



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 721

[EPA-HQ-OPPT-2017-0464; FRL-9998-12]

RIN 2070-AB27

Significant New Use Rules on Certain Chemical Substances (17-3)

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 19 chemical substances which are the subject of premanufacture notices (PMNs). The chemical substances are subject to Orders issued by EPA pursuant to TSCA section 5(e). This action requires persons who intend to manufacture (defined by statute to include import) or process any of these 19 chemical substances for an activity that is designated as a significant new use by this rule to notify EPA at least 90 days before commencing that activity. The required notification initiates EPA's evaluation of the use, under the conditions of use for that chemical substance, 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 by 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. (EST) 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*.

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SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you manufacture, process, or use the chemical substances contained in this 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 40 CFR 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 these SNURs under TSCA section 5(a)(2) for 19 substances which were the subject of PMNs. 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.

In the **Federal Register** of August 27, 2018, (83 FR 43607) (FRL-9982-25), EPA proposed a SNUR for these 19 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 for the direct final SNUR of August 27, 2019 (83 FR 43538)(FRL-9982-24). The record for the SNUR was established in the docket under docket ID number EPA–HQ–OPPT–2017-0464. That docket includes information considered by the Agency in developing the proposed and final rules.

EPA received public comments on the proposed rule. Those comments and EPA's responses are found in Unit IV.

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

TSCA section 5(a)(2) (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a

chemical substance is a “significant new use.” EPA must make this determination by rule after considering all relevant factors, including the four 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)). In the case of a determination other than not likely to present unreasonable risk, the applicable review period must also expire before manufacturing or processing for the new use may commence.

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 40 CFR 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 sections 5(h)(1), (h)(2), (h)(3), and (h)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUN, EPA must either determine that the use is not likely to present an unreasonable risk of injury under the conditions of use for the chemical substance or take such regulatory action as is associated with an alternative

determination before the manufacture or processing for the significant new use can commence. In the case of a determination other than not likely to present unreasonable risk, the applicable review period must also expire before manufacturing or processing for the new use may commence. If EPA determines that the 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

When the Agency issues an order under TSCA section 5(e), TSCA section 5(f)(4) requires that the Agency consider whether to promulgate a SNUR for any use not conforming to the restrictions of the TSCA section 5(e) Order or publish a statement describing the reasons for not initiating the rulemaking. TSCA section 5(a)(2) states that EPA's determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors, including:

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

In determining 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 TSCA section 5(a)(2) factors listed in this unit.

IV. Public Comments on Proposed Rule and EPA Responses

EPA received public comments from 8 entities on the proposed rule. The Agency's responses are described in this unit.

A. Anonymous Comments

EPA received 5 anonymous comments on the proposed rule. All of these comments were general in nature and not specific to or relevant to any of the proposed SNURs. No response is required.

B. Isocyanates

One commenter commented on proposed SNURs for these isocyanate-based polymers or prepolymers: Polyethylene glycol polymer with aliphatic polycarbodiimide bis(alkoxysilylpropyl) amine blocked (generic) (PMN P-16-99, 40 CFR 721.11098); Blocked polyester polyurethane, neutralized (generic) P-16-363, 40 CFR 721.11101); Alkanediol, 2,2-bis (substituted alkyl)- polymer with substituted alkane, heteromonocycles, alkenoate (generic) (P-17-170, 40 CFR 721.11107); 1,3,5-Triazine-2,4-diamine, 6-phenyl-, reaction products with polyalkylene glycol mono- alkyl ether and 2,4-toluene diisocyanate (generic) (P-17-222, 40 CFR 721.11111); and Fatty acids, polymers with benzoic acid, cyclohexanedicarboxylic acid anhydride, aliphatic diisocyanate, alkyl diol, alkyl triol, pentaerythritol, phthalic anhydride, polyalkylene glycol amine, and aromatic dicarboxylate sulfonic acid sodium salt (generic) (P-17-231, 40 CFR 721.11112).

Comment. The commenter stated that EPA should clarify the proposed SNURs to the extent it is basing them on concerns with excess or residual isocyanate monomers in mixture with an isocyanate-based polymer or prepolymer SNUR chemical. The commenter also stated

that EPA has not transparently identified those monomers as being subject to the proposed SNURs and, besides, EPA may not use its SNUR authority to address ongoing uses of the existing isocyanate monomers and must use its TSCA section 6 authority instead.

Response. EPA is concerned about the health effects of any residual monomer as well as unreacted isocyanate groups on a polymer when assessing the risks for new chemical substances. EPA has the authority under TSCA section 5 to address any risks associated with the manufacture, processing, and use of the new chemical substances. The SNUR applies to activities associated with the new chemical substances. Activities associated with the new chemical substance are not ongoing activities of the existing chemical substance. EPA did not receive specific, quantitative information that demonstrates the chemical substance subject to these proposed SNURs exhibit a lower potential for the hazards and potential risks or that they will specifically replace a chemical substance with a higher potential for hazards and risks. EPA is issuing the SNUR as proposed to provide the Agency with the opportunity to review any new uses for potential unreasonable risks. The diisocyanates, MDI and TDI, are well-known dermal and inhalation sensitizers and have been documented to cause asthma, lung damage, and in severe cases, fatal reactions. EPA is concerned about potential health effects that may result from exposures of consumers or self-employed workers while using products containing uncured (unreacted) MDI and TDI and its related polyisocyanates (e.g., spray- applied foam sealants, adhesives, and coatings) or incidental exposures to the general population. Due to the nature of the potential risk posed by these chemicals, EPA believes it is prudent to emphasize its concern through respiratory protection requirements where there is potential for inhalation exposure, in addition to proposing significant new uses such as consumer use and application method. Accordingly, the regulatory actions for new diisocyanates reflects EPA's policy of consistent

treatment of the entire class of potentially hazardous chemicals, regardless of their statutory status as “new” or “existing” chemicals. EPA continues to work to lessen the apparent inequity between regulations of new and existing chemicals.

Comment. The same commenter stated that EPA should clarify its basis for the imposed limitations on total residual isocyanates, because varying limitations on residual isocyanates appear in the regulatory text for these SNURs, i.e., greater than: 0.2% residual isocyanate (P-16-99), 0.1% residual isocyanate (P-16-363, P-17-170, P-17-222, and P-17-231), and 0.15% residual toluene isocyanate (P-17-222).

Response. For each PMN substance, where there is potential risk from residual chemicals or lower molecular weights if the polymer is manufactured differently, EPA attempts to minimize exposure based on information in the notification. Each of these PMNs contained information that the polymer was manufactured at a certain molecular weight and residual isocyanate level. EPA included restrictions for residual isocyanate in the TSCA section 5(e) Order and the proposed SNUR to prevent potential health risks.

Comment. The same commenter stated that EPA should clarify the basis for the derived New Chemical Exposure Limit (NCEL) of 0.9 mg/m³ (as an 8-hour time weighted average) for P-16-99. The commenter added that the requirement to develop a validated airborne monitoring method is overly burdensome and unnecessary and EPA should allow company industrial hygienists to use professional judgment instead.

Response. This substance is an alkoxysilane, with some residual isocyanate. The NCEL of 0.9 mg/m³ was derived using a No Observed Adverse Effect Level from a 90-day study on vinyltrimethoxysilane, as described in the new chemicals program category document for alkoxysilanes at <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control/>

act-tsca/new-chemicals-program-under-tsca. The SNUR does not require manufacturers or processors to develop validated monitoring methods or techniques. A manufacturer would be required to develop validated monitoring methods or techniques if they choose use the NCEL.

Comment. The same commenter stated that EPA should defer personal protective equipment (PPE) and hazard communication provisions to the applicable OSHA requirements.

Response. The TSCA section 5(e) Orders for the chemicals in this SNUR contain worker protection requirements, EPA proposed and is issuing a final SNUR retaining those requirements so that all manufacturers and processors are subject to the same requirements. If the underlying TSCA section 5(e) Orders are modified EPA would consider modifying the SNUR.

Comment. The same commenter stated that EPA should delete the provisions incorporating the recordkeeping requirements in 40 CFR 721.125, as it did in the proposed TDI SNUR, 80 FR 2068 (January 15, 2015), and some others.

Response. The SNURs cited by the commenter are existing chemical SNURs, where EPA determined recordkeeping was not needed. For example, when the significant new use for an existing chemical is “any use” there is typically no recordkeeping required because there are no records to be maintained that would inform EPA inspection or enforcement. Because the SNURs in this current rule are new chemical SNURs, EPA will continue to require recordkeeping for all new chemical SNUR to better allow EPA to inspect and enforce SNUR requirements at facilities where chemicals subject to SNURs are manufactured and processed.

C. Deviation from EPA’s PBT Policy

Comment. One commenter suggests that EPA has deviated from its Persistent, Bioaccumulative, and Toxic (PBT) New Chemical Substances Testing Policy (see final policy statement at 64 FR 60194; November 4, 1999) and failed to explain those deviations. Comments

relate to the chemical substances described in PMNs P-15-719, P-16-221, P-17-177, P-17-247, and P-17-248, which met criteria identified in the 1999 Policy Statement for persistence, bioaccumulation potential, and toxicity that would indicate they should be controlled more stringently, up to a ban on commercialization pending development of certain testing.

Response. These comments constitute challenges to certain TSCA section 5(a)(3) determinations rather than to the basis for or the content of the SNURs. EPA is not responding to these comments in this notice and declines to withdraw the SNURs on the basis of these comments, since they are not relevant to this rulemaking. The 1999 policy statement, which is not a rule, provides guidance criteria for persistence, bioaccumulation, and toxicity for new chemicals and advises the industry about our regulatory approach for chemicals meeting the criteria. Establishment of a PBT category alerts potential PMN submitters to possible assessment or regulatory issues associated with PBT new chemicals review. It also provides a vehicle by which the Agency may gauge the flow of PBT chemical substances through the TSCA New Chemicals Program and measure the results of its risk screening and risk management activities for PBT new chemical substances; as such, it is a major element in the Agency's overall strategy to further reduce risks from PBT pollutants.

The TSCA section 5(e) Orders for these PMNs do state that EPA estimates that the substances will persist in the environment for more than two months and estimates a bioaccumulation factor of greater than or equal to 1,000. The policy statement notes that even for "very" P (persistence in the environment for more than six months) and "very" B cases (bioaccumulation factor of greater than 5,000), where "because of the increased concern, more stringent control action would be a likely outcome, . . . it would not be appropriate to automatically trigger a "ban pending testing" at these cutoffs given the uncertainties about substance

properties, release, and environmental behavior that normally characterize PMN review.”

Accordingly, the Agency evaluates each PMN based on the use, exposure and release information submitted, and makes a case by case risk management decision. The proposed SNUR terms for these substances reflect the Agency’s determination under their respective TSCA section 5(e) Orders, that the controls stipulated in those TSCA section 5(e) Orders are protective of human health and environment, pending submission of further information that is identified in the TSCA section 5(e) Orders.

D. Ad Hoc Testing Policy Change

Comment. One commenter noted that EPA has instituted an *ad hoc* testing policy change without acknowledging it has done so and without meeting TSCA’s requirements. With these proposed SNURs, the commenter continues, EPA has implemented a significant departure from past policy and practice by ceasing to include any testing requirements or identifying any recommended testing. Instead, the commenter states, each chemical-specific description in Unit IV. of the proposed rule only identifies “potentially useful information” that EPA indicates is only being “provided for informational purposes;” EPA has not defined what it means for information to be only potentially useful and why EPA does not identify the information as useful or necessary. Finally, the commenter states that, moreover, EPA provides no explanation for why it no longer identifies testing as “recommended testing,” as it previously did, and instead only describes the associated information as “potentially useful.”

Response. The comment pertains to the preamble of each SNUR, which are not requirements for testing. EPA has modified language in its regulatory documents to ensure consistency with TSCA section 4(h) requirements to reduce testing on vertebrates to the extent practicable. TSCA section 5(e) Orders will now contain a statement of need that explains the

basis for any decision that requires the use of vertebrate animals. In addition, EPA is modifying language in its legal documents describing test requirements to reflect a preference for tiered testing and use of non-vertebrate testing strategies first and using that test data to inform whether higher tiered testing (including testing of vertebrates) is necessary. Similarly, EPA is modifying language in its SNURs to more generally describe the information EPA believes would help characterize chemical properties, fate and/or the potential human health and environmental effects associated with a significant new use of the chemical substance, rather than list specific recommended tests. EPA is encouraging companies to consult with the Agency on the potential for use of alternative test methods and strategies (also called New Approach Methodologies, or NAMs) to generate data to inform risk assessment. EPA encourages dialogue with Agency representatives to help determine how best the submitter can meet both the data needs and the objective of TSCA section 4(h).

E. Consistency Between SNURs and TSCA section 5(e) Orders

Comment. One commenter noted that for P-16-0533, P-16-0570, P-16-0363, P-17-0170, P-17-0179, and P-17-0247-48, the corresponding TSCA section 5(e) Orders prohibit distribution of the substance until it has been completely cured, while the proposed SNURs do not contain a corresponding notification requirement applicable to a company that intends to distribute the uncured substance. The commenter concludes that the final SNURs must do so. The commenter further notes that for P-16-0595 and P-17-0260 the proposed SNURs state that “[t]he requirements of this section do not apply to quantities of the substance after they have been reacted (cured),” while the underlying TSCA section 5(e) Order contains no such provision to lift its restrictions. The commenter concludes that the final SNURs should not provide an exemption from the requirements of the SNUR where such an exemption is not provided in the TSCA

section 5(e) Orders.

Response. For P-16-370 (P-16-570 is not contained in the proposed SNUR), P-16-363, P-17-170, P-17-179, and P-17-247-248, the TSCA section 5(e) Orders do not prohibit distribution of the substances until they are completely reacted (cured). The TSCA section 5(e) Orders allow distribution under certain conditions. The terms of the TSCA section 5(e) Orders including the distribution requirements are exempted for these PMNs when they have been fully reacted (cured). The final SNURs for these substances will contain the same exemption. Manufacturers and processors distributing chemicals in commerce subject to SNURs are subject to the notification requirements found in 40 CFR 721.5(a)(2). The TSCA section 5(e) Orders for P-16-533, P-16-595, and P-17-260 do not contain an exemption if the substance is completely reacted (cured). To be consistent with the TSCA section 5(e) Order, the final SNURs for these three substances will not contain that exemption.

F. Generic Chemical Names Must Comply with the Requirements of TSCA and EPA's Guidance

Comment. One commenter noted that prior to finalizing the SNUR for certain chemical substances identified, EPA must ensure that the generic names for these chemicals comply with the law and conform to EPA's Generic Name Guidance (83 FR 30173; June 27, 2018). The commenter continued that despite TSCA's requirement for generic names to be specific as practicable, and EPA's stated preference in its guidance for masking only a single structural element, we have identified a number of generic names covered by proposed SNURs that are or appear to be far from sufficiently specific. The specific chemical substances identified in this batch proposed SNUR were P-16-0221: Fluorinated organopolysilazane; P-16-0370: Methoxy-terminated polysiloxanes; P-16-0376: Hydroxystyrene resin; P-17-0179: Modified carboxypolyamine salt; P-17-0247: Branched alkyl (C=17) carboxylic acid; and P-17-0248:

Branched alkyl (C=18) alcohol.

Response. The statute, regulations, and guidance stipulate that generic names should be as specific as practicable and reveal the specific chemical identity to the maximum extent possible. See TSCA section 14(c)(1)(C), 40 CFR 720.85(a)(2-3), and “*Guidance for Creating Generic Names for Confidential Chemical Substance Identity Reporting under TSCA*” (see 83 FR 30173; June 27, 2018). EPA declares PMNs incomplete if they include generic names for confidential substances that are overly generic. However, EPA more thoroughly examines generic names provided after commencement of manufacture or import (i.e., in a Notice of Commencement, or NOC), in accordance with 40 CFR 720.85(b)(6). Because this may occur after finalization of a SNUR, a generic name provided in a SNUR may be improved upon regarding its specificity at a later date when the NOC is submitted to the Agency. Persons should also keep in mind that they do not have the benefit of seeing the full chemical identities of confidential substances which is necessary for determining the acceptability of generic names for such substances. Generic names that may appear overly generic may be acceptable for simple chemical substances that have very few functional groups or structural features.

G. Generic Use Descriptions

Comment. One commenter noted that despite EPA having provided PMN submitters instructions to the contrary, many of these generic use descriptions are overly broad or vague. The commenter provided these examples in this batch proposed SNUR: P-16-363: open, non-dispersive use; P-16-595: polymer; P-17-260: resin modifier; P-17-222: additive open non-dispersive use; and these described by the commenter as “slightly better”: P-16-99: additive for industrial coatings; P-16-359: pigment additive for industrial coatings; P-16-376: photolithography; and P-17-247/48: chemical raw materials. The commenter stated that these

generic use descriptions do not comply with EPA's own 2015 "Instruction Manual for Reporting under the TSCA §5 New Chemicals Program," which calls for the generic use description to include *both* (1) a description of the category of use, which "should reveal the intended category of use to the maximum extent possible;" and (2) a characterization of the "degree of containment," with examples cited such as "destructive use" or "open, non-dispersive use." Both components are needed; EPA's manual states: "a generic use description that solely describes the degree of containment such as 'open, non-dispersive use' is not acceptable." While a few of the examples cited previously come closer than others, the commenter concludes, none of them comply with the instructions.

Response. EPA notes the generic use description issue, with regards to PMN reporting. However, this comment does not pertain to the findings or requirements of the proposed SNURs. Accordingly, EPA is not making any changes to the final SNURs based on these comments.

H. Significant New Uses Should be for Any Uses Other Than What EPA has Evaluated

Comment. One commenter suggested that EPA should generally designate as a significant new use any use of a chemical substance other than the specific uses EPA evaluated in its PMN review and determined are not likely to present an unreasonable risk. The commenter identified P-17-247/248 as SNURs where the specific use is claimed as confidential by the PMN submitter, but the TSCA section 5(e) Order and SNURs restrict generically to use only as an intermediate, and it is not clear that EPA examined other intermediate uses beyond the specific use identified in the PMNs. The commenter believes that EPA must also require notification for any type of chemical intermediate use other than that which EPA has reviewed. The commenter also noted that the SNURs for P-16-359 and 16-370 do not include designation of *any* use that would

require notification (only process restrictions, no consumer use, application method, etc.).

Response. The commenter 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 section 5(a)(2) does not require EPA to take the broad approach advocated by the commenter. EPA believes a more tailored approach is warranted to avoid unduly burdensome regulations.

I. Misleading Use of 40 CFR 721.80 Reference

Comment. One commenter noted that certain proposed SNURs state that a significant new use related to Industrial, commercial, and consumer activities is listed as "requirements as specified in § 721.80" without specifying one of the 25 possible restrictions in that section.

Response. EPA understands the confusion and has deleted reference to 40 CFR 721.80 where no specific section is cited and simply writes the applicable significant new use, i.e., "*Industrial, commercial, and consumer activities*. It is a significant new use to...."

J. Consistency between TSCA section 5(e) Orders and SNURs: Hierarchy of Controls

Comment. One commenter stated that the provisions in many of the proposed SNURs that address "protection in the workplace" are not consistent with the underlying TSCA section 5(e) Orders, and unlike the TSCA section 5(e) Orders, do not accurately and sufficiently invoke the Industrial Hygiene Hierarchy of Controls (HOC), which is a foundational element of OSHA and NIOSH policy. The commenter also cites two TSCA section 5(e) Orders or preambles to the

SNURs for P-16-221 and P-16-370 that either fail to include language requiring preference for engineering and administrative controls over PPE or only include a general statement that encourages such controls.

Response. EPA believes that although the SNURs may not precisely mimic the language in the underlying TSCA section 5(e) Orders, the SNURs do incorporate the same requirements for HOC as found in the TSCA section 5(e) Orders. The commenter refers to this language generally used in TSCA section 5(e) Orders: “Engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible to each person who is reasonably likely to be [dermally exposed/exposed by inhalation] in the work area to the PMN substance ***. Where engineering, work practice, and administrative controls are not feasible or, if feasible, do not prevent exposure, each person subject to this exposure must be provided with, and is required to wear, [personal protective equipment] ***” The corresponding SNUR language is shortened to this: “engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible”. The language in the specific references under 40 CFR 721.63(a) regarding establishing a program to protect workers incorporates both the HOC and worker protection requirements of the SNUR. EPA believes that the intent and requirements are identical between the TSCA section 5(e) Orders and SNURs and that adding a phrase referring to PPE where engineering controls are not feasible would not serve to further clarify this SNUR notification requirement.

K. SNURs Should Include Workplace Protection Provisions Under 40 CFR 721.63

Comment. The same commenter noted that many of the SNURs do not include specific provisions to incorporate requirements for protection in the workplace regulations codified at 40 CFR 721.63. Specific SNURs cited were for PMNs P-16-376, P-16-595, P-17-172, P-17-222, P-17-231, and P-17-260. None of the TSCA section 5(e) Orders contained workplace controls.

Response. For the TSCA section 5(e) Orders listed, EPA achieved the necessary risk reduction in the workplace via provisions other than specific worker protection requirements. For P-16-376, the TSCA section 5(e) Order requires manufacture of the substance at a certain molecular weight and molecular weight distribution that effectively controls risk “upstream,” for the inherent hazard of the substance. For P-16-595, the TSCA section 5(e) Order requires certain (confidential) conditions of use that address potential risk. A bona fide and SNUN would be required before any other conditions of use can be evaluated and approved. For P-17-172, P-17-222, and P-17-260, lung toxicity concerns are addressed by prohibition on inhalation exposures, plus (in the case of P-17-222, a limitation on isocyanate residuals). P-17-231 achieves risk reduction solely via restriction on residual isocyanate in the manufactured substance.

L. Deferring Workplace Protections to OSHA or NIOSH

Comment. One commenter favored the idea that EPA should leave workplace protection to OSHA and NIOSH. Another commenter argued against that view, stating that nothing in the TSCA statute supports the assertion that EPA should rely on OSHA to regulate new chemicals in the workplace, *see* 15 U.S.C. 2604(f)(5); and due to the limitations on OSHA’s authority, the protections for workers would not meet TSCA’s requirement to “protect against an unreasonable risk of injury to health or the environment.” 15 U.S.C. 2604(e).

Response. To the extent these comments argue that the Agency should or should not have issued orders under sections 5(e) or 5(f) of TSCA that include worker protection conditions, EPA

believes they are beyond the scope of the SNUR for which EPA specifically solicited comments and are properly directed to the TSCA section 5(a)(3) determinations that pertain to the underlying PMNs for the SNUR. EPA is therefore not responding to these comments.

However, EPA in response 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”. TSCA section 5(a)(2) does not mandate that any specific uses be designated as significant. Instead, EPA has discretion as to which new uses to designate as significant. In exercising its discretion under TSCA 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.

M. Clarification of SNUR for P-17-222 (40 CFR 721.11111)

Comment. One commenter noted that in this proposed SNUR, EPA placed a notification requirement based on the concentration of residual isocyanate in the chemical as imported but has failed to include a similar express notification requirement on manufacturing. Specifically, the proposed SNUR (and the corresponding TSCA section 5(e) Order) states that “[i]t is a significant new use to *import* the chemical substance containing greater than 0.15 percent

residual isocyanate.” As written, the commenter continues, the TSCA section 5(e) Order and SNUR appear to allow domestic manufacture of the chemical without any limit on the residual level of isocyanate.

One commenter also noted that for P-17-222, the TSCA section 5(e) Order restricts the chemical to be imported “to contain maximum residual of *toluene diisocyanate (TDI)* no greater than 0.15 weight percent.” In contrast, the proposed SNUR states that a significant new use is “import [of] the chemical substance containing greater than 0.15 percent *residual isocyanate*.” The TSCA section 5(e) Order also prohibits *processing and use* of the chemical if it “contain[s] residual of toluene diisocyanate (TDI) greater than 0.15 weight percent.” In contrast, the SNUR applies that numerical residual limit only to import of the substance. In order to be consistent with the TSCA section 5(e) Order, the commenter states, the final SNUR must designate as a significant new use any import, *processing*, or *use* of the chemical containing greater than 0.15 percent residual *toluene diisocyanate (TDI)*.

Response: The Agency agrees that there was an oversight in the proposed rule. The final SNUR for that chemical substance is corrected to read “It is a significant new use to manufacture, process, or use the chemical substance containing greater than 0.15 percent residual toluene isocyanate.” Note that manufacture includes import. In addition, the previous sentence in the same proposed SNUR will be corrected to read “It is a significant new use to modify the manufacture, process or use activities if it results in inhalation exposure to vapor, mist, aerosol, or dust of (replacing *to*) the substance.”

N. CBI and Disclosure of Health and Safety Information

Comment. One 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-16-359 (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 TSCA section 14(b), including health and safety information. However, TSCA 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 TSCA section 14. With regard to EPA technical support reports underlying the section 5 determination, they are not covered by TSCA 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.

O. Vertebrate Testing

Comment. A commenter cited the TSCA section 5(e) Orders for P-15-719, P-16-99, P-

16-221, P-16-370, P-16-487, P-16-533, P-17-170, P-17-179, and P-17-247 that require animal testing by a specified production volume. The commenter requested that wherever EPA require vertebrate animal testing, it include the statutorily-mandated explanation of the bases for the such decision in each particular case. In addition, the commenter requested that EPA contact the PMN submitters for P-16-533, P-17-170, and P-17-247 to inform them that the local lymph node assay for skin sensitization should be replaced with a defined approach as identified in section 5 of the draft EPA policy document *Strategic Plan to Promote the Development and Implementation of Alternative Test Methods Within the TSCA Program* (see <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/strategic-plan-reduce-use-vertebrate-animals-chemical>).

Response. A request to review compliance with TSCA section 4(h)(3) for PMNs and TSCA section 5(e) Orders is not relevant to the proposed SNUR. Because SNURs do not require testing and only suggest the type of information that could address hazards identified by EPA, they include opportunities for EPA to engage submitters considering conducting testing. For SNURs with time or production volume limits, or if a SNUN submitter is required to conduct testing, EPA will include consideration of TSCA section 4(h)(3). When a company consults with EPA before submitting any SNUN as recommended by EPA when issuing SNURs, EPA will also have an opportunity to consider what testing if any should be conducted including consideration of TSCA section 4(h)(3).

V. Substances Subject to this Rule

EPA is establishing significant new use and recordkeeping requirements for 19 chemical substances in 40 CFR part 721, subpart E. In Unit IV. of the original August 27, 2018 direct final rule (83 FR 43538) (9982-24), EPA provides the following information for each chemical substance:

- PMN number.
- Chemical name (generic name, if the specific name is claimed as CBI).
- Chemical Abstracts Service (CAS) Registry number (if assigned for non-confidential chemical identities).
- Basis for the TSCA section 5(e) Order.
- Potentially Useful Information. This is information identified by EPA that would help characterize the potential health and/or environmental effects of the chemical substance in support of a request by the PMN submitter to modify the TSCA section 5(e) Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use designated by the SNUR.
- CFR citation assigned in the regulatory text section of this rule.

The regulatory text section of each rule specifies the activities designated as significant new uses. Certain new uses, including exceedance of production volume limits (i.e., limits on manufacture volume) and other uses designated in this rule, may be claimed as CBI. Unit IX. discusses a procedure companies may use to ascertain whether a proposed use constitutes a significant new use.

These final rules include 19 PMN substances that are subject to Orders under TSCA section 5(e)(1)(A)(ii)(I) where EPA determined that activities associated with the PMN substances may present unreasonable risk to human health or the environment. Those TSCA section 5(e) Orders require protective measures to limit exposures or otherwise mitigate the potential unreasonable risk. The SNURs identify as significant new uses any manufacturing, processing, use, distribution in commerce, or disposal that does not conform to the restrictions imposed by the underlying TSCA section 5(e) Orders, consistent with TSCA section 5(f)(4).

Where EPA determined that the PMN substance may present an unreasonable risk of injury to human health via inhalation exposure, the underlying TSCA section 5(e) Order usually requires, among other things, that potentially exposed employees wear specified respirators unless actual measurements of the workplace air show that air-borne concentrations of the PMN substance are below a New Chemical Exposure Limit (NCEL) that is established by EPA to provide adequate protection to human health. In addition to the actual NCEL concentration, the comprehensive NCELS provisions in TSCA section 5(e) Orders, which are modeled after Occupational Safety and Health Administration (OSHA) Permissible Exposure Limits (PELs) provisions, include requirements addressing performance criteria for sampling and analytical methods, periodic monitoring, respiratory protection, and recordkeeping. However, no comparable NCEL provisions currently exist in 40 CFR part 721, subpart B, for SNURs. Therefore, for these cases, the individual SNURs in 40 CFR part 721, subpart E, will state that persons subject to the SNUR who wish to pursue NCELS as an alternative to the 40 CFR 721.63 respirator requirements may request to do so under 40 CFR 721.30. EPA expects that persons whose 40 CFR 721.30 requests to use the NCELS approach for SNURs that are approved by EPA will be required to comply with NCELS provisions that are comparable to those contained in the corresponding TSCA section 5(e) Order for the same chemical substance.

VI. Rationale and Objectives of the Rule

A. Rationale

During review of the PMNs submitted for the chemical substances that are subject to these SNURs, EPA concluded that for all 19 chemical substances regulation was warranted under TSCA section 5(e), pending the development of information sufficient to make reasoned evaluations of the health or environmental effects of the chemical substances. The basis for such

findings is outlined in Unit IV. Based on these findings, TSCA section 5(e) Orders requiring the use of appropriate exposure controls were negotiated with the PMN submitters. As a general matter, EPA believes it is necessary to follow TSCA section 5(e) Orders with a SNUR that identifies the absence of those protective measures as Significant New Uses to ensure that all manufacturers and processors – not just the original submitter – are held to the same standard.

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:

- To 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 TSCA section 5(e) Orders, consistent with TSCA section 5(f)(4).
- To 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.
- To 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.
- To be able to either determine that the prospective manufacture or processing is not likely to present an unreasonable risk, or to take necessary regulatory action associated with any other determination, before the described significant new use of the chemical substance occurs.

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.

When chemical substances identified in this rule are added to the TSCA Inventory, EPA recognizes that, before the rule is effective, other persons might engage in a use that has been identified as a significant new use. However, TSCA section 5(e) Orders have been issued for all the chemical substances, and the PMN submitters are prohibited by the TSCA section 5(e) Orders from undertaking activities which will be designated as significant new uses. The identities of all 19 chemical substances subject to this rule have been claimed as confidential and EPA has not received any post-PMN *bona fide* submission (per 40 CFR 720.25 and 721.11) for a chemical substance covered by this action. Based on this, the Agency believes that it is highly unlikely that any of the significant new uses described in the regulatory text of this rule are ongoing.

Furthermore, EPA designated August 27, 2018 (the date of public release of the proposed and direct final rules) 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 August 27, 2018, that person will have to cease any such activity upon the effective date of the final rule. To resume their activities, these persons will have to first comply with all applicable SNUR notification requirements and wait until EPA has conducted a review of the notice, made an appropriate determination on the notice, and has taken such actions as are required with that determination.

VIII. Development and Submission of Information

EPA recognizes that TSCA section 5 does not require developing any particular new information (e.g., generating test data) before submission of a SNUN. There is an exception: 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 40 CFR 720.50). However, upon review of PMNs and SNUNs, the Agency has the authority to require appropriate testing. Unit IV. of the original direct final SNUR (83 FR 43538) lists potentially useful information for all SNURs listed here. Descriptions of this information is provided for informational purposes. The potentially useful information identified 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 on 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).

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

Any request by EPA for the triggered and pended testing described in the TSCA section 5(e) Orders was made based on EPA's consideration of available screening-level data, if any, as well as other available information on appropriate testing for the PMN substances. Further, any such testing request on the part of EPA that includes testing on vertebrates was made after consideration of available toxicity information, computational toxicology and bioinformatics, and high-throughput screening methods and their prediction models.

The potentially useful information identified in Unit IV. may not be the only means of

addressing the potential risks of the chemical substance. However, submitting a SNUN without any test data or other information 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 40 CFR 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 40 CFR 721.1725(b)(1) with that under 40 CFR 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 40 CFR 721.1(c), persons submitting a SNUN must comply with the same notification requirements and EPA regulatory procedures as persons submitting a PMN, 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

Additional information about these statutes and Executive Orders can be found at <http://www2.epa.gov/laws-regulations/laws-and-executive-orders>.

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

This action establishes SNURs for several new chemical substances that were the subject of PMNs and TSCA section 5(e) Orders. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011).

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, Regulatory Support Division, Office of Mission Support (2822T), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. Please remember to include the OMB control number in any correspondence, but do not submit any completed forms to this address.

C. Regulatory Flexibility Act (RFA)

Pursuant to RFA section 605(b) (5 U.S.C. 601 *et seq.*), the Agency hereby certifies that promulgation of this SNUR will 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, 14 in FY2017, and 18 in FY2018 and only a fraction of these were from small businesses. In addition, the Agency currently offers relief to qualifying small businesses by reducing the SNUN submission fee from \$16,000 to \$2,800. This lower fee reduces the total reporting and recordkeeping of cost of submitting a SNUN to about \$10,116 for qualifying small firms. Therefore, the potential economic impacts of complying with this 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: Federalism

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 (64 FR 43255, August 10, 1999).

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

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

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

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997), as applying only to those regulatory actions that concern health or safety risks, such that the analysis required under section 5–501 of Executive Order 13045 has the potential to influence the regulation. This action is not subject to Executive Order 13045 because it does not establish an environmental standard intended to mitigate health or safety risks disproportionately affecting children.

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

This action is not a “significant energy action” as defined in Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not likely to have a significant adverse effect on energy supply, distribution, or use.

I. National Technology Transfer and Advancement Act (NTTAA)

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: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

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

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: September 3, 2019.

Tala Henry,

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 §§ 721.11097 through 11115 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 | |
| * * * * | * * * |
| 721.11097 | 2070-0012 |
| 721.11098 | 2070-0012 |
| 721.11099 | 2070-0012 |
| 721.11100 | 2070-0012 |
| 721.11101 | 2070-0012 |
| 721.11102 | 2070-0012 |

| | |
|-----------|-----------|
| 721.11103 | 2070-0012 |
| 721.11104 | 2070-0012 |
| 721.11105 | 2070-0012 |
| 721.11106 | 2070-0012 |
| 721.11107 | 2070-0012 |
| 721.11108 | 2070-0012 |
| 721.11109 | 2070-0012 |
| 721.11110 | 2070-0012 |
| 721.11111 | 2070-0012 |
| 721.11112 | 2070-0012 |
| 721.11113 | 2070-0012 |
| 721.11114 | 2070-0012 |
| 721.11115 | 2070-0012 |
| * * * * * | * * * |

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PART 721--[AMENDED]

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

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

4. Add § 721.11097 to subpart E to read as follows:

§ 721.11097 Benzene, 1,4-bis(alkyl)-, homopolymer (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically benzene, 1,4-bis(alkyl)-, homopolymer (PMN P-15-719) is

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

(2) The significant new uses are:

(i) *Hazard communication*. Requirements as specified in § 721.72(a) through (e) (concentrations set at 1.0 percent), (f), (g)(4)(i), (iii), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System (GHS) and OSHA Hazard Communication Standard may be used.

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

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

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

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

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

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

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

5. Add § 721.11098 to subpart E to read as follows:

§ 721.11098 Polyethylene glycol polymer with aliphatic polycarbodiimide bis(alkoxysilylpropyl) amine blocked (generic).

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical

substance identified generically as polyethylene glycol polymer with aliphatic polycarbodiimide bis(alkoxysilylpropyl) amine blocked (PMN P-16-99) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i), (a)(3), (a)(4), when determining which persons are reasonably likely to be exposed as required for §721.63(a)(1) and (a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (a)(5) (respirators must provide a National Institute for Occupational Safety and Health with an assigned protection factor of at least 10), (a)(6)(particulate), (b)(concentrations set at 1.0 percent) and (c).

(A) As an alternative to the respirator requirements in paragraph (a)(2)(i) of this section, a manufacturer or processor may choose to follow the new chemical exposure limit (NCEL) provision listed in the TSCA section 5(e) Order for this substance. The NCEL is 0.9 mg/m³ as an 8-hour time weighted average. Persons who wish to pursue NCELs as an alternative to §721.63 respirator requirements may request to do so under §721.30. Persons whose §721.30 requests to use the NCELs approach are approved by EPA will be required to follow NCELs provisions comparable to those contained in the corresponding TSCA section 5(e) Order.

(B) [Reserved]

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e)(concentration set 1.0 percent), (f), (g)(1)(ii), (g)(2)(ii), (iii), (use respiratory protection or maintain workplace airborne concentrations at or below an 8-hour time-weighted average of 0.9

mg/m³), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k), (q) and (t). It is a significant new use to manufacture, process, or use the chemical substance for consumer use or for commercial uses that could introduce the substance into a consumer setting. It is a significant new use to manufacture the chemical substance containing greater than 0.2% residual isocyanate.

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

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

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

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

6. Add § 721.11099 to subpart E to read as follows:

§ 721.11099 Fluorinated organopolysilazane (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as a fluorinated organopolysilazane (PMN P-16-221) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(3),

(a)(4), when determining which persons are reasonably likely to be exposed as required for §721.63(a)(1) engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (a)(6)(particulate), (v), (vi), (b)(concentrations set at 1.0 percent), and (c).

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f), (p)(204 kilograms) and (s)(100 kilograms). It is a significant new use to use the substance other than in the confidential coating system allowed in the corresponding TSCA section 5(e) Order.

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

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

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

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

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

7. Add § 721.11100 to subpart E to read as follows:

§ 721.11100 Carbopolycycle-bis(diazonium), dihalo-, chloride (1:2), reaction products with metal hydroxide, 4-[(dioxoalkyl)amino]substituted benzene, 2-[(dioxoalkyl)amino]substituted benzene, 5-[(dioxoalkyl)amino]-2-hydroxy-substituted benzene and oxo-n-phenylalkanamide (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as carbopolycycle-bis(diazonium), dihalo-, chloride (1:2), reaction products with metal hydroxide, 4-[(dioxoalkyl)amino] substituted benzene, 2-[(dioxoalkyl)amino]substituted benzene, 5-[(dioxoalkyl) amino] 2-hydroxy-substituted benzene and oxo-n-phenylalkanamide (PMN P-16-359) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(3), (a)(4), when determining which persons are reasonably likely to be exposed as required for §721.63(a)(1), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (a)(6)(particulate), (b)(concentrations set at 0.1 percent) and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e)(concentration set 0.1 percent), (f), (g)(1)(iv), (vii), (g)(2)(i), (ii), (do not process or use at greater than 200 degrees Celsius), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f) and (q). It is a significant new use to process or use the PMN substance at a temperature greater than 200 degrees C.

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

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

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

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

8. Add § 721.11101 to subpart E to read as follows:

§ 721.11101 Blocked polyester polyurethane, neutralized (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as blocked polyester polyurethane, neutralized (PMN P-16-363) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), when determining which persons are reasonably likely to be exposed as required for §721.63(a)(1) engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (a)(2)(i) through (iii), (a)(3), (a)(6)(particulate), (v), (vi) (b)(concentrations set at 0.1 percent) and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e)(concentration set 0.1 percent), (f), (g)(1)(i), (ii), (g)(2)(i), (ii), (iii), (iv), and (g)(5).

Alternative hazard and warning statements that meet the criteria of the Globally Harmonized

System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture, process, or use the substance with a residual of free isocyanate monomers greater than 0.1 percent by weight. It is a significant new use to modify manufacture, process or use activities if it results in inhalation exposure to vapor, dust, mist or aerosols to the substance. It is a significant new use to manufacture, process, or use the substance for consumer use or for commercial uses that could introduce the substance into a consumer setting. It is a significant new use to manufacture, process, or use the substance other than in an aqueous formulation.

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

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

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

9. Add § 721.11102 to subpart E to read as follows:

§ 721.11102 Methoxy-terminated polysiloxane (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as methoxy-terminated polysiloxane (PMN P-16-370) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i),

(ii), (iii), (a)(3), (a)(4), when determining which persons are reasonably likely to be exposed as required for §721.63(a)(1) and (a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (a)(5) (respirators must provide a National Institute for Occupational Safety and Health assigned protection factor of at least 25), (a)(6)(particulate), (v), (vi), (b)(concentrations set at 1.0 percent), and (c).

(A) As an alternative to the respirator requirements in paragraph (a)(2)(i) of this section, a manufacturer or processor may choose to follow the new chemical exposure limit (NCEL) provision listed in the TSCA section 5(e) Order for this substance. The NCEL is 8.4 milligrams per cubic meter as an 8-hour time weighted average. Persons who wish to pursue NCELs as an alternative to §721.63 respirator requirements may request to do so under §721.30. Persons whose §721.30 requests to use the NCELs approach are approved by EPA will be required to follow NCELs provisions comparable to those contained in the corresponding TSCA section 5(e) Order.

(B) [Reserved]

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e)(concentration set 1.0 percent), (f), (g)(1)(i), (ii), (g)(2)(i), (ii), (iii), (use respiratory protection or maintain workplace airborne concentrations at or below an 8-hour time-weighted average of 8.4 mg/m³), (g)(2)(v), (do not use for spray application), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

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

721.80(q), and (y)(1). It is a significant new use to manufacture, process, or use the substance for consumer use or for commercial uses that could introduce the substance into a consumer setting.

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

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

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

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

10. Add § 721.11103 to subpart E to read as follows:

§ 721.11103 Hydroxystyrene resin (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as hydroxystyrene resin (PMN P-16-376) 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 PMN substance with an average molecular weight less than 2906 daltons and to have greater than 0.5 percent low weight molecular species less than 500 daltons and 1.0 percent low weight molecular species less than 1000 daltons.

(ii) [Reserved]

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

except as modified by this paragraph (b).

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

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

11. Add § 721.11104 to subpart E to read as follows:

§ 721.11104 Benzenesulfonic acid 1,2-diazenediylbis[6-ethenyl]-3-sulfophenyl diazenyl-2-sulfophenyl ethenyl salt (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as benzenesulfonic acid 1,2-diazenediylbis[6-ethenyl]-3-sulfophenyl diazenyl-2-sulfophenyl ethenyl salt (PMN P-16-487) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i), (a)(3), when determining which persons are reasonably likely to be exposed as required for §721.63(a)(1) engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (b)(concentration set 1.0 percent), and (c)

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e)(concentration set 1.0 percent), (f), (g)(1)(iv), (vi), (ix), (blood effects), (g)(2)(i), (v), (g)(3)(i), (ii), (g)(4)(water release restrictions apply), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard

Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80 (f), (k), and (q). It is a significant new use to import the substance other than in solution.

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where N= 55.

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

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

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

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

12. Add § 721.11105 to subpart E to read as follows:

§ 721.11105 Ethanaminium, alkyl-, salt with triazole (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as ethanaminium, alkyl-, salt with triazole (PMN P-16-533) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i), (ii), (iii), (a)(3), when determining which persons are reasonably likely to be exposed as required for §721.63(a)(1) engineering control measures (e.g., enclosure or confinement of the operation,

general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible,

(a)(6)(particulate), (v), (vi), (b)(concentration set 0.1 percent), and (c)

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e)(concentration set 0.1 percent), (f), (g)(1)(i), (iii), (v), (vii), (ix), (g)(2)(i) through (iii), (v), (g)(3)(i), (ii), (g)(4)(iii), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k) and (q). It is a significant new use to modify the manufacture, process or use activities if it results in inhalation exposure to vapor, dust, mist or aerosols to the substance.

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

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

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

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

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

13. Add § 721.11106 to subpart E to read as follows:

§ 721.11106 Substituted-(hydroxyalkyl)-alkyl-alkanoic acid, hydroxy-(substitutedalkyl)-alkyl-, polymer with alpha-hydro-omega-hydroxypoly[oxy (alkylethanediy)] and

isocyanato-(isocyanatoalkyl)-multialkylcycloalkane, salt, alkanol-blocked, compds.

(generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as substituted-(hydroxyalkyl)-alkyl-alkanoic acid, hydroxy-(substitutedalkyl)-alkyl-, polymer with alpha-hydro-omega-hydroxypoly [oxy(alkylethanediy)] and isocyanato-(isocyanatoalkyl)-multialkylcycloalkane, salt, alkanol-blocked, compds. (PMN P-16-595) 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(f) and (k). It is a significant new use to import the substance other than as required in the corresponding TSCA section 5(e) Order.

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

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

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) (b), (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)(iii) of this section.

14. Add § 721.11107 to subpart E to read as follows:

§ 721.11107 Alkanediol, 2,2-bis (substituted alkyl)- polymer with substituted alkane,

heteromonocycles, alkenoate (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as alkanediol, 2,2-bis (substituted alkyl)- polymer with substituted alkane, heteromonocycles, alkenoate (PMN P-17-170) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the PMN substance after they have been reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i), (a)(3), when determining which persons are reasonably likely to be exposed as required for §721.63(a)(1) engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (b)(concentration set 0.1 percent), and (c)

(ii) *Hazard communication.* Requirements as specified in § 721.72 (a) through (e)(concentration set 0.1 percent), (f), (g)(1)(i), (ii), (v), (vii), (ix), (g)(2)(i), (v), (g)(4) and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k)(ultraviolet curable coating resin for three-dimensional printing applications) and (p)(105,000 kilograms). It is a significant new use to modify the manufacture, process or use activities if it results in inhalation exposure to vapor, dust, mist or aerosols to the substance. It is a significant new use to manufacture the chemical substance containing greater than 0.1 percent

residual isocyanate or an average molecular weight below 1,000 daltons

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

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

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

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

15. Add § 721.11108 to subpart E to read as follows:

§ 721.11108 Sulfurized alkylphenol, calcium salts (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as sulfurized alkylphenol, calcium salts (PMN P-17-172) 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(k). It is a significant new use to modify the manufacture, process or use activities if it results in inhalation exposure to vapor, dust, mist or aerosols to the substance.

(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), (b), (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.

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

16. Add § 721.11109 to subpart E to read as follows:

§ 721.11109 Monoheteropentacycloalkane-4-carboxylic acid, substituted cyclo-alkyl ester (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as monoheteropentacycloalkane-4-carboxylic acid, substituted cyclo-alkyl ester (PMN P-17-177) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(3), when determining which persons are reasonably likely to be exposed as required for §721.63(a)(1) engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (b)(concentration set 0.1 percent), and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e)(concentration set 0.1 percent), (f), (g)(1)(i), (ii), (iv), (vi), (vii), (ix), (skin, eye, and mucous membrane irritation), (g)(2)(i) through (iii), (v), (g)(3)(i), (ii), (g)(4)(i) through (iii) and (g)(5).

Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

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

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

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

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

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

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

17. Add § 721.11110 to subpart E to read as follows:

§ 721.11110 Modified carboxypolyamine salt (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as modified carboxypolyamine salt (PMN P-17-179) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i), (iv), (a)(3), when determining which persons are reasonably likely to be exposed as required for

§721.63(a)(1) engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (a)(6)(particulate), (v), (vi), (b)(concentration set 0.1 percent), and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e)(concentration set 0.1 percent), (f), (g)(1)(i), (ii), (g)(2)(i), (ii), (v), (g)(3)(i), (ii), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f), (k)(dispersive additive for pigments in industrial paints and coatings) and (q). It is a significant new use to process or use the substance in a paint or coating formulation greater than 1 percent by weight or volume. It is a significant new use to process or use the substance resulting in inhalation exposure to a vapor, dust, mist or aerosol at greater than 1 percent by weight or volume.

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

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

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

18. Add § 721.11111 to subpart E to read as follows:

§ 721.11111 1,3,5-Triazine-2,4-diamine, 6-phenyl-, reaction products with polyalkylene glycol mono- alkyl ether and 2,4-toluene diisocyanate (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as 1,3,5-triazine-2,4-diamine, 6-phenyl-, reaction products with polyalkylene glycol mono- alkyl ether and 2,4-toluene diisocyanate (PMN P-17-222) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the PMN substance after they have been reacted (cured).

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* It is a significant new use to use the substance in a formulation for the use allowed in the corresponding TSCA section 5(e) Order with isocyanate residuals greater than 0.1 percent by weight or volume. It is a significant new use to manufacture, process, or use the substance for consumer use or for commercial uses that could introduce the substance into a consumer setting. It is a significant new use to modify the manufacture, process or use activities if it results in inhalation exposure to vapor, dust, mist or aerosols of the substance. It is a significant new use to manufacture, process, or use the substance containing greater than 0.15 percent residual toluene diisocyanate.

(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), (b), (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.

(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.

19. Add § 721.11112 to subpart E to read as follows:

§ 721.11112 Fatty acids, polymers with benzoic acid, cyclohexanedicarboxylic acid anhydride, aliphatic diisocyanate, alkyl diol, alkyl triol, pentaerythritol, phthalic anhydride, polyalkylene glycol amine, and aromatic dicarboxylate sulfonic acid sodium salt (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as fatty acids, polymers with benzoic acid, cyclohexanedicarboxylic acid anhydride, aliphatic diisocyanate, alkyl diol, alkyl triol, pentaerythritol, phthalic anhydride, polyalkylene glycol amine, and aromatic dicarboxylate sulfonic acid sodium salt (PMN P-17-231) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been reacted (cured).

(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 chemical substance containing greater than 0.1 percent residual isocyanate.

(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), (b), (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.

20. Add § 721.11113 to subpart E to read as follows:

§ 721.11113 Branched alkyl (C=17) carboxylic acid (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as branched alkyl (C=17) carboxylic acid (PMN P-17-247) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i) through (iii), (a)(3), when determining which persons are reasonably likely to be exposed as required for §721.63(a)(1) engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (b)(concentration set 1.0 percent), and (c).

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

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

721.80(f), (g) and (q). It is a significant new use to modify the manufacture, process or use activities if it results in inhalation exposure to vapor, dust, mist or aerosols to the substance.

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

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

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

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

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

21. Add § 721.11114 to subpart E to read as follows:

§ 721.11114 Branched alkyl (C=18) alcohol (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as branched alkyl (C=18) alcohol (PMN P-17-248) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i), (ii), (iii), (a)(3), when determining which persons are reasonably likely to be exposed as required for §721.63(a)(1) engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and

procedures) shall be considered and implemented to prevent exposure, where feasible, (b)(concentration set 1.0 percent), and (c).

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

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f), (g) and (q). It is a significant new use to modify the manufacture, process or use activities if it results in inhalation exposure to vapor, dust, mist or aerosols to the substance.

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

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

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

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

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

22. Add § 721.11115 to subpart E to read as follows:

§ 721.11115 Alkoxy silane modified butadiene styrene copolymer (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as alkoxy silane modified butadiene styrene copolymer (PMN P-

17-260) 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(k). It is a significant new use to modify the manufacture, process or use activities if it results in inhalation exposure to vapor, dust, mist or aerosols of the substance.

(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), (b), (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.

(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.

[FR Doc. 2019-19666 Filed: 9/17/2019 8:45 am; Publication Date: 9/18/2019]