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Title: **Significant New Use Rules on Certain Chemical Substances**

Action: Proposed Rule

FRL: 9984-93

Docket No.: **EPA-HQ-OPPT-2017-0575**

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[EPA-HQ-OPPT-2017-0575; FRL-9984-93]

RIN 2070-AB27

Significant New Use Rules on Certain Chemical Substances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing significant new use rules (SNURs) under the Toxic Substances Control Act (TSCA) for 13 chemical substances which are the subject of premanufacture notices (PMNs). This action would require persons to notify EPA at least 90 days before commencing manufacture (defined by statute to include import) or processing of any of these 13 chemical substances for an activity that is designated as a significant new use by this proposed rule. If this proposed rule is made final, persons may not commence manufacture or processing for the significant new use until they have submitted a Significant New Use Notice, and EPA has conducted a review of the notice, made an appropriate determination on the notice, and has taken any actions as are required as a result of that determination.

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-2017-0575], by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online

instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

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

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

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

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

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

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

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you manufacture, process, or use

the chemical substances contained in this 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 one or more subject chemical substances (NAICS codes 325 and 324110), e.g., chemical manufacturing and petroleum refineries.

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Chemical importers are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements promulgated at 19 CFR 12.118 through 12.127 and 19 CFR 127.28. Chemical importers must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA. Importers of chemicals subject to these proposed SNURs would need to certify their compliance with the SNUR requirements should these proposed rules be finalized. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, pursuant to 40 CFR 721.20, any persons who export or intend to export a chemical substance that is the subject of this proposed rule on or after [*insert date 30 days after date of publication in the **Federal Register***] are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)) 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 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 C.F.R. 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 these SNURs under TSCA section 5(a)(2) for 13 chemical substances which were the subjects of PMNs P-16-192, P-16-354 and P-16-355, P-16-380 through P-16-385, P-16-483 and P-16-484, P-16-575, and P-16-581. These proposed SNURs would require persons who intend to manufacture or process any of these chemical substances for an activity that is designated as a significant new use to notify EPA at least 90 days before commencing that activity.

The record for the proposed SNURs on these chemicals was established as docket EPA-HQ-OPPT-2017-0575. That record includes information considered by the Agency in developing these proposed SNURs.

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

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a “significant new use.” EPA must make this determination by rule after considering all relevant factors, including the four bulleted

TSCA section 5(a)(2) factors listed in Unit III. Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1)(B)(i) (15 U.S.C. 2604(a)(1)(B)(i)) requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture or process the chemical substance for that use. TSCA prohibits such manufacturing or processing from commencing until EPA has conducted a review of the SNUN, made an appropriate determination on the SNUN, and taken such actions as are required in association with that determination (15 U.S.C. 2604(a)(1)(B)(ii)). As described in Unit V., the general SNUR provisions are found at 40 CFR part 721, subpart A.

C. Applicability of General Provisions

General provisions for SNURs appear in 40 CFR part 721, subpart A. These provisions describe persons subject to the rule, recordkeeping requirements, exemptions to reporting requirements, and applicability of the rule to uses occurring before the effective date of the rule. Provisions relating to user fees appear at 40 CFR part 700. Pursuant to § 721.1(c), persons subject to these SNURs must comply with the same SNUN requirements and EPA regulatory procedures as submitters of PMNs under TSCA section 5(a)(1)(A) (15 U.S.C. 2604(a)(1)(A)). In particular, these requirements include the information submission requirements of TSCA sections 5(b) and 5(d)(1) (15 U.S.C. 2604(b) and 2604(d)(1)), the exemptions authorized by TSCA sections 5(h)(1), 5(h)(2), 5(h)(3), and 5(h)(5) and the regulations at 40 CFR part 720. Once EPA receives a SNUN, EPA must either determine that the significant new use is not likely to present an unreasonable risk of injury or take such regulatory action as is associated with an alternative determination before the manufacture or processing for the significant new

use can commence. If EPA determines that the significant new use is not likely to present an unreasonable risk, EPA is required under TSCA section 5(g) to make public, and submit for publication in the **Federal Register**, a statement of EPA's findings.

III. Significant New Use Determination

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

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

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

To determine what would constitute significant new uses for the chemical substances that are the subject of these SNURs, EPA considered relevant information about the toxicity of the chemical substances, and potential human exposures and environmental releases that may be associated with the conditions of use of the substances, in the context of the four bulleted TSCA section 5(a)(2) factors listed in this unit.

IV. Substances Subject to This Proposed Rule

EPA is proposing significant new use and recordkeeping requirements for 13 chemical substances in 40 CFR part 721, subpart E. In this unit, EPA provides the following information for each chemical substance:

- PMN number.
- Chemical name (generic name, if the specific name is claimed as CBI).
- Chemical Abstracts Service (CAS) Registry number (if assigned for non-confidential chemical identities).
- Basis for the SNUR.
- Information identified by EPA that would help characterize the potential health and/or environmental effects of the chemical substances if a manufacturer or processor is considering submitting a SNUN for a significant new use designated by the SNUR.

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

- CFR citation assigned in the regulatory text section of these proposed rules.

The regulatory text section of these proposed rules specifies the activities designated as significant new uses. Certain new uses, including production volume limits and other uses designated in the proposed rules, may be claimed as CBI.

The chemical substances that are the subject of these proposed SNURs are undergoing premanufacture review. EPA has initially determined under TSCA section 5(a)(2), 15 U.S.C. § 2604(a)(2), that certain changes from the conditions of use described in the PMNs could result in changes in the type or form of exposure to the chemical substances and/or increased exposures to the chemical substances and/or changes in the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of the chemical substances. Consequently, EPA is proposing to designate these changes as significant new uses.

PMN Number: P-16-192

Chemical Name: Silanized amorphous silica (generic).

CAS Number: Not available.

Basis for action: The PMN states that the use of the substance will be as a reinforcing filler for the production of rubber goods. Based on test data for crystalline silica, EPA identified concerns for lung effects if the chemical substance is not used following the limitations noted below. The conditions of use of the PMN substance as described in the PMN include the following protective measures:

1. Manufacture of the PMN substance in an amorphous form.

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

Potentially useful information: EPA has determined that certain information about the physical-chemical properties of the PMN substance may be potentially useful if a

manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that information about the physical form, particle size, and water solubility would help characterize the potential health effects of the PMN substance.

CFR citation: 40 CFR 721.11182

PMN Numbers: P-16-354 and P-16-355

Chemical name: Esteramine (generic).

CAS number: Not available.

Basis for action: The PMNs state that the generic (non-confidential) use of the substances will be as a chemical intermediate. Based on the physical/chemical properties of the PMN substances and Structure Analysis Relationships (SAR) analysis of test data on analogous substances, EPA has identified concerns for irritation and developmental/reproductive toxicity, and aquatic toxicity at surface water concentrations exceeding 1 part per billion (ppb), if the chemical substances are not used following the limitations noted below. The conditions of use of the PMN substances as described in the PMNs include the following protective measures:

1. No release of a manufacturing, processing, or use stream associated with any use of the substances, other than the confidential chemical intermediate use described in the PMNs, into the waters of the United States exceeding a surface water concentration of 1 ppb; and
2. No manufacturing, processing or use of the PMN substances resulting in inhalation exposures to the substances.

The proposed SNUR would designate as a “significant new use” the absence of these

protective measures.

Potentially useful information: EPA has determined that certain information about the aquatic and human health toxicity of the PMN substances may be potentially useful to characterize the health and environmental effects of the PMN substances if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of specific organ toxicity and aquatic toxicity testing would help characterize the potential health and environmental effects of the PMN substances.

CFR citation: 40 CFR 721.11183.

PMN Numbers: P-16-380, P-16-381, P-16-382, P-16-383, P-16-384, and P-16-385

Chemical Names: Formic acid, compds. with hydrolyzed bisphenol A-epichlorohydrin-polyethylene glycol ether with bisphenol A (2:1) polymer-N1-(1,3-dimethylbutylidene)-N2-[2-[(1, 3-dimethylbutylidene)amino]ethyl]-1,2-ethanediamine-dialdehyde-2-(methylamino)ethanol reaction products acetates (salts), (generic) (P-16-380), propanoic acid, 2-hydroxy-, compds. with hydrolyzed bisphenol A-epichlorohydrin-polyethylene glycol ether with bisphenol A (2:1) polymer-N1-(1,3-dimethylbutylidene)-N2-[2-[(1, 3-dimethylbutylidene)amino]ethyl]-1,2-ethanediamine-dialdehyde-2-(methylamino)ethanol reaction products formates (salts), (generic) (P-16-381), formic acid, compds. with hydrolyzed bisphenol A-epichlorohydrin-polyethylene glycol ether with bisphenol A (2:1) polymer-N1-(1,3-dimethylbutylidene)-N2-[2-[(1, 3-dimethylbutylidene)amino]ethyl]-1,2-ethanediamine-dialdehyde-2-(methylamino)ethanol reaction products sulfamates (salts), (generic) (P-16-382), formic acid, compds. with hydrolyzed bisphenol A-epichlorohydrin-polyethylene glycol ether with bisphenol A (2:1) polymer-N1-(1,3-

dimethylbutylidene)-N2-[2-[(1, 3-dimethylbutylidene)amino] ethyl]-1,2-ethanediamine-dialdehyde-2-(methylamino)ethanol reaction products acetates (salts), (generic) (P-16-383), propanoic acid, 2-hydroxy-, compds. with hydrolyzed bisphenol A-epichlorohydrin-polyethylene glycol ether with bisphenol A (2:1) polymer-N1-(1,3-dimethylbutylidene)-N2-[2-[(1, 3-dimethylbutylidene)amino]ethyl]-1,2-ethanediamine-dialdehyde-2-(methylamino)ethanol reaction products formates (salts), (generic) (P-16-384), formic acid, compds. with hydrolyzed bisphenol A-epichlorohydrin-polyethylene glycol ether with bisphenol A (2:1) polymer-N1-(1,3-dimethylbutylidene)-N2-[2-[(1, 3-dimethylbutylidene)amino]ethyl]-1,2-ethanediamine-dialdehyde-2-(methylamino)ethanol reaction products sulfamates (salts), (generic) (P-16-385).

CAS Numbers: Not available.

Basis for action: The PMNs state that the generic (non-confidential) use of the substances will be as a component of an electrocoat resin. Based on the physical/chemical properties of the PMN substances and test data on analogous substances, EPA has identified concerns for lung effects and toxicity to aquatic organisms at concentrations that exceed 16 ppb if the chemical substances are not used following the limitations noted below. The conditions of use of the PMN substances as described in the PMNs include the following protective measures:

1. No manufacturing, processing or use of the PMN substances resulting in inhalation exposures to the substances; and
2. No release of a manufacturing, processing, or use stream associated with any use of the substances exceeding a surface water concentration of 16 ppb.

The proposed SNUR would designate as a “significant new use” the absence of these

protective measures.

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

CFR citation: 40 CFR 721.11184 (P-16-380); 40 CFR 721.11185 (P-16-381); 40 CFR 721.11186 (P-16-382); 40 CFR 721.11187 (P-16-383); 40 CFR 721.11188 (P-16-384); and 40 CFR 721.11189 (P-16-385)

PMN Numbers: P-16-483 and P-16-484

Chemical names: Inorganic acids, metal salts, compds. with modified heteroaromatics, (generic) (P-16-483) and Inorganic acids, metal salts, compds. with substituted aromatic heterocycle, (generic) (P-16-484).

CAS numbers: Not available.

Basis for action: The PMNs state that the generic (non-confidential) use of P-16-483 will be as a plastic additive and the generic (non-confidential) use of P-16-484 will be as a chemical intermediate. Based on test data submitted on P-16-483 and data for analogous compounds, EPA has identified concerns for irritation, specific organ effects, and aquatic toxicity if the chemical is not used following the limitations noted below. The conditions of use of the PMN substances as described in the PMNs include the following protective measures:

1. No use of the substances other than the confidential use described in the

PMNs;

2. No release of a manufacturing, processing, or use stream associated with any use of the substances exceeding a surface water concentration of 34 ppb; and
3. No manufacturing, processing or use of the PMN substances without the engineering controls described in the PMNs to limit exposure to dust.

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

Potentially useful information: EPA has determined that certain information about the human health and environmental toxicity of the PMN substances may be potentially useful to characterize the effects of the PMN substances if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of aquatic toxicity and specific organ toxicity and aquatic toxicity testing would help characterize the potential health and environmental effects of the PMN substances.

CFR citations: 40 CFR 721.11190 (P-16-683) and 40 CFR 721.11191 (P-16-684).

PMN Number: P-16-575

Chemical name: Glucosyltransferase. International Union of Biochemistry and Molecular

Biology Number: 2.4.1.5

CAS number: 9032-14-8.

Basis for action: The PMN states that the use of the substance will be for polymerization of glucose. Based on the allergenic properties of proteins and review of surrogate enzymatic protein data submitted, EPA has identified concerns for respiratory sensitization if the chemical is not used following the limitations noted below. The

conditions of use of the PMN substance as described in the PMN include the following protective measure:

1. No manufacture, processing, or use of the PMN substance that results in inhalation exposures to the substance.

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

Potentially useful information: EPA has determined that certain information about the workplace exposure to the PMN substance may be potentially useful to characterize the health effects of the PMN substance if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of workplace air monitoring would help characterize the potential health effects of the PMN substance.

CFR citation: 40 CFR 721.11192.

PMN Number: P-16-581

Chemical name: Alpha 1,3-polysaccharide (generic).

CAS number: Not available.

Basis for action: The PMN states that the uses of the substance will be as a polymer additive, paper coating component, composite component, and fiber additive. Based on analogy to high molecular weight polymers, EPA has identified concerns for lung effects if the chemical is not used following the limitations noted below. The conditions of use of the PMN substance as described in the PMN include the following protective measures:

1. No use of the substance other than the uses described in the PMN; and
2. No manufacture, processing, or use with particle size less than 10

micrometers.

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

Potentially useful information: EPA has determined that certain information about the toxicity of the PMN substance may be potentially useful to characterize the health effects of the PMN substance if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of pulmonary effects toxicity testing of the PMN substance may be potentially useful in characterizing the health effects of the PMN substance.

CFR citation: 40 CFR 721.11193.

V. Rationale and Objectives of the Proposed Rule

A. Rationale

During review of the PMNs submitted for the chemical substances that are the subject of these proposed SNURs and as further discussed in Unit IV, EPA identified certain reasonably foreseen changes from the conditions of use identified in the PMNs and determined that those changes could result in changes in the type or form of exposure to the chemical substances and/or increased exposures to the chemical substances and/or changes in the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of the chemical substances.

B. Objectives

EPA is proposing SNURs for 13 specific chemical substances which are undergoing premanufacture review because the Agency wants to achieve the following objectives with regard to the significant new uses that would be designated in this

proposed rule:

- EPA would have an opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing or processing a listed chemical substance for the described significant new use.
- EPA would be obligated to make a determination under TSCA section 5(a)(3) regarding the use described in the SNUN, under the conditions of use. The Agency will either determine under section 5(a)(3)(C) that the significant new use is not likely to present an unreasonable risk, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, or make a determination under section 5(a)(3) (A) or (B) and take the required regulatory action associated with the determination, before manufacture or processing for the significant new use of the chemical substance can occur.

Issuance of a proposed SNUR for a chemical substance does not signify that the chemical substance is listed on the TSCA Inventory. Guidance on how to determine if a chemical substance is on the TSCA Inventory is available on the Internet at <http://www.epa.gov/opptintr/existingchemicals/pubs/tscainventory/index.html>.

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

To establish a significant new use, EPA must determine that the use is not ongoing. The chemical substances subject to this proposed rule were undergoing premanufacture review at the time of signature of this proposed rule and were not on the TSCA Inventory. In cases where EPA has not received a notice of commencement (NOC) and the chemical substance has not been added to the TSCA Inventory, no person

may commence such activities without first submitting a PMN. Therefore, for the chemical substances subject to this proposed SNUR, EPA concludes that the proposed significant new uses are not ongoing.

EPA designates October 10, 2018, as the cutoff date for determining whether the new use is ongoing. The objective of EPA's approach is to ensure that a person cannot defeat a SNUR by initiating a significant new use before the effective date of rule.inal

Persons who begin commercial manufacture or processing of the chemical substances for a significant new use identified on or after that date would have to cease any such activity upon the effective date of the final rule. To resume their activities, these persons would have to first comply with all applicable SNUR notification requirements and EPA would have to take action under section 5 allowing manufacture or processing to proceed.

VII. Development and Submission of Information

EPA recognizes that TSCA section 5 does not require development of 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 to or reasonably

ascertainable by them (see § 720.50). However, upon review of PMNs and SNUNs, the Agency has the authority to require appropriate testing. Unit IV. lists potentially useful information for all SNURs listed here. Descriptions are provided for informational purposes. The potentially useful information identified in Unit IV. will be useful to EPA's evaluation in the event that someone submits a SNUN for the significant new use. Companies who are considering submitting a SNUN are encouraged, but not required, to develop the 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 pertaining to protocol selection. Furthermore, pursuant to TSCA section 4(h), which pertains to reduction of testing in vertebrate animals, EPA encourages consultation with the Agency on the use of alternative test methods and strategies (also called New Approach Methodologies, or NAMs), if available, to generate the recommended test data. EPA encourages dialog with Agency representatives to help determine how best the submitter can meet both the data needs and the objective of TSCA section 4(h).

The potentially useful information described in Unit IV. may not be the only means of providing information to evaluate the chemical substance associated with the significant new uses. However, submitting a SNUN without any test data may increase the likelihood that EPA will take action under TSCA section 5(e) or 5(f). EPA recommends that potential SNUN submitters contact EPA early enough so that they will be able to conduct the appropriate tests.

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

- Human exposure and environmental release that may result from the significant new use of the chemical substances.

- Information on risks posed by the chemical substances compared to risks posed by potential substitutes.

VIII. SNUN Submissions

According to § 721.1(c), persons submitting a SNUN must comply with the same notification requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in § 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 § 720.40 and § 721.25. 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. EPA's complete economic analysis is available in the docket under docket ID number EPA-HQ-OPPT-2017-0575.

X. Statutory and Executive Order Reviews

A. Executive Order 12866

This proposed rule would establish SNURs for 13 new chemical substances that were the subject of PMNs. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “*Regulatory Planning and Review*” (58 FR 51735, October 4, 1993).

B. Paperwork Reduction Act (PRA)

According to PRA, 44 U.S.C. 3501 et seq., an Agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the Federal Register, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable.

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

Send any comments about the accuracy of the burden estimate, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques, to the Director, Collection Strategies Division, Office of Environmental Information (2822T), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. Please remember to include the OMB control number in any correspondence, but do not submit any completed forms to this address.

C. Regulatory Flexibility Act (RFA)

On February 18, 2012, EPA certified pursuant to RFA section 605(b) (5 U.S.C.

605(b)), that promulgation of a SNUR does not have a significant economic impact on a substantial number of small entities where the following are true:

1. A significant number of SNUNs would not be submitted by small entities in response to the SNUR.
2. The SNUN submitted by any small entity would not cost significantly more than \$9,816.

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

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

- A significant number of SNUNs would not be submitted by small entities in response to the SNUR.
- Submission of the SNUN would not cost any small entity significantly more than \$9.816.

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

D. Unfunded Mandates Reform Act (UMRA)

Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reasons to believe that any State, local, or Tribal government will be impacted by this proposed rule. As such, EPA has determined that this proposed rule 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. 1502, 1503, 1504, or 1505 *et seq.*).

E. Executive Order 13132

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).

F. Executive Order 13175

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

G. Executive Order 13045

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

H. Executive Order 13211

This proposed rule is not subject to Executive Order 13211, entitled “Actions

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

I. National Technology Transfer and Advancement Act (NTTAA)

In addition, since this action does not involve any technical standards, NTTAA § 12(d) (Pub. L. No. 104-113, § 12(d)), does not apply to this action.

J. Executive Order 12898

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

List of Subjects*40 CFR Part 721*

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

Dated: 10/05/18

A handwritten signature in cursive script, reading "Tala R. Henry", written over a horizontal line.

Tala R. Henry,

Acting Director, Office of Pollution Prevention and Toxics.

Therefore, it is proposed that 40 CFR part 721 is 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. Add § 721.11182 to subpart E to read as follows:

§ 721.11182 Silanized amorphous silica (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as silanized amorphous silica (P-16-192) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80. It is a significant new use to manufacture the substance other than in an amorphous form.

(ii) [Reserved]

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

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

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

3. Add § 721.11183 to subpart E to read as follows:

§ 721.11183 Esteramine (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substances identified generically as esteramine (PMN P-16-354 and P-16-355) are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80. It is a significant new use to manufacture, process, or use the substances in any manner that results in inhalation exposure. It is a significant new use to release a manufacturing, processing, or use stream associated with any use of the substances, other than the confidential chemical intermediate use described in the premanufacture notices, into the waters of the United States exceeding a surface water concentration of 1 part per billion (ppb) using the methods described in § 721.91.

(ii) [Reserved]

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

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

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

4. Add § 721.11184 to subpart E to read as follows:

§ 721.11184 Formic acid, compds. with hydrolyzed bisphenol A-epichlorohydrin-polyethylene glycol ether with bisphenol A (2:1) polymer-N1-(1,3-

dimethylbutylidene)-N2-[2-[(1, 3-dimethylbutylidene)amino]ethyl]-1,2-ethanediamine-dialdehyde-2-(methylamino)ethanol reaction products acetates (salts), (generic)

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as formic acid, compds. with hydrolyzed bisphenol A-epichlorohydrin-polyethylene glycol ether with bisphenol A (2:1) polymer-N1-(1,3-dimethylbutylidene)-N2-[2-[(1, 3-dimethylbutylidene)amino]ethyl]-1,2-ethanediamine-dialdehyde-2-(methylamino)ethanol reaction products acetates (salts), (P-16-380) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, Commercial, and consumer activities.* Requirements as specified in § 721.80. It is a significant new use to manufacture, process, or use the substance in any manner that results in inhalation exposure.

(ii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where N = 16.

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

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

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

5. Add § 721.11185 to subpart E to read as follows:

§ 721.11185 Propanoic acid, 2-hydroxy-, compds. with hydrolyzed bisphenol A-epichlorohydrin-polyethylene glycol ether with bisphenol A (2:1) polymer-N1-(1,3-dimethylbutylidene)-N2-[2-[(1, 3-dimethylbutylidene)amino]ethyl]-1,2-ethanediamine-dialdehyde-2-(methylamino)ethanol reaction products formates (salts), (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically as propanoic acid, 2-hydroxy-, compds. with hydrolyzed bisphenol A-epichlorohydrin-polyethylene glycol ether with bisphenol A (2:1) polymer-N1-(1,3-dimethylbutylidene)-N2-[2-[(1, 3-dimethylbutylidene)amino]ethyl]-1,2-ethanediamine-dialdehyde-2-(methylamino)ethanol reaction products formates (salts), (P-16-381) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, Commercial, and consumer activities.* Requirements as specified in § 721.80. It is a significant new use to manufacture, process, or use the substance in any manner that results in inhalation exposure.

(ii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where N = 16.

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

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

substance.

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

6. Add § 721.11186 to subpart E to read as follows:

§ 721.11186 Formic acid, compds. with hydrolyzed bisphenol A-epichlorohydrin-polyethylene glycol ether with bisphenol A (2:1) polymer-N1-(1,3-dimethylbutylidene)-N2-[2-[(1, 3-dimethylbutylidene)amino]ethyl]-1,2-ethanediamine-dialdehyde-2-(methylamino)ethanol reaction products sulfamates (salts), (generic),

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as formic acid, compds. with hydrolyzed bisphenol A-epichlorohydrin-polyethylene glycol ether with bisphenol A (2:1) polymer-N1-(1,3-dimethylbutylidene)-N2-[2-[(1, 3-dimethylbutylidene)amino]ethyl]-1,2-ethanediamine-dialdehyde-2-(methylamino)ethanol reaction products sulfamates (salts), (P-16-382) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, Commercial, and consumer activities.* Requirements as specified in § 721.80. It is a significant new use to manufacture, process, or use the substance in any manner that results in inhalation exposure.

(ii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where N = 16.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this

section except as modified by this paragraph (b).

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

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

7. Add § 721.11187 to subpart E to read as follows:

§ 721.11187 Formic acid, compds. with hydrolyzed bisphenol A-epichlorohydrin-polyethylene glycol ether with bisphenol A (2:1) polymer-N1-(1,3-dimethylbutylidene)-N2-[2-[(1, 3-dimethylbutylidene)amino]ethyl]-1,2-ethanediamine-dialdehyde-2-(methylamino)ethanol reaction products acetates (salts), (generic).

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance generically identified as formic acid, compds. with hydrolyzed bisphenol A-epichlorohydrin-polyethylene glycol ether with bisphenol A (2:1) polymer-N1-(1,3-dimethylbutylidene)-N2-[2-[(1, 3-dimethylbutylidene)amino]ethyl]-1,2-ethanediamine-dialdehyde-2-(methylamino)ethanol reaction products acetates (salts), (P-16-383) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, Commercial, and consumer activities*. Requirements as specified in § 721.80. It is a significant new use to manufacture, process, or use the substance in any manner that results in inhalation exposure.

(ii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where N = 16.

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

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

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

8. Add § 721.11188 to subpart E to read as follows:

§ 721.11188 Propanoic acid, 2-hydroxy-, compds. with hydrolyzed bisphenol A-epichlorohydrin-polyethylene glycol ether with bisphenol A (2:1) polymer-N1-(1,3-dimethylbutylidene)-N2-[2-[(1, 3-dimethylbutylidene)amino]ethyl]-1,2-ethanediamine-dialdehyde-2-(methylamino)ethanol reaction products formates (salts), (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as propanoic acid, 2-hydroxy-, compds. with hydrolyzed bisphenol A-epichlorohydrin-polyethylene glycol ether with bisphenol A (2:1) polymer-N1-(1,3-dimethylbutylidene)-N2-[2-[(1, 3-dimethylbutylidene)amino]ethyl]-1,2-ethanediamine-dialdehyde-2-(methylamino)ethanol reaction products formates (salts), (P-16-384) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, Commercial, and consumer activities.* Requirements as specified in § 721.80. It is a significant new use to manufacture, process, or use the substance in any manner that results in inhalation exposure.

(ii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where N = 16.

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

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

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

9. Add § 721.11189 to subpart E to read as follows:

§ 721.11189 Formic acid, compds. with hydrolyzed bisphenol A-epichlorohydrin-polyethylene glycol ether with bisphenol A (2:1) polymer-N1-(1,3-dimethylbutylidene)-N2-[2-[(1, 3-dimethylbutylidene)amino]ethyl]-1,2-ethanediamine-dialdehyde-2-(methylamino)ethanol reaction products sulfamates (salts), (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as formic acid, compds. with hydrolyzed bisphenol A-epichlorohydrin-polyethylene glycol ether with bisphenol A (2:1) polymer-N1-(1,3-dimethylbutylidene)-N2-[2-[(1, 3-dimethylbutylidene)amino]ethyl]-1,2-ethanediamine-dialdehyde-2-(methylamino)ethanol reaction products sulfamates (salts),

(P-16-385) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, Commercial, and consumer activities.* Requirements as specified in § 721.80. It is a significant new use to manufacture, process, or use the substance in any manner that results in inhalation exposure.

(ii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where N = 16.

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

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

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

10. Add § 721.11190 to subpart E to read as follows:

§ 721.11190 Inorganic acids, metal salts, compds. with modified heteroaromatics, (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as inorganic acids, metal salts, compds. with modified heteroaromatics, (PMN P-16-483) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(j). It is a significant new use to manufacture, process, or use the substance without the engineering controls described in the premanufacture notice to limit exposure to dust.

(ii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where N = 34 ppb.

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

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

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

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

11. Add § 721.11191 to subpart E to read as follows:

§ 721.11191 Inorganic acids, metal salts, compds. with substituted aromatic heterocycle, (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as inorganic acids, metal salts, compds. with substituted aromatic heterocycle, (PMN P-16-484) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in

§ 721.80(j). It is a significant new use to manufacture, process, or use the substance without the engineering controls described in the premanufacture to limit exposure to dust.

(ii) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where N = 34.

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

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

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

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

12. Add § 721.11192 to subpart E to read as follows:

§ 721.11192 Glucosyltransferase, International Union of Biochemistry and Molecular Biology Number: 2.4.1.5.

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified as glucosyltransferase, International Union of Biochemistry and Molecular Biology Number: 2.4.1.5 (PMN P-16-575, CAS No. 9032-14-8) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(y)(1) and (y)(2).

(ii) [Reserved]

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

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

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

13. Add § 721.11193 to subpart E to read as follows:

§ 721.11193 Alpha 1,3-polysaccharide (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as alpha 1,3-polysaccharide (generic) (PMN P-16-581) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80. It is a significant new use to use the substance other than as a polymer additive, paper coating component, composite component, or fiber additive. It is a significant new use to manufacture, process or use the PMN substance with particle size less than 10 micrometers.

(ii) [Reserved]

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

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

through (c) and (i) are applicable to manufacturers and processors of this substance.

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