15-di, polymers with diethylene glycol, glycerol, oleic acid, phthalic acid and sorbitol.

CAS number: 1877295-51-6.

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

Basis for TSCA section 5(e) Order: The PMN states that the use of the PMN substance will be as an aromatic polyester polyol for manufacturing rigid foam. Based on test data on an analog, EPA has identified concerns for reproductive and developmental toxicity.

Based on SAR analysis for esters, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 610 parts per billion (ppb). The Order was issued under TSCA sections 5(a)(3)(B)(i) and 5(e)(1)(A)(i), based on a determination that “the information available is insufficient to permit a reasoned evaluation of the human health effects and the PMN substance, “stating that “because of the absence of sufficient information to permit EPA to make such a determination and in light of the potential risk of human health effects posed by the uncontrolled manufacture (which includes import), processing, distribution in commerce, use and disposal of the PMN substance. EPA has concluded that uncontrolled manufacture, processing, distribution in commerce use, and disposal of the PMN substance may present an unreasonable risk of injury to human health.” To protect against these risks, the Order requires:

1. Submission of certain toxicity testing prior to exceeding the confidential production volume limit specified in the Order;
2. Use of personal protective equipment to prevent dermal exposures;
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 substance with residual phthalate not greater than 0.1% by weight;
5. Use of the PMN substance only as an aromatic polyester polyol for rigid foam;
6. No modification of manufacturing, processing or use activities of the PMN substance to result in the generation of a vapor, mist or aerosol; and
7. No release of the PMN substance into the waters of the United States.

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 human health toxicity of the PMN substance may be potentially useful to characterize the effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. The submitter has agreed not to exceed the confidential production limit without performing specific reproductive/developmental toxicity testing. In addition, EPA has determined that the results of acute aquatic toxicity testing may be potentially useful in characterizing the environmental effects of the PMN substance. 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 citation: 40 CFR 721.11123.

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 10 chemical substances, regulation was warranted under TSCA section 5(e), pending the development of information sufficient to make reasoned evaluations of the health or environmental effects of the chemical substances. The basis for such findings is outlined in Unit IV. Based on these findings, TSCA section 5(e) 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) Orders have been issued for all of the chemical substances, and the PMN submitters are prohibited by the TSCA section 5(e) Orders from undertaking activities which will be designated as significant new uses. The identities of 7 of the 10 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 this information 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). To access the OCSPP test guidelines referenced in this document electronically, please go to <http://www.epa.gov/ocspp> and select "Test Methods and Guidelines." The Organisation for Economic Co-operation and Development (OECD) test guidelines are available from the OECD Bookshop at <http://www.oecdbookshop.org> or SourceOECD at <http://www.sourceoecd.org>.

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

Any request by EPA for the triggered and 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.

The potentially useful information identified in Unit IV. may not be the only means of addressing the potential risks of the chemical substance. However, submitting a SNUN without any test data may increase the likelihood that EPA will take action under

TSCA section 5(e), particularly if satisfactory test results have not been obtained from a prior PMN or SNUN submitter. EPA recommends that potential SNUN submitters contact EPA early enough so that they will be able to generate useful information.

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

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

IX. Procedural Determinations

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

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

new use under the rule. Since most of the chemical 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-2017-0560.

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) 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: August 20, 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	
* * * * *	* * * * *
721.11116	2070-0012
721.11117	2070-0012
721.11118	2070-0012
721.11119	2070-0012
721.11120	2070-0012
721.11121	2070-0012

721.11122	2070-0012
721.11123	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 § 721.11116 to subpart E to read as follows:

§ 721.11116 Substituted carbocycle, N-[[[4-[[4-substituted carbocyclic)amino]sulfonyl]carbocyclic]amino]carbonyl]-4-methyl- (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as substituted carbocycle, N-[[[4-[[4-substituted carbocyclic)amino]sulfonyl]carbocyclic]amino]carbonyl]-4-methyl- (PMN P-13-307) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i), (a)(3), (a)(4) (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 10 or maintain workplace airborne concentrations), (a)(6)(particulate), (b)(concentrations set at 1.0%) and (c).

(A) As an alternative to the respirator requirements in paragraph (a)(2)(i) of this section, a manufacturer or processor may choose to follow the new chemical exposure limit (NCEL) provision listed in the TSCA section 5(e) Order for this substance. The NCEL is 4 mg/m^3 as an 8-hour time weighted average. Persons who wish to pursue NCELs as an alternative to §721.63 respirator requirements may request to do so under §721.30. Persons whose §721.30 requests to use the NCELs approach are approved by EPA will be required to follow NCELs provisions comparable to those contained in the corresponding TSCA section 5(e) Order.

(B) [Reserved]

(ii) *Hazard communication*. Requirements as specified in § 721.72(a), (b), (c), (d), (e)(concentration set at 1.0%), (f), (g)(1)(iv), (viii), (ix), (g)(2)(ii), (iii), (use respiratory protection or maintain workplace airborne concentrations below an 8-hour time-weighted average of 4 mg/m^3), (g)(2)(v), (g)(4)(i), (ii) and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System (GHS) and OSHA Hazard Communication Standard may be used.

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

(iv) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where $N=30 \text{ ppb}$.

(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), (i) and (k).

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

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

5. Add § 721.11117 to subpart E to read as follows:

§ 721.11117 Aliphatic polyester (generic).

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substances identified generically as aliphatic polyester (PMNs P-16-316 and P-16-317) are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(k). It is a significant new use to manufacture the PMN substances with an average molecular weight lower than 22,000 daltons for P16-316 and lower than 14,000 daltons for P-16-317 and containing more than 2 % by weight of molecular weight species less than 500 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 and processors of these substances.

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

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

6. Add § 721.11118 to subpart E to read as follows:

§ 721.11118 Modified acrylic polymer (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as modified acrylic polymer (PMN P-16-342) 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), (b), (c), (d), (e)(concentration set at 1.0%), (f), (g)(1)(ii), (g)(2)(ii), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System (GHS) and OSHA Hazard Communication Standard may be used.

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f). It is a significant new use for any use other than as a dispersant for deflocculation of pigments in industrial paints and coatings, any use in the paint/coating formulation at concentration greater than 1 percent by weight or volume, and any use of the substance that would allow inhalation exposure to the substance by vapor, dust, mist or aerosols at concentrations greater than 1 percent by weight or volume.

(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), (b), (c), (f), (g), (h), and (i) are applicable to manufacturers and processors of this substance.

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

7. Add § 721.11119 to subpart E to read as follows:

§ 721.11119 Functionalized polyimide (generic).

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substances identified as functionalized polyimide (PMN P-16-406 and P-16-407) are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(y)(1) and (2). It is a significant new use to use the substances other than as a coating for solid substrates. Any manufacturing process that results in inhalation exposure to the substances is a significant new use.

(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 and processors of these substances.

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

8. Add § 721.11120 to subpart E to read as follows:

**§ 721.11120 Siloxanes and Silicones, di-Me, 3-hydroxypropyl Me, Me
3,3,4,4,5,5,6,6,6-nonafluorohexyl.**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as siloxanes and silicones, di-Me, 3-hydroxypropyl Me, Me 3,3,4,4,5,5,6,6,6-nonafluorohexyl (CAS: 1610862-54-8) (PMN P-16-413) 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 are described in § 721.80(f) and (p)(40,000 kilograms and 151,300 kilograms). It is a significant new use to process or use the PMN substance in a manner that results in inhalation exposure to spray, mist or aerosol.

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

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

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

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

9. Add § 721.11121 to subpart E to read as follows:

§ 721.11121 Sodium tungsten oxide.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as sodium tungsten oxide (CAS No. 11120-01-7) (PMN P-16-455) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the PMN substance after they have been incorporated into a polymer matrix.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i), (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 1000, (a)(6)(particulate), (b)(concentrations set at 0.1%) and (c).

(A) As an alternative to the respirator requirements in paragraph (a)(2)(i) of this section, a manufacturer or processor may choose to follow the new chemical exposure limit (NCEL) provision listed in the TSCA section 5(e) Order for this substance. The NCEL is 0.3 mg/m³ as an 8-hour time weighted average. Persons who wish to pursue NCELs as an alternative to §721.63 respirator requirements may request to do so under §721.30. Persons whose §721.30 requests to use the NCELs approach are approved by EPA will be required to follow NCELs provisions comparable to those contained in the corresponding TSCA section 5(e) Order.

(B) [Reserved]

(ii) *Hazard communication*. Requirements as specified in § 721.72(a), (b), (c), (d), (e)(concentration set at 0.1%), (f), (g)(1)(lung effects), (g)(1)(vii), (g)(2)(ii), (iii), (g)(2)(use respiratory protection or maintain workplace airborne concentrations below an 8-hour time-weighted average of 0.3 mg/m³), (g)(3)(ii), (g)(4)(i), (iii) and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System (GHS) and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(q). It is a significant new use to use the substance other than as a component of infrared absorption material. It is a significant new use to use involving an application method that generates a dust, mist, or aerosol, unless the application method occurs within an enclosed process.

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

(v) *Release to water*. Requirements as specific 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 (k) are applicable to manufacturers and processors of this substance.

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

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

10. Add § 721.11122 to subpart E to read as follows:

§ 721.11122 Fatty acids, tall-oil, polymers with alkanolic acid, substituted carbomonocycle, alkyl peroxide-initiated (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as fatty acids, tall-oil, polymers with alkanolic acid, substituted carbomonocycle, alkyl peroxide-initiated (PMN P-16-503) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(g). It is a significant new use to manufacture the substance with an average molecular weight lower than 1,500 dalton or more than 24% by weight of acid monomer in the polymer.

(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 and processors of this substance.

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

11. Add § 721.11123 to subpart E to read as follows:

§ 721.11123 Carboxylic acids, C6-18 and C8-15-di, polymers with diethylene glycol, glycerol, oleic acid, phthalic, acid and sorbitol.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as Carboxylic acids, C6-18 and C8-15-di, polymers with diethylene glycol, glycerol, oleic acid, phthalic, acid and sorbitol (CAS: 1877295-51-6) (PMN P-16-570) 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), 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)(concentrations set at 0.1%) and (c).

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

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(q). It is a significant new use to use the substance other than as an aromatic polyester polyol for manufacturing rigid foam. It is a significant new use to manufacture the substance with residual phthalate greater than 0.1% by weight. It is a significant new

use to modify the manufacturing, processing or use activities of the PMN substance to result in the generation of a vapor, mist or aerosol.

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

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

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

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

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