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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 721

[EPA-HQ-OPPT-2017-0366; FRL-9994-72]

RIN 2070-AB27

Significant New Use Rules on Certain Chemical Substances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is issuing significant new use rules (SNURs) under the Toxic Substances Control Act (TSCA) for 145 chemical substances which are the subject of premanufacture notices (PMNs). The chemical substances are subject to Orders issued by EPA pursuant to section 5(e) of TSCA. This action requires persons who intend to manufacture (defined by statute to include import) or process any of these 145 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. (e.s.t.) on [*insert date 14 days after date of publication in the Federal Register*].

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

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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 § 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 145 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 1, 2018 (83 FR 37455) (FRL-9981-16), EPA proposed a SNUR for these 145 chemical substances in 40 CFR part 721, subpart E, and reopened the public comment period in the **Federal Register** of October 15, 2018 (83 FR 51910) (FRL-9984-72). This reopened comment period closed on November 14, 2018. More information on the specific chemical substances subject to this final rule can be found in the **Federal Register** documents proposing the SNUR. The record for the SNUR was established in the docket under docket ID number EPA-HQ-OPPT-2017-0366. 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?

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a "significant new use." EPA must make this determination by rule

after considering all relevant factors, including the four 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 § 721.1(c), persons subject to these SNURs must comply with the same SNUN requirements and EPA regulatory procedures as submitters of PMNs under TSCA section 5(a)(1)(A). In particular, these requirements include the information submission requirements of TSCA section 5(b) and 5(d)(1), the exemptions authorized by TSCA section 5(h)(1), (h)(2), (h)(3), and (h)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUN, EPA must either determine that the 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

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

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

In 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 bulleted TSCA section 5(a)(2) factors listed in this unit. Note that when the Agency issues an order under TSCA section 5(e), section 5(f)(4) requires that the Agency consider whether to promulgate a SNUR for any use not conforming to the restrictions of the order or publish a statement describing the reasons for not initiating the rulemaking.

IV. Public Comments on Proposed Rule and EPA Responses

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

Anonymous Comments

EPA received 8 anonymous comments on the proposed rule. These comments were general in nature and not specific to or relevant to any of the proposed SNURs. No response is required.

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 actually 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 preambles of each SNUR, which are not requirements for testing. The comment is misinformed, as section 5(a)(2) never has provided authority to require testing in SNURs. Rather, EPA has identified recommended testing that appeared likely to assist with review of a SNUR. That the testing is now characterized as "potentially useful"

rather than “recommended” takes into account the possibility that there may be a variety of information and/or data that would assist with the review of a SNUN, in addition to the testing that the Agency has identified. SNUN submitters may want to consider submitting information (i.e. exposure or toxicity data) that EPA had identified as potentially useful when the new chemical substance was originally reviewed. EPA is not establishing a new testing policy that is based on exposure considerations, as described under TSCA section 26(l)(3).

In addition, as stated on EPA’s new chemicals website (<https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/actions-under-tsca-section-5>): “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. 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).”

Isocyanates

One entity commented on proposed SNURs for two isocyanate-based polymers or prepolymers:

aliphatic N-alkyl urea polymer containing cyclohexyl groups and trimethoxy silanes (generic) (721.11029; P-15-706) and aliphatic N-alkyl urea polymer containing aspartic ester groups and trimethoxy silanes (generic) (721.11030; P-15-707). For both of these SNURs, EPA proposed that the absence of the protective measures in the underlying TSCA 5(e) Order - including exceeding a specified weight of residual isocyanates in the PMN substances, consumer use, exceeding a workplace exposure limit (NCEL), and manufacture, processing or use without personal protective equipment - would be reportable significant new uses.

Comment: The commenter made the following points:

- EPA should clarify the proposed and direct final SNURs to the extent it is basing them on concerns with excess or residual isocyanate monomers. EPA appears to be basing the proposed SNURs on the potential for the hazards or risks of excess or residual isocyanate monomer in mixture with this isocyanate-based polymer or prepolymer. These isocyanate monomers are existing chemicals with many ongoing uses, including use as a monomer or use in excess or residual monomer. EPA has not transparently identified those monomers as being subject to the proposed SNURs. EPA may not use its SNUR authority to address ongoing uses of the isocyanate monomers.
- EPA should clarify the basis, scope, and provisions of the proposed SNURs. In particular, EPA should clarify its basis for both the imposed limitations on residual isocyanates and the derived New Chemical Exposure Limit (NCEL). EPA should also clarify the proposed regulatory text and the preamble of the proposed SNURs, which include inconsistent language regarding when respiratory and dermal protection is needed.
- EPA should defer personal protective equipment (PPE) and hazard communication provisions to the applicable OSHA requirements.
- EPA should delete the provisions incorporating the recordkeeping requirements in 40 CFR

721.125, as it did in the proposed TDI SNUR, 80 Fed. Reg. 2068 (Jan. 15, 2015), and some others.

In response to this commenter, another commenter stated that regardless of whether there are separate ongoing uses for these isocyanates, their presence here as residuals is directly associated with the manufacture of a new chemical substance that EPA has reviewed and for which it has determined that the PMN substance may present an unreasonable risk. It is therefore appropriate in this and other such cases that EPA promulgates SNURs that would require notification and EPA review of potential risks posed by the residual isocyanates present in the PMN substance prior to allowing expanded manufacture or use. In addition, these isocyanates have never been used to produce the PMN substance before; this particular significant new use identified by EPA—i.e., manufacture of the PMN substance with a residual isocyanate level above 0.1%—would constitute a significant new use of both the relevant isocyanates and the PMN substance requiring notification under TSCA section 5.

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 the new chemical substances. EPA has the authority under section 5 of TSCA to address any risks associated with the manufacture, processing, and use of the new chemical substances even if those risks are based on the presence of existing chemical substances. The SNUR only 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 described in the proposed SNUR 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. As described in the Agency's 2011 Action Plan for MDI and TDI, diisocyanates are well-known dermal and inhalation sensitizers in the workplace 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 while such products are used in or around buildings including homes or schools. While workers may already be using protective controls in occupational settings, 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.

With regards to deferring PPE and hazard communication requirements to OSHA, and to the basis for imposed limitations on residual isocyanates and the derived New Chemical Exposure Limit (NCEL), the 5(e) Order included these protective measures and these comments constitute challenges to certain TSCA section 5(a)(3) determinations rather than to the basis for or the content of the SNURs, which EPA has promulgated using its discretion to issue SNURs under TSCA section 5(a)(2). Because these comments are not germane to this rulemaking, EPA is not responding to these comments in this notice and declines to modify the SNURs on the basis of these comments.

With regards to clarifying the proposed regulatory text and the preamble of the proposed SNURs, which include inconsistent language regarding when respiratory and dermal protection is needed, the regulatory text for §721.63 states that workers who are “reasonably likely to be exposed” are required to use the personal protective equipment identified in the SNUR. The preamble language is a summary of SNUR requirements and is not intended describe every detail of the SNUR requirements. Persons manufacturing or processing a chemical substance subject to a SNUR should follow the requirements cited in the regulatory text of the SNUR.

With regards to the comment about recordkeeping, the SNUR cited by the commenter are existing chemical SNURs where EPA determined recordkeeping was not needed for various reasons. 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 these are new chemical SNURs, EPA will continue to require recordkeeping for all new chemical SNURs to better allow EPA to inspect and enforce SNUR requirements at facilities where chemicals subject to SNURs are manufactured and processed.

Consistency between SNURs and Orders

(a). General

Comment: One commenter stated that the Lautenberg Act requires that SNUR requirements conform with requirements of TSCA section 5(e) and 5(f) actions and Orders or that EPA publish a statement explaining why EPA is not doing so, and that EPA should not deviate from prior policy and practice, which correctly implements the law. The commenter then identified instances where the Order requirements were not consistent with the SNUR requirements (see subsequent comments, below).

Response: In general, EPA agrees that SNURs should be consistent with the underlying action or order; however, EPA has never considered that SNURs must have exactly the same requirements. For example, when an Order requires certain testing before manufacture exceeding a certain production limit or time limit, the corresponding SNUR requires notification before exceeding that time or production volume limit. It does not require testing before exceeding the time or production volume limit. Under a TSCA section 5(e) Order, It would be problematic to require the same test from two different entities. The purpose of the SNUR requirement is for the manufacturer to notify EPA and for EPA to determine what, if any, testing should be required based on all available information available at the time of notification. In the sections that follow, EPA has listed those instances where the commenter identified differences between the Order and the SNUR and either explained the differences or made the change.

(b). Protection in the Workplace

Comment: One commenter noted that a number of the proposed SNURs identify a significant new use as any use where worker protection equipment is not provided, and that some but not all of the SNURs correctly mirror the corresponding 5(e) Order by requiring specific respirators, gloves, and other equipment to be used when the chemical is present in a specified “form” or physical state. For example, the Order for P-17-272 identified three forms (particulate, gas/vapor, or combination gas/vapor and particulate (e.g., paint spray mist)). However, the corresponding proposed SNUR does not identify any forms, rather, it only states that “*** [r]equirements as specified in § 721.63(a)(1), (a)(2)(i), (iii), (iv), (a)(3). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) engineering control measures *** or administrative control measures *** shall be considered and implemented to prevent exposure, where feasible.” This inconsistency is significant because if the form of the chemical substance is not identified in subpart E (i.e., in the proposed SNUR), the workplace protections required under § 721.63(a)(1) or (a)(4) will not fully

apply for the dermal and airborne exposures to those forms. Below are PMNs where one, or all, of the forms identified in the corresponding consent order are not specified in the proposed SNURs:

- Does not identify *any* of the forms identified in the Order: P-14-0472, P-14-0496, P-16-0358, P-17-0272-77, P-17-0278-80
- Does not identify particulate form: P-15-0707, P-16-0430, P-16-0513
- Does not identify gas/vapor form: P-16-0399
- Does not identify combination of gas/vapor and particulate (EPA provides as an example in the consent order, “paint spray mist”): P-14-0630, P-15-0450, P-15-0705-07, P-16-0322, P-16-0352 (chemicals A and B), P-16-0399, P-16-0430, P-16-0513, P-17-0032, P-17-0033-140

The commenter states that EPA must eliminate these inconsistencies in the final SNURs and ensure that all forms triggering worker protections specified in the Orders are also specified in the corresponding final SNURs.

Response: For P-14-472, P-14-496, P-14-630, P-15-0450, P-16-322, P-16-358, P-16-399, P-17-272 to P-17-277, P-17-278 to P-17-280, P-15-705-707, P-16-352, P-16-430, P-16-0513, P-17-0032. the Agency agrees that the form in the SNUR does not match the Order and has corrected that oversight in the final SNUR. For the SNURs for P-17-33 through P-17-140, all three forms - gas, vapor, and particulate - are correctly identified. Any combination of these forms requires the identified personal protective equipment.

(c). Industrial, Commercial, and Consumer Activities - Time Limits under 40 CFR 721.80 (p)

Comment: One commenter noted that a number of the 5(e) Orders require the manufacturing (including import) to cease after a period of time unless certain conditions have been met. For example, the Order for P-15-450 establishes a time limit that triggers testing requirements, effective from the Notice of Commencement of Manufacture or Import (NOC) date, after which the chemical substance can no longer be manufactured by the company subject to the Order unless the testing is

conducted. Other Orders establish a volume limit that cannot be exceeded unless the testing is conducted. The commenter continues by noting that the proposed SNURs appear to rely on 40 CFR 721.80(p) to effectuate this type of production limit restriction in the Orders. 40 CFR 721.80(p) states that, where a substance is specified as being subject to that section, a significant new use is the “[a]ggregate manufacture and importation volume for any use greater than that specified in subpart E of this part for the substance,” in the proposed SNURs. This delineation of a significant new use clearly only includes a *volume* limitation. In prior SNURs codified in subpart E, EPA cites to 40 CFR 721.80(p) and correctly specifies a volume limitation. *See, e.g.*, 40 CFR 721.10524 and 721.10935. The proposed SNURs covering the substances in P-15-450, P-16-289, P-16-399, and P-17-198 each propose to rely on this restriction for a *time* limitation. EPA’s reliance only on cross-referencing 40 CFR 721.80(p) is problematic because in a number of the proposed SNURs EPA cites 40 CFR 721.80(p) as identifying a significant new use but then only specifies a *time* limitation (e.g., 6 months, 12 months, 6 years), not a *volume* limitation. Including only a time limitation in the SNURs in subpart E while also citing 40 CFR 721.80(p) – which provides only for a volume limitation – creates confusion regarding the actual restriction applicable to the substance. If EPA’s intention is to impose a volume limitation, EPA should clearly identify the specific volume in the proposed SNUR. And if EPA wants to set a time limitation instead of or in addition to a volume limitation, EPA must spell that out in the proposed SNUR. For instance, in the past, EPA has set a limit at “any amount after [x date].” *See, e.g.*, 40 CFR 721.10522, 721.10527, and 721.10619. Regardless of the approach, EPA must ensure that the final SNURs capture all of the restrictions in the 5(e) Orders.

The commenter continues that EPA’s approach to specifying time limitations is made more confusing because the proposed SNURs fail to explain that the time limit originated and is specified in the Order, and more importantly fail to identify the trigger that starts the clock ticking toward the time limit. The proposed SNURs state that a significant new use is any use as described in 40 CFR 721.80(p), with a time period (e.g., six months) noted in parentheses but without any further

explanation. While the original PMN submitter may understand this in the context of its Order, the commenter states, any other company subject to the SNUR would not. Accordingly, EPA needs to specify, at a minimum, when the time period commences, which based on the Order is upon the PMN submitter's filing of a NOC. Even then, it is not clear how a second company would timely know that a NOC had been filed by the PMN submitter, thereby triggering the time period to start. It is also not clear how EPA would address a situation in which a SNUR is finalized preceding or otherwise in the absence of the filing of a NOC.

Second, the Order for P-16-0289 includes numerous time limitations on the manufacturing volume of the chemical substance, yet the corresponding proposed SNUR fails to include all but one of them. The proposed SNUR states that a significant new use is any use as described in 40 CFR 721.80(p), with "six months" in parentheses. In addition to the concern raised previously about the ambiguity of relying solely on a time limitation when EPA also intends to have a volume limitation, in this case the Order sets additional limitations *that are not included at all in the SNUR*. These include a prohibition on manufacturing unless the company "measures the particle size distribution to characterize the particle size distribution of fractions less than 10 microns of the dry particle PMN substance": (1) twice every twelve months *after* the six months is over, if there is commercial production, until a total of six tests are performed; and (2) if there are changes in the manufacturing process that could result in different particle sizes. Rather than rely solely on cross-referencing 40 CFR 721.80(p), EPA should spell out the restrictions from the Order in the proposed SNUR or cite to 40 CFR 721.80(k) and (q), which in turn cite to the restrictions set by the Order. Ultimately, whichever way EPA chooses to make this correction, EPA must make sure that the limits set by the final SNUR are clear, and fully conform to the limits in the Order.

Response: In response to this comment, in the final rule EPA presents the specific time restriction rather than cross-referencing §721.80(p). For all the SNURs cited, the time limits refer to the time

after – any manufacturer – begins manufacture of the PMN substance. Each manufacturer is permitted to manufacture up to the time limit identified in the SNUR from the time they begin manufacture. They are not required to base their time limit on the actions of other manufacturers or the notice of commencement. If that were the case some manufacturers could be required to notify EPA before they even begin manufacture. Therefore, EPA is removing the reference to §721.80(p) and clarifying that “It is a significant new use to manufacture for a period longer than *(time period cited in the underlying Order)*.” For those instances where there are multiple time limits in the Order, corresponding to multiple testing requirements, only the first limit will be included in the SNUR, because by the time of any SNUN submission, the Agency may possess new information that changes its initial data requirements and any new time limits would be the subject of EPA’s finding for the SNUN.

(d). Other Discrepancies between Orders and SNURs

Comment: The same commenter noted the following examples of other discrepancies between Orders and corresponding proposed SNURs with respect to the specification of significant new uses for industrial, commercial, and consumer activities:

For P-14-0630, the Order states that using the chemical substance in a consumer product that generates “vapor” is prohibited. The proposed SNUR does not include generation of vapor as a significant new use.

For P-16-0273-74, the Order states that the chemical substance can only be imported in totes. The proposed SNUR does not include that limitation.

For P-16-0495, the Order states that the chemical substance can only be used for a specific confidential use. The proposed SNUR sets no such limit. The SNUR should cite to 40 CFR 721.80(k) (“use other than allowed by the section 5(e) consent order”).

For P-17-0032, the Order includes a separate volume limit for *processing* the substance. The

SNUR only sets a volume limit for manufacture and import and not one for processing. EPA must include the processing limit in the SNUR.

Response: For the SNUR for P-16-495, the Agency has corrected the oversight in the proposed rule and the final SNUR for that chemical substance now cites 40 CFR 721.80(k). For the SNUR for P-17-32, the Agency agrees that there was an oversight in the proposed rule. The final SNUR for that chemical substance now also includes the statement “It is a significant new use to process the substance beyond the confidential annual volume cited in the 5(e) Order.” For the SNUR for P14-630 EPA has added generation of vapor in a consumer product as a significant new use because it is part of the Order but was inadvertently not included in the proposed rule. For the SNUR for P16-273 and 274 the Order erroneously references in the preamble a requirement to import the chemicals in totes. However, this is not a requirement of the Order. Therefore, EPA did not include that requirement for the final SNUR for P-16-273 and 274.

(e). Human Health, Environmental Hazard, Exposure, and Precautionary Statements:

Comment: One commenter noted inconsistencies between the hazard communication statements that would be required by the proposed SNURs and those required in the corresponding 5(e) Orders.

For P-14-0496, the SNUR is missing the “disposal restrictions apply” warning specified at 40 CFR 721.72(g)(4)(i). This warning is required by the underlying 5(e) Order for PMNs P14-0472 and P14-0496. For P-17-0272, the SNUR is missing the precautionary statement for developmental effects (40 CFR 721.72(g)(1)(vi)). This statement is required by the 5(e) Order for P-17-0272 through -0277.

Given that each of these precautionary statements is required by the corresponding Orders, they must be included in the final SNURs.

Response: This is an oversight and is corrected in the final SNURs for these substances.

Comment: The same commenter noted that for two of the proposed SNURs associated with the Order for P-17-33 through P-17140, the proposed SNURs are lacking a requirement for three hazards

statements: toxic to fish (40 CFR 721.72(g)(3)(i)), toxic to aquatic organisms (40 CFR 721.72(g)(3)(ii)), and disposal restrictions apply (40 CFR 721.72(g)(4)(i)). The two SNURs are for certain halogenated sodium benzoate salts, 40 CFR 721.11053, and certain halogenated sodium benzoic acids, 40 CFR 721.11054. Because the Order applies to multiple substances and redacts certain information (likely health and safety information not eligible for redaction under TSCA section 14), it is not possible for the public to know whether the hazard statements are or are not required for the chemicals subject to the SNURs noted above. EPA should ensure that there are no inconsistencies between the requirements of the SNURs and the Order for these chemicals.

Response: The hazard statements identified by the commenter only apply to the chemicals subject to the SNUR in 40 CFR 721.11055. Those hazard statements are not required in the Order for the chemicals subject to the SNUR in 40 CFR 721.11053 and 11054. EPA will finalize those requirements as proposed.

(f). Additional errors in the proposed SNURs.

Comment: For P-17-33 through P-17-140, there are three separate SNURs that cover the many chemicals covered by that one Order. One commenter noted that the SNUR for sodium benzoate salts states that a significant new use is any use other than those allowed in the Order, which is applicable to all of the substances P-17-33 through P-17-140 (to be codified at 40 CFR 721.11053(a)(2)(iii)) (citing 40 CFR 721.80(k)). This restriction, the commenter continues, is not specified in the other two SNURs (to be codified at 40 CFR 721.11054(a)(2)(iii), 721.11055(a)(2)(iii)), and EPA must fix this error and ensure that each proposed SNUR contains all of the restrictions governing the relevant chemicals that appear in the Order.

Response: The requirement cited in 40 CFR 11053(a)(2)(iii) for 40 CFR 721.80(k) was erroneously included in the proposed SNUR. The Order for P17-33 through P17-140 does not include a restriction on use. EPA has removed this requirement from the final SNUR.

Comment: Additionally, the commenter noted that P-16-352 had one Order covering two separate chemicals, with each having a proposed SNUR. The volume limitation set in the Order was for the substances combined. One commenter noted that both proposed SNURs contained errors. First, the combined volume limits set in §721.11039 are incorrect because it cites itself twice – “this substance and the substance subject to 721.11039” – instead of citing itself and the other PMN substance at § 721.11040. 83 FR at 37725. Second, § 721.11040 cites to an incorrect SNUR, “§ 721.9998,” for its combined volume limit, when it should cite to the other PMN substance at section 721.11039 *Id.* EPA must ensure that the combined volume limitations in the final SNURs are correct.

Response: EPA has corrected the cross-references in the final rule to the correct SNUR.

Chemical identity correction: SNUR for P-17-278 through P-17-280 (40 CFR 721.11058)

EPA has modified the generic chemical identity from “fatty acid amide alkyl amine salts” in the proposed rule to “fatty acid derived imidazoline salts” for the SNUR for P-17-278 through P-17-280 (40 CFR 721.11058), to agree with the generic name provided in the Notice of Commencement of Manufacture or Import (NOC) submitted for these PMN substances.

Comments specific to the proposed SNUR at 40 CFR 721.11027: Aluminum Cobalt Lithium Nickel Oxide (PMN P-15-0450; CASRN 177997-13-6).

Comment: Four entities commented on the SNUR for PMN P-15-450 (40 CFR 721.11027), aluminum cobalt lithium nickel oxide. One commenter suggested a different approach for control of air releases, rather than the proposed significant new use of any release of the chemical substance to air unless using the chemical transfer and air ventilation processes described in the PMN, including filtering through a high-efficiency particulate air filter with an efficiency rate of 99.99%. The commenter requested making the provision technology neutral instead, and exposure monitoring requirement more flexible (quarterly rather than monthly). The commenter states that there could be different processes to handle and transfer the PMN

substance, and control resulting air emissions, that will provide an equivalent or even improved level of control. For example, the commenter continued, there are control technologies that may have a removal efficiency rating of 99.99% that are not the high-efficiency particulate filters mentioned in the PMN. Therefore, a specific control technology does not need to be identified, but rather a specific rated efficiency (99.99%) or control target.

Response: The proposed SNUR provisions reflect the requirements of the underlying Order. In the proposed SNUR air releases are allowed only after the chemical transfer and air ventilation provisions described in the PMN which are not limited to but include HEPA filters that achieve 99.99% removal efficiency. This requirement remains in the final SNUR. The reason to include the lack of this control in the SNUR is to allow EPA to assess if other processes result in the same level of or lower air releases.

Comment: A commenter proposed a flexible monitoring schedule in lieu of mandatory monthly monitoring. The commenter noted that OSHA has addressed monitoring frequency to assess worker exposure. Section 6(b) of the OSHA Act gives OSHA authority to develop chemical specific standards. One such standard is 29 CFR 1910.1026 Chromium (VI). The OSHA Chromium (VI) workplace standard contains a flexible monitoring requirement based on results from initial monitoring. If initial monitoring indicates that employee exposures are below 50% (action level) of the determined limit, no further monitoring is required unless changes in the workplace result in new or additional exposures. If the initial determination reveals employee exposures to be at or above the action level, but below the determined limit, periodic monitoring must be performed at least every six months. If the initial monitoring reveals employee exposures to be above the determined limit, monitoring must be conducted at least every three months. Adjustments to the monitoring frequency are allowed based on monitoring results. The

preamble of the OSHA 1910.1026 Chromium (VI), P. 10341, states, “*OSHA believes that the frequency of six months for subsequent periodic monitoring for exposures at or above the action level but at or below the PEL, and three months for exposures above the PEL, provides intervals that are both practical for employers and protective for employees. This belief is supported by OSHA’s experience with comparable monitoring intervals in other standards, including those for cadmium (29 CFR 1910.1050), methylene chloride (29 CFR 1910.1052), and formaldehyde (29 CFR 1910.1048).*” Based on OSHA’s position given above, the commenter noted, it could be concluded that there are no benefits to worker protection in conducting monitoring more frequently than every 3 months, even when previous exposures exceeded exposure limits. The monthly monitoring is resource intensive and is likely to demonstrate the same results each month therefore providing minimal value. The commenter requested that EPA allow this periodic monitoring to occur on a quarterly basis, instead of monthly.

Response: Based on limited monitoring experience with the PMN substance, EPA believes monthly monitoring requirements as specified in the proposed SNUR are appropriate during the first year of manufacturing, processing, or use. After that time monitoring may be conducted quarterly if certain conditions are met. These are based on the requirements in the Order. Based on monitoring results EPA has received thus far for P-15-450, which have demonstrated monitoring results above and below the action level of 0.16 mg/m^3 identified in the Order, the final SNUR will retain the same requirements as required in the Order.

Comment: A commenter noted that 5(e) Orders on similar substances to that identified in P-15-450 allow metal reclamation disposal, whereas the Order for P-15-450 allows only landfill disposal.

Response: In response to the comment about allowing disposal by metal reclamation, the Agency

would need to review the specific metal reclamation disposal method to determine its acceptability to allow more flexibility in disposal methods. Because the underlying Order only allows disposal by landfill, the final rule only allows disposal by landfill.

Comment: One commenter pointed out that the reference to 40 CFR 721.63(a)(6) (referring to “particulate”) in this SNUR should be corrected to read “40 CFR 721.63(a)(6)(i)” (referring to “dust”).

Response: The proposed SNUR term 40 CFR 721.63(a)(6) (referencing “particulate”) reflects the requirement in the Order for P-15-450. Particulate allows for both liquid and solid particles which includes dust. The final rule retains the reference to particulate.

Comment 5: A commenter also requested that the SNUR not be finalized until a recently submitted 90-day inhalation toxicity study on the PMN substance is reviewed by EPA, as the testing could affect EPA’s underlying hazard concerns.

Response: The Agency has received and is currently reviewing the 90-day study data described by the commenter. Preliminary indications are that the results of the study would not change the Agency’s hazard concerns, or significantly alter the magnitude of the NCEL identified in the SNUR. It will take considerable time to determine if the study data will result in any changes for the Order and SNUR. EPA is issuing the final SNUR as proposed and will modify the Order and SNUR in the future based on the study data as appropriate.

Comment: Other comments to this proposed SNUR are that the references to “24 months” and “6 years” for production limits (40 CFR 721.80(p)) are unclear, and that the NCEL of 0.000092 mg/m³ as an 8-hour time weighted average doesn’t take into account OSHA PELs on the component metals.

Response: In response to the comment regarding the time-based production limits in the SNUR,

the time limits refer to the time after a manufacturer begins manufacture of the PMN substance. To exceed that time limit, a SNUN would need to be submitted and complete 90-day review by EPA. The NCEL for this chemical substance was established by EPA based on a 90-day inhalation study for a mixed metal oxide analogue. EPA's risk assessment for P-15-0450 in the public docket describes how the NCEL was calculated for the PMN substance based on the 90-day lowest observed adverse effect concentration (LOAEC). The analogue and data were identified by the submitter of P-15-450. As discussed in the previous comment and response EPA has received a 90-day inhalation study for P-15-450, that it is still reviewing and that confirms the potential hazard and a similar LOAEC. Based on the results of both studies EPA disagrees that OSHA PELs for the component metals should be used to estimate the potential effect levels of the PMN substance.

Comment: One commenter stated that the proposed SNUR for P-15-450 also would require monitoring and reporting for exposures to this chemical at an Occupational Exposure Limit (OEL) of 0.16 mg/m³ on an 8-hour TWA and is silent about how this should be sampled and measured.

Response: The SNUR references the terms of the Order that include parameters for how the monitoring should be sampled and measured. The submitter for P-15-450 has already submitted monitoring results required by the Order.

Comment: A commenter stated that the proposed NCEL presented no relief to the use of APF 1000 respirators, because there is currently no feasible monitoring method to reliably detect any constituent of the chemical mixture at that level of sensitivity.

Response: While the commenter is correct, persons manufacturing, processing, and using the chemical substance may eventually be able to develop such a detection method or develop

information that would increase the level of the NCEL that would allow a detection method to be developed.

Vertebrate Testing

Comment: A commenter noted that TSCA section 4(h)(3) states: “IN GENERAL. —Any person developing information for submission under this title on a voluntary basis and not pursuant to any request or requirement by the Administrator shall first attempt to develop the information by means of an alternative test method or strategy... before conducting new vertebrate animal testing.” The commenter continued that while EPA is not required to review the means by which these submitters conducted this voluntary testing, it is authorized to do so, and that reviewing compliance with this section is an opportunity to communicate TSCA’s requirement and EPA’s preference for alternatives to PMN submitters. Over time, the commenter states, this would lead submitters to consider such alternatives before conducting vertebrate animal tests. They requested that EPA review compliance with TSCA section 4(h)(3) whenever the results of vertebrate animal testing are included in PMNs.

Response: A request to review compliance with TSCA 4(h)(3) for PMNs and 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).

Ongoing Uses of SNUR chemicals.

Comment: One commenter stated there is reason to believe that some of the restrictions set forth

in the following SNURs conflict with ongoing uses: P-17-33, P-17-34, P-17-36, P-17-38, P-17-39, P-17-41, P-17-42, P-17-43, P-17-45, P-17-47, P-17-50, P-17-52, P-17-55, P-17-57, P-17-59, P-17-61, P-17-62, and P-17-63.

Response: EPA did not receive any further information to support this statement and therefore has finalized the SNURs as proposed.

V. Substances Subject to this Rule

EPA is establishing significant new use and recordkeeping requirements for 145 chemical substances in 40 CFR part 721, subpart E. In this unit, EPA provides the following information for each chemical substance:

- PMN number.
- Chemical name (generic name, if the specific name is claimed as CBI).
- Chemical Abstracts Service (CAS) Registry number (if assigned for non-confidential chemical identities).
- Basis for the TSCA section 5(e) consent order.
- 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 Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use designated by the SNUR. This information may include testing required in a TSCA section 5(e) Order to be conducted by the PMN submitter, as well as testing not required to be conducted but which would also help characterize the potential health and/or environmental effects of the PMN substance. Any recommendation for information identified by EPA was made based on EPA's consideration of available screening-level data, if any, as well as other available information on appropriate testing for the chemical substance. Further, any such testing

identified by EPA that includes testing on vertebrates was made after consideration of available toxicity information, computational toxicology and bioinformatics, and high-throughput screening methods and their prediction models. EPA also recognizes that whether testing/further information is needed will depend on the specific exposure and use scenario in the SNUN. EPA encourages all SNUN submitters to contact EPA to discuss any potential future testing. See Unit VIII. for more information.

- CFR citation assigned in the regulatory text section of 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 145 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 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 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 § 721.63 respirator requirements may request to do so under § 721.30. EPA expects that persons whose § 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.

PMN Numbers: P-14-472 and P-14-496

Chemical names: Polyphosphoric acids, 2-[alkyl-1-oxo-2-propen-1-yl]oxy]ethyl esters, compds. with N-(aminoiminomethyl)urea (generic) (P-14-472) and Polyphosphoric acids, 2-[(2-methyl-1-oxo-2-propen-1-yl)oxy]ethyl esters, compds. with alkyl amino, polymers with Bu acrylate, N-(hydroxymethyl)propenamide and styrene (generic) (P-14-496).

CAS numbers: Not available.

Effective date of TSCA section 5(e) Order: April 26, 2017.

Basis for TSCA section 5(e) Order: The PMN states that the generic (non-confidential) uses of the PMN substances are as a site-controlled intermediate (P-14-472) and a paper additive (P-14-496). Based on Structure Activity Relationship (SAR) analysis of test data on

acrylates/methacrylates, and other structurally similar substances, there is potential for irritation and sensitization for P-14-472. For P-14-496 there is concern for sensitization based on the presence of formaldehyde and concern for irritation and lung effects from the surfactant properties of the substance. Further, based on SAR analysis of test data on analogous phosphates, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 3 parts per billion (ppb) of P-14-472 and 4 ppb of P-14-496 in surface waters. The Order was issued under TSCA sections 5(a)(3)(B)(i) and 5(e)(1)(A)(i), based on a finding that the available information is insufficient to permit a reasoned evaluation of the human health effects of the PMN substances. Further, the Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that the substances may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

1. Submission of certain toxicity testing on the PMN substances prior to exceeding the confidential production volume limit as specified in the Order.
2. Use of personal protective equipment to prevent dermal exposure.
3. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the Safety Data Sheet (SDS).
4. No release of the PMN substances resulting in surface water concentrations that exceed 3 ppb for P-14-472 and 4 ppb for P-14-496.
5. No modification of the manufacturing process that results in inhalation exposure and no use involving application methods that generate a dust, mist, or aerosol.
6. Use of the PMN substances only as a site-limited intermediate (P-14-472) and the confidential use specified in the Order (P-14-496).

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

measures.

Potentially useful information: EPA has determined that certain information about the fate and human health toxicity of the PMN substances may be potentially useful to characterize the effects of the PMN substances in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. The submitter has agreed not to exceed the confidential production limit without performing a skin sensitization study and a biodegradation test on each substance. In addition, EPA has determined that the results of a pulmonary effects testing of the PMN substance may be potentially useful in characterizing the health effects of the PMN substances. Although the Order does not require this additional testing, the Order's restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other information that EPA determines is relevant and needed to evaluate a modification request.

CFR citations: 40 CFR 721.11024 (P-14-472) and 40 CFR 721.11025 (P-14-496).

PMN Number: P-14-630

Chemical name: Bismuth bromide iodide oxide.

CAS number: 340181-06-8.

Effective date of TSCA section 5(e) Order: May 10, 2017.

Basis for TSCA section 5(e) Order: The PMN states that the substance will be used as a pigment for liquid coatings solvent based system; a pigment for powder coatings; and a pigment for polymer materials. Based on test data and physical/chemical properties of the PMN substance, as well as SAR analysis of analogous respirable, poorly soluble particulates, EPA identified concerns for lung effects, including fibrosis. The Order was issued under TSCA sections

5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on insufficient information to make a reasoned evaluation and a finding that the substance may present an unreasonable risk of injury to human health. EPA assessed risks based on the specific manufacturing, processing, use, distribution/transportation, treatment and disposal processes, process equipment, engineering controls, and handling practices (including worker activities and cleaning procedures) described in the PMN. To protect against these risks, the Order requires:

1. Submission of certain toxicity testing on the PMN substance prior to exceeding the confidential production volume limit as specified in the Order.

2. Use of a National Institute for Occupational Safety and Health (NIOSH)-certified respirator with an Assigned Protection Factor (APF) of at least 10 (where there is a potential for inhalation exposures) or compliance with a New Chemical Exposure Limit (NCEL) of 2.4 milligram/meter³ (mg/m³) as an 8-hour time-weighted average.

3. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.

4. No use of the substance in a consumer product that generates a dust, mist, or aerosol. The SNUR will designate as a “significant new use” the absence of these protective measures

Potentially useful information: EPA has determined that certain information about the human health toxicity of the PMN substance may be potentially useful to characterize the effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. The submitter has agreed not to exceed the confidential production limit without performing specific target organ toxicity testing. In addition, EPA has determined that the results of a chronic toxicity/carcinogenicity test of the PMN substance may be

potentially useful in characterizing the health effects of the PMN substance. Although the Order does not require this additional testing, the Order's restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other information that EPA determines is relevant and needed to evaluate a modification request.

CFR citation: 40 CFR 721.11026.

PMN Number: P-15-450

Chemical name: Aluminum cobalt lithium nickel oxide.

CAS number: 177997-13-6.

Effective date of TSCA section 5(e) Order: March 23, 2017.

Basis for TSCA section 5(e) Order: The PMN states that the substance will be used as a mixed metal oxide for batteries. Based on test data on the PMN substance, EPA identified concerns for spleen and kidney toxicity. Based on physical/chemical properties of the PMN substance, as well as SAR analysis of analogous respirable, poorly soluble particulates, EPA identified concerns for lung effects based on lung overload. Based on the crystalline structure of the PMN substance, EPA identified concern for lung carcinogenicity. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on insufficient information to make a reasoned evaluation and a finding that the substance may present an unreasonable risk of injury to human health. EPA assessed risks based on the specific manufacturing, processing, use, distribution/transportation, treatment and disposal processes, process equipment, engineering controls, and handling practices (including worker activities and cleaning procedures) described in the PMN. To protect against these risks, the Order requires:

1. Submission of certain toxicity testing on the PMN substance prior to exceeding the

time limit as specified in the Order.

2. Use of personal protective equipment including impervious gloves and protective clothing (where there is a potential for dermal exposures).

3. Use of a NIOSH-certified respirator with an APF of at least 1,000 (where there is a potential for inhalation exposure) or compliance with a NCEL of 0.000092 ppm as an 8-hour time-weighted average.

4. Use of the chemical transfer processes and air ventilation processes described in the PMN and the exposure monitoring requirements described in the Order.

5. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.

6. Disposal of the PMN substance by landfill only. Air releases are limited by processes described in the PMN, including filtering through a high-efficiency particulate air filter with an efficiency rate of 99.99%.

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

Potentially useful information: EPA has determined that certain information about the human health toxicity of the PMN substance may be potentially useful to characterize the effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. The submitter has agreed not to exceed the time limit without performing specific target organ toxicity testing and carcinogenicity testing. In addition, EPA has determined that the results of medical monitoring of the workers exposed to the substance during manufacturing, processing, and use may be potentially useful in characterizing the health effects of the PMN substance. Although the Order does not require this medical monitoring, the Order’s

restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other information that EPA determines is relevant and needed to evaluate a modification request.

CFR citation: 40 CFR 721.11027.

PMN Number: P-15-705

Chemical name: Alkylarylamine (generic).

CAS number: Not available.

Effective date of TSCA section 5(e) Order: May 11, 2017.

Basis for TSCA section 5(e) Order: The PMN states that the substance will be used as a chemical intermediate and as an additive and octane booster in aviation fuels.

Based on test data on the PMN substance, EPA has identified concerns for dermal irritation, developmental toxicity, and blood effects. Based on test data on analogous anilines, EPA has identified concerns for cardiovascular, eye, liver, kidney, and pulmonary effects, as well as bladder cancer. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on insufficient information to make a reasoned evaluation and a finding that the substance may present an unreasonable risk of injury to human health. To protect against these risks, the Order requires:

1. Submission of certain toxicity testing on the PMN substance prior to exceeding the confidential production volume limit as specified in the Order.
2. Use of personal protective equipment including impervious gloves, full body chemical protective clothing and chemical goggles or equivalent eye protection (where there is a potential for dermal exposure).
3. Use of a NIOSH-certified respirator with an APF of at least 1,000 (where there is a

potential for inhalation exposure) or compliance with a NCEL of 0.48 mg/m³ as an 8-hour time-weighted average. (EPA's estimates indicate that variations of the parameters (including batch size, number of processing sites, days per year of operation) of the uses identified below would not result in inhalation exposure that would indicate a different respirator.)

4. No use of the substance in a consumer product.

5. No use other than as a chemical intermediate or as an additive and octane booster in aviation fuels.

6. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.

7. No release of the PMN substance resulting in surface water concentrations that exceed 1 ppb.

The SNUR will designate as a "significant new use" the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the human health and aquatic toxicity of the PMN substance may be potentially useful to characterize the effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. The submitter has agreed not to exceed the confidential production limit without performing specific target organ toxicity testing and a chronic aquatic toxicity test.

CFR citation: 40 CFR 721.11028.

PMN Numbers: P-15-706 and P-15-707

Chemical names: Aliphatic N-alkyl urea polymer containing cyclohexyl groups and trimethoxy silanes (generic) (P-15-706) and Aliphatic N-alkyl urea polymer containing aspartic ester groups

and trimethoxy silanes (generic) (P-15-707).

CAS numbers: Not available.

Effective date of TSCA section 5(e) Order: April 26, 2017.

Basis for TSCA section 5(e) Order: The PMNs state that the generic use of the substances will be as ingredients for multipurpose exterior coatings. Based on SAR analysis on reactive methoxy silane moieties, EPA has identified concerns for irritation to lungs, eyes, and mucus membranes. There are also concerns for acute toxicity, neurotoxicity, and developmental toxicity based on the presence of methanol, and for sensitization if there are residual isocyanates. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on insufficient information to make a reasoned evaluation and a finding that the substances may present an unreasonable risk of injury to human health. To protect against these risks, the Order requires:

1. Submission of certain toxicity testing on the PMN substance prior to exceeding the production limit as specified in the Order.
2. Use of personal protective equipment including impervious gloves (where there is a potential for dermal exposure).
3. Use of a NIOSH-certified respirator with an APF of at least 10 (where there is a potential for inhalation exposure) or compliance with a NCEL of 0.9 mg/m^3 as an 8-hour time-weighted average. (EPA's estimates indicate that variations of the parameters (including batch size, number of processing sites, days per year of operation) of the uses identified below would not result in inhalation exposure that would indicate a different respirator.)
4. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.
5. No manufacture beyond an annual production volume of 250,000 kilograms (kg).

6. Manufacture of the PMN substances to contain no more than 0.1 % residual isocyanate by weight.
7. No uses of the substances other than allowed in the Order.
8. No use of the substances in a consumer product.

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

Potentially useful information: EPA has determined that certain information about the human health toxicity of the PMN substances may be potentially useful to characterize the effects of the PMN substances in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. The submitter has agreed not to exceed the confidential production limit without performing specific target organ toxicity testing for P-15-706.

CFR citation: 40 CFR 721.11029 (P-15-706) and 40 CFR 721.11030 (P-15-707).

PMN Numbers: P-16-273 and P-16-274

Chemical names: Alkyl heteromonocycle, polymer with heteromonocycle, carboxyalkyl alkyl ethers (generic).

CAS numbers: Not available.

Effective date of TSCA section 5(e) Order: April 25, 2017.

Basis for TSCA section 5(e) Order: The PMNs state that the generic (non-confidential) use of the substances will be as ingredients in metalworking fluids. Based on submitted test data for P-16-273 and structurally similar surfactants, EPA has identified concerns for dermal sensitization and irritation and lung effects. Based on submitted toxicity data for P-16-273, EPA estimates toxicity to aquatic organisms may occur for both PMNs at concentrations that exceed 10 ppb of the PMN substances in surface waters. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and

5(e)(1)(A)(ii)(I), based on insufficient information to make a reasoned evaluation and a finding that the substances may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

1. No domestic manufacture of the PMN substances.
2. Use of the PMN substances only: (i) for the confidential uses specified in the Order, (ii) at a concentration no greater than 3% of the metalworking fluid, and (iii) used only in closed metalworking systems as specified in the PMNs with no modifications in the process that would result in worker inhalation exposure.
3. Use of personal protective equipment including impervious gloves (where there is a potential for dermal exposure).
4. No release of the PMN substances resulting in surface water concentrations that exceed 10 ppb.

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

Potentially useful information: EPA has determined that certain information about the fate and toxicity of the PMN substances may be potentially useful to characterize the health and environmental effects of the PMN substances in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of specific target organ toxicity testing and a biodegradation test of the PMN substances may be potentially useful in characterizing the health and environmental effects of the PMN substances.

Although the Order does not require these tests, the Order’s restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other information that EPA

determines is relevant and needed to evaluate a modification request.

CFR citation: 40 CFR 721.11031.

PMN Number: P-16-289

Chemical name: Benzene dicarboxylic acid, polymer with alkane dioic acid and aliphatic diamine (generic).

CAS number: Not available.

Effective date of TSCA section 5(e) Order: March 24, 2017.

Basis for TSCA section 5(e) Order: The PMN states the substance will be used as an extrusion compounding molding resin. Based on test data on analogous high molecular weight polymers, EPA has concerns for lung effects, which includes lung overload. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on insufficient information to make a reasoned evaluation and a finding that the substance may present an unreasonable risk of injury to human health. To protect against these risks, the Order requires:

1. Submission of particle size testing on the PMN substance prior to exceeding the time limit as specified in the Order.
2. Manufacture of the PMN substance such that the solid particle form has a particle size distribution where less than 1% of the particles are less than 10 microns.

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

Potentially useful information: EPA has determined that certain information about the physical/chemical characteristics of the PMN substance may be potentially useful to characterize the health effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. The submitter has agreed not to manufacture

beyond a certain time period without measuring the particle size distribution to characterize the fraction of the dry particle PMN substance less than 10 microns. In addition, EPA has determined that the results of specific target organ toxicity testing of the PMN substance may be potentially useful in characterizing the health effects of the PMN substance. Although the Order does not require this additional testing, the Order's restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other information that EPA determines is relevant and needed to evaluate a modification request.

CFR citation: 40 CFR 721.11032.

PMN Number: P-16-322

Chemical name: Manganese cyclic (tri)amine chloride complex (generic).

CAS number: Not available.

Effective date of TSCA section 5(e) Order: April 25, 2017.

Basis for TSCA section 5(e) Order: The PMN states that the generic (non-confidential) use of the substance will be as a pulp bleaching catalyst. Based on test data on an analog, EPA has identified concerns for kidney, blood, and thyroid effects, immunotoxicity, reproductive and developmental toxicity, and neurotoxicity. Based on test data on the PMN substance, EPA estimates that toxicity to aquatic organisms may occur at concentrations that exceed 18 ppb of the PMN substance in surface waters. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on insufficient information to make a reasoned evaluation and a finding that the substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

1. Submission of certain toxicity testing on the PMN substance prior to exceeding the

confidential production volume limit as specified in the Order.

2. Use of personal protective equipment to prevent dermal exposure (where there is a potential for dermal exposure).

3. Use of a NIOSH-certified respirator with an APF of at least 25 (where there is a potential for inhalation exposure) or compliance with a NCEL of 1.2 ppm as an 8-hour time-weighted average. (EPA's estimates indicate that variations of the parameters (including batch size, number of processing sites, days per year of operation) of the uses identified below would not result in inhalation exposure that would indicate a different respirator.)

4. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.

5. No domestic manufacture of the PMN substance.

6. Process and use of the PMN substance only for the confidential uses and formulation percentage specified in the Order.

7. No release of the PMN substance resulting in surface water concentrations that exceed 18 ppb.

The SNUR will designate as a "significant new use" the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the human health and aquatic toxicity of the PMN substance may be potentially useful to characterize the effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. The submitter has agreed not to exceed the confidential production limit without performing specific target organ toxicity testing, reproductive/developmental toxicity testing; and chronic aquatic toxicity testing.

CFR citation: 40 CFR 721.11033.

PMN Numbers: P-16-338, P-16-339, P-16-439, and P-16-440

Chemical names: Xanthylum, (sulfoaryl) - bis [(substituted aryl) amino]-, sulfo derivs., inner salts, metal salts (generic) (P-16-338); Substituted triazinyl metal salt, diazotized, coupled with substituted pyridobenzimidazolesulfonic acids, substituted pyridobenzimidazolesulfonic acids, diazotized substituted alkanesulfonic acid, diazotized substituted aromatic sulfonate, diazotized substituted aromatic sulfonate, metal salts (generic) (P-16-339); Carbon black, (organic acidic carbocyclic)-modified, inorganic salt (generic) (P-16-439); and Carbon black, (organic acidic carbocyclic)-modified, metal salt (generic) (P-16-440).

CAS numbers: Not available.

Effective date of TSCA section 5(e) Order: April 11, 2017.

Basis for TSCA section 5(e) Order: The PMN states that the generic (non-confidential) uses of the PMN substances will be as dyestuffs (P-16-0338 and P-16-0339) and as coloring agents (P-16-0439 and P-16-0440). Based on physical/chemical properties of the PMN substances and test data on analogous poorly respirable particles, EPA has identified concerns for irritation to the eyes, lungs, and mucous membranes, and lung effects. Further, based on SAR analysis of test data on analogous dyes, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 200 ppb of the PMN substances in surface waters. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on insufficient information to make a reasoned evaluation and a finding that the substances may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

1. No manufacture of the PMN substances beyond the confidential annual production volume specified in the Order.

2. No domestic manufacture of the PMN substances.

3. Import the PMN substances only according to the terms specified and for the confidential uses specified in the Order.

4. No release of the PMN substances to surface waters.

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

Potentially useful information: EPA has determined that certain information about the fate, human health toxicity, and aquatic toxicity of the PMN substances may be potentially useful to characterize the effects of the PMN substances in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of a biodegradation test, specific target organ toxicity testing, and acute and chronic aquatic toxicity testing of the PMN substances may be potentially useful in characterizing the health and environmental effects of the PMN substances. Although the Order does not require these tests, the Order’s restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other information that EPA determines is relevant and needed to evaluate a modification request.

CFR citations: 40 CFR 721.11034 (P-16-338), 40 CFR 721.11035 (P-16-339), 40 CFR 721.11036 (P-16-439), and 40 CFR 721.11037 (P-16-440).

PMN Number: P-16-350

Chemical name: Polyalkyl aryl ester of methacrylic acid (generic).

CAS number: Not available.

Effective date of TSCA section 5(e) Order: March 31, 2017.

Basis for TSCA section 5(e) Order: The PMN states that the generic (non-confidential) use of

the substance will be as a polymer reactant. Based on test data on methacrylate moieties, EPA has identified concerns for irritation and sensitization based on analogy to methacrylates. Based on SAR analysis of test data on structurally similar respirable surfactants, EPA has identified concerns for lung effects. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on insufficient information to make a reasoned evaluation and a finding that the substance may present an unreasonable risk of injury to human health. To protect against these risks, the Order requires:

1. Use of personal protective equipment including impervious gloves (where there is a potential for dermal exposure).
2. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.
3. Manufacture of the PMN substance such that it is not less than the minimum average molecular weight identified in the Order and does not contain more than the maximum weight percent of low molecular weight species below 1,000 Daltons.
4. Use of the PMN substance only for the confidential use specified in the Order.

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

Potentially useful information: EPA has determined that certain information about the toxicity of the PMN substance may be potentially useful to characterize the health effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of specific target organ toxicity testing and a sensitization test of the PMN substance may be potentially useful in characterizing the health effects of the PMN substance. Although the Order does not require these tests, the Order’s

restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other information that EPA determines is relevant and needed to evaluate a modification request.

CFR citation: 40 CFR 721.11038.

PMN Number: P-16-352

Chemical names: Phenol, 2-[[[3-(octyloxy)propyl]imino]methyl]- (P-16-352, chemical A) and Phenol, 2-[[[3-(decyloxy)propyl]imino]methyl]- (P-16-352, chemical B).

CAS numbers: 1858221-49-4 (P-16-352, chemical A) and 1858221-50-7 (P-16-352, chemical B).

Effective date of TSCA section 5(e) Order: April 21, 2017.

Basis for TSCA section 5(e) Order: The PMN states that the PMN substances will be used as co-catalysts in the manufacturing of release coatings for producing papers and films at a concentration of 1% or less. Based on SAR analysis of test data on analogous phenols, EPA has identified concerns for respiratory and dermal irritation and developmental toxicity. In addition, EPA has identified concerns for liver toxicity and reproductive effects based on the hydrolysis product o-hydroxybenzaldehyde. Further, based on SAR analysis of test data on analogous phenols, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PMN substances in surface waters. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on insufficient information to make a reasoned evaluation and a finding that the substances may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

1. Submission of certain toxicity testing on the PMN substance prior to exceeding the confidential production volume limit as specified in the Order.
2. Use of personal protective equipment including impervious gloves (where there is a

potential for dermal exposure).

3. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.

4. No domestic manufacture of the PMN substances.

5. No manufacture of the PMN substances beyond an annual production volume of 250 kg/yr.

6. No use of the PMN substances in application methods that generate a dust, mist, or aerosol.

7. No release of the PMN substance resulting in surface water concentrations that exceed 1 ppb.

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

Potentially useful information: EPA has determined that certain information about the human health and aquatic toxicity of the PMN substance may be potentially useful to characterize the effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. The submitter has agreed not to exceed the confidential production limit without performing specific target organ toxicity, reproductive/developmental toxicity, and acute aquatic toxicity testing.

CFR citations: 40 CFR 721.11039 (P-16-352, chemical A) and 40 CFR 721.11040 (P-16-352, chemical B).

PMN Number: P-16-358

Chemical name: Alkyl phenol (generic).

CAS number: Not available.

Effective date of TSCA section 5(e) Order: April 24, 2017.

Basis for TSCA section 5(e) Order: The PMN states that the substance will be used as a chemical intermediate. Based on SAR analysis of test data on analogous phenols, EPA has identified concerns for developmental toxicity. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on insufficient information to make a reasoned evaluation and a finding that the substance may present an unreasonable risk of injury to human health. To protect against these risks, the Order requires:

1. Submission of certain toxicity testing on the PMN substance prior to exceeding the confidential production volume limit as specified in the Order.
2. Use of personal protective equipment including impervious gloves (where there is a potential for dermal exposure).
3. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.
4. Use of the PMN substance only as a chemical intermediate.
5. No manufacture, process, or use of the PMN substance in any manner or method that generates a dust, mist, or aerosol or in a non-enclosed process.
6. No release of the PMN substance to surface waters.

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

Potentially useful information: EPA has determined that certain information about the human health toxicity of the PMN substance may be potentially useful to characterize the effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use will be designated by this SNUR. The submitter has agreed not to exceed the confidential production

limit without performing specific target organ toxicity and reproductive/developmental toxicity tests.

CFR citation: 40 CFR 721.11041.

PMN Number: P-16-364

Chemical name: Nitrile-butadiene-acrylate terpolymers (generic).

CAS number: Not available.

Effective date of TSCA section 5(e) Order: March 31, 2017

Basis for TSCA section 5(e) Order: The PMN states that the generic (non-confidential) use of the substance will be as a chemical intermediate. Based on SAR analysis of test data on structurally similar respirable particles, EPA has identified concerns for lung effects, including lung overload. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on insufficient information to make a reasoned evaluation and a finding that the substance may present an unreasonable risk of injury to human health. To protect against these risks, the Order requires:

1. Use of the PMN substance only as a site-limited chemical intermediate.
2. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.
3. No manufacture, process, or use of the PMN substance if it contains more than 5% of the particle size distribution less than 10 microns.

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

Potentially useful information: EPA has determined that certain information about the toxicity of the PMN substance may be potentially useful to characterize the effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or

processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of specific target organ toxicity testing of the PMN substance may be potentially useful in characterizing the health effects of the PMN substance. Although the Order does not require this test, the Order's restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other information that EPA determines is relevant and needed to evaluate a modification request.

CFR citation: 40 CFR 721.11042.

PMN Number: P-16-399

Chemical name: Starch, polymer with 2-propenoic acid, potassium salt, oxidized.

CAS number: 1638117-09-5.

Effective date of TSCA section 5(e) Order: April 6, 2017.

Basis for TSCA section 5(e) Order: The PMN states that the substance will be used as an agricultural soil amendment for field crops, agricultural soil amendment for turf applications and direct soil injection with fertilizers, and a compound to be used in preparation of advanced seed coatings. Based on SAR analysis of test data on structurally similar respirable particles, EPA has identified concerns for lung effects, including lung overload. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on insufficient information to make a reasoned evaluation and a finding that the substance may present an unreasonable risk of injury to human health. The Order was also issued under TSCA sections 5(a)(3)(B)(ii)(II) and 5(e)(1)(A)(ii)(II), based on a finding that the substance that the substance is or will be produced in substantial quantities and that the substance either enters or may reasonably be anticipated to enter the environment in substantial quantities, or there is or may be significant (or substantial)

human exposure to the substance. To protect against these risks, the Order requires:

1. Submission of certain toxicity testing on the PMN substance prior to exceeding the time limit as specified in the Order.
2. Use of personal protective equipment including impervious gloves (where there is a potential for dermal exposure).
3. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.
4. Manufacture of the substance with a particulate size greater than 30 microns.

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

Potentially useful information: EPA has determined that certain information about the toxicity of the PMN substance may be potentially useful to characterize the health and environmental effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. The submitter has agreed not to manufacture beyond a certain time limit without performing an acute aquatic toxicity test. In addition, EPA has determined that the results of specific target organ toxicity testing of the PMN substance may be potentially useful in characterizing the health effects of the PMN substance. Although the Order does not require this additional testing, the Order’s restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other information that EPA determines is relevant and needed to evaluate a modification request.

CFR citation: 40 CFR 721.11043.

PMN Number: P-16-430

Chemical name: Pentanedioic acid, 2-methyl-

CAS number: 617-62-9.

Effective date of TSCA section 5(e) Order: May 17, 2017.

Basis for TSCA section 5(e) Order: The PMN states the generic (non-confidential) use of the substance will be as a filler. Based on test data on the PMN substance, EPA has identified concerns for systemic and reproductive toxicity. Based on structural analysis on the acid groups and test data, EPA has identified concerns for dermal and respiratory irritation. Further, based on test data on the PMN substance and test data on analogous neutral organics, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 14 ppb of the PMN substance in surface waters. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on insufficient information to make a reasoned evaluation and a finding that the substance may present an unreasonable risk of injury to human health and the environment. EPA assessed risks based on the specific processing, use, distribution/transportation, treatment and disposal processes, process equipment, engineering controls, and handling practices (including worker activities and cleaning procedures) described in the PMN. To protect against these risks, the Order requires:

1. Use of personal protective equipment including impervious gloves (where there is a potential for dermal exposure).
2. Use of a NIOSH-certified respirator with an APF of at least 10 (where there is a potential for inhalation exposure). (EPA's estimates indicate that variations of the parameters (including batch size, number of processing sites, days per year of operation) of the uses identified below would not result in inhalation exposure that would indicate a different respirator.)

3. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.

4. No domestic manufacture of the PMN substance.

5. Import of the PMN substance at or below the maximum concentration specified in the Order.

6. No release of the PMN substance resulting in surface water concentrations that exceed 14 ppb.

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

Potentially useful information: EPA has determined that certain information about the human health toxicity of the PMN substance may be potentially useful to characterize the effects of the substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of specific target organ toxicity testing of the PMN substance may be potentially useful in characterizing the health effects of the PMN substance. Although the Order does not require this test, the Order’s restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other information.

CFR citation: 40 CFR 721.11044.

PMN Number: P-16-495

Chemical name: 2-Pentanol, 4-methyl-, reaction products with phosphorus oxide (P₂O₅), compounds with alkylamine (generic).

CAS number: Not available.

Effective date of TSCA section 5(e) Order: April 25, 2017.

Basis for TSCA section 5(e) Order: The PMN states that the generic use (non-confidential) of the substance will be as a lubricant additive. Based on test data on the substance, EPA has identified concerns for systemic effects, sensitization and irritation to the eyes and skin. Based on physical/chemical properties, EPA has concerns for lung effects, including lung surfactancy. Further, based on test data on analogous aliphatic amines for the cation and neutral organics for the anion as well as test data on the PMN substance, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 200 ppb of the PMN substance in surface waters. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on insufficient information to make a reasoned evaluation and a finding that the substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

1. Submission of certain toxicity testing on the PMN substance prior to exceeding the confidential production volume limit as specified in the Order.
2. Use of personal protective equipment (where there is a potential for dermal exposure).
3. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.
4. No manufacture in any manner or method that results in inhalation exposure.
5. No use of the PMN substance in an application method that generates a vapor, mist, or aerosol.
6. No release of the PMN substance resulting in surface water concentrations that exceed 200 ppb.

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

Potentially useful information: EPA has determined that certain information about the human

health and aquatic toxicity of the PMN substance may be potentially useful to characterize the effects of the PMN substance effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. The submitter has agreed not to exceed the confidential production limit without performing chronic aquatic toxicity tests. In addition, EPA has determined that the results of specific target organ toxicity testing of the PMN substance may be potentially useful in characterizing the health effects of the PMN substance. Although the Order does not require this additional testing, the Order's restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other information that EPA determines is relevant and needed to evaluate a modification request.

CFR citation: 40 CFR 721.11045.

PMN Number: P-16-513

Chemical name: Hydroxy alkylbiphenyl (generic).

CAS number: Not available.

Effective date of TSCA section 5(e) Order: May 2, 2017.

Basis for TSCA section 5(e) Order: The PMN states that the substance will be used as a chemical intermediate. Based on test data on an analog, EPA has identified concerns for developmental toxicity, systemic toxicity, blood effects, and corrosion of the skin, eyes, and mucous membranes. Further, based on SAR analysis of test data on analogous amides, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 17 ppb of the PMN substances in surface waters. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on insufficient information to make a reasoned evaluation and a finding

that the substances may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

1. Submission of certain toxicity testing on the PMN substance prior to exceeding the confidential production volume limit as specified in the Order.
2. Use of personal protective equipment (where there is a potential for dermal exposure).
3. Use of a NIOSH-certified respirator with an APF of at least 50 (where there is a potential for inhalation exposure). (EPA's estimates indicate that variations of the parameters (including batch size, number of processing sites, days per year of operation) of the uses identified below would not result in inhalation exposure that would indicate a different respirator.)
4. Use of the PMN substance only as a chemical intermediate.
5. No release of the PMN substance resulting in surface water concentrations that exceed 17 ppb.

The SNUR will designate as a "significant new use" the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the human health and aquatic toxicity of the PMN substance may be potentially useful to characterize the effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. The submitter has agreed not to exceed the confidential production limit without performing specific target organ toxicity and reproductive/developmental toxicity testing. In addition, EPA has determined that the results of acute aquatic toxicity tests may be potentially useful in characterizing the environmental effects of the PMN substance. Although the Order does not require these additional tests, the Order's

restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other information that EPA determines is relevant and needed to evaluate a modification request.

CFR citation: 40 CFR 721.11046.

PMN Numbers: P-16-534, P-16-535, and P-16-536

Chemical names: Alkyl alkenoic acid, polymer with alkenylcarbomonocycle telomer with substituted alkanolic acid hydroxyl alkyl substituted alkenyl substituted alkyl ester, polyalkylene glycol alkyl ether alkyl alkenoate, dialkylene glycol diheteromonocyclic ether and alkylcarbomonocyclic alkenoate, metal salt (generic) (P-16-534); Alkyl alkenoic acid, polymer with alkenylcarbomonocycle telomer with substituted alkanolic acid hydroxyl alkyl substituted alkenyl substituted alkyl ester, alkanediol diheteromonocyclic ether, polyalkylene glycol alkyl ether alkyl alkenoate and alkylcarbomonocyclic alkenoate, metal salt (generic) (P-16-535); and Alkyl alkenoic acid, polymer with bis heteromonocyclic substituted alkyl carbomonocycle, alkenylcarbomonocycle telomer with substituted alkanolic acid hydroxyl alkyl substituted alkenyl substituted alkyl ester, polyalkylene glycol alkyl ether alkyl alkenoate and alkylcarbomonocyclic alkenoate, metal salt (generic) (P-16-536).

CAS numbers: Not available.

Effective date of TSCA section 5(e) Order: April 4, 2017.

Basis for TSCA section 5(e) Order: The PMN states that the generic (non-confidential) use of the substances will be a component of ink. Based on test data on structurally similar respirable particles, EPA has identified concerns for lung effects if inhaled, based on lung overload. In addition, EPA has identified ecotoxicity concerns for the substances if made with an acid component exceeding 20% of the molecular weight due potential for increased absorption and

solubility. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on insufficient information to make a reasoned evaluation and a finding that the substances may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

1. Manufacture of the PMN substances such that the minimum average molecular weight is 1,800 daltons and the carboxylic acid content does not exceed 20%.

2. No domestic manufacture of the PMN substances.

3. Process or use of the PMN substances only for the use specified in the Order.

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

Potentially useful information: EPA has determined that certain information about the human health and aquatic toxicity of the PMN substances may be potentially useful to characterize the effects of the substances in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of specific target organ toxicity testing and an acute aquatic toxicity test of the PMN substances may be potentially useful in characterizing the health and environmental effects of the PMN substances. Although the Order does not require these tests, the Order’s restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other information that EPA determines is relevant and needed to evaluate a modification request.

CFR citations: 40 CFR 721.11047 (P-16-534), 40 CFR 721.11048 (P-16-535), and 40 CFR 721.11049 (P-16-536).

PMN Numbers: P-16-549, P-16-550, P-16-551, P-16-553, P-16-555, P-16-556, P-16-557, P-16-

558, P-16-560, P-16-561, P-16-562, P-16-563, P-16-564, P-16-565, and P-16-567

Chemical names: Alkaline functionalized methacrylate-substituted polymer (generic) (P-16-549, P-16-550, and P-16-551); Quaternary alkylamine functionalized methacrylate-substituted polymer (generic) (P-16-553); Neutral alcohol functionalized methacrylate-substituted polymer (generic) (P-16-555 and P-16-556); Neutral alkyl salt functionalized methacrylate-substituted polymer (generic) (P-16-557, P-16-558, and P-16-560); Acid functionalized methacrylate-substituted polymer (generic) (P-16-561, P-16-562, P-16-563, P-16-564, and P-16-565); and Alkylamine functionalized methacrylate-substituted polymer (generic) (P-16-567).

CAS numbers: Not available.

Effective date of TSCA section 5(e) Order: May 2, 2017.

Basis for TSCA section 5(e) Order: The PMN states the substances will be used as crosslinked resins for chromatographic separation of biomolecules and biocatalysts. Based on test data on structurally similar respirable particles, EPA has identified concerns for lung effects, including lung overload. EPA has also identified irritation concerns for skin and eyes. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on insufficient information to make a reasoned evaluation and a finding that the substances may present an unreasonable risk of injury to human health. To protect against these risks, the Order requires:

1. Use of personal protective equipment including impervious gloves (where there is a potential for dermal exposure).
2. Manufacture of the PMN substances only in the physical form of spherical beads and with less than 0.1% below a particle size of 10 microns.
3. No domestic manufacture of the PMN substances.
4. Process or use of the PMN substances only for the uses specified in the Order.

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

Potentially useful information: EPA has determined that certain information about the human health toxicity of the PMN substances may be potentially useful to characterize the effects of the substances in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of specific target organ toxicity testing of the PMN substances may be potentially useful in characterizing the health effects of the PMN substances. Although the Order does not require this testing, the Order’s restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other information that EPA determines is relevant and needed to evaluate a modification request.

CFR citations: 40 CFR 721.11050.

PMN Number: P-16-579

Chemical name: Waste plastics, poly(ethylene terephthalate), depolymd. with polypropylene glycol ether with glycerol (3:1), polymers with alkenoic and alkanolic acids (generic).

CAS number: Not available.

Effective date of TSCA section 5(e) Order: March 13, 2017.

Basis for TSCA section 5(e) Order: The PMN states that the substance will be used as an ultraviolet curable coating resin. Based on test data on similar structural moieties, EPA has identified concerns for dermal and respiratory sensitization and irritation of mucous membranes. In addition, EPA has identified human health and environmental concerns for the substance if made with lower molecular weight due potential for increased absorption and solubility. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on

insufficient information to make a reasoned evaluation and a finding that the substances may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

1. Use of personal protective equipment including gloves and protective clothing (where there is a potential for dermal exposure).
2. Use of a NIOSH-certified full-face respirator with an APF of at least 50 (where there is a potential for inhalation exposure). (EPA's estimates indicate that variations of the parameters (including batch size, number of processing sites, days per year of operation) of the uses identified below would not result in inhalation exposure that would indicate a different respirator.)
3. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.
4. No manufacture of the PMN substance with an average molecular weight less than 1,100 Daltons.
5. Use of the PMN substance only as an ultraviolet curable coating resin.

The SNUR will designate as a "significant new use" the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the physical-chemical properties and human health and aquatic toxicity of the PMN substance may be potentially useful to characterize the effects of the substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that measurement of certain physical-chemical properties, the results of specific target organ toxicity, reproductive/developmental toxicity, sensitization, and acute and chronic aquatic toxicity testing

may be potentially useful in characterizing the health and environmental effects of the PMN substances. Although the Order does not require these tests, the Order's restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other information that EPA determines is relevant and needed to evaluate a modification request.

CFR citation: 40 CFR 721.11051.

PMN Number: P-17-32

Chemical name: 1,3,5-Naphthalenetrisulfonic acid.

CAS number: 6654-64-4.

Effective date of TSCA section 5(e) Order: March 22, 2017.

Basis for TSCA section 5(e) Order: The PMN states that the generic (non-confidential) use of the substance is for monitoring of oil/gas well performance. Based on test data on an analog and physical/chemical properties of the PMN substance, EPA has identified concerns for dermal and respiratory irritation, developmental toxicity, and blood effects. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on insufficient information to make a reasoned evaluation and a finding that the substance may present an unreasonable risk of injury to human health. To protect against these risks, the Order requires:

1. Submission of certain toxicity testing on the PMN substance prior to exceeding the confidential production volume limit as specified in the Order.
2. Use of personal protective equipment including NIOSH-approved respirator (APF 50) and impervious gloves (where there is a potential for inhalation or dermal exposure). (EPA's estimates indicate that variations of the parameters (including batch size, number of processing sites, days per year of operation) of the uses identified below would not result in inhalation

exposure that would indicate a different respirator.)

3. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.

4. No manufacture or processing of the PMN substance beyond a confidential annual production volume specified in the Order.

5. No manufacture, processing, or use using application methods that intentionally generate a vapor, mist or aerosol.

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

Potentially useful information: EPA has determined that certain information about the human health toxicity of the PMN substance may be potentially useful to characterize the effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. The submitter has agreed not to exceed the confidential production limit without performing specific target organ toxicity and developmental toxicity testing.

CFR citation: 40 CFR 721.11052.

PMN Numbers: P-17-33, P-17-34, P-17-36, P-17-38, P-17-39, P-17-41, P-17-42, P-17-43, P-17-45, P-17-47, P-17-50, P-17-52, P-17-55, P-17-57, P-17-59, P-17-61, P-17-62, P-17-63, P-17-64, P-17-66, P-17-67, P-17-69, P-17-71, P-17-72, P-17-73, P-17-75, P-17-76, P-17-79, P-17-80, P-17-83, P-17-85, P-17-87, P-17-90, P-17-91, P-17-93.

Chemical names and CAS Numbers:

Chemical Name	CAS Number
Benzoic acid, 2-fluoro-, sodium salt (1:1) (P-17-33)	6654-64-4
Benzoic acid, 4-fluoro-, sodium salt (1:1) (P-17-34)	499-90-1
Benzoic acid, 2,3,4,5-tetrafluoro-, sodium salt (1:1) (P-17-36)	67852-79-3
Benzoic acid, 2-(trifluoromethyl)-, sodium salt (1:1) (P-17-38)	2966-44-1
Benzoic acid, 4-(trifluoromethyl)-, sodium salt (1:1) (P-17-39)	25832-58-0

Benzoic acid, 2,5-difluoro-, sodium salt (1:1) (P-17-41)	522651-42-9
Benzoic acid, 3-fluoro-, sodium salt (1:1) (P-17-42)	499-57-0
Benzoic acid, 2,6-difluoro-, sodium salt (1:1) (P-17-43)	6185-28-0
Benzoic acid, 3,5-difluoro-, sodium salt (1:1) (P-17-45)	530141-39-0
Benzoic acid, 2,4-difluoro-, sodium salt (1:1) (P-17-47)	1765-08-8
Benzoic acid, 3,4-difluoro-, sodium salt (1:1) (P-17-50)	522651-44-1
Benzoic acid, 3,4,5-trifluoro-, sodium salt (1:1) (P-17-52)	1180493-12-2
Benzoic acid, 2,3,4-trifluoro-, sodium salt (1:1) (P-17-55)	402955-41-3
Benzoic acid, 2,4,5-trifluoro-, sodium salt (1:1) (P-17-57)	522651-48-5
Benzoic acid, 2,3-difluoro-, sodium salt (1:1) (P-17-59)	1604819-08-0
Benzoic acid, 3-(trifluoromethyl)-, sodium salt (1:1) (P-17-61)	69226-41-1
Benzoic acid, 2-chloro-, sodium salt (1:1) (P-17-62)	17264-74-3
Benzoic acid, 4-chloro-, sodium salt (1:1) (P-17-63)	3686-66-6
Benzoic acid, 3-chloro-, sodium salt (1:1) (P-17-64)	17264-88-9
Benzoic acid, 2,3-dichloro-, sodium salt (1:1) (P-17-66)	118537-84-1
Benzoic acid, 2,5-dichloro-, sodium salt (1:1) (P-17-67)	63891-98-5
Benzoic acid, 3,5-dichloro-, sodium salt (1:1) (P-17-69)	154862-40-5
Benzoic acid, 2,6-dichloro-, sodium salt (1:1) (P-17-71)	10007-84-8
Benzoic acid, 3,4-dichloro-, sodium salt (1:1) (P-17-72)	17274-10-1
Benzoic acid, 2,4-dichloro-, sodium salt (1:1) (P-17-73)	38402-11-8
Benzoic acid, 2-chloro-4-fluoro-, sodium salt (P-17-75)	855471-43-1
Benzoic acid, 3-chloro-4-fluoro-, sodium salt (P-17-76)	1421761-18-3
Benzoic acid, 5-chloro-2-fluoro-, sodium salt (P-17-79)	1382106-78-6
Benzoic acid, 4-chloro-3-fluoro-, sodium salt (P-17-80)	1421029-88-0
Benzoic acid, 4-chloro-2-fluoro-, sodium salt (P-17-83)	1382106-64-0
Benzoic acid, 5-bromo-2-chloro-, sodium salt (P-17-85)	1938142-12-1
Benzoic acid, 3-bromo-4-fluoro-, sodium salt (P-17-87)	938142-13-2
Benzoic acid, 2-bromo-5-fluoro-, sodium salt (P-17-90)	1938142-14-3
Benzoic acid, 4-bromo-2-fluoro-, sodium salt (P-17-91)	1938142-15-4
Benzoic acid, 4-bromo-3-fluoro-, sodium salt (P-17-93)	1535169-81-3

Effective date of TSCA section 5(e) Order: March 22, 2017.

Basis for TSCA section 5(e) Order: The PMNs state that the generic (non-confidential) use of the substances are for monitoring of oil/gas well performance. Based on test data on an analog, EPA has identified concerns for reproductive, developmental and neuro-toxicity, as well as lung toxicity and dermal irritation. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on insufficient information to make a reasoned evaluation and a finding that the substances may present an unreasonable risk of injury to human health. EPA assessed

risks based on the specific manufacturing, processing, use, process equipment, engineering controls, and handling practices (including worker activities and cleaning procedures) described in the PMN. To protect against these risks, the Order requires:

1. Submission of certain toxicity testing on the PMN substances prior to exceeding the production volume limit as specified in the Order.

2. Use of personal protective equipment including impervious gloves (where there is a potential for dermal exposure).

3. Use of a NIOSH-certified respirator with an APF of at least 50 (where there is a potential for inhalation exposure) or compliance with a NCEL of 0.0184 ppm as an 8-hour time-weighted average.

4. Use of processes, process equipment, engineering controls, and handling practices specified in the Order for manufacturing and processing.

5. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.

6. No manufacture or process of the PMN substances beyond a confidential annual production volume specified in the Order.

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

Potentially useful information: EPA has determined that certain information about the human health toxicity of the PMN substances may be potentially useful to characterize the effects of the PMN substances in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. The submitter has agreed not to exceed the confidential production limit without performing specific target organ toxicity testing on P-17-0091.

CFR citations: 40 CFR 721.11053.

PMN Numbers: P-17-35, P-17-37, P-17-40, P-17-44, P-17-46, P-17-48, P-17-51, P-17-53, P-17-54, P-17-56, P-17-58, P-17-60, P-17-65, P-17-68, P-17-70, P-17-74, P-17-77, P-17-78, P-17-81, P-17-82, P-17-84, P-17-88, P-17-89, P-17-92, P-17-97.

Chemical names and CAS Numbers:

Chemical Name	CAS Number
Benzoic acid, 2,3,4,5-tetrafluoro- (P-17-35)	1201-31-6
Benzoic acid, 2-(trifluoromethyl)- (P-17-37)	433-97-6
Benzoic acid, 2,5-difluoro- (P-17-40)	2991-28-8
Benzoic acid, 2,6-difluoro- (P-17-44)	385-00-2
Benzoic acid, 3,5-difluoro- (P-17-46)	455-40-3
Benzoic acid, 2,4-difluoro- (P-17-48)	1583-58-0
Benzoic acid, 3,4-difluoro- (P-17-51)	455-86-7
Benzoic acid, 3,4,5-trifluoro- (P-17-53)	121602-93-5
Benzoic acid, 2,3,4-trifluoro- (P-17-54)	61079-72-9
Benzoic acid, 2,4,5-trifluoro- (P-17-56)	446-17-3
Benzoic acid, 2,3-difluoro- (P-17-58)	4519-39-5
Benzoic acid, 3-(trifluoromethyl)- (P-17-60)	454-92-2
Benzoic acid, 2,3-dichloro-(P-17-65)	50-45-3
Benzoic acid, 3,5-dichloro- (P-17-68)	51-36-5
Benzoic acid, 2,6-dichloro-(P-17-70)	50-30-6
Benzoic acid, 2-chloro-4-fluoro- (P-17-74)	2252-51-9
Benzoic acid, 5-chloro-2-fluoro- (P-17-77)	394-30-9
Benzoic acid, 3-chloro-4-fluoro- (P-17-78)	403-16-7
Benzoic acid, 4-chloro-3-fluoro- (P-17-81)	403-17-8
Benzoic acid, 4-chloro-2-fluoro- (P-17-82)	446-30-0
Benzoic acid, 5-bromo-2-chloro- (P-17-84)	21739-92-4
Benzoic acid, 3-bromo-4-fluoro- (P-17-88)	11007-16-5
Benzoic acid, 2-bromo-5-fluoro- (P-17-89)	394-28-5
Benzoic acid, 4-bromo-3-fluoro- (P-17-92)	153556-42-4
Benzoic acid, 4-bromo-2-fluoro- (P-17-97)	112704-79-7

Effective date of TSCA section 5(e) Order: March 22, 2017.

Basis for TSCA section 5(e) Order: The PMNs state that the generic (non-confidential) use of the substances are for monitoring of oil/gas well performance. Based on test data on an analog, EPA has identified concerns for reproductive, developmental and neuro-toxicity, as well as lung toxicity and dermal irritation. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and

5(e)(1)(A)(ii)(I), based on insufficient information to make a reasoned evaluation and a finding that the substances may present an unreasonable risk of injury to human health. EPA assessed risks based on the specific manufacturing, processing, use, process equipment, engineering controls, and handling practices (including worker activities and cleaning procedures) described in the PMN. To protect against these risks, the Order requires:

1. Submission of certain toxicity testing on the PMN substances prior to exceeding the production volume limit as specified in the Order.

2. Use of personal protective equipment including impervious gloves (where there is a potential for dermal exposure).

3. Use of a NIOSH-certified respirator with an APF of at least 50 (where there is a potential for inhalation exposure) or compliance with a NCEL of 0.0184 ppm as an 8-hour time-weighted average to prevent inhalation exposure.

4. Use of processes, process equipment, engineering controls, and handling practices specified in the Order for manufacturing and processing.

5. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.

6. No manufacture or process of the PMN substances beyond a confidential annual production volume specified in the Order.

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

Potentially useful information: EPA has determined that certain information about the human health toxicity of the PMN substances may be potentially useful to characterize the effects of the PMN substances in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will

be designated by this SNUR. The submitter has agreed not to exceed the confidential production limit without performing specific target organ toxicity and reproductive/developmental toxicity testing on both P-17-35 and P-17-37.

CFR citations: 40 CFR 721.11054.

PMN Numbers: P-17-94, P-17-95, P-17-96, P-17-98, P-17-99, P-17-100, P-17-101, P-17-102, P-17-103, P-17-104, P-17-105, P-17-114, P-17-122, P-17-123, P-17-124, P-17-125, P-17-126, P-17-127, P-17-128, P-17-129, P-17-130, P-17-131, P-17-132, P-17-133, P-17-134, P-17-135, P-17-136, P-17-137, P-17-138, P-17-139, and P-17-140.

Chemical names and CAS Numbers:

Chemical Name	CAS Number
Benzoic acid, 2,3,4,5-tetrafluoro-, ethyl ester (P-17-94)	122894-73-9
Benzoic acid, 4-(trifluoromethyl)-, ethyl ester (P-17-95)	583-02-8
Benzoic acid, 2-(trifluoromethyl)-, ethyl ester (P-17-96)	577-62-8
Benzoic acid, 2,6-difluoro-, ethyl ester (P-17-98)	19064-14-3
Benzoic acid, 2,5-difluoro-, ethyl ester (P-17-99)	708-25-8
Benzoic acid, 2,3,4-trifluoro-, ethyl ester (P-17-100)	351354-50-2
Benzoic acid, 2-bromo-5-fluoro-, ethyl ester (P-17-101)	351354-50-2
Benzoic acid, 3,5-difluoro-, ethyl ester (P-17-102)	350-19-6
Benzoic acid, 5-bromo-2-chloro-, ethyl ester (P-17-103)	76008-73-6
Benzoic acid, 3-chloro-, ethyl ester (P-17-104)	1128-76-3
Benzoic acid, 2-chloro-, ethyl ester (P-17-105)	7335-25-3
Benzoic acid, 3-chloro-4-fluoro-, ethyl ester (P-17-114)	137521-81-4
Benzoic acid, 4-bromo-2-fluoro-, ethyl ester (P-17-122)	474709-71-2
Benzoic acid, 2-bromo-4,5-difluoro-, ethyl ester (P-17-123)	144267-97-0
Benzoic acid, 4-bromo-3-fluoro-, ethyl ester (P-17-124)	1130165-74-0
Benzoic acid, 3-bromo-4-fluoro-, ethyl ester (P-17-125)	23233-33-2
Benzoic acid, 4-chloro-2-fluoro-, ethyl ester (P-17-126)	4793-20-8
Benzoic acid, 2,5-dichloro-, ethyl ester (P-17-127)	35112-27-7
Benzoic acid, 4-chloro-3-fluoro-, ethyl ester (P-17-128)	203573-08-4
Benzoic acid, 2-chloro-4-fluoro-, ethyl ester (P-17-129)	167758-87-4
Benzoic acid, 5-chloro-2-fluoro-, ethyl ester (P-17-130)	773139-56-3
Benzoic acid, 2,4-difluoro-, ethyl ester (P-17-131)	108928-00-3
Benzoic acid, 3,4-difluoro-, ethyl ester (P-17-132)	144267-96-9
Benzoic acid, 3,4,5-trifluoro-, ethyl ester (P-17-133)	495405-09-9
Benzoic acid, 2,4,5-trifluoro-, ethyl ester (P-17-134)	351354-41-1
Benzoic acid, 3-(trifluoromethyl)-, ethyl ester (P-17-135)	76783-59-0

Benzoic acid, 2,3-difluoro-, ethyl ester (P-17-136)	773134-65-9
Benzoic acid, 2,6-dichloro-, ethyl ester (P-17-137)	81055-73-4
Benzoic acid, 3,5-dichloro-, ethyl ester (P-17-138)	91085-56-2
Benzoic acid, 2,4-dichloro-, ethyl ester (P-17-139)	56882-52-1
Benzoic acid, 3,4-dichloro-, ethyl ester (P-17-140)	28394-58-3

Effective date of TSCA section 5(e) Order: March 22, 2017.

Basis for TSCA section 5(e) Order: The PMNs state that the substances are for monitoring oil/gas well performance. Based on test data on an analog, EPA has identified concerns for reproductive, developmental and neuro-toxicity, as well as lung toxicity and dermal irritation. Further, based on SAR analysis of test data on analogous neutral organics, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 15 ppb of the PMN substances in surface waters. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on insufficient information to make a reasoned evaluation and a finding that the substances may present an unreasonable risk of injury to human health and the environment. EPA assessed risks based on the specific manufacturing, processing, use, process equipment, engineering controls, and handling practices (including worker activities and cleaning procedures) described in the PMNs. To protect against these risks, the Order requires:

1. Submission of certain toxicity testing on the PMN substances prior to exceeding the production volume limit as specified in the Order.
2. Use of personal protective equipment including impervious gloves (where there is a potential for dermal exposure).
3. Use of a NIOSH-certified respirator with an APF of at least 1,000 (where there is a potential for inhalation exposure) or compliance with a NCEL of 0.0184 ppm as an 8-hour time-weighted average.
4. Use of processes, process equipment, engineering controls, and handling practices

specified in the Order for manufacturing and processing.

5. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.

6. No manufacture or process of the PMN substances beyond a confidential annual production volume specified in the Order.

7. No release of the PMN substances resulting in surface water concentrations that exceed 15 ppb.

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

Potentially useful information: EPA has determined that certain information about the human health and aquatic toxicity of the PMN substances may be potentially useful to characterize the effects of the PMN substances in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. The submitter has agreed not to exceed the confidential production limit without performing specific target organ toxicity and reproductive/developmental toxicity testing on P-17-127; specific target organ toxicity testing on P-17-101; and acute aquatic toxicity testing on both P-17-101 and P-17-127.

CFR citations: 40 CFR 721.11055.

PMN Number: P-17-198

Chemical name: Neodymium aluminium alkyl polymer complexes (generic).

CAS number: Not available.

Effective date of TSCA section 5(e) Order: April 27, 2017.

Basis for TSCA section 5(e) Order: The PMN states the generic (non-confidential) use of the substance will be as a catalyst in a closed process. Based on physical/chemical properties of the

substance and test data on the PMN substance, EPA has identified concerns for dermal and respiratory irritation, corrosion, developmental toxicity, and lung effects. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on insufficient information to make a reasoned evaluation and a finding that the substance may present an unreasonable risk of injury to human health. To protect against these risks, the Order requires:

1. Submission of glove permeation testing on the PMN substance prior to exceeding the production volume limit as specified in the Order.

2. Use of personal protective equipment including impervious gloves (where there is a potential for dermal exposure).

3. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.

4. No domestic manufacture of the PMN substance.

5. No use in any manner or method where there is potential for inhalation exposure.

6. Use of the PMN substance in a closed system as specified in the PMN.

The SNUR will designate as a “significant new use” the absence of these protective measure.

Potentially useful information: EPA has determined that the results of glove permeability testing will help characterize the effectiveness of protective measures to mitigate human health risk of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. The submitter has agreed not to manufacture beyond a certain time period without performing glove permeability testing.

CFR citation: 40 CFR 721.11056.

PMN Numbers: P-17-272, P-17-273, P-17-274, P-17-275, P-17-276 and P-17-277

Chemical name: Fatty acid amide alkyl amine salts (generic).

CAS numbers: Not available.

Effective date of TSCA section 5(e) Order: August 4, 2017.

Basis for TSCA section 5(e) Order: The PMNs state that the generic (non-confidential) use of the substances will be as a component in asphalt emulsion. Based on SAR analysis of test data on analogous substances, EPA has identified concerns for dermal and respiratory irritation, corrosion, developmental toxicity, systemic effect, sensitization and lung effects. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on insufficient information to make a reasoned evaluation and a finding that the substances may present an unreasonable risk of injury to human health and environment. To protect against these risks, the Order requires:

1. Use of the PMN substances only for the use specified in the Order.
2. Use of personal protective equipment for workers exposed dermally to the PMN substances (including impervious gloves, chemical goggles or equivalent eye protection and clothing which covers any other exposed areas of the arms and torso).
3. No modification of the manufacture, process or use of the PMN substances if it results in inhalation exposure to vapor, dust, mist or aerosol.
4. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.
5. No release of the PMN substances into the waters of the United States.

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

Potentially useful information: EPA has determined that certain information about the human health and aquatic toxicity of the PMN substances may be potentially useful to characterize the

effects of the PMN substances in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of specific target organ toxicity testing of the PMN substances, and acute and chronic aquatic toxicity testing of the PMN substances may be potentially useful in characterizing the health and environmental effects of the PMN substances. Although the Order does not require these tests, the Order's restrictions on manufacture, processing and distribution in commerce, will remain in effect until the Order is modified or revoked by EPA based on submission of this or other information that EPA determines is relevant and needed to evaluate a modification request.

CFR citations: 40 CFR 721.11057.

PMN Numbers: P-17-278, P-17-279 and P-17-280

Chemical name: Fatty acid derived imidazoline salts (generic).

CAS numbers: Not available.

Effective date of TSCA section 5(e) Order: August 4, 2017.

Basis for TSCA section 5(e) Order: The PMNs state that the generic (non-confidential) use of the substances will be as a component in asphalt emulsion. Based on SAR analysis of test data on analogous substances, EPA has identified concerns for irritation, corrosion, developmental toxicity, systemic effect, sensitization and lung effects. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on insufficient information to make a reasoned evaluation and a finding that the substances may present an unreasonable risk of injury to human health and environment. To protect against these risks, the Order requires:

1. Use of the PMN substances only for the use specified in the Order.
2. Use of personal protective equipment for workers exposed dermally to the PMN

substances (including impervious gloves, chemical goggles or equivalent eye protection and clothing which covers any other exposed areas of the arms and torso).

3. No modification of the manufacture, process or use of the PMN substances if it results in inhalation exposure to vapor, dust, mist or aerosol.

4. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.

5. No release of the PMN substances into the waters of the United States.

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

Potentially useful information: EPA has determined that certain information about the human health and aquatic toxicity of the PMN substances may be potentially useful to characterize the effects of the PMN substances in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of specific target organ toxicity testing and acute and chronic aquatic toxicity testing of the PMN substances may be potentially useful in characterizing the health and environmental effects of the PMN substances. Although the Order does not require these tests, the Order’s restrictions on manufacture, processing and distribution in commerce will remain in effect until the Order is modified or revoked by EPA based on submission of this or other information that EPA determines is relevant and needed to evaluate a modification request.

CFR citations: 40 CFR 721.11058.

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 145 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.

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 regards to the significant new uses designated in this rule:

- EPA will receive notice of any person's intent to manufacture or process a listed chemical substance for the described significant new use before that activity begins.
- EPA will have an opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing or processing a listed chemical substance for the described significant new use.
- EPA will 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.
- EPA will identify as significant new uses any manufacturing, processing, use, distribution in commerce, or disposal that does not conform to the restrictions imposed by the underlying Orders, consistent with TSCA section 5(f)(4).

Issuance of a SNUR for a chemical substance does not signify that the chemical substance is listed on the TSCA Chemical Substance Inventory (TSCA Inventory). Guidance on

how to determine if a chemical substance is on the TSCA Inventory is available on the Internet at <http://www.epa.gov/opptintr/existingchemicals/pubs/tscainventory/index.html>.

VII. Applicability of the Significant New Use Designation

To establish a significant new use, EPA must determine that the use is not ongoing. The chemical substances subject to this rule have undergone premanufacture review. In cases where EPA has not received a notice of commencement (NOC) and the chemical substance has not been added to the TSCA Inventory, no person may commence such activities without first submitting a PMN. Therefore, for chemical substances for which a 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) consent orders have been issued for all the chemical substances, and the PMN submitters are prohibited by the TSCA section 5(e) consent orders from undertaking activities which will be designated as significant new uses. The identities of 38 of the 145 chemical substances subject to this rule have been claimed as confidential and EPA has received one post-PMN *bona fide* submission (per §§ 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.

EPA designated August 1, 2018 (the date of public release of the proposed rule) as the cutoff date for determining whether the new use is ongoing. The objective of EPA's approach has been to ensure that a person could not defeat a SNUR by initiating a significant new use before the effective date of the final rule.

In the unlikely event that a person began commercial manufacture or processing of the chemical substances for a significant new use identified as of August 1, 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. lists potentially useful information for all SNURs listed here. Descriptions of this information is provided for informational purposes. The potentially useful information identified in Unit IV. will be useful to EPA's evaluation in the event that someone submits a SNUN for the significant new use. Companies who are considering submitting a SNUN are encouraged, but not required, to develop the information on the substance, which may assist with EPA's analysis of the SNUN.

EPA strongly encourages persons, before performing any testing, to consult with the Agency pertaining to protocol selection. Furthermore, pursuant to TSCA section 4(h), which pertains to reduction of testing in vertebrate animals, EPA encourages consultation with the Agency on the use of alternative test methods and strategies (also called New Approach Methodologies, or NAMs), if available, to generate the recommended test data. EPA encourages dialog with Agency representatives to help determine how best the submitter can meet both the data needs and the objective of TSCA section 4(h).

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. Under recent TSCA section 5(e) Orders, each PMN submitter is required to submit each study at least 14 weeks (earlier TSCA section 5(e) Orders required submissions at least 12 weeks) before reaching the specified production limit. 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 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 § 721.1725(b)(1).

Under these procedures a manufacturer or processor may request EPA to determine whether a proposed use would be a significant new use under the rule. The manufacturer or processor must show that it has a *bona fide* intent to manufacture or process the chemical

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

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

X. SNUN Submissions

According to § 721.1(c), persons submitting a SNUN must comply with the same notification requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in 40 CFR 720.50. SNUNs must be submitted on EPA Form No. 7710-25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in 40 CFR 720.40 and 721.25. E-PMN software is available electronically at <http://www.epa.gov/opptintr/newchems>.

XI. Economic Analysis

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

XII. Statutory and Executive Order Reviews

A. Executive Order 12866

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

B. Paperwork Reduction Act (PRA)

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

comment to amend it is unnecessary. As a result, EPA finds that there is “good cause” under section 553(b)(3)(B) of the Administrative Procedure Act (5 U.S.C. 553(b)(3)(B)) to amend this table without further notice and comment.

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

Send any comments about the accuracy of the burden estimate, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques, to the Director, 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 section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency hereby certifies that promulgation of this SNUR 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

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

F. Executive Order 13175

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

G. Executive Order 13045

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

H. Executive Order 13211

This action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply, distribution, or use and

because this action is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

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

J. Executive Order 12898

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

XIII. Congressional Review Act

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

List of Subjects

40 CFR Part 9

Environmental protection, Reporting and recordkeeping requirements.

40 CFR Part 721

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

Dated: July 18, 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 §§ 721.11024 through 721.11028 and 721.11031 through 721.11058 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	
* * * * *	* * * * *
721.11024	2070-0012
721.11025	2070-0012
721.11026	2070-0012
721.11027	2070-0012
721.11028	2070-0012
721.11031	2070-0012
721.11032	2070-0012
721.11033	2070-0012
721.11034	2070-0012
721.11035	2070-0012
721.11036	2070-0012
721.11037	2070-0012
721.11038	2070-0012
721.11039	2070-0012

721.11040	2070-0012					
721.11041	2070-0012					
721.11042	2070-0012					
721.11043	2070-0012					
721.11044	2070-0012					
721.11045	2070-0012					
721.11046	2070-0012					
721.11047	2070-0012					
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721.11055	2070-0012					
721.11056	2070-0012					
721.11057	2070-0012					
721.11058	2070-0012					
*	*	*	*	*	*	*

* * * * *

PART 721--[AMENDED]

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

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

4. Add § 721.11024 to subpart E to read as follows:

§ 721.11024 Polyphosphoric acids, 2-[alkyl-1-oxo-2-propen-1-yl]oxy]ethyl esters, compds. with N-(aminoiminomethyl)urea (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as polyphosphoric acids, 2-[alkyl-1-oxo-2-propen-1-yl]oxy]ethyl esters, compds. with N-(aminoiminomethyl)urea (PMN P-14-472) 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), (3), and (6)

(particulate) and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1)(i) and (ii), (sensitization), (g)(2)(i) and (v), (g)(3)(i) and (ii), (g)(4)(i), 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.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(h), (q), and (y)(1). It is a significant new use to have manufacturing activities that result in inhalation exposure.

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where N=3.

(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.

5. Add § 721.11025 to subpart E to read as follows:

§ 721.11025 Polyphosphoric acids, 2-[(2-methyl-1-oxo-2-propen-1-yl)oxy]ethyl esters, compds. with alkyl amino, polymers with Bu acrylate, N-(hydroxymethyl)propenamide and styrene (generic).

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

substance identified generically as polyphosphoric acids, 2-[(2-methyl-1-oxo-2-propen-1-yl)oxy]ethyl esters, compds. with alkyl amino, polymers with Bu acrylate, N-(hydroxymethyl)propanamide and styrene (PMN P-14-496) 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), (3), and (6) (particulate) and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1)(i) and (ii), (sensitization), (g)(2)(i) and (v), (g)(3)(i) and (ii), (g)(4)(i), 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.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k), (q), and (y)(1). It is a significant new use to have manufacturing activities that result in inhalation exposure.

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

(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.

6. Add § 721.11026 to subpart E to read as follows:

§ 721.11026 Bismuth bromide iodide oxide.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as bismuth bromide iodide oxide (PMN P-14-630, CAS No. 340181-06-8) 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)(4), when determining which persons are reasonably likely to be exposed as required for §721.63(a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (a)(5) (respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 10), (a)(6) (particulate), (a)(6)(v) and (vi), (b)(concentration set at 1.0%), 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 2.4 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 at 1.0%), (f), (g)(1)(ii), (g)(2)(ii), (use respiratory protection or maintain workplace airborne concentrations at or below an 8-hour time-weighted average of 2.4 mg/m³), 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.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(q). It is a significant new use to vary or alter, the manufacturing, processing, and use, distribution/transportation, treatment and disposal processes, process equipment, engineering controls, and handling practices (including worker activities and cleaning procedures) described in the PMN in such a way as to change the magnitude of inhalation exposure. It is a significant new use to use the substance for a consumer product that generates a dust, vapor, mist, or aerosol.

(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 (d) and (f) 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.

7. Add § 721.11027 to subpart E to read as follows:

§ 721.11027 Aluminum cobalt lithium nickel oxide.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as aluminum cobalt lithium nickel oxide (PMN P-15-450, CAS No. 177997-13-6) 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), (3), and (4), when determining which persons are reasonably likely to be exposed as required for §721.63(a)(1) and (4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (a)(5) (respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 1,000), (a)(6) (particulate), (a)(6)(v) and (vi), (b) (concentration set at 0.1%), and (c). It is a significant new use to manufacture or process the substance without the chemical transfer processes and air ventilation processes described in the PMN and the exposure monitoring requirements described in the corresponding TSCA section 5(e) Order.

(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 0.000092 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 0.1%), (f), (g)(1)(ii), (this substance may cause damage to the lung, kidney, and spleen), (g)(1)(vii), (g)(2)(i), (ii), and (iii), (when using this substance wear protective gloves/protective clothing/eye protection/face protection), the following human health precautionary statement must appear on the SDS as specified in § 721.72(c): (When using this substance use respiratory protection or maintain workplace airborne concentrations at or below an 8-hour time-weighted average of 0.000092 mg/m³), (g)(2)(v), 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.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80 It is a significant new use to manufacture the substance for a period longer than 24 months.

(iv) *Disposal.* Requirements as specified in § 721.85(a)(2), (b)(2), and (c)(2). It is a significant new use to release this chemical substance to air unless using the chemical transfer and air ventilation processes described in P-15-0450 including filtering through a high-efficiency particulate air filter with an efficiency rate of 99.99% before release to air.

(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 (j) 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 § 721.11028 to subpart E to read as follows:

§ 721.11028 Alkylarylamine (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as alkylarylamine (PMN P-15-705) 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), and (iii), (a)(3) and (4), when determining which persons are reasonably likely to be exposed as required for §721.63(a)(1) and (4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (a)(5) (respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 1,000), (a)(6) (particulate), (a)(6)(v), (vi), (v), and (vi), (b)(concentration set at 0.1%), 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 0.48 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 at 0.1%), (f), (g)(1)(i), (ii), (iv), (vi), (vii), and (ix), (g)(2)(i), (ii), and (iii), (use respiratory protection or maintain workplace airborne concentrations at or below an 8-hour time-weighted average of 0.48 mg/m³), (g)(2)(v), (g)(3)(ii), (g)(4)(i), 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.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o) and (q). It is a significant new use to use the substance other than as a chemical intermediate or as an additive and octane booster in aviation fuels.

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

9. Add § 721.11029 to subpart E to read as follows:

§ 721.11029 Aliphatic N-alkyl urea polymer containing cyclohexyl groups and trimethoxy

silanes (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as aliphatic N-alkyl urea polymer containing cyclohexyl groups and trimethoxy silanes (PMN P-15-706) 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), (iii), and (iv), (a)(3) and (4), when determining which persons are reasonably likely to be exposed as required for §721.63(a)(1) and (4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (a)(5)(respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 10), (a)(6)(particulate), (a)(6)(v) and (vi), (b)(concentration set at 1.0%), 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 at 1.0%), (f), (g)(1)(ii) and (ix), (g)(2)(i), (ii), and (iii), (use respiratory protection or maintain workplace airborne concentrations at or below an 8-hour time-weighted average of 0.9 mg/m³), (g)(2)(v), 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.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k), (o), (p) (594,000 kilograms, P-15-706 and P-15-707 combined), and (t) (250,000 kilograms, P-15-706 and P-15-707 combined). A significant new use is any manufacture, processing, or use of the PMN substance with more than 0.1% residual isocyanate by weight.

(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 § 721.11030 to subpart E to read as follows:

§ 721.11030 Aliphatic N-alkyl urea polymer containing aspartic ester groups and trimethoxy silanes (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as aliphatic N-alkyl urea polymer containing aspartic ester

groups and trimethoxy silanes (PMN P-15-707) 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), (iii), and (iv), (a)(3) and (4), when determining which persons are reasonably likely to be exposed as required for §721.63(a)(1) and (4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (a)(5) (respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 10), (a)(6)(i), (v), and (vi), (b) (concentration set at 1.0%), 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 at 1.0%), (f), (g)(1)(ii) and (ix), (g)(2)(i), (ii), and (iii), (use respiratory protection or maintain workplace airborne concentrations at or below an 8-hour time-weighted

average of 0.9 mg/m³), (g)(2)(v), 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.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k), (o), (p) (594,000 kilograms, P-15-706 and P-15-707 combined), and (t)(250,000 kilograms, P-15-706 and P-15-707 combined). A significant new use is any manufacture, processing, or use of the PMN substance with more than 1% residual isocyanate by weight.

(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.

11. Add § 721.11031 to subpart E to read as follows:

§ 721.11031 Alkyl heteromonocycle, polymer with heteromonocycle, carboxyalkyl alkyl ether (generic).

(a) *Chemical substances and significant new uses subject to reporting.* (1) The chemical substances identified generically as alkyl heteromonocycle, polymer with heteromonocycle, carboxyalkyl alkyl ether (PMNs P-16-273 and P-16-0274) are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i) and (iii), (a)(3), (b) (concentration set at 1.0%), and (c). 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.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e) (concentration set at 1.0%), (f), (g)(1)(i) and (ii), (dermal sensitization), (g)(2)(i), (ii), (iii), and (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 (GHS) and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f). It is a significant new use to use the substances for the uses specified in the TSCA 5(e) Order, at a concentration greater than 3% of the metal working fluid and use other than the closed metal working systems as specified in the PMNs with no modifications in the process that would result in worker inhalation exposure.

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where N=10.

(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.

12. Add § 721.11032 to subpart E to read as follows:

§ 721.11032 Benzene dicarboxylic acid, polymer with alkane dioic acid and aliphatic diamine (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as generically as benzene dicarboxylic acid, polymer with alkane dioic acid and aliphatic diamine (PMN P-16-289) 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) (manufacture only in a form with a particle size distribution where less than 1.0 percent of the particles are less than 10 microns). It is a significant new use to manufacture the substance for a period longer than six months.

(ii) [Reserved]

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

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

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

13. Add § 721.11033 to subpart E to read as follows:

§ 721.11033 Manganese cyclic (tri)amine chloride complex (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as manganese cyclic (tri)amine chloride complex (PMN P-16-322) 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), (3), and (4), when determining which persons are reasonably likely to be exposed as required for §721.63(a)(1) and (4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (a)(5)(respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 25), (a)(6) (particulate), (a)(6)(v) and (vi), (b)(concentration set at 1.0 %), 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 1.2 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 at 1.0%), (f), (g)(1)(iv), (vi), (viii), and (ix), (g)(2)(i), (ii), and (iii), (use respiratory protection or maintain workplace airborne concentrations at or below an 8-hour time-weighted average of 1.2 mg/m³), (g)(2)(v), (g)(3) (this substance may be toxic to algae. This substance may be harmful to invertebrates), (g)(4)(i) and (ii), (do not release to water to yield surface water concentrations above 18 ppb.), 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.

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

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where N=18.

(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.

14. Add § 721.11034 to subpart E to read as follows:

§ 721.11034 Xanthylum, (sulfoaryl) - bis [(substituted aryl) amino]-, sulfo derivs., inner salts, metal salts (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as xanthylium, (sulfoaryl) - bis [(substituted aryl) amino]-, sulfo derivs., inner salts, metal salts (PMN P-16-338) 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), (k), and (t).

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

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

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

15. Add § 721.11035 to subpart E to read as follows:

§ 721.11035 Substituted triazinyl metal salt, diazotized, coupled with substituted pyridobenzimidazolesulfonic acids, substituted pyridobenzimidazolesulfonic acids, diazotized substituted alkanesulfonic acid, diazotized substituted aromatic sulfonate, diazotized substituted aromatic sulfonate, metal salts (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as substituted triazinyl metal salt, diazotized, coupled with

substituted pyridobenzimidazolesulfonic acids, substituted pyridobenzimidazolesulfonic acids, diazotized substituted alkanesulfonic acid, diazotized substituted aromatic sulfonate, diazotized substituted aromatic sulfonate, metal salts (PMN P-16-339) 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), (k), and (t).

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

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

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

16. Add § 721.11036 to subpart E to read as follows:

§ 721.11036 Carbon black, (organic acidic carbocyclic)-modified, inorganic salt (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as carbon black, (organic acidic carbocyclic)-modified, inorganic salt (PMN P-16-439) 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), (k), and (t).

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

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

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

17. Add § 721.11037 to subpart E to read as follows:

§ 721.11037 Carbon black, (organic acidic carbocyclic)-modified, metal salt (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as carbon black, (organic acidic carbocyclic)-modified, metal salt (PMN P-16-440) 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), (k), and (t).

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

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

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

18. Add § 721.11038 to subpart E to read as follows:

§ 721.11038 Polyalkyl aryl ester of methacrylic acid (generic).

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified as generically as polyalkyl aryl ester of methacrylic acid (PMN P-16-350) 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, and (c).

(ii) *Hazard communication*. Requirements as specified in § 721.72(a) through (d), (f), (g)(1)(i) and (ii), (sensitization), (mutagenicity), (g)(2)(i), (ii), (iii), and (v), 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.

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

721.80(k). It is a significant new use to manufacture the substance lower than the minimum average molecular weight identified in the corresponding TSCA section 5(e) Order and to contain more than the maximum weight percent of low molecular weight species below 1,000 daltons identified in the Order.

(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.

19. Add § 721.11039 to subpart E to read as follows:

§ 721.11039 Phenol, 2-[[[3-(octyloxy)propyl]imino]methyl]-.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as phenol, 2-[[[3-(octyloxy)propyl]imino]methyl]- (PMN P-16-352, chemical A; CAS No. 1858221-49-4) 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)(6) (particulate), (a)(6)(v) and (vi), (b) (concentration set at 1.0%), and (c). 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.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e) (concentration set at 1.0%), (f), (g)(1)(i), (iv), (vi), and (ix), (g)(2)(i) and (v), (g)(3)(i) and (ii), 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.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f), (p)(10,500 and 13,000 kilograms, respectively, for the total of this substance and the substance subject to § 721.11040), (t)(250 kilograms for the total of this substance and the substance subject to § 721.11040), and (y)(1).

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

20. Add § 721.11040 to subpart E to read as follows:

§ 721.11040 Phenol, 2-[[[3-(decyloxy)propyl]imino]methyl]-.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as phenol, 2-[[[3-(decyloxy)propyl]imino]methyl]- (PMN P-16-352, chemical B; CAS No. 1858221-50-7) 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)(6) (particulate), (a)(6)(v) and (vi), (b) (concentration set at 1.0%), and (c). 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.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e) (concentration set at 1.0%), (f), (g)(1)(i), (iv), (vi), and (ix), (g)(2)(i) and (v), (g)(3)(i) and (ii), 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.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f), (p) (10,500 and 13,000 kilograms respectively for the total of this substance and the substance subject to § 721.11039), (t) (250 kilograms for the total of this substance and the substance subject to § 721.11039), and (y)(1).

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

21. Add § 721.11041 to subpart E to read as follows:

§ 721.11041 Alkyl phenol (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as alkyl phenol (PMN P-16-358) 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), (iii), and (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, (b)(concentration set at 1.0%), and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e) (concentration set at 1.0%), (f), (g)(1)(ix), (g)(2)(i), (ii), (iii), and (v), (g)(4)(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.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(a) through (c), (g), (q), and (y)(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) 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 § 721.11042 to subpart E to read as follows:

§ 721.11042 Nitrile-butadiene-acrylate terpolymers (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as nitrile-butadiene-acrylate terpolymers PMN P-16-364) 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)(concentration set at 1.0%), (f), (g)(1)(ii), (g)(2)(ii), 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(h), (k) (manufacture of the substance with a particle size distribution where greater than 5.0 percent of the particles are less than 10 microns).

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

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

23. Add § 721.11043 to subpart E to read as follows:

§ 721.11043 Starch, polymer with 2-propenoic acid, potassium salt, oxidized.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as starch, polymer with 2-propenoic acid, potassium salt, oxidized (PMN P-16-399, CAS No. 1638117-09-5) 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)(6) (particulate), (a)(6)(v) and (vi), 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 at 1.0%), and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (d), (e)(concentration set 1.0%), (f), (g)(1)(ii), (g)(2)(ii), 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.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k) (manufacture of the substance with a particulate size less than 30 microns). It is a significant new use to manufacture the substance for a period longer than 12 months.

(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 (d) and (f) 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.

24. Add § 721.11044 to subpart E to read as follows:

§ 721.11044 Pentanedioic acid, 2-methyl-

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified as pentanedioic acid, 2-methyl- (PMN P-16-430, CAS No. 617-62-9) 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) and (4), when determining which persons are reasonably likely to be exposed as required for §721.63(a)(1) and (4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (a)(5)(respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 10), (a)(6) (particulate), (a)(6)(v) and (vi), (b) (concentration set at 1.0%), and (c).

(ii) *Hazard communication*. Requirements as specified in § 721.72(a) through (e) (concentration set at 1.0%), (f), (g)(1)(i), (ii), and (vi), (g)(2)(i), (ii), (iii), (iv), and (v), (g)(3)(i) and (ii), (g)(4)(i), 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.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f) and (k)(import of the substance at or below the maximum concentration specified in the corresponding TSCA section 5(e) Order).

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where N=14.

(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.

25. Add § 721.11045 to subpart E to read as follows:

§ 721.11045 2-Pentanol, 4-methyl-, reaction products with phosphorus oxide (P2O5), compounds with alkylamine (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as generically as 2-pentanol, 4-methyl-, reaction products with phosphorus oxide (P2O5), compounds with alkylamine (PMN P-16-495) 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) and (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), (b) (concentration set at 1.0%), and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e) (concentration set at 1.0%), (f), (g)(1)(i), (ii), and (iv), (g)(2)(i), (ii), and (v), (g)(3)(i) and (ii), (g)(4)(i), 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.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k), (q), and (y)(1). A significant new use is any manner or method of manufacturing that results in inhalation exposure.

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where $N=200$.

(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.

26. Add § 721.11046 to subpart E to read as follows:

§ 721.11046 Hydroxy alkylbiphenyl (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as hydroxy alkylbiphenyl (PMN P-16-513) 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), (3), and (4), when determining which persons are reasonably likely to be exposed as required for §721.63(a)(1) and (4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (a)(5) (respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 50), (a)(6) (particulate), (a)(6)(v) and (vi), (b) (concentration set at 1.0%), and (c).

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

(iii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where N=17.

(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)(ii) of this section.

27. Add § 721.11047 to subpart E to read as follows:

§ 721.11047 Alkyl alkenoic acid, polymer with alkenylcarbomonocycle telomer with substituted alkanoic acid hydroxyl alkyl substituted alkenyl substituted alkyl ester, polyalkylene glycol alkyl ether alkyl alkenoate, dialkylene glycol diheteromonocyclic ether and alkylcarbomonocyclic alkenoate, metal salt (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as alkyl alkenoic acid, polymer with alkenylcarbomonocycle telomer with substituted alkanoic acid hydroxyl alkyl substituted alkenyl substituted alkyl ester, polyalkylene glycol alkyl ether alkyl alkenoate, dialkylene glycol diheteromonocyclic ether and alkylcarbomonocyclic alkenoate, metal salt (PMN P-16-534) 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 manufacture the substance such that the lowest number average molecular weight is less than 1,800 daltons and the carboxylic acid content exceeds 20 percent.

(ii) [Reserved]

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

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

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

(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.

28. Add § 721.11048 to subpart E to read as follows:

§ 721.11048 Alkyl alkenoic acid, polymer with alkenylcarbomonocycle telomer with substituted alkanolic acid hydroxyl alkyl substituted alkenyl substituted alkyl ester, alkanediol diheteromonocyclic ether, polyalkylene glycol alkyl ether alkyl alkenoate and alkylcarbomonocyclic alkenoate, metal salt (generic).

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified generically as alkyl alkenoic acid, polymer with alkenylcarbomonocycle telomer with substituted alkanolic acid hydroxyl alkyl substituted alkenyl substituted alkyl ester, alkanediol diheteromonocyclic ether, polyalkylene glycol alkyl ether alkyl alkenoate and alkylcarbomonocyclic alkenoate, metal salt (PMN P-16-535) 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 manufacture the substance such that the lowest number average molecular weight is less than 1,800 daltons and the carboxylic acid content exceeds 20 percent.

(ii) [Reserved]

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

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

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

(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.

29. Add § 721.11049 to subpart E to read as follows:

§ 721.11049 Alkyl alkenoic acid, polymer with bis heteromonocyclic substituted alkyl carbomonocycle, alkenylcarbomonocycle telomer with substituted alkenoic acid hydroxyl alkyl substituted alkenyl substituted alkyl ester, polyalkylene glycol alkyl ether alkyl alkenoate and alkylcarbomonocyclic alkenoate, metal salt (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as alkyl alkenoic acid, polymer with bis heteromonocyclic substituted alkyl carbomonocycle, alkenylcarbomonocycle telomer with substituted alkenoic acid hydroxyl alkyl substituted alkenyl substituted alkyl ester, polyalkylene glycol alkyl ether alkyl alkenoate and alkylcarbomonocyclic alkenoate, metal salt (PMN P-16-536) 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 manufacture the substance such that the lowest

number average molecular weight is less than 1,800 daltons, and the carboxylic acid content exceeds 20 percent.

(ii) [Reserved]

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

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

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

(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.

30. Add § 721.11050 to subpart E to read as follows:

§ 721.11050 Certain functionalized methacrylate-substituted polymers.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substances listed in Table 1 of this section 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 substances after they have been reacted (cured).

Table 1 to § 721.11050 – Functionalized Methacrylate-substituted polymers

PMN Number	Chemical Name
P-16-549	Alkaline functionalized methacrylate-substituted polymer (generic)
P-16-550	Alkaline functionalized methacrylate-substituted polymer (generic)
P-16-551	Alkaline functionalized methacrylate-substituted polymer (generic)
P-16-553	Quaternary alkylamine functionalized methacrylate-substituted polymer (generic)
P-16-555	Neutral alcohol functionalized methacrylate-substituted polymer (generic)
P-16-556	Neutral alcohol functionalized methacrylate-substituted polymer (generic)
P-16-557	Neutral alkyl salt functionalized methacrylate-substituted polymer (generic)

P-16-558	Neutral alkyl salt functionalized methacrylate-substituted polymer (generic)
P-16-560	Neutral alkyl salt functionalized methacrylate-substituted polymer (generic)
P-16-561	Acid functionalized methacrylate-substituted polymer (generic)
P-16-562	Acid functionalized methacrylate-substituted polymer (generic)
P-16-563	Acid functionalized methacrylate-substituted polymer (generic)
P-16-564	Acid functionalized methacrylate-substituted polymer (generic)
P-16-565	Acid functionalized methacrylate-substituted polymer (generic)
P-16-567	Alkylamine functionalized methacrylate-substituted polymer (generic)

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i) and (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), (b) (concentration set at 1.0%), and (c).

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f) and (k) (crosslinked resin used for chromatographic separation of biomolecules and biocatalysts). It is a significant new use to import the substance in any form other than spherical beads with 0.1 percent less than 10 microns.

(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) 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.

31. Add § 721.11051 to subpart E to read as follows:

§ 721.11051 Waste plastics, poly(ethylene terephthalate), depolymerized with polypropylene

glycol ether with glycerol (3:1), polymers with alkenoic and alkanolic acids (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as waste plastics, poly(ethylene terephthalate), depolymerized with polypropylene glycol ether with glycerol (3:1), polymers with alkenoic and alkanolic acids (PMN P-16-579) 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) and (4), when determining which persons are reasonably likely to be exposed as required for §721.63(a)(1) and (4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (a)(5) (respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 50), (a)(6) (particulate), (b) (concentration set 1.0%), and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e) (concentration set at 1.0%), (f), (g)(1) (required label statements: This substance may cause respiratory and dermal irritation. This substance may cause irritation of the mucous membranes. This substance may cause respiratory and dermal sensitization. This substance may cause mutagenicity), (g)(2)(i) through (v), 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.

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

721.80(k) (an ultraviolet curable coating resin). It is a significant new use to manufacture the substance with an average molecular weight less than 1,100 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.

32. Add § 721.11052 to subpart E to read as follows:

§ 721.11052 1,3,5-Naphthalenetrisulfonic acid.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 1,3,5-naphthalenetrisulfonic acid (PMN P-17-32, CAS No. 6654-64-4) 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) and (iv), (a)(3) and (4), when determining which persons are reasonably likely to be exposed as required for §721.63(a)(1) and (4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (a)(5) (respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor of at least 50, (a)(6)(v) and (vi), (particulate), (b) (concentration set at 1.0%), and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e) (concentration set at 1.0%), (f), (g)(1)(i), (ii), (iv), and (ix), (g)(2)(i), (ii), (iii), and (v), 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.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(q) and (t). It is a significant new use to process the substance beyond the confidential annual volume cited in the TSCA 5(e) Order.

(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.

33. Add § 721.11053 to subpart E to read as follows:

§ 721.11053 Certain halogenated sodium benzoate salts.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substances listed in Table 1 of this section is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

Table 1 to § 721.11053 – Halogenated sodium benzoate salts

PMN Number	CAS Number	Chemical Name
P-17-33	6654-64-4	Benzoic acid, 2-fluoro-, sodium salt (1:1)
P-17-34	499-90-1	Benzoic acid, 4-fluoro-, sodium salt (1:1)
P-17-36	67852-79-3	Benzoic acid, 2,3,4,5-tetrafluoro-, sodium salt (1:1)

P-17-38	2966-44-1	Benzoic acid, 2-(trifluoromethyl)-, sodium salt (1:1)
P-17-39	25832-58-0	Benzoic acid, 4-(trifluoromethyl)-, sodium salt (1:1)
P-17-41	522651-42-9	Benzoic acid, 2,5-difluoro-, sodium salt (1:1)
P-17-42	499-57-0	Benzoic acid, 3-fluoro-, sodium salt (1:1)
P-17-43	6185-28-0	Benzoic acid, 2,6-difluoro-, sodium salt (1:1)
P-17-45	530141-39-0	Benzoic acid, 3,5-difluoro-, sodium salt (1:1)
P-17-47	1765-08-8	Benzoic acid, 2,4-difluoro-, sodium salt (1:1)
P-17-50	522651-44-1	Benzoic acid, 3,4-difluoro-, sodium salt (1:1)
P-17-52	1180493-12-2	Benzoic acid, 3,4,5-trifluoro-, sodium salt (1:1)
P-17-55	402955-41-3	Benzoic acid, 2,3,4-trifluoro-, sodium salt (1:1)
P-17-57	522651-48-5	Benzoic acid, 2,4,5-trifluoro-, sodium salt (1:1)
P-17-59	1604819-08-0	Benzoic acid, 2,3-difluoro-, sodium salt (1:1)
P-17-61	69226-41-1	Benzoic acid, 3-(trifluoromethyl)-, sodium salt (1:1)
P-17-62	17264-74-3	Benzoic acid, 2-chloro-, sodium salt (1:1)
P-17-63	3686-66-6	Benzoic acid, 4-chloro-, sodium salt (1:1)
P-17-64	17264-88-9	Benzoic acid, 3-chloro-, sodium salt (1:1)
P-17-66	118537-84-1	Benzoic acid, 2,3-dichloro-, sodium salt (1:1)
P-17-67	63891-98-5	Benzoic acid, 2,5-dichloro-, sodium salt (1:1)
P-17-69	154862-40-5	Benzoic acid, 3,5-dichloro-, sodium salt (1:1)
P-17-71	10007-84-8	Benzoic acid, 2,6-dichloro-, sodium salt (1:1)
P-17-72	17274-10-1	Benzoic acid, 3,4-dichloro-, sodium salt (1:1)
P-17-73	38402-11-8	Benzoic acid, 2,4-dichloro-, sodium salt (1:1)
P-17-75	855471-43-1	Benzoic acid, 2-chloro-4-fluoro-, sodium salt
P-17-76	1421761-18-3	Benzoic acid, 3-chloro-4-fluoro-, sodium salt
P-17-79	1382106-78-6	Benzoic acid, 5-chloro-2-fluoro-, sodium salt
P-17-80	1421029-88-0	Benzoic acid, 4-chloro-3-fluoro-, sodium salt
P-17-83	1382106-64-0	Benzoic acid, 4-chloro-2-fluoro-, sodium salt
P-17-85	1938142-12-1	Benzoic acid, 5-bromo-2-chloro-, sodium salt
P-17-87	938142-13-2	Benzoic acid, 3-bromo-4-fluoro-, sodium salt
P-17-90	1938142-14-3	Benzoic acid, 2-bromo-5-fluoro-, sodium salt
P-17-91	1938142-15-4	Benzoic acid, 4-bromo-2-fluoro-, sodium salt
P-17-93	1535169-81-3	Benzoic acid, 4-bromo-3-fluoro-, sodium salt

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i) and (iv), (a)(3), when determining which persons are reasonably likely to be exposed as required for §721.63(a)(4), engineering control measures (*e.g.*, enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.*, workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (a)(5)

(respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor of at least 50), (a)(6) (particulate), (a)(6)(v) and (vi), (b) (concentration set at 1.0%), 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 0.0184 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 at 1.0%), (f), (g)(1)(i), (ii), (iii), (iv), (vi), and (ix), (g)(2)(i), (ii), and (iii), (use respiratory protection or maintain workplace airborne concentrations at or below an 8-hour time-weighted average of 0.0184 mg/m³), (g)(2)(v), 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.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(q) and (t). It is a significant new use to manufacture or process the substances other than for the processes described in the corresponding TSCA section 5(e) Order.

(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.

34. Add § 721.11054 to subpart E to read as follows:

§ 721.11054 Certain halogenated benzoic acids.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substances listed in Table 1 of this section is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

Table 1 to § 721.11054 – Halogenated benzoic acids

PMN Number	CAS Number	Chemical Name
P-17-35	1201-31-6	Benzoic acid, 2,3,4,5-tetrafluoro-
P-17-37	433-97-6	Benzoic acid, 2-(trifluoromethyl)-
P-17-40	2991-28-8	Benzoic acid, 2,5-difluoro-
P-17-44	385-00-2	Benzoic acid, 2,6-difluoro-
P-17-46	455-40-3	Benzoic acid, 3,5-difluoro-
P-17-48	1583-58-0	Benzoic acid, 2,4-difluoro-
P-17-51	455-86-7	Benzoic acid, 3,4-difluoro-
P-17-53	121602-93-5	Benzoic acid, 3,4,5-trifluoro-
P-17-54	61079-72-9	Benzoic acid, 2,3,4-trifluoro-
P-17-56	446-17-3	Benzoic acid, 2,4,5-trifluoro-
P-17-58	4519-39-5	Benzoic acid, 2,3-difluoro-
P-17-60	454-92-2	Benzoic acid, 3-(trifluoromethyl)-
P-17-65	50-45-3	Benzoic acid, 2,3-dichloro-
P-17-68	51-36-5	Benzoic acid, 3,5-dichloro-
P-17-70	50-30-6	Benzoic acid, 2,6-dichloro-
P-17-74	2252-51-9	Benzoic acid, 2-chloro-4-fluoro-
P-17-77	394-30-9	Benzoic acid, 5-chloro-2-fluoro-
P-17-78	403-16-7	Benzoic acid, 3-chloro-4-fluoro-
P-17-81	403-17-8	Benzoic acid, 4-chloro-3-fluoro-
P-17-82	446-30-0	Benzoic acid, 4-chloro-2-fluoro-
P-17-84	21739-92-4	Benzoic acid, 5-bromo-2-chloro-
P-17-88	11007-16-5	Benzoic acid, 3-bromo-4-fluoro-
P-17-89	394-28-5	Benzoic acid, 2-bromo-5-fluoro-

P-17-92	153556-42-4	Benzoic acid, 4-bromo-3-fluoro-
P-17-97	112704-79-7	Benzoic acid, 4-bromo-2-fluoro-

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i) and (v), (a)(3) and (4), when determining which persons are reasonably likely to be exposed as required for §721.63(a)(1) and (4), engineering control measures (*e.g.*, enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.*, workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (a)(5) (respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor of at least 50, (a)(6) (particulate), (a)(6)(v) and (vi), (b) (concentration set at 1.0%), 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 0.0184 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 at 1.0%), (f), (g)(1)(i), (ii), (iii), (iv), (vi), and (ix), (g)(2)(i), (ii), and (iii), (use respiratory protection or maintain workplace airborne concentrations at or below an 8-hour time-weighted average of 0.0184 mg/m³), (g)(2)(v), 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.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(q) and (t). It is a significant new use to manufacture or process the substances other than for the processes described in the corresponding TSCA section 5(e) Order.

(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.

35. Add § 721.11055 to subpart E to read as follows:

§ 721.11055 Certain halogenated benzoic acids ethyl esters.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substances listed in Table 1 of this section is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

Table 1 to § 721.11055 – Halogenated benzoic acid ethyl esters

PMN Number	CAS Number	Chemical Name
P-17-94	122894-73-9	Benzoic acid, 2,3,4,5-tetrafluoro-, ethyl ester
P-17-95	583-02-8	Benzoic acid, 4-(trifluoromethyl)-, ethyl ester
P-17-96	577-62-8	Benzoic acid, 2-(trifluoromethyl)-, ethyl ester
P-17-98	19064-14-3	Benzoic acid, 2,6-difluoro-, ethyl ester
P-17-99	708-25-8	Benzoic acid, 2,5-difluoro-, ethyl ester
P-17-100	351354-50-2	Benzoic acid, 2,3,4-trifluoro-, ethyl ester
P-17-101	351354-50-2	Benzoic acid, 2-bromo-5-fluoro-, ethyl ester
P-17-102	350-19-6	Benzoic acid, 3,5-difluoro-, ethyl ester
P-17-103	76008-73-6	Benzoic acid, 5-bromo-2-chloro-, ethyl ester

P-17-104	1128-76-3	Benzoic acid, 3-chloro-, ethyl ester
P-17-105	7335-25-3	Benzoic acid, 2-chloro-, ethyl ester
P-17-114	137521-81-4	Benzoic acid, 3-chloro-4-fluoro-, ethyl ester
P-17-122	474709-71-2	Benzoic acid, 4-bromo-2-fluoro-, ethyl ester
P-17-123	144267-97-0	Benzoic acid, 2-bromo-4,5-difluoro-, ethyl ester
P-17-124	1130165-74-0	Benzoic acid, 4-bromo-3-fluoro-, ethyl ester
P-17-125	23233-33-2	Benzoic acid, 3-bromo-4-fluoro-, ethyl ester
P-17-126	4793-20-8	Benzoic acid, 4-chloro-2-fluoro-, ethyl ester
P-17-127	35112-27-7	Benzoic acid, 2,5-dichloro-, ethyl ester
P-17-128	203573-08-4	Benzoic acid, 4-chloro-3-fluoro-, ethyl ester
P-17-129	167758-87-4	Benzoic acid, 2-chloro-4-fluoro-, ethyl ester
P-17-130	773139-56-3	Benzoic acid, 5-chloro-2-fluoro-, ethyl ester
P-17-131	108928-00-3	Benzoic acid, 2,4-difluoro-, ethyl ester
P-17-132	144267-96-9	Benzoic acid, 3,4-difluoro-, ethyl ester
P-17-133	495405-09-9	Benzoic acid, 3,4,5-trifluoro-, ethyl ester
P-17-134	351354-41-1	Benzoic acid, 2,4,5-trifluoro-, ethyl ester
P-17-135	76783-59-0	Benzoic acid, 3-(trifluoromethyl)-, ethyl ester
P-17-136	773134-65-9	Benzoic acid, 2,3-difluoro-, ethyl ester
P-17-137	81055-73-4	Benzoic acid, 2,6-dichloro-, ethyl ester
P-17-138	91085-56-2	Benzoic acid, 3,5-dichloro-, ethyl ester
P-17-139	56882-52-1	Benzoic acid, 2,4-dichloro-, ethyl ester
P-17-140	28394-58-3	Benzoic acid, 3,4-dichloro-, ethyl ester

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i) and (v), (a)(3) and (4), when determining which persons are reasonably likely to be exposed as required for §721.63(a)(1) and (4), engineering control measures (*e.g.*, enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.*, workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (a)(5) (respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor of at least 1000), (a)(6) (particulate), (a)(6)(v) and (vi), (b) (concentration set at 1.0%), 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 0.0184 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 at 1.0%), (f), (g)(1)(i), (ii), (iii), (iv), (vi), and (ix), (g)(2)(i), (ii), and (iii), (use respiratory protection or maintain workplace airborne concentrations at or below an 8-hour time-weighted average of 0.0184 mg/m³), (g)(2)(v), (g)(3)(i) and (ii), (g)(4)(i), 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.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(q) and (t). It is a significant new use to manufacture or process the substances other than for processes described in the corresponding TSCA section 5(e) Order.

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where N=15 ppb.

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

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

36. Add § 721.11056 to subpart E to read as follows:

§ 721.11056 Neodymium aluminium alkyl polymer complexes (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as neodymium aluminium alkyl polymer complexes (PMN P-17-198) 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), and (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%), and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e) (concentration set 1.0%), (f), (g)(1)(ix), (the substance may react violently with water, (this substance may cause skin irritation and corrosion), (this substance may cause respiratory complications, irritation, and corrosion), (g)(2)(i), (ii), (iii), (when using this substance use in closed system to prevent any inhalation exposure), (when using this substance use skin and eye protection), 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.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(c) (it is a significant new use to process the substance in manner that results in inhalation

exposure) and (f). It is a significant new use to manufacture the substance for a period longer than 8 months.

(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.

37. Add § 721.11057 to subpart E to read as follows:

§ 721.11057 Fatty acid amide alkyl amine salts (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substances identified generically as fatty acid amide alkyl amine salts (PMN P-17-272, P-17-273, P-17-274, P-17-275, P-17-276 and P-17-277) are 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 substances 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), (iii), and (iv), (a)(3), and (a)(6) (particulate), (a)(6)(v) and (vi). 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.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e) (concentration set at 1.0%), (f), (g)(1)(vi), (skin irritation), (respiratory complication), (internal organ effect), (systemic effect), (sensitization), (g)(2)(i), (ii), (iii), and (v), (g)(3)(i) and (ii), (g)(4)(i) and (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.

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

(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.

38. Add § 721.11058 to subpart E to read as follows:

§ 721.11058 Fatty acid derived imidazoline salts (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substances identified generically as fatty acid derived imidazoline salts (PMN P-17-278, P-17-279 and P-17-280) are 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 substances 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), (iii), and (iv), (a)(3), and (a)(6) (particulate), and (a)(6)(v) and (vi). 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.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e) (concentration set at 1.0%), (f), (g)(1) (skin irritation), (respiratory complication), (internal organ effect),(systemic effect), (sensitization), (g)(2)(i), (ii), (iii), and (v), (g)(3)(i) and (ii), (g)(4)(i) and (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.

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

(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.

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