E 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[EPA-HQ-OPPT-2020-0690; FRL-9864-01-OCSPP]

RIN 2070-AB27

Modification of Significant New Uses of Certain Chemical Substances (21-1.M)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to amend the significant new use rules (SNURs) for certain chemical substances identified herein, which were the subject of one or more premanufacture notices (PMNs) and in some cases significant new use notices (SNUNs). This action would amend the SNURs to allow certain new uses reported in the SNUNs or PMNs without additional notification requirements and modify the significant new use notification requirements based on the actions and determinations for the SNUN or PMN submissions or based on the examination of new test data or other information. EPA is proposing these amendments based on our review of new and existing data for the chemical substances.

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, through the *Federal eRulemaking Portal* at *https://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. Additional instructions on commenting and visiting the docket, along with more information about dockets generally, is available at *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*.

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

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

II. Background

A. What action is the Agency taking?

EPA is 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. 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 in association 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.

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, 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

In this unit, EPA provides the following information for each chemical substance subject to the proposed amendments presented in this document:

- CFR citation for the existing SNUR that EPA is proposing to amend.
- PMN and SNUN number(s), as applicable.
- Chemical name (generic name, if the specific name is claimed as CBI).
- Chemical Abstracts Service (CAS) number (if assigned for non-confidential chemical identities).
- Final rule citation (*Federal Register* citation for the final SNUR previously issued).
- 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: 40 CFR 721.5185.

PMN and SNUN numbers: P-95-169, S-08-7, S-14-1, S-17-10, and S-19-0006.

Chemical name: 2-Propen-1-one, 1-(4-morpholinyl)-.

CAS number: 5117-12-4.

Final rule citations: 65 FR 354, January 5, 2000 (FRL-6055-2), amended at 76 FR 27910, May 13, 2011 (FRL-8871-5), 80 FR 37161, June 30, 2015 (FRL-9928-93), and 85 FR 67996, October 27, 2020 (FRL-10013-53).

Basis for the modified significant new use rule: P-95-169 describes the intended use as a diluent for ultraviolet and electron beam curable resins for coatings, inks, and curable adhesives, S-08-7 is for use in energy production, S-14-1 is for use as a monomer in ultraviolet ink jet applications, and S-17-10 is for use as a monomer for use in stereolithography. On February 6, 2018, EPA issued an Order for S-17-10 under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a determination that the use may present an unreasonable risk of injury to human health and the environment. EPA identified concerns based on acute toxicity, neurotoxicity, eye irritation, sensitization, liver toxicity, and aquatic toxicity test data for the chemical substance. In addition to the dermal protection, hazard communication, use, and water release notification requirements under the previously published SNUR, the Order for S-17-10 required respirators to prevent inhalation exposure during the use of the chemical substance as a monomer in stereolithography. The SNUR for this chemical substance was then amended to remove the use described in SNUN S-17-10 from the scope of the significant new use, except where that use does not include the protective measures described in the Order for S-17-10.

On September 20, 2019, EPA received SNUN S-19-6 for the generic (non-confidential) significant new use as a component for 3D printing formulations. Based on available data on the chemical substance and data on analogous chemicals, EPA identified the following human health hazards: acute toxicity, skin and eye irritation, skin sensitization, genotoxicity, carcinogenicity, and specific target organ toxicity. Based on the activities described in the SNUN, EPA determined in accordance with TSCA section 5(a)(3)(C) that the significant new use is not likely to present an unreasonable risk of injury to health or the environment under the conditions of use.

Pursuant to 40 CFR 721.185(a)(3), EPA determined that there is no need to require additional notice from persons who propose to engage in activities identical to those described in SNUN S-19-6. Accordingly, the proposed amendment to the SNUR would remove use as a component for 3D printing formulations from the scope of the significant new use, except where that use does not include the protective measures described in the SNUR.

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

CFR citation: 40 CFR 721.5192.

PMN and SNUN numbers: P-87-1036, S-06-5, and S-16-6.

Chemical name: Oxirane, 2,2'-[1,6-naphthalenediylbis(oxymethylene)]bis-.

CAS number: 27610-48-6.

Final rule citation: 60 FR 45072, August 30, 1995 (FRL-4926-2).

Basis for the modified significant new use rule: P-87-1036 describes the generic intended use as a component for preparing polymer composites, S-06-5 is for use as an adhesive additive, and S-

16-6 is for use as a resin. The Order for P-87-1036 was issued under sections 5(e)(1)(A)(i), (ii)(I) and (ii)(II) of TSCA based on a finding that the chemical substance may present an unreasonable risk of injury to human health and the environment and that the chemical substance will be produced in substantial quantities and that it may reasonably be anticipated to enter the environment in substantial quantities or there may be significant or substantial human exposure. EPA issued a SNUR designating significant new uses based on and consistent with the Order requirements.

On March 24, 2006, EPA received SNUN S-06-05 for the generic (non-confidential) significant new use as an adhesive additive. Based on the activities described in the SNUN, EPA took no action and allowed the significant new use. On December 9, 2015, EPA received SNUN S-16-6 for the generic (non-confidential) significant new use as a resin and to exceed the confidential aggregate production volume limit. Based on the SNUN submitter's amendment to S-16-6 confirming its intention to abide by the workplace protection, hazard communication, no domestic manufacture, disposal by incineration or landfill, and release to water restrictions in the SNUR, EPA did not determine the manufacturing, processing, use, or disposal of this substance in the manner described in S-16-6 may present an unreasonable risk to human health or the environment. The decision not to regulate the SNUN substance was based on limiting human exposure through the use of appropriate personal protective equipment by exposed workers, hazard communication warnings, import of the SNUN substance (i.e., no domestic manufacture), and because the use described in the SNUN is not in consumer products. EPA continues to have concerns for toxicity to human health where workers are reasonably likely to be exposed. EPA also confirms that once the SNUN substance is completely polymerized it will have been completely reacted to form a different chemical substance and the SNUR does not apply to that chemical substance.

Pursuant to 40 CFR 721.185(a)(3), EPA determined that there is no need to require additional notice from persons who propose to engage in activities identical to those described in

S-06-05 and S-16-6. Accordingly, the proposed amendment to the SNUR would remove the uses described in both SNUNs from the scope of the significant new uses and remove the aggregate production volume limit. It would also exempt SNUR requirements when the substance has been completely reacted or cured. The chemical substance which is the subject of this SNUR is now on the public TSCA Inventory. Because of that EPA is proposing to amend the SNUR to include the specific chemical name and CAS number.

Potentially Useful Information: Certain information may be potentially useful to characterize the health and environmental 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 specific target organ toxicity, carcinogenicity, and aquatic toxicity testing would help characterize the potential health and environmental effects of the chemical substance.

CFR citation: 40 CFR 721.7280.

PMN number: P-89-632

Chemical name: 1,3-Propanediamine, N,N′-1,2-ethanediylbis-, polymer with 2,4,6-trichloro-1,3,5-triazine, reaction products with N-butyl-2,2,6,6-tetramethyl-4-piperidinamine.

CAS number: 136504-96-6.

Final rule citation: 55 FR 33296, August 15, 1990 (FRL-3741-8).

Basis for the modified significant new use rule: P-89-632 states that the generic (non-confidential) intended use of the substance is as light stabilizer for thermoplastics. Based on submitted test data, EPA has concerns for immunotoxicity, effects on the liver, blood and gastrointestinal tract, and reproductive toxicity and aquatic toxicity. An Order was issued under TSCA sections 5(e)(1)(A)(i) and (ii)(I), based on a finding that the substance may present an unreasonable risk of injury to human health and the environment. EPA issued a SNUR designating significant new uses based on and consistent with the Order requirements.

EPA received a request from the PMN submitter to amend the Order when the substance

is completely bound in the polymer matrix. EPA agreed that when the PMN substance is completely bound in the polymer matrix, exposures and risks are adequately mitigated. On January 27, 2010, EPA modified the Order to add the exemption that the requirements of the Order do not apply to quantities of the PMN substance after they have been completely incorporated into the polymer matrix. For consistency with the modified Order, the proposed amendment to the SNUR would similarly exempt from the requirements of the SNUR quantities of the substance after they have been completely incorporated into a polymer matrix. EPA also received a request from the PMN submitter to revise the de minimus concentration for exempt mixtures from 0.1% to 1% in worker protection requirements in the SNUR to make it consistent with the Order. EPA is proposing that change to the SNUR to be consistent with the terms of the original Order. EPA is also proposing to add a de minimus concentration exemption of 1% to the hazard communication requirements in the SNUR to be consistent with the original Order.

Potentially Useful Information: Certain information may be potentially useful to characterize the health and environmental 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, reproductive toxicity, and aquatic toxicity testing would help characterize the potential health and environmental effects of the chemical substance.

CFR citation: 40 CFR 721.9502.

PMN and SNUN numbers: P-00-1132, S-03-15, and S-11-5.

Chemical name: Siloxanes and silicones, aminoalkyl, fluorooctyl, hydroxy-terminated salt (generic).

CAS number: Not Available.

Final rule citations: 68 FR 15088, March 28, 2003 (FRL-6758-7), amended at 80 FR 37165, June 30, 2015 (FRL-9924-10).

Basis for the modified significant new use rule: P-00-1132 describes the intended use of the

chemical substance as use in anti-graffiti systems; S-11-5 is for use as a surface treatment and additive for coatings, adhesives, sealants, paste, insulation and textiles for porous, non- porous, ceramic, metal, glass, plastic, wood and leather surfaces; and a surface treatment agent for inorganic filler particles; and S-03-15 is for use in anti-graffiti systems, and in surface treatment of fabrics and porous mineral surfaces. The original SNUR for P-00-1132 was issued based on meeting the concern criteria at 40 CFR 721.170(b)(3)(ii). The original SNUR required notification for use other than as described in the PMN (graffiti systems) and for use involving an application method that generates a vapor, mist, or aerosol. On January 5, 2011, EPA received a SNUN, S-11-5, for the chemical substance describing uses different than those in the PMN. EPA also reviewed a 90-day inhalation study that was submitted for the substance in the SNUN. The results of the study demonstrated a Lowest Observed Adverse Effect Level (LOAEL) of 30 milligram/cubic meter (mg/m3) for lung effects. The 90-day review period for the SNUN expired with the Agency not taking action on the significant new uses described in the SNUN. Because EPA continued to find that significant worker exposure was unlikely when used as described in the PMN and SNUN, EPA did not determine that the proposed manufacturing, processing, and use of the substance may present an unreasonable risk. EPA did determine that other uses of the substance or applications that generate a vapor, mist, or aerosol could result in exposures which may cause serious health effects. Based on this information the substance continued to meet the concern criteria at 40 CFR 721(b)(3)(ii) and EPA modified the SNUR on June 30, 2015, to remove the new uses identified in S-11-5 from the scope of the significant new use but continued to require notification for uses other than identified in P-00-1132 or S-11-5 and for applications that generate a vapor, mist, or aerosol.

On June 30, 2003, EPA received SNUN S-03-15 for the chemical substance describing uses different than those in the PMN including uses that generate a vapor, mist, or aerosol. After review of this SNUN was completed on August 30, 2017, EPA determined according to TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I) that the new uses may present an unreasonable risk

to human health and that an Order was required to protect against those risks. The Order requires that the substance is used only for anti-graffiti systems and surface treatment of mineral porous systems, requires use of a NIOSH-approved respirator with an APF of 100 for workers who are exposed by inhalation, allows as an alternative to the respirators maintaining a New Chemicals Exposure Limit (NCEL) of 0.03 mg/m^3 as described in the Order, requires import only (no manufacture in the United States), limits residuals and impurities < 0.1%, does not allow consumer use, and requires hazard communication for labels and SDSs. Based on the review of S-03-15 and the provisions included in the Order, EPA is proposing a SNUR modification to remove the notification requirement for use in applications generating a vapor, mist, or aerosol, and to instead designate as significant new uses the absence of protections required in the Order for S-03-15 when use of the chemical substance may generate a vapor, mist, aerosol.

Potentially Useful Information: Certain information may be potentially useful to characterize the exposure and environmental fate 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 worker monitoring, composition analysis, and decomposition testing would help characterize the potential effects of the chemical substance.

CFR citation: 40 CFR 721.10395.

PMN numbers: P-10-458 and P-18-67.

Chemical name: Fatty acids, C14-18 and C16-18-unsatd., polymers with adipic acid and triethanolamine, di-Me sulfate-quaternized.

CAS number: 1211825-32-9.

Final rule citation: 77 FR 25236, April 27, 2012 (FRL-9343-4).

Basis for the modified significant new use rule: On July 20, 2010, EPA received P-10-458 describing the generic (non-confidential) intended use of the substance as an adjuvant agent. Based on test data on the PMN substance and EcoSAR analysis of test data on analogous polycationic polymers, EPA predicted toxicity to aquatic organisms may occur at concentrations

that exceed 5 ppb of the PMN substance in surface waters. As described in the PMN, releases of the substance are not expected to result in surface water concentrations that exceed 5 ppb. Therefore, EPA did not determine that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA determined that any use of the substance resulting in surface water concentrations exceeding 5 ppb may cause significant adverse environmental effects. Based on this information, EPA determined that the PMN substance met the concern criteria at 40 CFR 721.170(b)(4)(i) and (b)(4)(ii), and issued a SNUR requiring notification for release to water from manufacturing, processing, or use resulting in a surface water concentration exceeding 5 ppb.

On December 18, 2017, before a Notice of Commencement was submitted that would add the substance to the TSCA Inventory, EPA received PMN P-18-67 which identified the generic (non-confidential) intended use of the substance as an adjuvant agent. Based on available data on the new chemical substance and data on analogous chemicals, EPA identified concerns for systemic and developmental effects. Based on the activities described in the PMN, EPA determined in accordance with TSCA section 5(a)(3)(C) that the PMN substance is not likely to present an unreasonable risk of injury to health or the environment under the conditions of use. The PMN submitter sent to EPA six 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 575 ppb (i.e., acute concentration of concern) and 67 ppb (i.e., chronic concentration of concern). The proposed amendment to the SNUR would change the surface water concentration trigger for the significant new uses from 5 ppb to 67 ppb based on the new concentrations of concern determined by EPA.

Potentially Useful Information: EPA has determined that certain information about the human health and environmental effects of the SNUN substance may be potentially useful 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 skin irritation, eye irritation,

and specific target organ toxicity and aquatic toxicity testing may be potentially useful to characterize the human health and environmental effects of the SNUN substance.

CFR citation: 40 CFR 721.10996.

PMN numbers: P-15-310 and P-19-46.

Chemical name: 1,2,4-Benzenetricarboxylic acid, mixed decyl and octyl triesters.

CAS number: 90218-76-1.

Final rule citation: 82 FR 48637, October 19, 2017 (FRL-9964-42).

Basis for the modified significant new use rule: PMN P-15-310 describes the intended use of the chemical substance as a lubricating agent. The Order for P-15-310 was issued under TSCA sections 5(a)(3)(B)(ii)(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 and the environment. Based on test data, EPA identified concerns for blood and adrenal gland effects to unprotected workers from repeated dermal exposures. The Order requires the submitter of P-15-310 to not exceed the 2,440,000 kilograms aggregate production volume limit without performing an Extended One-Generation Reproductive Toxicity Study (OECD Test Guideline 443), worker dermal protection, hazard communication requirements, not exceed an annual production volume of 150,000 kg, and refrain from using the chemical substance other than as lubricant in chain oils for conveyor belts. EPA issued a SNUR designating significant new uses based on and consistent with the Order requirements.

On January 31, 2019, before a Notice of Commencement was submitted that would add the substance to the TSCA Inventory, EPA received PMN P-19-46 for the new chemical substance describing its intended use as a lubricating agent. Based on submitted data on the new chemical substance and data on analogous chemicals, EPA identified concerns for blood, liver, maternal, and developmental toxicity. Based on the activities described in the PMN, EPA determined in accordance with TSCA section 5(a)(3)(C) that the PMN substance is not likely to present an unreasonable risk of injury to health or the environment under the conditions of use.

The proposed amendment to the SNUR would revise and replace certain significant new uses to better tailor the SNUR to current risk concerns following EPA's review and determination for P-19-46. The proposed amendment would remove the significant new uses of annual production volume greater than 150,000 kilograms and use other than as a lubricant in chain oils for conveyor belts. EPA is proposing to remove these new uses from the SNUR as these uses are no longer expected to result in changes to human exposures or environmental releases that could result in risk. In lieu of the removed uses, the proposed amendments would add the significant new uses of release to water above 20,000 ppb and any manufacture, processing, or use resulting in inhalation exposure. EPA is proposing to designate these uses as significant new uses because these uses could result in significant changes to human exposures or environmental releases that could result in health risk.

Recommended Testing: EPA has determined that the results of certain human health toxicity testing would help characterize the effects of the PMN substance. The submitter of PMN P-15-310 has agreed not to exceed the aggregate production volume limit without performing an Extended One-Generation Reproductive Toxicity Study (OECD Test Guideline 443).

CFR citation: **40 CFR 721.11005.**

PMN numbers: P-16-309 and P-16-310.

Chemical name: 12-Hydroxystearic acid, reaction products with alkylene diamine and alkanoic acid (generic).

CAS number: Not Available.

Final Rule citation: 82 FR 48637, October 19, 2017 (FRL-9964-42).

Basis for the modified significant new use rule: P-16-309 and P-16-310 state that the generic (non-confidential) intended use of the substances is as rheological or thixotropic agents used in the production of solvent based industrial coatings, high solid aromatic paints, adhesives, sealants, and other types of paints and topcoats. Based on submitted test data, EPA predicted blood and hematology effects. Further, based on SAR analysis of test data on analogous amides,

EPA predicted toxicity to aquatic organisms may occur at concentrations that exceed 2 parts per billion (ppb) of the PMN substances in surface waters. An Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that the substances may present an unreasonable risk of injury to human health and the environment. The submitter of P-16-309 and P-16-310 is subject to the following Order requirements: no domestic manufacturing, no manufacture beyond the confidential annual production volume limit, use of the PMN substances only for the use specified in the Order, compliance with the release to water provisions, and submission of certain aquatic toxicity tests before exceeding a certain production volume. EPA issued a SNUR designating significant new uses based on and consistent with the Order requirements.

On September 28, 2018, the PMN submitter sent to EPA seven ecotoxicity studies pursuant to the requirements of the Order. EPA evaluated the studies and determined that toxicity to aquatic organisms may occur at concentrations that exceed 13 ppb (i.e., acute concentration of concern) and 4 ppb (i.e., chronic concentration of concern). The PMN submitter also submitted an OECD 422 test guideline combined repeated dose toxicity study with reproduction/developmental toxicity screening test for P-16-310. EPA evaluated that study and determined that the LOAEL of 100 mg/kg-bw/day is considered a low hazard benchmark and the updated risk assessment for the PMN substances did not demonstrate potential health risks. Based on the results of the studies, EPA modified the Order to remove the annual production volume limitation and change the water release limitation from 2 ppb to 4 ppb. Consistent with the modification to the Order, 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 into surface waters that exceed 4 ppb, instead of 2 ppb as provided in the original SNUR. Because the company has submitted the required aquatic toxicity studies and there will continue to be a release to water restriction (i.e., water trigger), the proposed amendment to the SNUR would also remove the significant new use notification

requirement for exceeding the aggregate and annual production volume limits, consistent with the modification to the Order. Finally, EPA is proposing a clerical amendment to the SNUR to remove an unnecessary cross-reference to the procedures for determining whether a specific use is subject to the SNUR; those procedures are not relevant to this SNUR because the significant new uses described in the SNUR do not involve confidential business information.

Potentially Useful Information: None.

CFR citation: 40 CFR 721.11227.

PMN numbers: P-16-271, P-16-450, and P-20-111.

Chemical name: 1,2,4-Benzenetricarboxylic acid, 1,2,4-trinonyl ester.

CAS number: 35415-27-1.

Final Rule citation: 84 FR 66599, December 5, 2019 (FRL-10002-30).

Basis for the modified significant new use rule: The intended use of the chemical substance described in P-16-271 and P-16-450 is as a plasticizer in wire and cable insulation. EPA issued Orders for P-16-271 and P-16-450 under sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I) of TSCA based on a finding that the chemical substance may present an unreasonable risk of injury to human health and the environment, and sections 5(a)(3)(B)(ii)(II) and 5(e)(1)(A)(ii)(II) of TSCA based on a finding that the chemical substance will be produced in substantial quantities and that it may reasonably be anticipated to enter the environment in substantial quantities or there may be significant or substantial human exposure. Based on test data on other trimellitate esters, EPA identified concerns for developmental and reproductive toxicity. The Orders required the PMN submitters to submit to EPA certain toxicity testing (Tier I testing) before manufacturing (including import) a total of 1,750,000 kilograms of the PMN substance, submit to EPA additional toxicity testing which will be determined upon EPA review of the Tier I testing results, have workers wear dermal protection, implement a hazard communication program, refrain from manufacturing the PMN substance in the United States (i.e., import only), and refrain from using the PMN substance other than as a plasticizer in wire and cable insulation.

EPA issued a SNUR designating significant new uses based on and consistent with the Order requirements.

On June 9, 2020, before a Notice of Commencement was submitted that would add the substance to the TSCA Inventory, EPA received PMN P-20-111 describing the generic (non-confidential) intended use as a component in flexible automotive interior parts. Based on available data on the new chemical substance and data on analogous chemicals, EPA identified concerns for systemic and developmental effects. Based on the activities described in PMN P-20-111, EPA determined in accordance with TSCA section 5(a)(3)(C) that the PMN substance is not likely to present an unreasonable risk of injury to health or the environment under the conditions of use.

Based on EPA's review and determination for PMN P-20-111, the proposed amendment would remove use as a component in flexible automotive interior parts from the scope of the significant new use. Based on the PMN submitter for P-20-111 identifying use of a NIOSH certified respirator with an assigned protection factor of 10 and hazard communication that includes hazards for eye irritation and specific target organ toxicity, the proposed amendment would add significant new uses for use without worker personal protective equipment of a NIOSH certified respirator with an assigned protection factor of 10 and hazard communication that does not include eye irritation and specific target organ toxicity. The proposed significant new use for specific target organ toxicity hazard communication would replace the existing significant new use for internal organ effects hazard communication to better harmonize the hazard communication language with the Globally Harmonized System and OSHA Hazard Communication Standard. EPA also proposes to remove the significant new use requirement specified in 40 CFR 721.63(a)(2) as that was a typographical error in the original SNUR.

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 reproductive effects and specific target organ toxicity testing would help characterize the potential health effects of the chemical substance.

V. Rationale for the Proposed Rule

In those instances where EPA expanded the scope of the significant new use, the Agency identified concerns, as discussed in Unit IV., associated with certain potential 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.

In those instances where EPA narrowed the scope of a significant new use, EPA has (1) received significant new use or premanufacture notices for some of the activities designated as significant new uses of the substance and, after reviewing such notices, concluded that there is no need to require additional notice from persons who propose to engage in identical or similar activities; or (2) received test data or other information that led the Agency to conclude that certain activities designated as significant new uses are not likely to present an unreasonable risk of injury to health or the environment. For the SNUR for P-89-632 EPA is proposing changes to be consistent with the Order (as modified) for that 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 the additional requirements if a vapor, mist, or aerosol is generated for the SNUR at 40 CFR 721.9502, use without worker personal protective equipment of a NIOSH certified respirator with an assigned

protection factor of 10 and hazard communication that does not include eye irritation and specific target organ toxicity for the SNUR at 40 CFR 721.11227, and any manufacture, processing, or use that results in inhalation exposure or water release exceeding the surface water concentration limit for the SNUR at 40 CFR 721.10996.

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 (15 U.S.C. 2603), then TSCA section 5(b)(1)(A) (15 U.S.C. 2604(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. of this document 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/filing-pre-manufacture-notice-epa.*

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 rule. EPA's complete economic analysis is available in the docket for this rulemaking.

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 action proposes to modify SNURs for chemical substances that were the subject of PMNs and SNUNs. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011).

B. 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). OMB has previously approved the information collection activities contained in the existing regulations and has assigned OMB control number 2070-0012 (EPA ICR No. 0574). 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.

According to the PRA, 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.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA (5 U.S.C. 601 *et seq*.). The small entities subject to the requirements of this action are small entities that would engage in the potential manufacture and/or processing of the chemical substances for the designated significant new uses covered by the proposed rule. The requirement to submit a SNUN applies to any person (including small or large entities) who intends to engage in any activity described in the final rule 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 $19,020 to $3,330. This lower fee

reduces the total reporting and recordkeeping of cost of submitting a SNUN to about $11,164 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 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.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA (2 U.S.C. 1531–1538) and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments. 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 rulemaking.

E. Executive Order 13132: Federalism

This action does not have federalism implications, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). It will not have substantial direct effects on the 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.

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

This action does not have tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). This action is not expected to have substantial direct effects on Indian Tribes, significantly nor uniquely affect the communities of Indian Tribal governments and does not involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of Executive Order 13175 do not apply to this proposed rule.

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

Risks

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997), as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of "covered regulatory action" in section 2-202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

H. 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 has not otherwise been designated as a significant energy action by the Administrator of the Office of Information and Regulatory Affairs.

I. National Technology Transfer and Advancement Act (NTTAA)

This action does not involve technical standards. As such, NTTAA section 12(d), 15 U.S.C. 272 note, does not apply to this action.

J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations and Executive Order 14008: Tackling the Climate Crisis at Home and Abroad

EPA believes that this action is not subject to Executive Order 12898 (59 FR 7629, February 16, 1994) and Executive Order 14008 (86 FR 7619, January 27, 2021) because it does not establish an environmental health or safety standard.

List of Subjects in 40 CFR Part 721

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

Dated: August 29, 2022.

Tala Henry,

Deputy Director, Office of Pollution Prevention and Toxics.

Therefore, for the reasons set forth in the preamble, EPA proposes to amend 40 CFR part 721 as follows:

PART 721-SIGNIFICANT NEW USES OF CHEMICAL SUBSTANCES

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

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

2. Amend § 721.5185 by revising paragraphs (a)(1) and (a)(2)(i)(B) and (iii) to read as follows:

§ 721.5185 2-Propen-1-one, 1-(4-morpholinyl)-.

(a) * * * (1) The chemical substance identified as 2-propen-1-one, 1-(4-morpholinyl)- (PMN P-95-169; SNUN S-08-7; SNUN S-14-1; SNUN S-17-10; and SNUN S-19-6; CAS No. 5117-12-4) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this rule do not apply to quantities of the chemical substance after it has been completely reacted (cured) because 2-propen-1-one, 1-(4-morpholinyl)- will no longer exist.

(2) * * *

(i) * * *

(A) * * *

(B) Additional requirements for use as a monomer for stereolithography and 3D printing: Requirements as specified in § 721.63(a)(4) and (5), (a)(6)(v), 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 50.

* * * * *

(iii) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(y)(1). It is a significant new use to use the chemical substance for any use other than as a monomer for use in ultraviolet ink jet applications, stereolithography, or 3D printing, unless the chemical substance is processed and used in an enclosed process.

* * * * *

3. Amend § 721.5192 by revising the section heading and paragraphs (a)(1) and (a)(2)(iii) to read as follows:

§ 721.5192 Oxirane, 2,2'-[1,6-naphthalenediylbis(oxymethylene)]bis-.

(a) * * * (1) The chemical substance identified as oxirane, 2,2'-[1,6-naphthalenediylbis(oxymethylene)]bis- (PMN P-87-1036, SNUN S-06-5, and SNUN S-16-6; CAS No. 27610-48-6) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this rule do not apply to quantities of the chemical substance after it has been completely reacted (cured).

* * * * *

(2) * * *

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f). It is a significant new use to use the chemical substance other than for the confidential uses allowed in the TSCA section 5(e) consent order for PMN P-87-1036 or the confidential uses described in SNUNs S-06-5 and S-16-6.

* * * * *

4. Amend § 721.7280 by revising paragraphs (a)(1) and (a)(2)(i) and (ii) to read as follows:

§ 721.7280 1,3-Propanediamine, N,N′-1,2-ethanediylbis-, polymer with 2,4,6-trichloro-1,3,5-triazine, reaction products with N-butyl-2,2,6,6-tetramethyl-4-piperidinamine.

(a) * * * (1) The chemical substance identified as 1,3-propanediamine, N,N′-1,2-ethanediylbis-, polymer with 2,4,6-trichloro-1,3,5-triazine, reaction products with N-butyl-2,2,6,6-tetramethyl-4-piperidinamine (PMN P-89-632; CAS No. 136504-96-6) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely incorporated into a polymer matrix.

(2) * * *

(i) *Protection in the workplace*. Requirements as specified in § 721.63(a)(1), (a)(2)(iii), (a)(3), (a)(4), (a)(5)(i), (a)(5)(ii), (a)(5)(iv), (a)(5)(v), (a)(6)(i), (a)(6)(ii), (b), and (c). For purposes of § 721.63(b) the concentration is set at 1.0%.

(ii) *Hazard communication program*. Requirements as specified in § 721.72(a) through (f), (g)(1)(iv), (g)(1)(viii), (g)(2)(i) through (v), and (g)(5). For purposes of § 721.72(e) the concentration is set at 1.0%.

* * * * *

5. Amend § 721.9502 by revising paragraphs (a)(1). (a)(2)(i) and (ii), and (b)(1) to read as follows:

§ 721.9502 Siloxanes and silicones, aminoalkyl, fluorooctyl, hydroxy-terminated salt (generic).

(a) * * * (1) The chemical substance identified generically as siloxanes and silicones, aminoalkyl, fluorooctyl, hydroxy-terminated salt (PMN P-00-1132, SNUN S-03-15, and SNUN S-11-5) is subject to reporting under this section for the significant new use described in paragraph (a)(2) of this section.

(2) * * *

(i) *Industrial, commercial, and consumer activities.* A significant new use is any use of the chemical substance other than in graffiti systems, as surface treatment and additive for coatings, adhesives, sealants, paste, insulation and textiles for porous, non-porous, ceramic,

metal, glass, plastic, wood and leather surfaces, surface treatment of fabrics and porous mineral surfaces, or a surface treatment agent for inorganic filler particles.

(ii) *Requirements if a vapor, mist or aerosol is generated.* (A) *Protection in the workplace*. Requirements as specified in § 721.63(a)(4) through (6), (b) 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 1000. For purposes of §721.63(a)(6), the form is particulate. As an alternative to the respiratory requirements listed here, a manufacturer, importer, or processor may choose to follow the New Chemical Exposure Limit (NCEL) provisions listed in the TSCA section 5(e) Order for these substances. The NCEL is 0.03 mg/m3 as an 8-hour time weighted average verified by actual monitoring data. 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) *Hazard communication program*. Requirements as specified in § 721.72(a) through (f), (g)(1)(ii), (g)(2)(ii), and (g)(5). For purposes of § 721.72(e) concentration is set at 1 percent. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(C) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(f) and (o). It is a significant new use to manufacture the chemical substance if residuals or impurities are greater than 0.1%.

(b) * * *

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

and (f) through (i) are applicable to manufacturers, importers, and processors of this substance.

* * * * *

6. Amend § 721.10395 by revising paragraphs (a)(1) and (a)(2)(i) to read as follows:

§ 721.10395 Fatty acids, C14-18 and C16-18-unsatd., polymers with adipic acid and triethanolamine, di-Me sulfate-quaternized.

(a) * * * (1) The chemical substance identified as fatty acids, C14-18 and C16-18-unsatd., polymers with adipic acid and triethanolamine, di-Me sulfate-quaternized (PMNs P-10-458 and P-18-67; CAS No. 1211825-32-9) is subject to reporting under this section for the significant new use 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=67.

* * * * *

7. Amend § 721.10996 by revising paragraphs (a)(1), (a)(2)(ii), and (b)(1), and adding paragraph (a)(2)(iv) to read as follows:

§ 721.10996 1,2,4-Benzenetricarboxylic acid, mixed decyl and octyl triesters.

(a) * * * (1) The chemical substance identified as 1,2,4-Benzenetricarboxylic acid, mixed decyl and octyl triesters (PMNs P-15-310 and P-19-46; CAS No. 90218-76-1) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) * * *

(ii) *Industrial commercial, and consumer activities*. Requirements as specified in § 721.80(p) (2,440,000 kilograms). It is a significant new use to manufacture, process, or use the PMN substance in any manner that results in inhalation exposure.

* * * * *

(iv) *Releases to water*. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4),

where N = 20,000 ppb.

(b) * * *

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

* * * * *

8. Amend § 721.11005 by revising paragraphs (a)(2)(i) and (ii) and removing paragraph (b)(3) to read as follows:

§ 721.11005 12-Hydroxystearic acid, reaction products with alkylene diamine and alkanoic acid (generic).

(a) * * * (1) The chemical substances identified as 12-Hydroxystearic acid, reaction products with alkylene diamine and alkanoic acid (generic) (PMNs P-16-309 and P-16-310) are 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(f). It is a significant new use to use the PMN substance other than as a rheological or thixotropic agent used in the production of solvent based industrial coatings, high solid aromatic paints, adhesives, sealants, and other types of paints and topcoats.

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

* * * * *

9. Amend § 721.11227 by revising paragraphs (a)(1) and (2)(i) through (iii) to read as follows:

§ 721.11227 1,2,4-Benzenetricarboxylic acid, 1,2,4-trinonyl ester.

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified as 1,2,4-Benzenetricarboxylic acid, 1,2,4-trinonyl ester (PMNs P-16-271, P-

16-450, and P-20-111; CAS No. 35415-27–1) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been incorporated into a polymer matrix.

(2) * * *

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (3) through (6), (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 exposures, 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 form is particulate. 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)(i), (vi) and (ix), (2)(i) and (v), and (4)(i) through (iii) and (v). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used. For purposes of § 721.72(e) the concentration is set at 1.0%. For purposes of § 721.72(g)(1) this substance may cause eye irritation and specific target organ toxicity.

(iii) *Industrial commercial, and consumer activities*. Requirements as specified in § 721.80(f) and (p) (1,750,000 kilograms). It is a significant new use to use the substance other than as a plasticizer in wire and cable insulation and as a component in flexible automotive interior parts.

* * * * *

[FR Doc. 2022-19023 Filed: 9/14/2022 8:45 am; Publication Date: 9/15/2022]