

**BILLING CODE 6560-50-P** 

## ENVIRONMENTAL PROTECTION AGENCY

**40 CFR Parts 9 and 721** 

[EPA-HQ-OPPT-2017-0414; FRL-9971-37]

RIN 2070-AB27

Significant New Use Rules on Certain Chemical Substances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Direct final rule.

SUMMARY: EPA is promulgating significant new use rules (SNURs) under the Toxic Substances Control Act (TSCA) for 27 chemical substances which were 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 27 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 intended use within the applicable review period. Persons may not commence manufacture or processing for the significant new use until EPA has conducted a review of the notice, made an appropriate determination on the notice, and has taken such actions as are required with 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**].

Written adverse comments on one or more of these SNURs must be received on or before [insert date 30 days after date of publication in the Federal Register] (see Unit VI. of the SUPPLEMENTARY INFORMATION). If EPA receives written adverse comments on one or more of these SNURs before [insert date 30 days after date of publication in the Federal Register], EPA will withdraw the relevant sections of this direct final rule before its effective date.

For additional information on related reporting requirement dates, see Units I.A., VI., and VII. of the **SUPPLEMENTARY INFORMATION**.

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2017-0414, by one of the following methods:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail*: Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <a href="http://www.epa.gov/dockets/contacts.html">http://www.epa.gov/dockets/contacts.html</a>.

Additional instructions on commenting or visiting the docket, along with more

information about dockets generally, is available at http://www.epa.gov/dockets.

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

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

#### SUPPLEMENTARY INFORMATION:

#### I. General Information

# A. Does this Action Apply to Me?

You may be potentially affected by this action if you manufacture, process, or use the chemical substances contained in this 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.

- B. What Should I Consider as I Prepare My Comments for EPA?
- 1. Submitting CBI. Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.
- 2. *Tips for preparing your comments*. When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html*.

## II. Background

- A. What Action is the Agency Taking?
- 1. *Direct Final Rule*. EPA is promulgating these SNURs using direct final procedures.

  These SNURs will require persons to notify EPA at least 90 days before commencing the

manufacture or processing of a chemical substance for any activity designated by these SNURs as a significant new use. Receipt of such notices obligates EPA to assess risks that may be associated with the significant new uses under the conditions of use and, if appropriate, to regulate the proposed uses before they occur.

2. Proposed Rule. In addition to this Direct Final Rule, elsewhere in this issue of the Federal Register, EPA is issuing a Notice of Proposed Rulemaking for this rule. If EPA receives no adverse comment, the Agency will not take further action on the proposed rule and the direct final rule will become effective as provided in this action. If EPA receives adverse comment on one or more of SNURs in this action by [insert date 30 days after date of publication in the Federal Register] (see Unit VI. of the SUPPLEMENTARY INFORMATION), the Agency will publish in the Federal Register a timely withdrawal of the specific SNURs that the adverse comments pertain to, informing the public that the actions will not take effect. EPA would then address all adverse public comments in a response to comments document in a subsequent final rule, based on the proposed rule.

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

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a "significant new use." EPA must make this determination by rule after considering all relevant factors, including the four bulleted TSCA section 5(a)(2) factors listed in Unit III. Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1)(B) requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture or process the chemical substance for that use (15 U.S.C. 2604(a)(1)(B)(i)).

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

## C. Applicability of General Provisions

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

## **III. Significant New Use Determination**

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

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

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

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

## IV. Substances Subject to this Rule

EPA is establishing significant new use and recordkeeping requirements for 27 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 nonconfidential chemical identities).
- Basis for the TSCA section 5(e) 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 rules include 27 PMN substances that are subject to Orders issued under TSCA section 5(e)(1)(A)(ii)(I) where EPA determined that it has insufficient information to conduct a reasoned evaluation and the 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-12-277, P-12-278, P-12-280, P-12-281, P-12-282, P-12-283, and P-12-284.

*Chemical names*: Alkanes, C<sub>20-28</sub>, chloro (P-12-277), Slack waxes (petroleum), chloro (P-12-278), Hexacosane, chloro derivs. and octacosane, chloro derivs. (P-12-280), Alkanes, C<sub>20-24</sub>, chloro (P-12-281), Alkanes, C<sub>14-16</sub>, chloro (P-12-282), Tetradecane, chloro derivs. (P-12-283), and Octadecane, chloro derivs. (P-12-284).

CAS numbers: 2097144-43-7 (P-12-277), 2097144-44-8 (P-12-278), 2097144-46-0 and 2097144-47-1 (P-12-280), 2097144-45-9 (P-12-281), 1372804-76-6 (P-12-282), 198840-65-2 (P-12-283), 2097144-48-2 (P-12-284).

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

Basis for TSCA section 5(e) Order: The PMNs state that the PMN substances will be used as flame retardants and plasticizers in polyvinyl chloride (PVC), polymers, and rubber; flame retardants, plasticizers, and lubricants in adhesives, caulk, sealants, and coatings; additives in lubricants including metalworking fluids; and flame retardants and

waterproofers in textiles. Based on the physical/chemical properties of the PMN substances (as described in the New Chemical Program's PBT category at 64 FR 60194; November 4, 1999; FRL-6097-7) and test data on structurally similar medium-chain chlorinated paraffins (MCCP), the PMN substances are a potentially persistent, bioaccumulative, and toxic (PBT) chemicals. EPA estimates that the PMN substances will persist in the environment more than 2 months and estimates a bioaccumulation factor of greater than or equal to 1,000. Based on data on MCCP, EPA has identified concerns for systemic toxicity as well as aquatic and terrestrial toxicity. 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 health or the environment. To protect against these risks, the Order requires:

- Submission of certain toxicity testing on the representative congener groups prior to exceeding a certain time period specified in the Order.
- 2. Use of the PMN substances only for the uses specified in the Order: flame retardants and plasticizers in PVC, polymers, and rubber; flame retardants, plasticizers, and lubricants in adhesives, caulk, sealants, and coatings; additives in lubricants including metalworking fluids; and flame retardants and waterproofers in textiles.

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 terrestrial 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 a certain time limit without performing chronic aquatic and terrestrial toxicity and biodegradation testing.

*CFR citations:* 40 CFR 721.11068 (P-12-277), 40 CFR 721.11069 (P-12-278), 40 CFR 721.11070 (P-12-280), 40 CFR 721.11071 (P-12-281), 40 CFR 721.11072 (P-12-282 and P-14-684), 40 CFR 721.11073 (P-12-283 and P-14-683), and 40 CFR 721.11074 (P-12-284).

**PMN Numbers:** P-12-433, P-12-453, and P-12-505

Chemical names: Alkanes,  $C_{18-20}$ , chloro (P-12-433), Alkanes,  $C_{14-17}$ , chloro (P-12-453) and Alkanes,  $C_{22-30}$ , chloro (P-12-505).

*CAS numbers*: 106262-85-3 (P-12-433), 85535-85-9 (P-12-453) and 288260-42-4 (P-12-505).

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

Basis for TSCA section 5(e) Order: The PMN states that the PMN substances will be used as flame retardants and plasticizers in PVC, polymers, and rubber; flame retardants, plasticizers, and lubricants in adhesives, caulk, sealants, and coatings; additives in lubricants including metalworking fluids; and flame retardants and waterproofers in textiles. Based on the physical/chemical properties of the PMN substances (as described in the New Chemical Program's PBT category at 64 FR 60194; November 4, 1999; FRL-6097-7) and test data on structurally similar medium-chain chlorinated paraffins (MCCP), the PMN substances are potentially persistent, bioaccumulative, and toxic (PBT) chemicals. EPA estimates that the PMN substances will persist in the environment

more than 2 months and estimates a bioaccumulation factor of greater than or equal to 1,000. Based on test data on MCCP EPA has identified concerns for systemic toxicity as well as aquatic and terrestrial toxicity. 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 health or the environment. To protect against these risks, the Order requires:

- Submission of certain toxicity testing on the representative congener groups
  prior to exceeding a certain time period specified in the Order.
- 2. Use of the PMN substances only for the uses specified in the Order: flame retardants and plasticizers in PVC, polymers, and rubber; flame retardants, plasticizers, and lubricants in adhesives, caulk, sealants, and coatings; additives in lubricants including metalworking fluids; and flame retardants and waterproofers in textiles.

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 terrestrial 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 a certain time limit without performing chronic aquatic and terrestrial toxicity and biodegradation testing.

CFR citations: 40 CFR 721.11075 (P-12-433), 40 CFR 721.11076 (P-12-453), 40 CFR 721.11077 (P-12-505).

**PMN Numbers:** P-14-683 and P-14-684

*Chemical names*: Tetradecane, chloro derivs. (P-14-683) and Alkanes, C<sub>14-16</sub>, chloro (P-14-684)

CAS numbers: 198840-65-2 (P-14-683) and 1372804-76-6 (P-14-684)

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

Basis for TSCA section 5(e) Order: The PMNs state that the substances will be used as flame retardants and plasticizers in PVC, polymers, and rubber; flame retardants, plasticizers, and lubricants in adhesives, caulk, sealants, and coatings; additives in lubricants including metalworking fluids; and flame retardants and waterproofers in textiles. Based on the physical/chemical properties of the PMN substances (as described in the New Chemical Program's PBT category at 64 FR 60194; November 4, 1999; FRL-6097-7) and test data on structurally similar medium-chain chlorinated paraffins (MCCP), the PMN substances are potentially persistent, bioaccumulative, and toxic (PBT) chemicals. EPA estimates that the PMN substances will persist in the environment more than 2 months and estimates a bioaccumulation factor of greater than or equal to 1,000. Further, EPA has identified concerns for systemic toxicity, as well as aquatic and terrestrial toxicity. 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 health or the environment. To protect against these risks, the Order requires:

 Submission of certain toxicity testing on the representative congener groups prior to exceeding a certain time period specified in the Order.

2. Use of the PMN substances only for the uses specified in the Order: flame

retardants and plasticizers in PVC, polymers, and rubber; flame retardants,

plasticizers, and lubricants in adhesives, caulk, sealants, and coatings;

additives in lubricants including metalworking fluids; and flame retardants

and waterproofers in textiles.

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 terrestrial 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 a certain time limit without performing chronic aquatic and

terrestrial toxicity and biodegradation testing.

CFR citations: 40 CFR 721.11072 (P-12-282 and P-14-684), 40 CFR 721.11073 (P-12-

283 and P-14-683).

**PMN Number:** P-16-150

Chemical name: Chloroflurocarbon (generic).

CAS number: Not available.

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

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

use of the substance will be as an intermediate. Based on test data on the PMN substance,

EPA identified concerns for acute human toxicity. Based on analogue data EPA

identified concerns for toxicity to aquatic and terrestrial organisms. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I), 5(a)(3)(B)(ii)(II) and 5(e)(1)(A)(ii)(I), based on a finding that the substance may present an unreasonable risk of injury to health and the environment and that the substance will be produced in substantial quantities and may be reasonably anticipated to enter the environment in substantial quantities. To protect against these risks, the Order requires:

- Submission of certain toxicity testing on the substance prior to exceeding the production limits 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 National Institute of Occupational Safety and Health (NIOSH)-certified respirator with an assigned protection factor (APF) of at least 1000 (where there is a potential for inhalation exposure) in conjunction with a minimum set of engineering controls described in the PMN, or compliance with a new chemical exposure limit (NCEL) of 170 parts per billion (ppb) as an 8-hour time-weighted average to prevent inhalation exposure.
- Use of engineering controls to limit worker exposure and air release of the PMN substance to the environment.
- Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the Safety Data Sheet (SDS).
- 6. Manufacture, processing, and use in an enclosed process.
- 7. Use only as a chemical intermediate.

8. No release of the substance resulting in surface water concentrations that

exceed 240 ppb.

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

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 and developmental toxicity testing, and acute

and chronic aquatic toxicity testing.

CFR citation: 40 CFR 721.11078

**PMN Number:** P-16-379

Chemical name: Silane, 1,1'-(1,2-ethanediyl)bis[1,1-dichloro-1-methyl]-, hydrolysis

products with chloroethenyldimethylsilane.

CAS number: 1485477-78-8.

Effective date of TSCA section 5(e) Order: June 8, 2017.

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

use of the substance is as a chemical intermediate for polymer synthesis. Based on SAR

analysis of test data on analogous substances, EPA has identified concerns for liver

toxicity and mutagenicity. 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 health and the environment. To protect against these risks, the Order requires:

- 1. Submission of certain toxicity testing on the substance prior to exceeding the confidential production volume limit specified in the Order.
- Use of personal protective equipment including impervious gloves and clothing which covers any other exposed areas of the arms, legs and torso (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 substance.
- 5. Use of the substance only for the confidential uses specified in the Order.
- 6. No use involving application methods that generate a dust, mist, vapor, or aerosol.
- 7. Disposal of the substance only by water or landfill.

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 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 mutagenicity testing. In addition, EPA has determined that the results of other

characterizing the health effects of the PMN substance. Although the Order does not require this additional testing, the Order's restrictions on manufacture, processing,

specific target organ toxicity testing of the PMN substance may be potentially useful in

distribution in commerce, use, 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 721.11079

**PMN Number:** P-16-410

Chemical name: Silicophosphonate - sodium silicate (generic).

CAS number: Not available.

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

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

use of the substance will be as an automotive engine fluid additive. Based on test data on

the PMN substance, EPA has identified concerns for skin and eye irritation, corrosion,

and systemic toxicity. 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 substance may present an unreasonable risk

of injury to human health. To protect against these risks, the Order requires:

1. No domestic manufacture of the substance.

2. Use of the substance in formulations containing no greater than 0.2% of the

chemical substance and for the confidential uses specified in the Order.

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

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 irritation testing 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, use, 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 721.11080.

**PMN Number:** P-16-438

*Chemical name*: 3-Butenenitrile, 2-(acetyloxy)-.

*CAS number*: 15667-63-7.

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

Basis for TSCA section 5(e) Order: The PMN states the substance will be used as a

chemical intermediate for a pesticide inert. Based on test data on the PMN substance,

EPA identified concerns for acute toxicity, irritation to all tissues, developmental toxicity,

and neurotoxicity. EPA identified concerns for aquatic organism toxicity based on

submitted data. 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 substance may present an unreasonable risk

of injury to health and the environment. Further, based on SAR analysis of test data on

analogous vinyl/ allyl esters vinyl/ allyl esters nitriles and test data on the PMN

substance, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 8 ppb in surface waters. To protect against these risks, the Order requires:

- 1. Submission of monitoring data on the substance.
- 2. Use of personal protective equipment including impervious gloves and protective clothing (where there is a potential for dermal exposures) and a NIOSH-certified powered air purifying particulate respirator with an Assigned Protection Factor (APF) of at least 1000 (where there is a potential for inhalation exposures).
- 3. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.
- 4. Manufacture, process, and use of the substance in a closed system as specified in the PMN.
- 5. Use of the substance only as a chemical intermediate.
- 6. No release of the substance into the surface waters of the United States.

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 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. EPA has determined that the results of chronic aquatic toxicity testing of the PMN substance may be potentially useful in characterizing the environmental effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions on manufacture, processing,

distribution in commerce, and use 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 721.11081.

**PMN Number:** P-16-543

Chemical name: Halogenophosphoric acid metal salt (generic)

CAS number: Not available.

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

Basis for TSCA section 5(e) Order: The PMN states that the generic (non-confidential) use will be as a battery ingredient. Based on test data on the PMN substance and an analogue, EPA has identified concerns for irritation, corrosion, acute toxicity, immunotoxicity, developmental toxicity, neurotoxicity, and cancer. Further, based on test data on the PMN substance, EPA identified concerns for aquatic organism toxicity at surface water concentrations that exceed 3 ppb. 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 substance may present an unreasonable risk of injury to health and the environment. To protect against these risks, the Order requires:

- 1. Submission of monitoring data as specified in the Order.
- 2. Use of personal protective equipment as specified in the Order (where there is a potential for dermal exposure).
- 3. Use of a NIOSH-certified respirator with an APF of at least 1000 (where there is a potential for inhalation exposure).

- 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 substance.
- 6. Use of the substance only in an enclosed process.
- 7. Use of the substance only for the confidential uses specified in the Order.
- 8. Manufacture, process, or use of the substance without the engineering controls required by the Order to control dermal and inhalation exposure.
- Disposal of the substance by hazardous waste incineration except when in wastewater.
- 10. No release of the substance resulting in surface water concentrations that exceed 3 ppb.

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 human health toxicity, human exposure, aquatic toxicity, and fate 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 to conduct an exposure monitoring program for employees who are reasonably likely to be exposed to the PMN substance and a hydrolysis product of the PMN substance. In addition, EPA has determined that the results of specific target organ toxicity, acute aquatic toxicity, and biodegradation testing of the PMN substance may be potentially useful in characterizing the health and

environmental effects of the PMN substance. Although the Order does not require this additional testing, the Order's restrictions on manufacture, processing, distribution in commerce, use, 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 721.11082.

**PMN Number:** P-16-596

Chemical names: Alkenoic acid, reaction products with polyethylene glycol ether with

hydroxyalkyl substituted alkane (generic).

*CAS numbers*: Not available.

*Effective date of TSCA section 5(e) Order*: June 5, 2017.

Basis for TSCA section 5(e) Order: The PMN states that the substance will be used as a site-limited intermediate used for production of ultraviolet (UV) curable coating resin. Based on SAR analysis on structurally similar substances, EPA has identified concerns for irritation, sensitization, developmental toxicity, liver and kidney effects, and oncogenicity. 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 health and the environment. EPA's estimates indicate that variations of the

of the uses identified below would not result in inhalation exposure. To protect against

parameters (including batch size, number of processing sites, days per year of operation)

these risks, the Order requires:

1. Submission of test data on the substance prior to exceeding the confidential production volume limit 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 substance.

5. Use of the substance only as a site-limited intermediate for the production of

UV curable coating resin.

6. No release of the substance to surface waters of the United States.

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

human health toxicity of the PMN substance 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 reproductive/developmental toxicity testing may be potentially useful in

characterizing the health effects of the PMN substance. The submitter has agreed not to

manufacture beyond a certain production volume limit without performing

reproductive/developmental toxicity testing.

CFR citation: 40 CFR 721.11083

PMN Number: P-17-10

Chemical name: Alkyl substituted alkenoic acid, alkyl ester, polymer with alkyl

substituted alkenoate and alkenoic acid, hydroxy substituted[(oxoalkyl)oxy]alkyl ester,

reaction products with alkanoic acid, dipentaerythritil and isocyanate substituted carbomonocycle, compds. with alkylamine (generic).

CAS number: Not available.

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

Basis for TSCA section 5(e) Order: The PMN states that the substance will be used as a UV curable coating resin. Based on test data on structurally similar substances, EPA has identified concerns for irritation, sensitization, developmental effects, internal organ effects (liver and kidney), and cancer. 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 substance may present an unreasonable risk of injury to health and the environment. To protect against these risks, the Order requires:

- 1. Use of personal protective equipment including impervious gloves to prevent dermal exposure (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. No domestic manufacture of the substance.
- 4. No manufacture, process, or use of the substance that results in generation of a vapor, mist, or aerosol.
- 5. No manufacture of the substance where there is more than 0.1% residual isocyanate by weight.
- 6. Use of the substance only as a UV curable coating resin.
- 7. Only import the substance in totes.

8. Manufacture of the substance to have an average molecular weight of greater

than 2000 daltons.

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

human health toxicity of the PMN substance 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 reproductive/developmental toxicity testing 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 use 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 721.11084.

PMN Number: P-17-15

Chemical name: Heteromonocycle ester with alkanediol (generic).

CAS numbers: Not available.

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

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

use of the PMN substance is a precursor for a photochromatic substance. Based on SAR

analysis of test data on analogous esters, EPA has identified concerns for irritation to

skin, eye, and mucous membrane, and systemic toxicity. Further, based on SAR analysis of test data on analogous nonionic esters, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 3 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 a finding that the substances may present an unreasonable risk of injury to health and the environment. 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. To protect against these risks, the Order requires:

- Submission of certain toxicity testing on the substance prior to exceeding the confidential production volume limit specified in the Order.
- 2. Use of personal protective equipment including impervious gloves to prevent dermal exposure (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 substance.
- 5. No use of the substance other than other than for the confidential uses identified in the Order.
- 6. No release of the substance resulting in surface water concentrations that exceed 3 ppb.

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 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 reproductive/developmental toxicity and acute aquatic toxicity testing.

*CFR citation:* 40 CFR 721.11085

PMN Number: P-17-29

Chemical name: Substituted carbomonocycle, polymer with (aminoalkyl)-alkanediamine, (haloalkyl)oxirane, dialkyl-alkanediamine and alkyl-alkanamine, reaction products with dialkanolamine and [[(alkyl)oxy]alkyl]oxirane (generic).

CAS number: Not available.

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

Basis for TSCA section 5(e) Order: The PMN states that the generic (non-confidential) use of the substance is an intermediate prepolymer. Based on the physical/chemical properties of the substance and SAR analysis of test data on analogous aliphatic amines, EPA has identified concerns for irritation, lung effects, and aquatic toxicity. 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 substance may present an unreasonable risk of injury to health and the environment. To protect against these risks, the Order requires:

- 1. Submission of certain toxicity testing on the substance prior to exceeding the confidential production volume limit specified in the Order.
- 2. Use of personal protective equipment including impervious gloves to prevent dermal exposure (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 use other than for the confidential uses identified in the Order.

5. No use involving an application method that generates a vapor, mist, or aerosol

6. No domestic manufacture of the substance.

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

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 irritation

and acute aquatic toxicity testing. 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 substance. Although the Order does not

require this additional testing, the Order's restrictions on manufacture, processing,

distribution in commerce, use, 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 721.11086.

**PMN Numbers:** P-17-154, P-17-155, and P-17-156

Chemical names: Carboxylic acid amine (1:1) (generic) (P-17-154), Mix fatty acids compd. with amine (1:1) (generic) (P-17-155), and Mix fatty acids compd. with amine (1:1) (generic) (P-17-156).

CAS number: Not available.

Effective date of TSCA section 5(e) Order: June 15, 2017.

Basis for TSCA section 5(e) Order: The PMN states that the generic (non-confidential) use of the substances is as a coating. Based on physical/chemical properties of the substances and SAR analysis of test data on amines, EPA identified concerns for irritation, corrosion, developmental toxicity, reproductive toxicity, neurotoxicity, and thyroid toxicity. Further, based on test data on analogous anionic surfactants and aliphatic amines, EPA identified concern for toxicity to aquatic organisms at surface water concentrations that exceed 240 ppb. 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 health and the environment. EPA's estimates indicate that variations of the parameters (including batch size, number of processing sites, days per year of operation) of the uses for the chemical substance would not result in increased inhalation exposure. To protect against these risks, the Order requires:

- Submission of certain toxicity testing on the substances prior to exceeding the confidential production volume limit specified in the Order.
- 2. Use of personal protective equipment to prevent dermal exposure (where there is a potential for dermal exposure).
- Establishment and use of a hazard communication program, including human health and environmental precautionary statements on each label and in the SDS.

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 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 to not exceed a confidential production volume without performing reproductive/developmental toxicity testing.

CFR citation: 40 CFR 721.11087 (P-17-154), 40 CFR 721.11088 (P-17-155), 40 CFR 721.11089 (P-17-156).

**PMN Number:** P-17-218

Chemical name: Bicyclo[2.2.1]heptane-1-methanesulfonic acid, 7,7-dimethyl-2-oxo-, compd. with N,N-diethylethanamine (1:1).

*CAS number*: 67019-84-5.

Effective date of TSCA section 5(e) Order: May 19, 2017.

Basis for TSCA section 5(e) Order: The PMN states that the generic (non-confidential) use of the substance is a processing aid for membrane production. Based on SAR analysis of test data on structurally similar respirable particles, EPA identified concerns for corrosivity, irritation, sensitization, developmental toxicity, specific target organ toxicity, and neurotoxicity. 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 substance may present an unreasonable risk of injury to health and the environment. To protect against these risks, the Order requires:

- Submission of certain toxicity testing on the substance prior to exceeding the confidential production volume limit specified in the Order.
- 2. Use of personal protective equipment including impervious gloves to prevent dermal exposure (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, processing, or use involving an application method that generates a vapor, mist, aerosol, or dust.

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 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 a skin sensitization study. In addition, EPA has determined that the results of reproductive/developmental 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 use 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 721.11090.

**PMN Number:** P-17-226

Chemical name: Manganese(2+), bisoctahydro-1,4,7-trimethyl-1H-1,4,7-triazonine-

.kappa.N1,.kappa.N4,.kappa.N7)tri-.mu.-oxidi-, hexafluorophosphate(1-) (1:2).

*CAS number*: 116633-52-4.

*Effective date of TSCA section 5(e) Order:* June 15, 2017.

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

the substance will be as a detergent additive. Based on test data on the substance and

analogue test data, EPA has identified concerns for eye irritation, thyroid, blood, and

liver toxicity, male reproductive toxicity, neurotoxicity, immunosuppression, respiratory

sensitization, and mutagenicity. Based on test data on the substance and test data on

analogous neutral organics, EPA identified concern for toxicity to aquatic organisms at

surface water concentrations that exceed 240 ppb. 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 substance may

present an unreasonable risk of injury to health and the environment. To protect against

these risks, the Order requires:

1. Use of personal protective equipment to prevent dermal exposure (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. No use other than the confidential use allowed in the Order.

4. No domestic manufacture of the substance.

5. No processing without appropriate engineering controls to prevent inhalation

exposure, including dust removal with 99.9% efficiency when loading or

unloading the substance in powder form.

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

240 ppb.

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

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. 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 use 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 721.11091.

**PMN Numbers:** P-17-228 and P-17-229

Chemical names: 2'-Fluoro-4"-alkyl-4-propyl-1,1':4'1"-terphenyl (generic) (P-17-228)

and 4-ethyl-2'-fluoro-4"-alkyl-1,1':4'1"-terphenyl (generic) (P-17-229).

*CAS numbers*: Not available.

Effective date of TSCA section 5(e) Order: May 18, 2017.

Basis for TSCA section 5(e) Order: The PMN states that the generic (non-confidential) use of the substances is a coating for displays. Based on the physical/chemical properties of the substances (as described in the New Chemical Program's PBT category at 64 FR 60194; November 4, 1999; FRL-6097-7) and test data on structurally similar substances, the substances are potentially persistent, bioaccumulative, and toxic (PBT) chemicals. EPA estimates that the substances will persist in the environment more than 2 months and estimates a bioaccumulation factor of greater than or equal to 1,000. Further, based on test data on structurally similar chemicals, EPA has identified concerns for reproductive effects, adrenal and liver toxicity. 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 health and the environment. To protect against these risks, the Order requires:

- 1. Use of personal protective equipment including impervious gloves to prevent dermal exposure (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. No manufacture beyond the confidential annual production volume limit specified in the Order.
- 4. No processing or use of the substances in an application method that generates a dust, mist, or aerosol.

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. EPA has determined that the results of biodegradation and reproductive/developmental 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 additional testing, the Order's restrictions on manufacture, processing, distribution in commerce, use, 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 721.11092 (P-17-228) and 40 CFR 721.11093 (P-17-229).

**PMN Number:** P-17-261

Chemical name: Poly(oxy-1,2-ethanediyl),-.alpha.-(2-benzoylbenzoyl)-.omega.-[(2benzoylbenzoyl)oxy]-.

CAS number: Not available.

Effective date of TSCA section 5(e) Order: June 19, 2017.

Basis for TSCA section 5(e) Order: The PMN states that the substance will be used as a difunctional type II photoinitiator for use in inks and coatings. Based on physical/chemical properties, SAR analysis and test data on analogous esters with branched polyols, EPA has identified concerns for corrosion of the skin, eyes, and mucous membranes, developmental toxicity, systemic toxicity, and blood effects. The

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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 substance may present an unreasonable risk of injury to health and the

environment. 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 for the

chemical substance would not result in increased inhalation exposure. To protect against

these risks, the Order requires:

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

confidential production volume limit 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 substance.

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

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 in the Order without performing irritation

testing.

CFR citation: 40 CFR 721.11094.

## V. 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 27 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.

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).

## B. Objectives

EPA is issuing these SNURs for specific chemical substances which have undergone premanufacture review because the Agency wants to achieve the following objectives with regard to the significant new uses designated in this rule:

- EPA will receive notice of any person's intent to manufacture or process a listed chemical substance for the described significant new use before that activity begins.
- EPA will have an opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing or processing a listed chemical substance for the described significant new use.
  - EPA 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.

### VI. Direct Final Procedures

EPA is issuing these SNURs as direct final rules. The effective date of these rules is [insert date 60 days after date of publication in the Federal Register] without further notice, unless EPA receives written adverse comments before [insert date 30 days after date of publication in the Federal Register].

If EPA receives written adverse comments on one or more of these SNURs before [insert date 30 days after date of publication in the Federal Register], EPA will withdraw the relevant sections of this direct final rule before its effective date.

This rule establishes SNURs for a number of chemical substances. Any person who submits adverse comments must identify the chemical substance and the new use to which it applies. EPA will not withdraw a SNUR for a chemical substance not identified in the comment.

# VII. Applicability of the Significant New Use Designation

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

When chemical substances identified in this rule are added to the TSCA Inventory, EPA recognizes that, before the rule is effective, other persons might engage in a use that has been identified as a significant new use. However, TSCA section 5(e) Orders have been issued for all of the chemical substances, and the PMN submitters are prohibited by the TSCA section 5(e) Orders from undertaking activities which will be designated as significant new uses. The identities of 13 of the 27 chemical substances subject to this rule have been claimed as confidential and EPA has received no post-PMN bona fide submissions (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.

Therefore, EPA designates [insert date of publication in the **Federal Register**] 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 direct final rule.

Persons who begin commercial manufacture or processing of the chemical substances for a significant new use identified as of that date 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: development of test data is required where the chemical substance subject to the SNUR is also subject to a rule, order or consent agreement under TSCA section 4 (see TSCA section 5(b)(1)).

In the absence of a TSCA section 4 test rule 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 of the listed SNURs. Descriptions of this information are provided for informational purposes. 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). To access the OCSPP test guidelines referenced in this document electronically, please go to <a href="http://www.epa.gov/ocspp">http://www.epa.gov/ocspp</a> and select "Test Methods and Guidelines." The Organisation for Economic Co-operation and Development (OECD) test guidelines are available from the OECD Bookshop at <a href="http://www.oecdbookshop.org">http://www.oecdbookshop.org</a> or SourceOECD at <a href="http://www.sourceoecd.org">http://www.sourceoecd.org</a>.

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,

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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.

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), particularly if satisfactory test results have not been obtained from a prior PMN or SNUN submitter. EPA recommends that potential SNUN submitters contact EPA early enough so that they will be able to generate useful information.

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 <a href="http://www.epa.gov/opptintr/newchems">http://www.epa.gov/opptintr/newchems</a>.

## 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-2017-0414.

## 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) Orders. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993).

### B. Paperwork Reduction Act (PRA)

According to PRA (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in

title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable. EPA is amending the table in 40 CFR part 9 to list the OMB approval number for the information collection requirements contained in this action. This listing of the OMB control numbers and their subsequent codification in the CFR satisfies the display requirements of PRA and OMB's implementing regulations at 5 CFR part 1320. This Information Collection Request (ICR) was previously subject to public notice and comment prior to OMB approval, and given the technical nature of the table, EPA finds that further notice and comment to amend it is unnecessary. As a result, EPA finds that there is "good cause" under section 553(b)(3)(B) of the Administrative Procedure Act (5 U.S.C. 553(b)(3)(B)) to amend this table without further notice and comment.

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

Send any comments about the accuracy of the burden estimate, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques, to the Director, Collection Strategies Division, Office of Environmental Information (2822T), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. Please remember to include the

OMB control number in any correspondence, but do not submit any completed forms to this address.

# C. Regulatory Flexibility Act (RFA)

On February 18, 2012, EPA certified pursuant to RFA section 605(b) (5 U.S.C. 601 *et seq.*), that promulgation of a SNUR does not have a significant economic impact on a substantial number of small entities where the following are true:

- 1. A significant number of SNUNs would not be submitted by small entities in response to the SNUR.
- 2. The SNUR submitted by any small entity would not cost significantly more than \$8,300.

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

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

- A significant number of SNUNs would not be submitted by small entities in response to the SNUR.
- Submission of the SNUN would not cost any small entity significantly more than \$8,300.

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

# D. Unfunded Mandates Reform Act (UMRA)

Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not

have any reasons to believe that any State, local, or Tribal government will be impacted by this 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).

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# **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: August 3, 2018.

Mark A. Hartman,

Acting Director, Office of Pollution Prevention and Toxics.

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

# PART 9--[AMENDED]

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

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

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

# § 9.1 OMB approvals under the Paperwork Reduction Act.

\* \* \* \* \*

40 CFR citation				OMB control No.		
*	*	*	*	*	*	*
	S	significant Nev	w Uses of C	hemical Subs	tances	
*	*	*	*	*	*	*
721.11068			207	70-0012		
721.11069			207	70-0012		
721.11070			207	70-0012		
721.11071			207	70-0012		
721.11072			207	70-0012		
721.11073			207	70-0012		

721.11074	2070-0012
721.11075	2070-0012
721.11076	2070-0012
721.11077	2070-0012
721.11078	2070-0012
721.11079	2070-0012
721.11080	2070-0012
721.11081	2070-0012
721.11082	2070-0012
721.11083	2070-0012
721.11084	2070-0012
721.11085	2070-0012
721.11086	2070-0012
721.11087	2070-0012
721.11088	2070-0012
721.11089	2070-0012
721.11090	2070-0012
721.11091	2070-0012
721.11092	2070-0012
721.11093	2070-0012
721.11094	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 § 721.11068 to subpart E to read as follows:

# § 721.11068 Alkanes, C<sub>20-28</sub>, chloro.

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as alkanes,  $C_{20-28}$ , chloro (PMN P-12-277, CAS No. 2097144-43-7) 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) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(k) (flame retardants and plasticizers in polyvinyl chloride, polymers, and rubber; flame retardant, plasticizer, and lubricant in adhesives, caulk, sealants, and coatings; additive in lubricants including metalworking fluids; and flame retardant and waterproofer in textiles). It is a significant new use to manufacture the chemical substance more than 5 years.
  - (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.

5. Add § 721.11069 to subpart E to read as follows:

# § 721.11069 Slack waxes (petroleum), chloro.

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as slack waxes (petroleum), chloro (PMN P-12-278, CAS No. 2097144-44-8) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
  - (2) The significant new uses are:
- (i) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(k) (flame retardants and plasticizers in polyvinyl chloride, polymers, and rubber; flame retardant, plasticizer, and lubricant in adhesives, caulk, sealants, and coatings; additive in lubricants including metalworking fluids; and flame retardant and waterproofer in textiles). It is a significant new use to manufacture the chemical substance more than 5 years.
  - (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.
  - 6. Add § 721.11070 to subpart E to read as follows:

### § 721.11070 Hexacosane, chloro derivs. and octacosane, chloro derivs.

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as hexacosane, chloro derivs. and octacosane, chloro derivs. (PMN P-12-280, CAS Nos. 2097144-46-0 and 2097144-47-1) 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) (flame retardants and plasticizers in polyvinyl chloride, polymers, and rubber; flame retardant, plasticizer, and lubricant in adhesives, caulk, sealants, and coatings; additive in lubricants including metalworking fluids; and flame retardant and waterproofer in textiles). It is a significant new use to manufacture the chemical substance more than 5 years.
  - (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.
  - 7. Add § 721.11071 to subpart E to read as follows:

# § 721.11071 Alkanes, C<sub>20-24</sub>, chloro.

(a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as alkanes,  $C_{20-24}$ , chloro (PMN P-12-281, CAS No.

2097144-45-9) 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) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(k) (flame retardants and plasticizers in polyvinyl chloride, polymers, and rubber; flame retardant, plasticizer, and lubricant in adhesives, caulk, sealants, and coatings; additive in lubricants including metalworking fluids; and flame retardant and waterproofer in textiles). It is a significant new use to manufacture the chemical substance more than 5 years.
  - (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.
  - 8. Add § 721.11072 to subpart E to read as follows:

# § 721.11072 Alkanes, C<sub>14-16</sub>, chloro.

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as alkanes,  $C_{14-16}$ , chloro (PMNs P-12-282 and P-14-684, CAS No. 1372804-76-6) 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) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(k) (flame retardants and plasticizers in polyvinyl chloride, polymers, and rubber; flame retardant, plasticizer, and lubricant in adhesives, caulk, sealants, and coatings; additive in lubricants including metalworking fluids; and flame retardant and waterproofer in textiles). It is a significant new use to manufacture the chemical substance more than 5 years.
  - (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.
  - 9. Add § 721.11073 to subpart E to read as follows:

# § 721.11073 Tetradecane, chloro derivs.

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as tetradecane, chloro derivs. (PMNs P-12-283 and P-14-683, CAS No. 198840-65-2) 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) (flame retardants and plasticizers in polyvinyl chloride, polymers, and rubber; flame retardant, plasticizer, and lubricant in adhesives, caulk, sealants, and

coatings; additive in lubricants including metalworking fluids; and flame retardant and waterproofer in textiles). It is a significant new use to manufacture the chemical substance more than 5 years.

- (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.
  - 10. Add § 721.11074 to subpart E to read as follows:

### § 721.11074 Octadecane, chloro derivs.

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as octadecane, chloro derivs. (PMN P-12-284, CAS No. 2097144-48-2) 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) (flame retardants and plasticizers in polyvinyl chloride, polymers, and rubber; flame retardant, plasticizer, and lubricant in adhesives, caulk, sealants, and coatings; additive in lubricants including metalworking fluids; and flame retardant and waterproofer in textiles). It is a significant new use to manufacture the chemical substance more than 5 years.

- (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.
  - 11. Add § 721.11075 to subpart E to read as follows:

# § 721.11075 Alkanes, C<sub>18-20</sub>, chloro.

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as alkanes,  $C_{18-20}$ , chloro (PMN P-12-433, CAS No. 106262-85-3) 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) (flame retardants and plasticizers in polyvinyl chloride, polymers, and rubber; flame retardant, plasticizer, and lubricant in adhesives, caulk, sealants, and coatings; additive in lubricants including metalworking fluids; and flame retardant and waterproofer in textiles). It is a significant new use to manufacture the chemical substance more than 5 years.
  - (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.
  - 12. Add § 721.11076 to subpart E to read as follows:

# § 721.11076 Alkanes, C<sub>14-17</sub>, chloro.

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as alkanes,  $C_{14-17}$ , chloro (PMN P-12-453, CAS No. 85535-85-9) 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) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(k) (flame retardants and plasticizers in polyvinyl chloride polymers, and rubber; flame retardant, plasticizer, and lubricant in adhesives, caulk, sealants, and coatings; additive in lubricants including metalworking fluids; and flame retardant and waterproofer in textiles). It is a significant new use to manufacture the chemical substance more than 5 years.
  - (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 § 721.11077 to subpart E to read as follows:

# § 721.11077 Alkanes, C<sub>22-30</sub>, chloro.

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as alkanes,  $C_{22-30}$ , chloro (PMN P-12-505, CAS No. 288260-42-4) 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) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(k) (flame retardants and plasticizers in polyvinyl chloride, polymers, and rubber; flame retardant, plasticizer, and lubricant in adhesives, caulk, sealants, and coatings; additive in lubricants including metalworking fluids; and flame retardant and waterproofer in textiles). It is a significant new use to manufacture the chemical substance more than 5 years.
  - (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.
  - 14. Add § 721.11078 to subpart E to read as follows:

## § 721.11078 Chloroflurocarbon (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as chloroflurocarbon (PMN P-16-150) 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)(liquid), 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 170 ppb 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 (d), (f), (g)(1)(fatal if inhaled), (g)(2)(ii), (iv), (use respiratory protection or maintain workplace airborne concentrations at or below an 8-hour time-weighted average of 170 ppb), (g)(2)(v), (g)(3)(i), (ii), (g)(4)(release to water restrictions apply), 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), and (q). It is a significant new use to manufacture, process, or use the PMN substance without the engineering controls described in the corresponding TSCA section 5(e) Order to prevent worker and environmental exposures. It is a significant new use to manufacture the chemical substance more than one year.
- (iv) Release to water. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where N=240.
- (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.
  - 15. Add § 721.11079 to subpart E to read as follows:

- § 721.11079 Silane, 1,1'-(1,2-ethanediyl)bis[1,1-dichloro-1-methyl]-, hydrolysis products with chloroethenyldimethylsilane.
- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as Silane, 1,1'-(1,2-ethanediyl)bis[1,1-dichloro-1-methyl]-, hydrolysis products with chloroethenyldimethylsilane (PMN P-16-379, CAS No. 1485477-78-8) 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)(1), (a)(2)(i), (iv), (a)(3), when determining which persons are reasonably likely to be exposed as required for §721.63(a)(1) engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (a)(6)(particulate), (a)(6)(v), (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) (liver toxicity), (mutagenicity), (g)(2)(i), (ii), (iii), (v), (g)(4)(i), (do not incinerate), 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), (q), (y)(1) and (2).

- (iv) *Disposal*. Requirements as specified in § 721.85(a) (water), (a)(2), (b) (water), (b)(2), (c) (water), and (c)(2).
- (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.
  - 16. Add § 721.11080 to subpart E to read as follows:

# § 721.11080 Silicophosphonate - sodium silicate (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as silicophosphonate sodium silicate (PMN P-16-410) 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). A significant new use is any use in formulations containing greater than 0.2% of the chemical substance.
  - (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) 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)(i) of this section.
  - 17. Add § 721.11081 to subpart E to read as follows:

# § 721.11081 3-Butenenitrile, 2-(acetyloxy).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as 3-butenenitrile, 2-(acetyloxy) (PMN P-16-438, CAS No. 15667-63-7) 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), (ii), (iii), (a)(3), (a)(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 1000), (a)(6)(particulate), (a)(6)(v), (vi), (b)(concentration set at 1.0%), and (c). It is a significant new use to manufacture, process or use the substance without

following the monitoring procedure as specified in the worker protection section of the corresponding TSCA section 5(e) Order.

- (ii) *Hazard communication*. Requirements as specified in § 721.72(a) through (e)(concentration set at 1.0%), (f), (g)(1)(fatal if swallowed), (fatal if in contact with skin), (toxic if inhaled), (g)(2)(i), (ii), (iii), (iv), (v), (g)(3)(i), (ii), (g)(4)(i), (ii), (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(g). It is a significant new use to manufacture or use the substance other than in an enclosed system as described in the PMN.
- (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.
  - 18. Add § 721.11082 to subpart E to read as follows:

# § 721.11082 Halogenophosphoric acid metal salt (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as halogenophosphoric acid metal salt (PMN P-16-543) 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)(the confidential dermal protection described in the corresponding TSCA section 5(e) Order "the Order"), (a)(2)(ii), (iii), (iv), (a)(3), (a)(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 1,000), (a)(6)(particulate), (a)(6)(v), (vi), (b)(concentration set at 0.1%), and (c). It is a significant new use to manufacture, process or use the substance without following the monitoring procedure as specified in the worker protection section of the Order.
- (ii) *Hazard communication*. Requirements as specified in § 721.72(a) through (e)(concentration set at 0.1%), (f), (g)(1)(i), (ii), (iii), (iv), (v), (vii), (viii), (ix), (g)(2)(i), (ii), (iii), (use protective engineering controls or equipment for dermal and inhalation protection, (g)(3)(i), (ii), (g)(4)(i), (ii), (water release restrictions apply), 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), (f), and (k). 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 increase the magnitude of inhalation exposure.
- (iv) *Disposal*. Requirements as specified in § 721.85. It is a significant new use to dispose of the substance other than by hazardous waste incineration according to 40 CFR parts 260 through 299 unless the substance is in waste water. When the substance is in wastewater it may be disposed of as required in paragraph (a)(2)(v) of this section.
- (v) *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 (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 paragraphs (a)(2)(i) and (iii) of this section.
  - 19. Add § 721.11083 to subpart E to read as follows:
- § 721.11083 Alkenoic acid, reaction products with polyethylene glycol ether with hydroxyalkyl substituted alkane (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as alkenoic acid, reaction products with polyethylene glycol ether with hydroxyalkyl substituted alkane (PMN P-16-596) 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), (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 0.1%), and (c).
- (ii) *Hazard communication*. Requirements as specified in § 721.72 (a) through (e)(concentration set at 0.1%), (f), (g)(1)(i), (dermal sensitization), (g)(1)(iv), (cancer, if inhaled), (g)(1)(ix), (g)(2)(i), (ii), (iii), (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(f), (k), and (q).
- (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.
  - 20. Add § 721.11084 to subpart E to read as follows:
- § 721.11084 Alkyl substituted alkenoic acid, alkyl ester, polymer with alkyl substituted alkenoate and alkenoic acid, hydroxy substituted[(oxoalkyl)oxy]alkyl ester, reaction products with alkanoic acid, dipentaerythritil and isocyanate substituted carbomonocycle, compds. with alkylamine (generic).
- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as alkyl substituted alkenoic acid, alkyl ester, polymer with alkyl substituted alkenoate and alkenoic acid, hydroxy substituted[(oxoalkyl)oxy]alkyl ester, reaction products with alkanoic acid, dipentaerythritil and isocyanate substituted carbomonocycle, compds. with alkylamine (PMN P-17-10) 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), (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), (a)(6)(v), (vi), (b)(concentration set at 0.1%), and (c).
- (ii) *Hazard communication*. Requirements as specified in § 721.72(a) through (e)(concentration set at 0.1%), (f), (g)(1)(i), (sensitization), (g)(1)(vii), (systemic effects), (g)(1)(ix), (g)(2)(i), (ii), (iii), (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(f), (k)(ultraviolet curable coating resin), and (y)(1). It is a significant new use to manufacture the chemical substance with an average molecular weight below 2,000 daltons or containing greater than 0.1% residual isocyanate. It is a significant new use to import the substance other than in totes.
- (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.

21. Add § 721.11085 to subpart E to read as follows:

## § 721.11085 Heteromonocycle ester with alkanediol (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as heteromonocycle ester with alkanediol (PMN P-17-15) 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), (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)(i), (g)(2)(i), (ii), (iii), (v), (g)(3)(i), (ii), (g)(4) (release to water restrictions apply), 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=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.
  - 22. Add § 721.11086 to subpart E to read as follows:
- § 721.11086 Substituted carbomonocycle, polymer with (aminoalkyl)-alkanediamine, (haloalkyl)oxirane, dialkyl-alkanediamine and alkyl-alkanamine, reaction products with dialkanolamine and [[(alkyl)oxy]alkyl]oxirane (generic).
- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as substituted carbomonocycle, polymer with (aminoalkyl)-alkanediamine, (haloalkyl)oxirane, dialkyl-alkanediamine and alkyl-alkanamine, reaction products with dialkanolamine and [[(alkyl)oxy]alkyl]oxirane (PMN P-17-29) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been reacted (cured).
  - (2) The significant new uses are:
- (i) *Protection in the workplace*. Requirements as specified in § 721.63(a)(1), (a)(2)(i), (ii), (iii), (a)(3), when determining which persons are reasonably likely to be exposed as required for §721.63(a)(1) engineering control measures (e.g., enclosure or

confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (b)(concentration set 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), (eye irritation), (g)(1)(ii), (g)(2)(i), (ii), (iii), (v), (g)(3)(i), (ii), (g)(4)(iii), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System (GHS) and OSHA Hazard Communication Standard may be used.
- (iii) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(f), (k), (q), and (y)(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) 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.
  - 23. Add § 721.11087 to subpart E to read as follows:

## § 721.11087 Carboxylic acid amine (1:1) (generic).

(a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as carboxylic acid amine (1:1) (PMN P-17-154) is subject to reporting under this section for the significant new uses described in

paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been reacted (cured).

- (2) The significant new uses are:
- (i) *Protection in the workplace*. Requirements as specified in § 721.63(a)(1), (a)(2)(i), (ii), (iv), (a)(3), when determining which persons are reasonably likely to be exposed as required for §721.63(a)(1) engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (a)(6)(particulate), (a)(6)(v), (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), (iii), (thyroid effects), (g)(1)(vi), (ix), (g)(2)(i), (ii), (iii), (v), (g)(3)(i), (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(q).
- (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.
  - 24. Add § 721.11088 to subpart E to read as follows:

#### § 721.11088 Mix fatty acids compd with amine (1:1) (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as mix fatty acids compd with amine (1:1) (PMN P-17-155) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the PMN substance after they have been reacted (cured).
  - (2) The significant new uses are:
- (i) *Protection in the workplace*. Requirements as specified in § 721.63(a)(1), (a)(2)(i), (ii), (iv), (a)(3), when determining which persons are reasonably likely to be exposed as required for §721.63(a)(1) engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (a)(6)(particulate), (a)(6)(v), (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), (iii), (thyroid effects), (g)(1)(vi), (ix), (g)(2)(i), (ii), (iii), (v), (g)(3)(i), (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(q).
- (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.
  - 25. Add § 721.11089 to subpart E to read as follows:

## § 721.11089 Mix fatty acids compd with amine (1:1) (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as mix fatty acids compd with amine (1:1) (PMN P-17-156) 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), (iv), (a)(3), when determining which persons are reasonably likely to be exposed as required for §721.63(a)(1) engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented

to prevent exposure, where feasible, (a)(6)(particulate), (a)(6)(v), (vi), (b)(concentration set a 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), (iii), (thyroid effects), (g)(1)(vi), (ix), (g)(2)(i), (ii), (iii), (v), (g)(3)(i), (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(q).
- (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.
  - 26. Add § 721.11090 to subpart E to read as follows:
- § 721.11090 Bicyclo[2.2.1]heptane-1-methanesulfonic acid, 7,7-dimethyl-2-oxo-, compd. with N,N-diethylethanamine (1:1).
- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as bicyclo[2.2.1]heptane-1-methanesulfonic acid, 7,7-dimethyl-2-oxo-, compd. with N,N-diethylethanamine (1:1) (PMN P-17-218. CAS No.

67019-84-5) 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)(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, (a)(6)(particulate), (a)(6)(v),(vi), (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)(i), (corrosivity), (sensitization), (g)(1)(iii), (iv), (ix), (g)(2)(i), (ii), (iii), (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), (y)(1) and (2).
- (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.
  - 27. Add § 721.11091 to subpart E to read as follows:
- § 721.11091 Manganese (2+), bisoctahydro-1,4,7-trimethyl-1H-1,4,7-triazonine-.kappa.N1,,kappa.N4,,kappa.N7) tri-.mu.-oxidi-, hexafluorophosphate(1-) (1:2).
- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as manganese (2+), bisoctahydro-1,4,7-trimethyl-1H-1,4,7-triazonine-.kappa.N1,.kappa.N4,.kappa.N7) tri-.mu.-oxidi-, hexafluorophosphate(1-) (1:2) (1:1) (PMN P-17-226, CAS No. 116633-52-4) 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), (ii), (iii), (a)(3), when determining which persons are reasonably likely to be exposed as required for §721.63(a)(1) engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (a)(6)(particulate), (b) (concentration set at 0.1%), and (c).
- (ii) *Hazard communication*. Requirements as specified in § 721.72(a) through (e)(concentration set at 0.1%), (f), (g)(1)(eye irritation), (respiratory sensitization), (g)(1)(iii), (iv), (vi), (vii), (viii), (g)(2)(i), (ii), (iii), (v), (g)(3)(i), (ii), (g)(4)(release to water provisions apply), 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). It is a significant new use to process or use the substance without engineering controls to prevent exposure, including dust removal with 99.9% efficiency when loading or unloading the substance in powder form.
- (iv) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where N=240.
- (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.
  - 28. Add § 721.11092 subpart E to read as follows:

## § 721.11092 2'-Fluoro-4''-alkyl-4-propyl-1,1':4'1''-terphenyl (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as 2'-fluoro-4"-alkyl-4-propyl-1,1':4'1"-terphenyl (PMN P-17-228) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
  - (2) The significant new uses are:

- (i) *Protection in the workplace*. Requirements as specified in § 721.63(a)(1), (a)(2)(i), (a)(3), when determining which persons are reasonably likely to be exposed as required for §721.63(a)(1) engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (b) (concentration set 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)(vi), (adrenal effects), (liver effects), (g)(2)(i), (ii), (iii), (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(t) and (y)(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) 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 § 721.11093 to subpart E to read as follows:

#### § 721.11093 4-ethyl-2'-fluoro-4"-alkyl-1,1':4',1"-terphenyl (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as 4-ethyl-2'-fluoro-4"-alkyl-1,1':4',1"-terphenyl (PMN P-17-229) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
  - (2) The significant new uses are:
- (i) *Protection in the workplace*. Requirements as specified in § 721.63(a)(1), (a)(2)(i), (a)(3), when determining which persons are reasonably likely to be exposed as required for §721.63(a)(1) engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (b)(concentration set 1.0%), and (c).
- (ii) *Hazard communication*. Requirements as specified in § 721.72(a) through (e)(concentration set 1.0%), (f), (g)(1)(vi), (adrenal effects), (liver effects), (g)(2)(i), (ii), (iii), (v), and (g)(5).
- (iii) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(t) and (y)(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) 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 § 721.11094 to subpart E to read as follows:

# § 721.11094 Poly(oxy-1,2-ethanediyl),alpha-(2-benzoyl)-omega-[(2-benzoylbenzoyl)oxy]-.

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as poly(oxy-1,2-ethanediyl),alpha-(2-benzoyl)-omega-[(2-benzoylbenzoyl)oxy]- (PMN P-17-261) 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), (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)(irritation), (photosensitization), (g)(2)(i), (ii), (iii), (v), and (g)(5).
- (iii) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(f) and (q).

- (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.

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