



## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 721

[EPA-HQ-OPPT-2020-0302; FRL-10013-54]

RIN 2070-AB27

### Modification of Significant New Uses of Certain Chemical Substances (20-2.M)

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** EPA is proposing to amend significant new use rules (SNURs) issued under the Toxic Substances Control Act (TSCA) for certain chemical substances, which were the subject of a premanufacture notice (PMN) and a significant new use notice (SNUN). EPA is proposing these amendments following review of SNUNs for the chemical substances and based on review of new and existing data. Specifically, this action proposes to amend the SNURs to allow certain new uses reported in the SNUNs without additional notification requirements and modify the significant new use notification requirements based on the actions and determinations for the SNUN submissions.

**DATES:** Comments must be received on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2020-0302, using the Federal eRulemaking Portal at <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.

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on EPA/DC services and docket access, visit <https://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** *For technical information contact:* William Wysong, New Chemicals Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-4163; email address: [wysong.william@epa.gov](mailto:wysong.william@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](mailto: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 proposed 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 the chemical substance (NAICS codes 325 and 324110), e.g., chemical manufacturing and petroleum refineries.

This proposed rule may 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 and must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA. Importers of chemicals subject to a SNUR must certify their compliance with the SNUR requirements. Any person who exports or intends to export the chemical substance that is the subject of a final rule are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)) and 40 CFR 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 <https://www.epa.gov/dockets/commenting-epa-dockets>.

## **II. Background**

*A. What action is the Agency taking?*

EPA is proposing amendments to the SNURs for certain chemical substances in 40 CFR part 721, subpart E. A SNUR for a chemical substance designates certain activities as a significant new use. Persons who intend to manufacture or process the chemical substance for the significant new use must notify EPA at least 90 days before commencing that activity. The required notification (i.e., a SNUN) initiates EPA's evaluation of the intended use within the applicable review period. Manufacture and processing for the significant new use may not commence until EPA has conducted a review of the notice, made an appropriate determination on the notice, and taken such actions as are required with that determination.

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

TSCA section 5(a)(2) (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 and may issue or modify a TSCA section 5(e) order and/or

amend the SNUR promulgated under TSCA section 5(a)(2). Procedures and criteria for modifying or revoking SNUR requirements appear at 40 CFR 721.185.

*C. How do the SNUR general provisions apply to this action?*

General provisions for SNURs appear in 40 CFR part 721, subpart A. These provisions describe persons subject to the final rule, recordkeeping requirements, exemptions to reporting requirements, and applicability of the rule to uses occurring before the effective date of the final rule. Provisions relating to user fees appear at 40 CFR part 700. According to 40 CFR 721.1(c), persons subject to these SNURs must comply with the same notice 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 sections 5(b) and 5(d)(1), the exemptions authorized by TSCA sections 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**

TSCA section 5(a)(2) 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 determining whether and how to modify the significant new uses for the chemical substances that are the subject of these SNURs, and as described in the preamble to the proposed rule, EPA considered relevant information about the toxicity of the chemical substance, likely human exposures and environmental releases associated with possible uses, and the four TSCA section 5(a)(2) factors listed in this unit.

#### **IV. Substances Subject to Proposed Significant New Use Rule Amendments and Proposed Changes**

EPA is proposing to amend the significant new use and recordkeeping requirements for chemical substances in 40 CFR part 721, subpart E. In this unit, EPA provides the following information for each chemical substance:

- PMN number and SNUN number.
- Chemical name (generic name, if the specific name is claimed as CBI).
- Chemical Abstracts Service (CAS) number (if assigned for non-confidential chemical identities).
- Citation for the final SNUR. This is the citation to the final rule that established the SNUR that EPA is proposing to amend.
- Basis for the proposed amendment.
- Potentially Useful Information. This is 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 TSCA 5(e) order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use designated as such by the SNUR.
- CFR citation. This is the citation for the codified SNUR that EPA is proposing to amend.

**PMN P-99-1202 and SNUN S-15-6.**

*Chemical name:* Sulfonyl azide intermediate (generic).

*CAS number:* Not Available.

*Citation for the final SNUR:* December 17, 2003 (68 FR 70174) (FRL-7307-3).

*Basis for the modified significant new use rule:* P-99-1202 and S-15-6 state that the generic (non-confidential) use of the substance is as a reactive additive for polymers. Based on submitted test data, EPA identified concerns for blood, kidney and lung toxicity from inhalation exposure to the PMN substance. Based on analogue data, EPA identified concerns for aquatic toxicity. The original SNUR was issued based on EPA's determination that the chemical substance met the concern criteria at 40 CFR 721.170(b)(3)(i) and (b)(4)(ii) and requires notification if the substance is released to water, manufactured domestically, or processed or used as a powder.

On March 6, 2015, EPA received a SNUN (S-15-6) for the significant new use of importing the chemical substance as a powder. The applicable review period for the SNUN expired on June 18, 2015. Based on submitted test data, EPA identified concerns for blood, kidney and lung toxicity from inhalation exposure to the PMN substance. EPA did not find that import of the granular form of the SNUN substance would cause an unreasonable risk to human health because it contained particles that are greater than 200 microns and would not result in inhalation exposures. The proposed amendment to the SNUR would modify the significant new use notification requirement to require notification if the chemical substance as a powder contains greater than 1% of particles by weight less than 200 microns.

This proposed amendment is based on 721.185, EPA's review of a significant new use notice. After reviewing the notice, EPA concluded that there is no need to require additional notice from persons who propose to engage in identical or similar activities.

*Potentially Useful Information:* Certain information may be potentially useful to characterize the health and environmental effects of the chemical substance in support of submitting a SNUN for a significant new use that would be designated by this proposed SNUR. The results of specific organ toxicity and aquatic toxicity testing would help characterize the potential health and

environmental effects of the chemical substance.

*CFR citation:* 40 CFR 721.983.

**PMN P-90-226; SNUNs P-96-1408, S-08-6, S-09-4, S-13-49, S-16-5, and S-17-6.**

*Chemical name:* Titanate [Ti<sub>6</sub>O<sub>13</sub> (2-)], dipotassium

*CAS number:* 12056-51-8.

*Citation for the final SNUR:* November 13, 2015 (80 FR 70171) (FRL-9935-43).

*Basis for the modified significant new use rule:* The generic use of the chemical substance is as a friction material. An order for P-90-226 was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) based on a finding that the chemical substance may present an unreasonable risk of injury to human health. Based on test data for the substance, EPA identified concerns for lung effects. The final SNUR issued on November 13, 2015 required notification for domestic manufacture, non-industrial use, manufacture other than by the methods described in premanufacture notice P-90-226 and significant new use notices P-96-1408, S-08-6, S-09-4, and S-13-49, and manufacture producing respirable, acicular fibers with an average aspect ratio of greater than 5. The average aspect ratio is defined as the ratio of average length to average diameter.

On June 22, 2016, EPA received S-16-5 for the generic (non-confidential) use of abrasion resistant applications. The applicable review period expired on February 8, 2019. Based on test data for the substance, EPA identified concerns for lung effects. Based on the activities described in the SNUN, an order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a determination that the chemical substance may present an unreasonable risk of injury to human health. In addition to the restrictions identified for the SNUR, the TSCA section 5(e) order for S-16-5 required that the substance be manufactured as described in the SNUN.

On February 14, 2017, EPA received S-17-6 for the generic (non-confidential) use of physical characteristics modifier for industrial use in certain solid composite articles. The applicable review period expired on June 14, 2018. Based on test data for the substance, EPA

identified concerns for lung effects. Based on the activities described in the SNUN, an order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a determination that the chemical substance may present an unreasonable risk of injury to human health. In addition to the restrictions identified for the SNUR, the TSCA section 5(e) order for S-17-6 required that the substance be manufactured as described in the SNUN including the resulting particle size distribution. The order also required respiratory protection for workers exposed by inhalation and included a new chemical exposure limit of 0.8 mg/m<sup>3</sup>.

The proposed amendment to the SNUR would retain the existing significant new use notification requirements but would remove the manufacturing processes described in S-16-5 and S-17-6 from the scope of the significant new use. It would also add worker inhalation protection requirements for workers who are exposed by inhalation to S-17-6, along with related recordkeeping requirements.

This proposed amendment is based on 721.185, EPA's review of a significant new use notice. After reviewing the notice, EPA concluded that there is no need to require additional notice from persons who propose to engage in identical or similar activities.

*Potentially Useful Information:* Certain information may be potentially useful to characterize the health effects of the chemical substances if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated as such by this proposed SNUR. The results of pulmonary effects testing would help characterize the potential health effects of the chemical substance.

*CFR citations:* 40 CFR 721.9675.

**PMN P-11-316.**

*Chemical name:* Cyclohexane, oxidized, by-products from, distn. residues.

*CAS number:* 1014979-92-0.

*Citation for the final SNUR:* April 4, 2012 (77 FR 20296) (FRL-9333-3).

*Basis for the modified significant new use rule:* P-11-316 identified the generic (non-

confidential) uses for the substance as an industrial solvent in closed and open systems, and as an accelerant in permitted industrial explosives. The SNUR was issued based on EPA's determination that the chemical substance met the concern criteria at 40 CFR 721.170(b)(4)(ii). Based on test data on analogous esters, EPA predicted toxicity to aquatic organisms may occur at concentrations that exceed 4 parts per billion (ppb) of the PMN substance in surface waters. The SNUR required notification for manufacturing, processing or use resulting in releases to surface waters that exceed 4 ppb.

On July 22, 2017, the PMN submitter sent four acute ecotoxicity studies to address the environmental toxicity concerns identified for the SNUR. EPA evaluated the studies and determined that toxicity to aquatic organisms may occur at concentrations that exceed 470 ppb. Because there is still potential for water releases that exceed 470 ppb, the proposed amendment to the SNUR would modify the significant new use notification requirement to require notification for manufacturing, processing, or use resulting in releases in surface waters that exceed 470 ppb.

This proposed amendment is based on EPA's determination under 40 CFR 721.185(a)(1) that the test data sent to EPA provide a reasonable basis for concluding that activities designated as significant new uses of the substance will not present an unreasonable risk of injury to human health or the environment.

*Potentially Useful Information:* Certain information may be potentially useful to characterize the environmental effects of the chemical substance if a manufacturer or processor is considering submitting a SNUN. The results of chronic aquatic toxicity testing would help characterize the potential environmental effects of the chemical substance.

*CFR citation:* 40 CFR 721.10288.

**PMN P-98-1028; and SNUNs S-14-9, S-17-12, and S-17-15.**

*Chemical name:* 1,2,4,5,7,8-hexoxonane, 3,6,9-triethyl-3,6,9-trimethyl-

*CAS number:* 24748-23-0.

*Citation for the final SNUR:* September 21, 2012 (77 FR 58666) (FRL-9357-2)

*Basis for the modified significant new use rule:* P-98-1028 states that the use of the chemical substance is as a viscosity modifier in the manufacture of polypropylene manufactured and supplied as a solution in at least 40 percent mineral spirits. The SNUR was issued based on EPA's determination that the chemical substance met the concern criteria at 40 CFR 721.170(b)(4)(ii). Based on test data on analogous peroxides, EPA predicted toxicity to aquatic organisms. The SNUR required notification for use of the chemical substance other than as a viscosity modifier in the manufacture of polypropylene manufactured and supplied as a solution in at least 40 percent mineral spirits.

On March 21, 2014, EPA received S-14-9 for the generic (non-confidential) use of a polymerization initiator. The applicable review period for the SNUN expired on June 18, 2014. Based on test data on analogous peroxides, EPA identified concerns for toxicity to aquatic organisms at a concentration as low as 1 ppb. Based on information contained in the SNUN, EPA did not find that use of the substance as a polymerization initiator would cause an unreasonable risk to human health or the environment.

On March 22, 2017, EPA received S-17-12 for the generic (non-confidential) use of a polymerization initiator. The applicable review period expired on March 18, 2019. Based on test data for the substance, EPA identified concerns for lung, liver, kidney, and blood effects, reproductive/developmental toxicity, dermal sensitization, and aquatic toxicity. Based on the activities described in the SNUN, an order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a determination that the chemical substance may present an unreasonable risk of injury to human health and the environment. The TSCA section 5(e) order for S-17-12 required dermal and respiratory protection for exposed workers, hazard communication requirements, no application method that generates a mist, vapor or aerosol, and no releases to surface waters that exceed 56 ppb (a change from the assessment of 1 ppb for S-14-9).

On August 31, 2017, EPA received S-17-15 for the generic (non-confidential) use of a polymerization initiator. The applicable review period expired on March 18, 2019. Based on test data for the substance, EPA identified concerns for lung, liver, kidney, and blood effects, reproductive/developmental toxicity, dermal sensitization, and aquatic toxicity. Based on the activities described in the SNUN, an order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a determination that the chemical substance may present an unreasonable risk of injury to human health and the environment. The TSCA section 5(e) order for S-17-15 required dermal and respiratory protection for exposed workers, hazard communication requirements, no application method that generates a mist, vapor or aerosol, and no releases to surface waters that exceed 56 ppb.

The proposed amendment to the SNUR would remove use of the chemical substance other than as a viscosity modifier in the manufacture of polypropylene manufactured and supplied as a solution in at least 40 percent mineral spirits from the scope of the significant new use. It would also add notification requirements for worker protection, hazard communication, releases to surface waters exceeding 56 ppb, and application methods that generate a mist, vapor, or aerosol based on the TSCA 5(e) orders issued for S-17-12 and S-17-15, along with related recordkeeping requirements.

This proposed amendment is based on 721.185, EPA's review of a significant new use notice. After reviewing the notice, EPA concluded that there is no need to require additional notice from persons who propose to engage in identical or similar activities.

*Potentially Useful Information:* Certain information may be potentially useful to characterize the health and environmental effects of the chemical substance in support of a request to modify the TSCA section 5(e) order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated as such by this proposed SNUR. The results of a toxicokinetics and chronic aquatic toxicity testing would help characterize the potential health and environmental effects of the chemical substance.

*CFR citation:* 40 CFR 721.10432.

**PMN P-15-326 and SNUN S-17-11.**

*Chemical name:* Polyfluorohydrocarbon.

*CAS number:* Not Available.

*Citation for the final SNUR:* May 16, 2016 (81 FR 30452) (FRL-9944-77).

*Basis for the modified significant new use rule:* P-15-326 states that the generic (non-confidential) use of the chemical substance is as a specialty gas and transfer fluid. The SNUR was issued based on EPA's determination that the chemical substance met the concern criteria at § 721.170(b)(3)(i) and (b)(3)(ii). Based on test data on the chemical substance and structure-activity relationship (SAR) analysis of test data on analogous substances, EPA identified concerns for neurotoxicity, developmental toxicity, and cardiac sensitization. The SNUR requires notification for any use of the substance other than the confidential uses listed in the PMN or any use in a consumer product.

On January 19, 2017, EPA received SNUN S-17-11 for the significant new use generically described as a foam additive. The applicable review period for the SNUN expired on January 22, 2020. Based on submitted tests for the chemical substance, EPA identified concerns for neurotoxicity, systemic toxicity, and developmental toxicity. Based on the activities described in the SNUN, EPA determined under TSCA section 5(a)(3)(C) that the significant new use is not likely to present an unreasonable risk.

The proposed amendment to the SNUR would remove the confidential use described in S-17-11 from the scope of the significant new use. It would also designate as a significant new use any use other than the confidential uses described in P-15-326 and S-17-11.

This proposed amendment is based on 721.185, EPA's review of a significant new use notice. After reviewing the notice, EPA concluded that there is no need to require additional notice from persons who propose to engage in identical or similar activities.

*Potentially Useful Information:* Certain information may be potentially useful to characterize the

health effects of the chemical substance if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated as such by this proposed SNUR. The results of specific target organ toxicity testing would help characterize the potential health effects of the chemical substance.

*CFR citation:* 40 CFR 721.10907.

**PMN P-15-607 and S-17-13.**

*Chemical name:* 1,2,4,5,7,8-hexoxonane, 3,6,9-trimethyl-, 3,6,9-tris(alkyl) derivs.

*CAS number:* Not Available.

*Citation for the final SNUR:* May 16, 2016 (81 FR 30542) (FRL-9944-77).

*Basis for the modified significant new use rule:* P-15-607 states that the generic (non-confidential) use of the chemical substance is as a polymerization initiator. The SNUR was issued based on EPA's determination that the chemical substance met the concern criteria at 40 CFR 721.170(b)(4)(i) and (ii). Based on test data on the substance and on analogous peroxides, EPA predicted toxicity to aquatic organisms at concentrations in surface waters that exceed 55 ppb. The SNUR required notification for any use other than the confidential use specified in the PMN.

On March 22, 2017, EPA received S-17-13 for the generic (non-confidential) use of a polymerization initiator. The applicable review period expired on March 18, 2019. Based on test data for an analogous peroxide chemical, EPA identified concerns for lung, liver, kidney, and blood effects, reproductive/developmental toxicity, dermal sensitization, and aquatic toxicity. Based on the activities described in the SNUN, an order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a determination that the chemical substance may present an unreasonable risk of injury to human health and the environment. The TSCA section 5(e) order for S-17-13 required dermal and respiratory protection for exposed workers, hazard communication requirements, no application method that generates a mist, vapor or aerosol, and no releases to surface waters that exceed 56 ppb.

The proposed amendment to the SNUR would remove *uses other than the confidential use* described in P-15-607 from the scope of the significant new use. It would also add notification requirements for worker protection, hazard communication, releases to water exceeding 56 ppb, and application methods that generate a mist, vapor, or aerosol based on the TSCA 5(e) order issued for S-17-13, along with related recordkeeping requirements.

This proposed amendment is based on 721.185, EPA's review of a significant new use notice. After reviewing the notice, EPA concluded that there is no need to require additional notice from persons who propose to engage in identical or similar activities.

*Potentially Useful Information:* Certain information may be potentially useful to characterize the health and environmental effects of the chemical substance in support of a request to modify the TSCA section 5(e) order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated as such by this proposed SNUR. The results of a toxicokinetics and chronic aquatic toxicity testing would help characterize the potential health and environmental effects of the chemical substance.

*CFR citation:* 40 CFR 721.10922.

## **V. Rationale for the Proposed Rule**

In those instances where EPA expanded the scope of or added a significant new use, as discussed in Unit IV., the Agency identified concerns associated with certain uses. In those instances where EPA eliminated significant new uses, the Agency no longer identified concerns with those new uses. In addition to considering the factors discussed in Unit IV., EPA determined that those uses could result in changes in the type or form of exposure to the chemical substance, increased exposures to the chemical substance, and/or changes in the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of the chemical substance.

## **VI. Applicability of the Proposed Rule to Uses Occurring Before Effective Date of the Final Rule**

To establish a significant new use, EPA must determine that the use is not ongoing. EPA solicits comments on whether any of the uses that are not currently a significant new use under the SNURs addressed in this proposed rule, but which would be regulated as a “significant new use” if this proposed rule is finalized, are ongoing. These specific new uses are use without certain worker protection for the SNUR at 40 CFR 721.9675, and processing or use involving an application method that generates a dust, vapor, mist, or aerosol, worker protection, hazard communication, and water release requirements for the SNURs at 40 CFR 721.10432 and 10922. EPA designates [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] as the cutoff date for determining whether the use is ongoing. EPA has decided that the intent of TSCA section 5(a)(1)(B) is best served by designating a use as a significant new use as of the date of public release of the proposed SNUR rather than as of the effective date of the final rule. If uses begun after public release were considered ongoing rather than new, it would be difficult for EPA to establish SNUR notice requirements, because a person could defeat the SNUR by initiating the proposed significant new use before the rule became effective, and then argue that the use was ongoing as of the effective date of the final rule.

Thus, any persons who begin commercial manufacture or processing activities with the chemical substance that are not currently a significant new use under the current rule but which would be regulated as a “significant new use” if this proposed rule is finalized, must cease any such activity as of the effective date of the rule if and when finalized. To resume their activities, these persons would have to comply with all applicable SNUR notice requirements and wait until the notice review period, including all extensions, expires.

## **VII. Development and Submission of Information**

TSCA section 5 generally does not require developing any particular new information (e.g., generating test data) before submission of a SNUN. There is an exception: If a person is required to submit information for a chemical substance pursuant to a rule, order or consent agreement under TSCA section 4, then TSCA section 5(b)(1)(A) requires such information to be

submitted to EPA at the time of submission of the SNUN.

In the absence of a rule, order, or consent agreement under TSCA section 4 covering the chemical substance, persons are required only to submit information in their possession or control and to describe any other information known or reasonably ascertainable (40 CFR 720.50). Unit IV. lists potentially useful information for all SNURs addressed in this proposed rule. Descriptions of this information are provided for informational purposes. The potentially useful information identified in Unit IV. will be useful to EPA's evaluation of a chemical substance in the event that someone submits a SNUN for a significant new use pursuant to the SNURs address in this proposed rule. Companies who are considering submitting a SNUN are encouraged, but are not required, to develop the potentially useful information on the substance, which may assist with EPA's analysis of the SNUN.

EPA strongly encourages persons, before performing any testing, to consult with the Agency. Furthermore, pursuant to TSCA section 4(h), which pertains to reduction of testing on vertebrate animals, EPA encourages dialogue 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 dialogue with Agency representatives to help determine how best the submitter can meet both the data needs and the objective of TSCA section 4(h).

The potentially useful information listed in Unit IV may not be the only means of providing information to evaluate the chemical substance. 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; and information on risks posed by the chemical substances compared to risks posed by potential substitutes.

## **VIII. SNUN Submissions**

According to 40 CFR 721.1(c), persons submitting a SNUN must comply with the same notification requirements and EPA regulatory procedures as persons submitting a PMN under 40 CFR part 720, 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 721.25 and 40 CFR 720.40. E-PMN software is available electronically at

*<https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca>.*

## **IX. Economic Analysis**

EPA has evaluated the potential costs of establishing SNUN requirements for potential manufacturers and processors of the chemical substances subject to this proposed rule. The EPA's complete economic analysis is available in the docket under docket ID number EPA-HQ-OPPT-2020-0302.

## **X. Statutory and Executive Order Reviews**

Additional information about these statutes and Executive Orders can be found at *<https://www.epa.gov/laws-regulations-and-executive-orders>*.

*A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulations and Regulatory Review*

This proposed rule would modify SNURs for chemical substances that were the subject of a PMN and a SNUN. 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. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs*

This action is not subject to Executive Order 13771 (82 FR 9339, February 3, 2017), because this action is not a significant regulatory action under Executive Order 12866.

*C. Paperwork Reduction Act (PRA)*

This action does not impose any new information collection burden under the PRA (44 U.S.C. 3501 *et seq.*). Burden is defined in 5 CFR 1320.3(b). The information collection activities associated with new chemical SNURs have already been approved under OMB control number 2070-0012 (EPA ICR No. 0574). This action does not impose any burden requiring additional OMB approval.

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. 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.

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. 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, Regulatory Support Division, Office of Mission Support (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.

*D. Regulatory Flexibility Act (RFA)*

Pursuant to RFA section 605(b) (5 U.S.C. 601 *et seq.*), the Agency hereby certifies that promulgation of this SNUR would not have a significant adverse economic impact on a substantial number of small entities. The requirement to submit a SNUN applies to any person (including small or large entities) who intends to engage in any activity described in this SNUR as a “significant new use.” Because these uses are “new” based on all information currently available to EPA it appears that no small or large entities presently engage in such activities. A SNUR requires that any person who intends to engage in such activity in the future must first notify EPA by submitting a SNUN. EPA’s experience to date is that, in response to the promulgation of SNURs covering over 1,000 chemicals, the Agency receives only a small number of notices per year. For example, the number of SNUNs received was seven in Federal fiscal year (FY) 2013, 13 in FY2014, six in FY2015, 10 in FY2016, 14 in FY2017, and 18 in FY2018 and only a fraction of these were from small businesses. In addition, the Agency currently offers relief to qualifying small businesses by reducing the SNUN submission fee from \$16,000 to \$2,800. This lower fee reduces the total reporting and recordkeeping of cost of submitting a SNUN to about \$10,116 for qualifying small firms. Therefore, the potential economic impacts of complying with this proposed SNUR are not expected to be significant or adversely impact a substantial number of small entities. In a SNUR that published in the *Federal Register* of June 2, 1997 (62 FR 29684) (FRL-5597-1), the Agency presented its general determination that final SNURs are not expected to have a significant economic impact on a substantial number of small entities, which was provided to the Chief Counsel for Advocacy of the Small Business Administration.

#### *E. 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.*).

*F. Executive Order 13132: Federalism*

This action would 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).

*G. Executive Order 13175: Consultation and Coordination with Indian Tribe Governments*

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 would 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.

*H. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks*

This proposed rule is not subject to Executive Order 13045 (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. EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that EPA has reason to believe may disproportionately affect children, per the definition of “covered regulatory action” in section 2-202 of the Executive Order.

*I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use*

This action is not subject to Executive Order 13211 (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.

*J. National Technology Transfer and Advancement Act (NTTAA)*

This action does not involve any technical standards and is therefore not subject to considerations under NTTAA section 12(d) (15 U.S.C. 272 note).

*K. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations*

This action does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898 (59 FR 7629, February 16, 1994).

**List of Subjects**

*40 CFR Part 721*

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

Dated: November 3, 2020.

**Tala Henry,**

*Deputy Director, Office of Pollution Prevention and Toxics.*

Therefore, for the reasons stated in the preamble, it is proposed that 40 CFR part 721 be amended as follows:

**PART 721--[AMENDED]**

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

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

2. Amend § 721.983 by revising paragraphs (a)(1) and (2)(ii) to read as follows:

**§ 721.983 Sulfonyl azide intermediate (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as sulfonyl azide intermediate (PMN P-99-1202 and SNUN S-15-6) is subject to reporting under this section for the significant new use described in paragraph (a)(1) of this section.

(2) \* \* \*

(i) \* \* \*

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f). It is a significant new use to import, process, or use this chemical substance as a powder unless less than 1% of particles by weight are less than 200 microns.

\* \* \* \* \*

3. Amend § 721.9675 by revising paragraphs (a)(1), (2)(i) and (ii), and (b)(1) to read as follows:

**§ 721.9675 Titanate [Ti6O13 (2-)], dipotassium.**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as titanate [Ti6O13 (2-)], dipotassium (PMN P-90-226; SNUNs P-96-1408, S-08-6, S-09-4, S-13-49, S-16-5, and S-17-6; CAS No. 12056-51-8)) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) \* \* \*

(i) *Protection in the workplace.* For manufacturing, processing, and use of SN-17-6:

Requirements as specified in § 721.63(a)(4) through (6), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(4), engineering control measures (*e.g.*, enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.*, workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health assigned protection factor of at least 10. For purposes of § 721.63(a)(6), the airborne form(s) of the substance include particulate including solid or liquid droplets.

(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) consent order for this substance. The NCEL is 0.8 mg/m<sup>3</sup> 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 that are approved by EPA, will be required to follow NCELs provisions comparable to those contained in the corresponding TSCA section 5(e) consent order.

(B) [Reserved]

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f) and (l). In addition, a significant new use of the substance is importation of the chemical substance if: (A) Manufactured by other than the method described in premanufacture notice P-90-226 and significant new use notices P-96-1408, S-08-6, S-09-4, S-13-49, S-16-5, and S-17-6.

(B) Manufactured producing respirable, acicular fibers with an average aspect ratio of greater than 5. The average aspect ratio is defined as the ratio of average length to average diameter. For manufacture of S-17-6: Manufacture with a particle size distribution containing greater than 30% of particles less than 10 microns.

(b) \* \* \*

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

\* \* \* \* \*

4. Amend § 721.10288 by revising paragraphs (a)(1) and (2)(i) to read as follows:

**§ 721.10288 Cyclohexane, oxidized, by-products from, distn. residues.**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as cyclohexane, oxidized, by-products from, distn. residues (PMN P-11-316; CAS No. 1014979-92-0) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) \* \* \*

(i) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4) where N = 470 ppb.

\* \* \* \* \*

5. Amend § 721.10432 by revising paragraphs (a)(1), (2)(i) through (iv) and (b)(2) to read as follows:

**§ 721.10432 1,2,4,5,7,8-Hexoxonane, 3,6,9-triethyl-3,6,9-trimethyl-**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 1,2,4,5,7,8-hexoxonane, 3,6,9-triethyl-3,6,9-trimethyl- (PMN P-98-1028 and SNUNs S-14-9, S-17-12, and S-17-15; CAS No. 24748-23-0) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) \* \* \*

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (3) through (5) and (6)(v), and (b), and (c). 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. For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health assigned protection factor of at least 50. For purposes of § 721.63(b) the concentration is set at 1.0%.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), and (g)(1)(iv) and (vi), (2)(v), (3), (4)(i) and (5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), required human health hazard statements include allergic skin reaction. For purposes of § 721.72(g)(2), required human health precautionary statements include where engineering controls are not determined to be adequate, use respiratory protection. For purposes of § 721.72(g)(3), required environmental hazard statements include this substance may cause long lasting harmful effects to aquatic life. 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.* It is a significant new use to process or use the substance with an application method that generates a mist, vapor, or aerosol.

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4) where N = 56 ppb.

(b) \* \* \*

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

\* \* \* \* \*

6. Amend § 721.10907 by revising paragraphs (a)(1) and (2)(i) to read as follows:

**§ 721.10907 Polyfluorohydrocarbon (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as polyfluorohydrocarbon (PMN P-15-326 and SNUN S-17-11) is subject to reporting under this section for the significant new uses described in paragraph

(a)(2) of this section.

(2) \* \* \*

(i) *Industrial commercial, and consumer activities.* Requirements as specified in § 721.80(o). It is a significant new use to use the substance other than for the confidential uses described in PMN P-15-326 and SNUN S-17-11.

\* \* \* \* \*

7. Amend § 721.10922 by:

- a. Revising paragraphs (a)(1) through (2)(ii);
- b. Adding paragraphs (a)(2)(iii) and (iv);
- c. Revising paragraph (b)(1); and
- d. Removing paragraph (b)(3).

The revisions and additions read as follows:

**§ 721.10922 1,2,4,5,7,8-Hexoxonane, 3,6,9-trimethyl-, 3,6,9-tris(alkyl) derivs. (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as 1,2,4,5,7,8-hexoxonane, 3,6,9-trimethyl-, 3,6,9-tris(alkyl) derivs. (PMN P-15-607 and SNUN S-17-13) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) \* \* \*

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (3) through (5) and (6)(v), and (b) and (c). 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. For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health assigned protection factor of at least 50. For purposes of § 721.63(b) the concentration is set at 1.0%.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1)(iv) and (vi), (2)(v), (3), (4)(i) and (5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), required human health hazard statements include allergic skin reaction. For purposes of § 721.72(g)(2), required human health precautionary statements include where engineering controls are not determined to be adequate, use respiratory protection. For purposes of § 721.72(g)(3), required environmental hazard statements include this substance may cause long lasting harmful effects to aquatic life. 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.* It is a significant new use to process or use the substance with an application method that generates a mist, vapor, or aerosol.

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4) where N = 56 ppb.

(b) \* \* \*

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

\* \* \* \* \*