PRE-PUBLICATION NOTICE

On Wednesday, March 27, 2019, Tala Henry, the EPA Acting Deputy Director of the Office of Pollution Prevention and Toxics, signed the following document:

Action:	Final Rule.
Title:	**Significant New Use Rules on Certain Chemical Substances**
FRL #:	9991-19
Docket ID #:	EPA-HQ-OPPT-2017-0575

EPA is submitting this document for publication in the *Federal Register* (FR). EPA is providing this document solely for the convenience of interested parties. It is not the official version of the document for purposes of public notice and comment under the Administrative Procedure Act. This document is not disseminated for purposes of EPA's Information Quality Guidelines and does not represent an Agency determination or policy. While we have taken steps to ensure the accuracy of this Internet version of the document that was signed, the official version will publish in a forthcoming FR publication, which will appear on the Government Printing Office's govinfo website (https://www.govinfo.gov/app/collection/fr) and on Regulations.gov (https://www.regulations.gov) in the docket identified above. Notwithstanding the fact that EPA is posting a pre-publication version, the final rule will not be promulgated until published in the *Federal Register*.

Once the official version of this document is published in the *Federal Register*, this version will be removed from the Internet and replaced with a link to the official version. At that time, you will also be able to access the on-line docket for this *Federal Register* document at http://www.regulations.gov.

For further information about the docket and, if applicable, instructions for commenting, please consult the ADDRESSES section in the front of the Federal Register document.

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BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 721

[EPA-HQ-OPPT-2017-0575; FRL-9919-19]

RIN 2070-AB27

Significant New Use Rules on Certain Chemical Substances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is issuing 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 requires persons to notify EPA 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 rule. The required notification initiates EPA's evaluation of the intended use within the applicable review period. Persons may not commence manufacture or processing for the significant new use until EPA has conducted a review of the notice, made an appropriate determination on the notice, and has taken such actions as are required as a result of that determination.

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

FOR FURTHER INFORMATION CONTACT: *For technical information contact*: Kenneth Moss, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001;

telephone number: (202) 564-9232; email address: *moss.kenneth@epa.gov*.

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

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Chemical importers are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements promulgated at 19 CFR 12.118 through 12.127 and 19 CFR 127.28. Chemical importers must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA. Importers of chemicals subject to these SNURs must certify their compliance with the SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export a chemical substance that is the subject of this rule on or after [*insert date 30 days after date of publication in the* **Federal Register**] are subject to the

export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)) (see § 721.20), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

II. Background

A. What Action is the Agency Taking?

EPA is finalizing a SNUR under TSCA section 5(a)(2) for 13 chemical substances which were the subject 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 SNURs 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.

Previously, in the **Federal Register** of October 16, 2018 (83 FR 52179) (FRL-9984-93), EPA proposed a SNUR for these 13 chemical substances in 40 CFR part 721 subpart E. More information on the specific chemical substances subject to this final rule can be found in the **Federal Register** documents proposing the SNUR. The record for the SNUR was established in the docket under docket ID number EPA–HQ–OPPT–2017–0575. That docket includes information considered by the Agency in developing the proposed and final rules.
EPA received a number of public comments on this rule. Those comments and EPA's responses are found in Unit IV.

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

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a "significant new use." EPA must make this determination by rule after considering all relevant factors, including the four bulleted TSCA section 5(a)(2) factors listed in Unit III. Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1)(B) requires persons to submit a significant new use notice (SNUN) to

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

C. Applicability of General Provisions

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

III. Significant New Use Determination

Section 5(a)(2) of TSCA states that EPA's determination that a use of a chemical

substance is a significant new use must be made after consideration of all relevant factors, including:

• The projected volume of manufacturing and processing of a chemical substance.

• The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.

• The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.

• The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

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

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

IV. Public Comments on Proposed Rule and EPA Responses

EPA received public comments from 15 entities on the proposed rule. The Agency's responses are described below.

Anonymous and Generally Supportive Comments

EPA received a number of anonymous (and submitter-identified) comments in support of the Agency's proposed Significant New Use Rules (SNURs). These comments were general in nature, citing the importance of Agency review of these 13 chemicals to protect human health and the environment. No response is required.

Challenges to Underlying TSCA §5(a)(3) Determinations

Comment 1: EPA received multiple comments regarding the manner in which these proposed Significant New Use Rules (SNURs) operate. One comment requested that, in light of alleged legal and factual deficiencies, EPA withdraw both the proposed SNURs and the underlying "not likely" determinations and instead issue determinations, section 5(e) orders, and post-order section 5(f) SNURs based on a finding that the chemical substances "may present an unreasonable risk to health or the environment" under section 5(a)(3)(B). Another comment stated that EPA may not rely on "non-5(e) SNURs" to make a "not likely" finding under section 5(a)(3)(C) and has failed to provide a legal and factual basis for its determination as required by section 5(g), but nevertheless supports the need to promulgate these SNURs at this time because otherwise there will be no protections at all in place for these chemical substances. The commenter stated that EPA found risks to workers for a number of the chemical substances subject to these proposed SNURs, absent protective measures that EPA expects will be implemented and will provide sufficient protection, and that EPA's risk determination for these chemicals should not assume there will be full compliance with all of the controls recommended in an associated Safety Data Sheet and that such compliance would be adequate to protect workers.

Response: These comments constitute challenges to certain TSCA §5(a)(3) determinations rather than to the basis for or the content of the SNURs, which EPA has promulgated using its discretion to issue SNURs under TSCA §5(a)(2). Because these comments are not germane to this rulemaking, EPA is not responding to these comments in this notice and declines to withdraw the SNURs on the basis of these comments. Regardless, EPA has already defended the legal and factual basis for the TSCA §5(a)(3) determinations that these comments reference in a

prior legal challenge. *See* Brief of U.S. Environmental Protection Agency in *NRDC v. USEPA*, 2d Cir. Docket No. 18-25.

Regulation of workplace risks

Comment 2: Several commenters argued that where EPA finds unreasonable risks to workers in the absence of certain protective measures (e.g., personal protective equipment, engineering controls, etc.), EPA must identify as a significant new use any use of the chemical that occurs without those protections. Specifically, the commenters stated that, where EPA finds unreasonable risk to workers absent certain protective measures, the Agency must issue an order to address workplace risks – as well as consider promulgating a significant new use rule – because in these circumstances "the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, may present an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed subpopulation." 15 U.S.C. § 2604(e)(1)(A)(ii)(I). In following, the commenters state EPA "shall issue an order…to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of such substance or to prohibit or limit any combination of such activities to the extent necessary to protect against an unreasonable risk of injury to health or the environment." *Id.* § 2604(e)(1)(A). After issuing that order, EPA must consider whether to promulgate a significant new use rule "that identifies as a significant new use any manufacturing, processing, use, distribution in commerce, or disposal of the chemical substance that does not conform to the restrictions imposed by the *** order" or publish a statement justifying the decision not to promulgate the SNUR. 15 U.S.C. § 2604(f)(4). According to the commenters, Congress spoke clearly and required EPA to regulate unreasonable risks that a chemical substance "may present" under

TSCA. The commenters contend that nothing in the text of TSCA allows EPA to simply assume that sufficient protective measures will be implemented to eliminate potential unreasonable risks; such an assumption essentially negates TSCA § 5(e), which could not be Congress's intention. And, the commenters claim, EPA cannot find that a chemical is not likely to present an unreasonable risk based solely on EPA's unjustified "expectation" that sufficient protective measures will be implemented…EPA effectively found risks to workers for several chemical substances subject to these proposed SNURs, absent protective measures that EPA simply "expects" will be implemented and will provide sufficient protection. Commenters assert that EPA's risk determination for these chemicals should not assume there will be full compliance with all of the controls recommended in an associated Safety Data Sheet and that such compliance would be adequate to protect workers. Because EPA relied on these protective measures in its analysis of risk, commenters state that EPA should identify any condition of use without these protective measures to be a significant new use, meriting advance notification to EPA.

Response: To the extent these comments argue that the Agency should have issued orders under Section 5(e) or 5(f) of TSCA, EPA believes they are beyond the scope of the SNUR for which EPA is specifically soliciting comments and are properly directed to the Section 5(a)(3) determinations that pertain to the underlying PMNs for the SNUR. EPA is therefore not responding to these comments here. However, EPA is responding to comments that pertain specifically to the SNUR, i.e., those regarding the uses that should be subject to the SNUR, as well as the assertion that EPA must include certain worker protection provisions in the SNURs on the basis of TSCA Section 5(f)(4).

EPA disagrees with the comment that, with respect to scenarios where EPA expects that worker protection requirements under other federal/state authorities would mitigate risks to workers, EPA must designate all uses without those protections as "significant new uses". Section 5(a)(2) of TSCA does not mandate that any specific uses be designated as significant. Instead, EPA has discretion as to which new uses to designate as significant. As mentioned in the "not likely" determination documents for the subject PMNs in this batch SNUR (see *https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/chemicals-determined-not-likely*), in exercising its discretion regarding which new uses should be designated as significant under section 5(a)(2), EPA expects compliance with federal and state laws, such as worker protection standards or disposal restrictions, unless case-specific facts indicate otherwise. Further, any workplace risks will be mitigated if exposures are appropriately controlled, and EPA expects that employers will require and workers will use the appropriate controls (e.g., personal protective equipment such as impervious gloves and/or respirators), consistent with the Safety Data Sheet prepared by the PMN submitter, in a manner adequate to protect them.

With respect to comments regarding TSCA Section 5(f)(4), EPA notes that because no applicable TSCA Section 5(e) or 5(f) orders have been issued, the requirements of TSCA Section 5(f)(4) are not triggered. Therefore, EPA need not make changes in the proposed SNUR to correspond to Section 5(e) and 5(f) orders that have not been issued.

SNURs Lack Provisions to Notify Downstream Processors and Users of Agency Concerns

Comment 3: One commenter suggested that the proposed SNURs lack notification requirements for worker protection and hazard communication programs to ensure that risks to workers and the public from downstream activities are identified and addressed and fail to provide notice to

downstream processors and users of the PMN substance's environmental effects and EPA's required limits on release to water.

Response: 40 CFR 721.5 requires manufacturers and processors to either file a SNUN before distributing the chemical substance in commerce or notify downstream customers of the existence of a SNUR on a particular chemical substance (or determine that such users have notice). Thus, one of two possibilities will occur: (1) downstream customers do receive notice of the SNUR, or (2) notification of downstream uses becomes unnecessary because the manufacturer or processors submits a SNUN to EPA, and the Agency either determines that such manufacture and processing is not likely to present unreasonable risk, or takes appropriate regulatory action to address the risks.

Impact on Downstream Users

Comment 4: One commenter similarly identified impacts of SNURs on downstream users who "often must struggle to figure out when a product they use is covered by a SNUR," particularly when the proposed SNUR provides only the generic name of a confidential chemical substance, or when the proposed SNUR covers the use of a chemical substance in an article. The comment also notes that the burden and compliance risks are greatest when the proposed SNUR contains reporting requirements. The commenter indicates that downstream users may depend on voluntary disclosure by the supplier or a downstream formulator/distributor, in contrast to the mandatory reporting requirements in place under a 5(e) order. The comment concludes that EPA should take steps to close the gap between proposal and finalization of SNURs by finalizing SNURs expeditiously, by notifying submitters of EPA's likelihood of promulgating a SNUR, and by requesting companies alert downstream users of impending SNURs.

Response: The Agency is aware of the impacts of the issuance of a SNUR, including and beyond those specific to the actual TSCA notification requirement. EPA's focus is to take appropriate action under TSCA to control potential risks to human health or the environment from exposure or release of a new chemical, including requiring notification of potential significant new uses.

CBI and Disclosure of Health and Safety Information

Comment 5: EPA received multiple comments critical of EPA's process in promulgating the proposed SNURs. One comment requested that EPA extend the comment period and make CBI available for review with appropriate safeguards to avoid depriving the public of a meaningful opportunity to participate. The commenter stated that TSCA does not extend CBI protection to any health and safety study which is submitted under TSCA, including underlying information and occupational exposure studies. In addition to the scientific analyses developed by EPA (e.g., engineering reports, Structure Activity Team reports), which fall under this definition, other information that is generally required to be submitted with PMNs, such as toxicity studies, information on worker exposure, and the majority of information in Safety Data Sheets, also fall under this definition. EPA must disclose this information to the public. Despite these mandates, the commenter argues that EPA has failed to disclose this health and safety information. The comment states that EPA's SAT reports, engineering reports, and exposure reports all constitute or contain health and safety information that EPA must disclose, yet for P-16-575 (as an example provided by the commenter) EPA has largely redacted these documents.

Response: EPA recognizes that TSCA Section 14 does not protect from disclosure certain confidential information described in Section 14(b), including health and safety information. However, Section 14 does not require that EPA make a final confidentiality determination for all information submitted under TSCA and claimed as CBI as part of a PMN review, and EPA has

not made a determination regarding the eligibility for confidential treatment of the information referenced in the comment. Here, EPA balanced the need for sufficient information in the public record to fully explain the bases for its decisions with the protections for CBI in section 14. With regard to EPA technical support reports underlying the section 5 determination, they are not covered by section 14(b)(2), which specifically refers to health and safety studies submitted to EPA. EPA provided sufficient information in the public record to fully explain the bases for its decisions while preserving the submitter's confidentiality claims through generally accepted means, including the aggregation of certain data in the public docket, presentation of ranges of values, or masking of manufacturing site locations to prevent CBI disclosure.

Identifying "Significant New Uses" for SNURs

Comment 6: The commenter considers the approach taken for these proposed SNURs that found "not likely to present an unreasonable risk" under the conditions of use described in the PMNs to be generally consistent with the requirements of the 2016 amendments to TSCA. To the extent that this approach also represents potential improvements in the Agency's ability to provide more timely review of PMNs, the commenter supports the approach. The commenter encourages EPA to take a risk-based approach – with particular focus on changes occurring in the conditions of use of a substance that can affect exposure (i.e., human exposure and environmental releases) – in identifying what changes in the conditions of use that will constitute significant new uses, and to consider the potential burden on downstream users when designating potential new uses to be significant. The commenter further encouraged EPA to use its discretion to consider "all relevant factors," including the cost of submitting SNUNs, the burden of compliance with SNUR reporting requirements such as Chemical Data Reporting (CDR) and TSCA section 12(b) export notification reporting, and the compliance risk caused by vague

regulations, in promulgating 5(a)(2) SNURs to minimize regulatory burdens on downstream users.

Response: EPA agrees that it should - and does - identify significant new uses only after consideration of the "relevant factors" identified in TSCA section (a)(2) ((1) the "projected manufacturing or processing volume of a chemical substance"; (2) the "type or form of exposure of human beings or the environment" to the chemical substance; (3) the "magnitude and duration of exposure of human beings or the environment" to the environment; and (4) the "reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal" of the chemical substance). However, the Agency typically does not have all of the data specific enough for each of the aforementioned factors to support risk assessment(s) for anticipated changes that are not part of the PMN. Hence, such information would be provided if and when a SNUN is submitted that would provide such information for the significant new use. Another commenter supported this approach, explaining that future risks not contemplated in the PMN will be addressed by analysis of a significant new use notice (SNUN) which streamlines the current system which typically runs much longer than 90 days proscribed in TSCA. As to other regulatory requirements such as CDR or export notification, the Agency understands the impact and coordinates with those programs to eliminate inefficiencies. Furthermore, the Agency flags chemical substances on the TSCA Inventory that are regulated with a SNUR. For interpretation of SNUR notification requirements, the regulated community is encouraged to contact the Agency by using the options outlined in the "Addresses" and "For Further Information Contact" sections of the SNUR preamble.

Catch-All Significant New "Use"

Comment 7: One commenter suggested that EPA should generally designate as a significant new use any *use* of a chemical substance other than the *uses* EPA evaluated in its PMN review and determined are not likely to present an unreasonable risk. In particular, the commenter identified P-16-192, P-16-380-385, and 16-575, as SNURs for which other types of triggers for notification (e.g., manufacture in a certain physical form, or manufacture, processing, or use to result in inhalation exposure) were used. Although the commenter supports inclusion of these triggers, it comments that EPA must also require notification for *use* other than that which EPA has reviewed.

Response: Commenters suggested approach is overly broad. TSCA requires that EPA evaluate new chemicals under their conditions of use, including the intended, known and reasonably foreseen circumstances of manufacture, processing, distribution in commerce, use and disposal. Based upon EPA's review of the relevant PMNs, the Agency identified uses that are appropriate for designation as "significant new uses" in order to ensure that EPA has an opportunity to review those uses in a SNUN submission at a later date and address any unreasonable risks at that time. TSCA §5(a)(2) does not require EPA to take the catch-all approach advocated by commenters, and EPA believes a more tailored approach is warranted to avoid unduly burdensome regulations.

Being more specific in 40 CFR 721.80

Comment 8: One commenter suggested that EPA must clearly specify the cross references to EPA's general regulations in the SNURs. A number of proposed SNURs state that the significant new uses are "requirements as specified in 721.80." Since 40 CFR 721.80 contains 25 possible significant new use designations, this is misleading.

Response: The Agency understands the confusion. Where one of the 25 specific significant new use designations in 721.80 is not being used, in the interest of transparency and clarity, the Agency generally lists "*Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80" and follows with a complete sentence describing the actual activity. EPA will modify its approach so that where it is not citing a specific designation in 721.80, the Agency will drop the phrase "Requirements as specified in § 721.80." For example, the SNUR at 40 CFR 721.11182 is finalized simply as:

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

In response to this comment, the Agency is making a similar change to these 721.80 designations in all the final SNURs in this batch rule, except the SNURs at 721.11190 and 721.11191. Those two SNURs specifically cite 721.80(j), which is the confidential use identified in the associated PMN submission for those SNURs.

Regulatory Burden of SNURs for Safer Chemicals

Comment 9: One comment was regarding an enzyme used in the polymerization of glucose that would be subject to a proposed SNUR due to concerns with respiratory sensitization. The commenter stated that enzymes are recognized to have a positive and sustainable environmental profile and inherently low toxicity compared to other chemicals, and that this SNUR is a signal that it will be significantly more challenging to bring new enzymes to market and may decrease innovation that can address global challenges as highlighted by the UN Sustainable Development Goals. The commenter additionally voiced concern for the lengthy review time for PMN submissions.

Response: To the extent commenter is disputing the outcome of a PMN review, these comments are more properly directed to the specific PMN determination and not this SNUR rulemaking. As mentioned previously in the response to Comment 1, this comment constitutes challenges to the corresponding TSCA §5(a)(3) determinations rather than to the basis for or the content of the SNURs, which EPA has promulgated using its discretion to issue SNURs under TSCA §5(a)(2). Nonetheless, the Agency is aware of, and working to remedy, the increased length of time it has been taking to review and reach decision on section 5 notices as it implements the amendments to TSCA.

Non-Animal Testing

Comment 10: One commenter supports this approach of addressing potential risks that the subject chemicals may present under reasonably foreseen conditions of use, while finding that under the intended conditions of use, they are not likely to present unreasonable risks. In contrast, the commenter states, in its early implementation of the amended TSCA, EPA addressed such potential risks in consent agreements with PMN submitters. In these cases, the commenter notes, EPA frequently required health and ecotoxicity testing, including hundreds of vertebrate animal tests requiring tens of thousands of animals. The commenter therefore supports EPA's new approach, which is consistent with TSCA's requirements to reduce and replace the use of vertebrate animals in the testing of chemical substances and promote the development and timely incorporation of new test methods and strategies that are not based on vertebrate animals. In addition, it protects human health and the environment by addressing potential risks when the conditions of use under which they arise are intended, either as identified in PMNs or in SNUNs, while reducing the burden on PMN submitters and streamlining the review process.

Response: As mentioned in the preamble to this SNUR, 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. 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).

Do not use SNURs as information gathering tool, tracking tool.

Comment 11: One commenter urged EPA to not rely on SNURs as tools for tracking use and production of chemical or for otherwise gathering potentially useful information, but instead suggested that EPA rely on provisions like section 8 which specifically authorize such acts.

Response: EPA is not issuing a requirement to develop any data or information as a result of these SNURs. It is the responsibility of a SNUN submitter to provide any such information as required by TSCA section 5 and SNUN regulations at 40 CFR part 721. Regarding potentially useful information, EPA encourages all SNUN submitters to contact EPA to discuss any potential future testing. 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).

V. Substances Subject to this Rule

EPA is establishing 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 VIII. for more information.

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

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

The chemical substances that are the subject of these SNURs completed 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 designating 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:

Manufacture of the PMN substance in an amorphous form.

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

Potentially useful information: EPA has determined that certain information about the physical-chemical properties of the PMN substance may be potentially useful if a manufacturer or processor is considering submitting a SNUN for a significant new use designated by this 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 SNUR designates 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 designated by this 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 SNUR designates as a "significant new use" the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the health and environmental effects of the PMN substances may be potentially useful if a manufacturer or processor is considering submitting a SNUN for a significant new use designated by this 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 SNUR designates as a ‘‘significant new use’’ the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the human health and environmental toxicity of the PMN 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 designated by this 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:

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

The SNUR designates as a ‘‘significant new use’’ the absence of this protective measure.

Potentially useful information: EPA has determined that certain information about the 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 designated by this 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 SNUR designates 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 designated by this 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.

VI. Rationale and Objectives of the Rule

A. Rationale

During review of the PMNs submitted for the chemical substances that are the subject of these SNURs and as further discussed in Unit IV, EPA identified certain reasonably foreseen conditions of use and other circumstances different from the intended 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 issuing these SNURs for specific chemical substances which have undergone premanufacture review because the Agency wants to achieve the following objectives with regard to the significant new uses designated in this rule:

• EPA will receive notice of any person's intent to manufacture or process a listed chemical substance for the described significant new use before that activity begins.

• EPA will have an opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing or processing a listed chemical substance for the described significant new use.

• EPA is 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.

• EPA will identify as significant new uses any manufacturing, processing, use, distribution in commerce, or disposal that does not conform to the restrictions imposed by the underlying Orders, consistent with TSCA section 5(f)(4).

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

VII. Applicability of the Significant New Use Designation

To establish a significant new use, EPA must determine that the use is not ongoing. The chemical substances subject to this rule have undergone premanufacture review. In cases where EPA has not received a notice of commencement (NOC) and the chemical substance has not been added to the TSCA Inventory, no person may commence such activities without first submitting a PMN. Therefore, for chemical substances for which an NOC has not been submitted EPA concludes that the designated significant new uses are not ongoing.

EPA designated October 9, 2018 (the date of web posting of the proposed rule) as the cutoff date for determining whether the new use is ongoing. The objective of EPA's approach has been to ensure that a person could not defeat a SNUR by initiating a significant new use before the effective date of the final rule.

In the unlikely event that a person began commercial manufacture or processing of the chemical substances for a significant new use identified as of October 9, 2018, that person will have to cease any such activity upon the effective date of the final rule. To resume their

activities, that person would have to first comply with all applicable SNUR notification requirements and wait until EPA has conducted a review of the notice, made an appropriate determination on the notice, and has taken such actions as are required with that determination.

VIII. Development and Submission of Information

EPA recognizes that TSCA section 5 does not require 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.

IX. Procedural Determinations

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

Under these procedures a manufacturer or processor may request EPA to determine

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

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

X. SNUN Submissions

According to § 721.1(c), persons submitting a SNUN must comply with the same notification requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in 40 CFR 720.50. SNUNs must be submitted on EPA Form No. 7710-25, generated using e-PMN software,

and submitted to the Agency in accordance with the procedures set forth in 40 CFR 720.40 and § 721.25. E-PMN software is available electronically at *http://www.epa.gov/opptintr/newchems*.

XI. Economic Analysis

EPA has evaluated the potential costs of establishing SNUN requirements for potential manufacturers and processors of the chemical substances subject to this rule. EPA's complete economic analysis is available in the docket under docket ID number EPA-HQ-OPPT-2017-0366.

XII. Statutory and Executive Order Reviews

A. Executive Order 12866

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

B. Paperwork Reduction Act (PRA)

According to PRA (44 U.S.C. 3501 *et seq*.), an agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable. EPA is amending the table in 40 CFR part 9 to list the OMB approval number for the information collection requirements contained in this action. This listing of the OMB control numbers and their subsequent codification in the CFR satisfies the display requirements of PRA and OMB's implementing regulations at 5 CFR part 1320. This

Information Collection Request (ICR) was previously subject to public notice and comment prior to OMB approval, and given the technical nature of the table, EPA finds that further notice and comment to amend it is unnecessary. As a result, EPA finds that there is "good cause" under section 553(b)(3)(B) of the Administrative Procedure Act (5 U.S.C. 553(b)(3)(B)) to amend this table without further notice and comment.

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

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

C. Regulatory Flexibility Act (RFA)

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency hereby certifies that promulgation of this SNUR would not have a significant adverse economic impact on a substantial number of small entities. The requirement to submit a SNUN applies to any person (including small or large entities) who intends to engage in any activity

described in 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. Although some small entities may decide to pursue a significant new use in the future, EPA cannot presently determine how many, if any, there may be. However, 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, and 14 in FY2017, and only a fraction of these were from small businesses. In addition, the Agency currently offers relief to qualifying small businesses by reducing the SNUN submission fee from $16,000 to $2,800. This lower fee reduces the total reporting and recordkeeping of cost of submitting a SNUN to about $10,116 for qualifying small firms. Therefore, the potential economic impacts of complying with this SNUR are not expected to be significant or adversely impact a substantial number of small entities. In a SNUR that published in the **Federal Register** of June 2, 1997 (62 FR 29684) (FRL–5597–1), the Agency presented its general determination that final SNURs are not expected to have a significant economic impact on a substantial number of small entities, which was provided to the Chief Counsel for Advocacy of the Small Business Administration.

D. Unfunded Mandates Reform Act (UMRA)

Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reasons to believe that any State, local, or Tribal government will be impacted by this action. As such, EPA has determined that this action does not impose any enforceable duty, contain any unfunded

mandate, or otherwise have any effect on small governments subject to the requirements of UMRA sections 202, 203, 204, or 205 (2 U.S.C. 1501 *et seq*.).

E. Executive Order 13132

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

F. Executive Order 13175

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

G. Executive Order 13045

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

H. Executive Order 13211

This action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May

22, 2001), because this action is not expected to affect energy supply, distribution, or use and because this action is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

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

J. Executive Order 12898

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

XIII. Congressional Review Act

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

List of Subjects

40 CFR Part 9

Environmental protection, Reporting and recordkeeping requirements.

40 CFR Part 721

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

Dated: _____.

Tala R. Henry,

Acting Deputy Director, Office of Pollution Prevention and Toxics.

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

PART 9--[AMENDED]

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

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

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

§ 9.1 OMB approvals under the Paperwork Reduction Act.

* * * * *

40 CFR citation	**OMB control No.**
* * *	* * * *
Significant New Uses of Chemical Substances	
* * *	* * * *
721.11182	2070-0012
721.11183	2070-0012
721.11184	2070-0012
721.11185	2070-0012
721.11186	2070-0012
721.11187	2070-0012

721.11188	2070-0012
721.11189	2070-0012
721.11190	2070-0012
721.11191	2070-0012
721.11192	2070-0012
721.11193	2070-0012
* * * * * * *	

* * * * *

PART 721--[AMENDED]

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

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

4. Amend the Table of Contents for part 721, subpart E to include the headings for 721.11182 through 721.11193:

Subpart E—Significant New Uses for Specific Chemical Substances

Sec.

* * * * *

§ 721.11182 Silanized amorphous silica (generic).

§ 721.11183 Esteramine (generic).

§ 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)

§ 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).

§ 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),

§ 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).

§ 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).

§ 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).

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

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

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

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

5. 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.* 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.* 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.* 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.* 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.* 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.* 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.* 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.* 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.

(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.* It is a significant new use to manufacture, process, or use the substance in any manner that results in inhalation exposure.

(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.* 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.