

## Congressional Review Act

This regulatory action may be considered a major rule under the Congressional Review Act, 5 U.S.C. 801–08, because it may result in an annual effect on the economy of \$100 million or more. Although this regulatory action may constitute a major rule within the meaning of the Congressional Review Act, 5 U.S.C. 804(2), it is not subject to the 60-day delay in effective date applicable to major rules under 5 U.S.C. 801(a)(3) because the Secretary finds that good cause exists under 5 U.S.C. 808(2) to make this regulatory action effective on January 1, 2015, consistent with the reasons given for the publication of this interim final rule. Increasing the copayment amount on January 1, 2015, might cause a significant financial hardship for some veterans and may decrease patient adherence to medical plans and have other unpredictable negative health effects. Accordingly, the Secretary finds that additional advance notice and public procedure thereon are impracticable, unnecessary, and contrary to the public interest. In accordance with 5 U.S.C. 801(a)(1), VA will submit to the Comptroller General and to Congress a copy of this regulatory action and VA's Regulatory Impact Analysis (RIA).

## Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually for inflation) in any one year. This interim final rule will have no such effect on State, local, and tribal governments, or on the private sector.

## Regulatory Flexibility Act

The Secretary hereby certifies that this interim final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. This interim final rule will temporarily freeze the copayments that certain veterans are required to pay for prescription drugs furnished by VA. This rule directly affects individuals and will not directly affect small entities. Therefore, pursuant to 5 U.S.C. 605(b), this rulemaking is exempt from the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604.

## Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance numbers and titles for the programs affected by this document are as follows: 64.005, Grants to States for Construction of State Home Facilities; 64.007, Blind Rehabilitation Centers; 64.008, Veterans Domiciliary Care; 64.009, Veterans Medical Care Benefits; 64.010, Veterans Nursing Home Care; 64.011, Veterans Dental Care; 64.012, Veterans Prescription Service; 64.013, Veterans Prosthetic Appliances; 64.014, Veterans State Domiciliary Care; 64.015, Veterans State Nursing Home Care; 64.016, Veterans State Hospital Care; 64.018, Sharing Specialized Medical Resources; 64.019, Veterans Rehabilitation Alcohol and Drug Dependence; 64.022, Veterans Home Based Primary Care; and 64.024, VA Homeless Providers Grant and Per Diem Program.

## Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Jose D. Riojas, Chief of Staff, Department of Veterans Affairs, approved this document on September 25, 2014, for publication.

## List of Subjects in 38 CFR Part 17

Administrative practice and procedure, Alcohol abuse, Alcoholism, Claims, Day care, Dental health, Drug abuse, Foreign relations, Government contracts, Grant programs—health, Grant programs—veterans, Health care, Health facilities, Health professions, Health records, Homeless, Medical and dental schools, Medical devices, Medical research, Mental health programs, Nursing homes, Philippines, Reporting and recordkeeping requirements, Scholarships and fellowships, Travel and transportation expenses, Veterans.

Dated: October 22, 2014.

**William F. Russo,**

*Acting Director, Office of Regulation Policy & Management, Office of the General Counsel, U.S. Department of Veterans Affairs.*

For the reasons set out in the preamble, VA amends 38 CFR part 17 as follows:

## PART 17—MEDICAL

■ 1. The authority citation for part 17 continues to read as follows:

**Authority:** 38 U.S.C. 501(a), and as noted in specific sections.

## § 17.110 [Amended]

■ 2. Amend § 17.110 as follows:

■ a. In paragraphs (b)(1)(i), (ii), and (iii), remove all references to “December 31, 2014” and adding in each place “December 31, 2015”.

■ b. In paragraph (b)(2) remove all references to “December 31, 2014” and adding in each place “December 31, 2015”.

[FR Doc. 2014–25454 Filed 10–24–14; 8:45 am]

BILLING CODE 8320–01–P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Parts 9 and 721

[EPA–HQ–OPPT–2014–0390; FRL–9914–56]

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 52 chemical substances which were the subject of premanufacture notices (PMNs). Nine of these chemical substances are subject to TSCA section 5(e) consent orders issued by EPA. This action requires persons who intend to manufacture (including import) or process any of these 52 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 will provide EPA with the opportunity to evaluate the intended use and, if necessary, to prohibit or limit that activity before it occurs.

**DATES:** This rule is effective on December 26, 2014. For purposes of judicial review, this rule shall be promulgated at 1 p.m. (e.s.t.) on November 10, 2014.

Written adverse or critical comments, or notice of intent to submit adverse or critical comments, on one or more of these SNURs must be received on or before November 26, 2014 (see Unit VI. of the **SUPPLEMENTARY INFORMATION**). If EPA receives written adverse or critical comments, or notice of intent to submit adverse or critical comments, on one or more of these SNURs before November 26, 2014, 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–2014–0390, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

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

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

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

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

Kenneth Moss, Chemical Control Division (7405 M), 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](mailto: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](mailto: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 a proposed or final rule 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](http://www.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 submitting comments, remember to:

- i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).
- ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- iv. Describe any assumptions and provide any technical information and/or data that you used.
- v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

- vi. Provide specific examples to illustrate your concerns and suggest alternatives.

- vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

- viii. Make sure to submit your comments by the comment period deadline identified.

## **II. Background**

### *A. What action is the Agency taking?*

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 allows EPA to assess risks that may be presented by the intended uses and, if appropriate, to regulate the proposed use before it occurs.

Additional rationale and background to these rules are more fully set out in the preamble to EPA's first direct final SNUR published in the **Federal Register** of April 24, 1990 (55 FR 17376; FRL–3658–5). Consult that preamble for further information on the objectives, rationale, and procedures for SNURs and on the basis for significant new use designations, including provisions for developing test data.

### *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. Persons who must report are described in § 721.5.

### *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 may take regulatory action under TSCA sections 5(e), 5(f), 6, or 7 to control the activities for which it has received the SNUN. If EPA does not take action, EPA is required under TSCA section 5(g) to explain in the **Federal Register** its reasons for not taking action.

### 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 authorized EPA to consider any other relevant factors.

To determine what would constitute a significant new use for the 52 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 52 chemical substances in 40 CFR part 721, subpart E. In this unit, EPA provides the following information for each chemical substance:

- PMN number.
- Chemical name (generic name, if the specific name is claimed as CBI).
- Chemical Abstracts Service (CAS) Registry number (if assigned for non-confidential chemical identities).
- Basis for the TSCA section 5(e) consent order or, the basis for TSCA

non-section 5(e) SNURs (i.e., SNURs without TSCA section 5(e) consent orders).

- Tests recommended by EPA to provide sufficient information to evaluate the chemical substance (see Unit VIII. for more information).
- CFR citation assigned in the regulatory text section of this rule.

The regulatory text section of this rule specifies the activities designated as significant new uses. Certain new uses, including 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.

This rule includes 9 PMN substances (P-11-224, P-11-226, P-12-41, P-12-404, P-12-405, P-12-406, P-13-175, P-13-176, and P-13-239) that are subject to "risk-based" consent orders under TSCA section 5(e)(1)(A)(ii)(I) where EPA determined that activities associated with the PMN substances may present unreasonable risk to human health or the environment. Those consent orders require protective measures to limit exposures or otherwise mitigate the potential unreasonable risk. The so-called "TSCA section 5(e) SNURs" on these PMN substances are promulgated pursuant to § 721.160, and are based on and consistent with the provisions in the underlying consent orders. The TSCA section 5(e) SNURs designate as a "significant new use" the absence of the protective measures required in the corresponding consent orders.

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) consent 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 NCEs provisions in TSCA section 5(e) consent 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 NCEs 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 NCEs approach for SNURs are approved by EPA will be required to comply with NCEs provisions that are comparable to those contained in the corresponding TSCA section 5(e) consent order for the same chemical substance.

This rule also includes SNURs on 43 PMN substances that are not subject to consent orders under TSCA section 5(e). In these cases, for a variety of reasons, EPA did not find that the use scenario described in the PMN triggered the determinations set forth under TSCA section 5(e). However, EPA does believe that certain changes from the use scenario described in the PMN could result in increased exposures, thereby constituting a "significant new use." These so-called "TSCA non-section 5(e) SNURs" are promulgated pursuant to § 721.170. EPA has determined that every activity designated as a "significant new use" in all TSCA non-section 5(e) SNURs issued under § 721.170 satisfies the two requirements stipulated in § 721.170(c)(2), i.e., these significant new use activities, are different from those described in the premanufacture notice for the substance, including any amendments, deletions, and additions of activities to the premanufacture notice, and may be accompanied by changes in exposure or release levels that are significant in relation to the health or environmental concerns identified for the PMN substance.

#### PMN Number P-10-235

*Chemical name:* Pyridine, 4-decyl-

*CAS number:* 1815-99-2.

*Basis for action:* The PMN states that the generic (non-confidential) use of the substance is as a fragrance component. Based on test data on the PMN substance, as well as ecological structure-activity relationship (SAR) analysis of test data on analogous neutral organic compounds, EPA predicts chronic toxicity to aquatic organisms may occur at concentrations that exceed 1 part per billion (ppb) of the PMN substance in surface waters for greater than 20 days per year. This 20-day criterion is derived from partial life cycle tests (daphnid chronic and fish early-life stage tests) that typically range from 21 to 28 days in duration. EPA predicts toxicity to aquatic organisms may occur if releases of the PMN

substance to surface water exceed releases from the use described in the PMN. For the use described in the PMN, environmental releases did not exceed the concentration of concern for more than 20 days per year. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance other than as described in the PMN, or any use of the substance resulting in surface water concentrations exceeding 1 ppb from manufacturing or processing waste stream releases, may result in significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(i) and (b)(4)(ii).

**Recommended testing:** EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400) and a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300) would help characterize the environmental effects of the PMN substance.

**CFR citation:** 40 CFR 721.10766.

#### PMN Number P-11-224

**Chemical name:** Fluoroether (generic).

**CAS number:** Claimed confidential.

**Effective date of TSCA section 5(e) consent order:** August 5, 2011.

**Basis for TSCA section 5(e) consent order:** The PMN states that the PMN will be used as an electrolyte for electrical/electronic equipment. Based on test data on the PMN substance, EPA identified concerns for subchronic toxicity, systemic toxicity, reproductive effects; as well as toxicity to aquatic organisms at concentrations that exceed 9 ppb of the PMN substance in surface waters. The Order was issued under TSCA section 5(e)(1)(A)(i), 5(e)(1)(A)(ii)(I), and 5(e)(1)(A)(ii)(II) based on a finding that the substance may present an unreasonable risk of injury to human health and the environment, the substance may be produced in substantial quantities and may reasonably be anticipated to enter the environment in substantial quantities, and there may be significant (or substantial) human exposure to the substance. To protect against these risks, the consent order requires:

1. Submission of certain toxicity and fate testing prior to exceeding the confidential production volume limit specified in the consent order.
2. Manufacturing, processing, and use of the substance only as an electrolyte for electrical/electronic equipment as described in the consent order.

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

**Recommended testing:** EPA has determined that the test data from certain human health, environmental fate, and ecotoxicity testing identified in the consent order would help characterize possible effects of the substances and their degradation products. The company has agreed not to exceed the confidential production limit without performing a bacterial reverse mutation test (OPPTS Test Guideline 870.5100); a mammalian erythrocyte micronucleus test (OPPTS Test Guideline 870.5395); a UV/Visible absorption test (Organisation for Economic Co-Operation and Development (OECD) Test Guideline 101); and an atmospheric half-life test (as referenced in the Consent Order). EPA has also determined that the results of a reproduction/development toxicity test (OPPTS Test Guideline 870.3550); a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); and information to address cardiac sensitization (as described in the Consent Order) would help characterize the human health and ecotoxicity effects of the PMN substance. The consent order does not require submission of this pended testing detailed in the consent order at any specified time or production volume. However, the consent order's restrictions on manufacture, processing, distribution in commerce, use, and disposal of the PMNs will remain in effect until the consent order is modified or revoked by EPA based on submission of that or other relevant information.

**CFR citation:** 40 CFR 721.10767.

#### PMN Number P-11-226

**Chemical name:** N-(2-hydroxyethyl) alkenamide (generic).

**CAS number:** Claimed confidential.

**Effective date of TSCA section 5(e) consent order:** February 27, 2014.

**Basis for TSCA section 5(e) consent order:** The PMN states that the generic (non-confidential) use of the substance will be as a component of adhesives and cosmetics. Based on SAR analysis of test data on analogous acrylamides, EPA identified concerns for carcinogenicity, heritable mutagenicity, reproductive and developmental toxicity, and neurotoxicity from dermal and inhalation exposures. Consistent with the establishment of a Safe Drinking Water Act maximum contaminant level goal (MCLG) of zero for acrylamides, EPA identified concerns for nervous system and blood effects from general

population drinking water exposures to the PMN substance. The consent order was issued under TSCA section 5(e)(1)(A)(i) and 5(e)(A)(ii)(I) based on a finding that the uncontrolled manufacture, processing, distribution in commerce, use, and disposal of the PMN substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the consent order requires:

1. Risk notification. If as a result of the test data required, the company becomes aware that the PMN substance may present a risk of injury to human health or the environment, the company must incorporate this new information, and any information on methods for protecting against such risk into a Material Safety Data Sheet (MSDS), within 90 days.

2. Use of personal protective equipment including gloves impervious to the substances, when there is a potential dermal exposure; and a National Institute of Occupational Safety and Health (NIOSH)-certified respirator with an assigned protection factor (APF) of at least 1,000 or compliance with a NCEL of 0.03 mg/m<sup>3</sup> as an 8-hour time-weighted average (when there is potential inhalation exposure), when there is potential inhalation exposure.

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

4. Submission of certain testing prior to exceeding the confidential production volume limits of the PMN substance specified in the consent order.

5. Disposal of all waste streams containing the PMN substance either by incineration (destruction and removal efficiency of 99.99%) or underground injection control (class 1 well, deep well injection for hazardous wastes)

6. No use of the substances resulting in releases to surface water.

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

**Recommended testing:** EPA has determined that the test data from certain human health, testing identified in the consent order would help characterize possible effects of the substance. The company has agreed not to exceed the first confidential production limit without performing a 90-day oral toxicity test (OPPTS Test Guideline 870.3100) in rodents, with a functional observational battery for neuropathology (OPPTS Test Guideline 870.6300); a rodent oral dominant lethal

assay (OPPTS Test Guideline 870.5450); and, depending on the results of the rodent oral dominant lethal assay, an oral rodent heritable translocation test (OPPTS Test Guideline 870.5460) may be required. The company has agreed not to exceed the second confidential production limit without performing a 2-year oral carcinogenicity test (OPPTS Test Guideline 870.4200) in rats and mice.

*CFR citation:* 40 CFR 721.10768.

*PMN Number P-12-41*

*Chemical name:* 1-Octadecanaminium, N,N-dimethyl-N-[3-(triethoxysilyl)propyl]-, chloride (1:1), reaction products with ethylene glycol.

*CAS number:* 1314035-96-5.

*Effective date of TSCA section 5(e) consent order:* March 3, 2014.

*Basis for TSCA section 5(e) consent order:* The PMN states that the uses of the PMN substance will be for waterproofing inorganic substrates, an asphalt binder modifier, and waterproofing of soil. The consent order was issued under TSCA section 5(e)(1)(A)(i), 5(e)(1)(A)(ii)(I), and 5(e)(1)(A)(ii)(II) based on a finding that the substance may present an unreasonable risk of injury to human health; and the substance may be produced in substantial quantities and there may be significant (or substantial) human exposure to the substance. To protect against these risks, the consent order requires:

1. Risk notification. If as a result of the test data required, the company becomes aware that the PMN substance may present a risk of injury to human health or the environment, the company must incorporate this new information, and any information on methods for protecting against such risk into an MSDS, within 90 days.

2. No domestic manufacture of the PMN substance.

3. Import, processing and use of the PMN substance only for waterproofing inorganic substrates, an asphalt binder modifier, and waterproofing of soil.

4. Submission of certain human health testing prior to exceeding an aggregate production volume limit of 839,000 kilograms.

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

*Recommended testing:* EPA has determined that the results of certain toxicity testing would help characterize possible health effects of the PMN substance. The company has agreed not to exceed the 839,000 kilogram production limit without performing a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465). EPA has also

determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); a fish acute toxicity mitigated by humic acid test (OPPTS Test Guideline 850.1085); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test (Office of Chemical Safety and Pollution Prevention (OCSPP) Test Guideline 850.4500) would help characterize the environmental effects of the PMN substance. The consent order does not require submission of this aquatic toxicity testing at any specified time or production volume. However, the consent order's restrictions on manufacture, processing, distribution in commerce, use, and disposal of the PMN will remain in effect until the consent order is modified or revoked by EPA based on submission of that or other relevant information.

*CFR citation:* 40 CFR 721.10769.

*PMN Numbers P-12-404, P-12-405, P-12-406*

*Chemical names:* Fluoroalkyl sulfonamide derivatives (generic).

*CAS numbers:* Claimed confidential.

*Effective date of TSCA section 5(e) consent order:* March 14, 2014.

*Basis for TSCA section 5(e) consent order:* The PMNs state that the generic (non-confidential) use of the substances are as a chemical intermediate (P-12-404) and a surfactant (P-12-405 and P-12-406). Based on test data submitted on P-12-405, P-12-406, and closely analogous perfluorinated substances, as well as test data on analogous perfluorobutane sulfonate (PFBS), EPA identified concerns for liver, blood, kidney, developmental, and systemic toxicity. The consent order was issued under TSCA section 5(e)(1)(A)(i), 5(e)(1)(A)(ii)(I), and 5(e)(1)(A)(ii)(II) based on a finding that these substances may present an unreasonable risk of injury to human health and the environment; and these substances may be produced in substantial quantities and may reasonably be anticipated to enter the environment in substantial quantities, and there may be significant (or substantial) human exposure to the substances and their potential degradation products. To protect against these risks, the consent order requires:

1. Risk notification. If as a result of the test data required, the company becomes aware that the PMN substances may present a risk of injury to human health or the environment, the company must incorporate this new information, and any information on methods for protecting against such risk into an MSDS, within 90 days.

2. Use of personal protective equipment including impervious gloves (when there is potential dermal exposure) for PMNs P-12-404 and P-12-406.

3. Use of personal protective equipment including impervious gloves (when there is potential for dermal exposures), and either a NIOSH-certified respirator with an APF of at least 10 or compliance with a NCEL of 0.7 mg/m<sup>3</sup> as an 8-hour time-weighted average (when there is potential inhalation exposure) for the PMN substance P-12-405.

4. Establishment and use of a hazard communication program.

5. Submission of certain environmental fate and human health testing prior to exceeding the confidential production volume limits of the aggregate amount of the PMN substances, P-12-405 and P-12-406, specified in the consent order.

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

*Recommended testing:* EPA has determined that the results of certain environmental fate and toxicity testing would help characterize the possible effects of the PMN substances. The company has agreed not to exceed the first confidential production limit without performing a semi-continuous activated sludge (SCAS) test (OPPTS Test Guideline 835.5045) modified, on PMN substance P-12-406. The PMN submitter has also agreed not to exceed the second confidential production limit without performing a metabolism and pharmacokinetics test (OPPTS Test Guideline 870.7485) and a combined repeated dose toxicity test (OPPTS Test Guideline 870.3650) on the predominant degradation product identified in the SCAS test. EPA has also determined that the results of a combined chronic toxicity/carcinogenicity test (OPPTS Test Guideline 870.4300) on PFBS would help characterize the human health and environmental effects of the PMN substances. The consent order does not require submission of this test on PFBS at any specified time or production volume. However, the consent order's restrictions on manufacture, processing, distribution in commerce, use, and disposal of the PMN substances will remain in effect until the consent order is modified or revoked by EPA based on submission of that or other relevant information.

*CFR citation:* 40 CFR 721.10770.

*PMN Numbers P-13-175 and P-13-176*

*Chemical names:* (P-13-175) Hexane, 1,6-diisocyanato-, homopolymer,

.alpha.-[1-[[[3-[[3-(dimethylamino)propyl]amino]propyl]amino]carbonyl]-1,2,2,2-tetrafluoroethyl]-.omega.-(1,1,2,2,3,3,3-heptafluoropropoxy)poly[oxy(trifluoro(trifluoromethyl)-1,2-ethanediy)]-blocked; and (P-13-176) Fluorinated oxirane polymer (generic).

*CAS numbers:* (P-13-175) 1279108-20-1; and (P-13-176) Claimed confidential.

*Effective date of TSCA section 5(e) consent order:* December 13, 2013.

*Basis for TSCA section 5(e) consent order:* The PMNs state that the substances will be used as a coating additive in paper and paperboard to impart grease, alcohol, and solvent resistance (P-13-175) and an intermediate for use in the manufacture of a polymer (P-13-176). For the PMN substance P-13-176, where the average number molecular width <1,000 daltons is less than 0.5%, ecotoxicity concerns were low based on ecological SAR analysis of test data on analogous esters. However, based on potential concerns for perfluoro ethers, and the uncertainties regarding toxicity of the lower molecular weight portions, EPA predicts toxicity to aquatic organisms for P-13-176 if the average number molecular weight of <1,000 daltons is greater than 0.5%. The consent order was issued under TSCA section 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) based on a finding that the substances may present an unreasonable risk of injury to the environment. To protect against these risks, the consent order requires:

1. Manufacture the PMN substance P-13-175 using the PMN substance P-13-176 as the starting raw material.

2. Manufacture the PMN substance P-13-176: (a) Where the average number molecular weight less than 1,000 Daltons is less than or equal to 0.5% and (b) for use as a chemical intermediate to manufacture PMN substance P-13-175.

*Recommended testing:* EPA has determined that the results of either a Zahn-Wellens/EMPA test (OPPTS Test Guideline 835.3200) or a SCAS test (OPPTS Test Guideline 835.3210) modified; and a sediment-water lumbriculus toxicity test (OECD Test Guideline 225) using spiked sediment, on P-13-176, would help characterize the effects of the PMN substances. The consent order does not require submission of the testing at any specified time or production volume. However, the consent order's restrictions on manufacture, processing, distribution in commerce, use, and disposal of the PMNs will remain in effect until the consent order is modified or revoked by EPA based on

submission of that or other relevant information.

*CFR citation:* 40 CFR 721.10771 (P-13-175) and 40 CFR 721.10772 (P-13-176).

*PMN Number P-13-223*

*Chemical name:* Methylene bisacetophenone derivative (generic).

*CAS number:* Claimed confidential.

*Basis for action:* The PMN states that the generic (non-confidential) use of the substance is as a photoinitiator for coatings and inks. Based on test data on the PMN substance, EPA identified concerns for reproductive and developmental effects from dermal and inhalation exposures. In addition, based on test data on the PMN substance, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 5 ppb of the PMN substance in surface waters. As described in the PMN, significant occupational dermal and inhalation exposures are not expected due to the use of impervious gloves and a NIOSH-certified respirator with an APF of at least 10. Further, releases to water are not expected to result in surface water concentrations that exceed 5 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use will present an unreasonable risk. However, EPA has determined that any use of the substance without impervious gloves, where there is a potential for dermal exposures; any use of the substance without a NIOSH-certified respirator with an APF of at least 10, where there is a potential for inhalation exposures; or any use of the substance resulting in surface water concentrations exceeding 5 ppb may result in serious health effects and significant adverse environmental effects. Based on this information, the PMN meets the concern criteria at § 721.170 (b)(3)(i) and (b)(4)(i).

*Recommended testing:* EPA has determined that the results of a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465); a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); and a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300) would help characterize the human health and environmental effects of the PMN substance. EPA also recommends that the guidance document on aquatic toxicity testing of difficult substances and mixtures (OECD Test Guideline 23) be followed to facilitate solubility of the PMN substance in the test media.

*CFR citation:* 40 CFR 721.10773.

*PMN Number P-13-239*

*Chemical name:* Amine adduct (generic).

*CAS number:* Claimed confidential.

*Effective date of TSCA section 5(e) consent order:* January 15, 2014.

*Basis for TSCA section 5(e) consent order:* The PMN states that the generic (non-confidential) use of the PMN substance will be as a membrane hardener. Based on test data on the PMN substance, as well as ecological SAR analysis of test data on analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PMN substance in surface waters and general population exposures from incineration and landfill releases. The consent order was issued under TSCA section 5(e)(1)(A)(i), 5(e)(1)(A)(ii)(I), and 5(e)(1)(A)(ii)(II) based on a finding that the substance may present an unreasonable risk of injury to human health and the environment, may be produced in substantial quantities and may reasonably be anticipated to enter the environment in substantial quantities, and there may be significant (or substantial) human exposure to the substance. To protect against these risks, the consent order requires:

1. No domestic manufacture of the PMN substance.

2. Import, processing and use of the PMN substance only as described in the consent order.

3. Submission of certain toxicity and fate testing prior to exceeding the confidential production volume limit specified in the consent order.

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

*Recommended testing:* EPA has determined that the results of certain toxicity testing would help characterize possible health effects of the PMN substance. The company has agreed not to exceed the confidential production limit specified in the consent order without performing an in vitro mammalian chromosome aberration test (OECD Test Guideline 473); an in vitro mammalian cell gene mutation test (OECD Test Guideline 476) by the hypoxanthine-guanine phosphoribosyl transferase (HPRT) path; and a combined repeated dose toxicity study with reproduction/developmental toxicity screening (OPPTS Test Guideline 870.3670 or OECD Test Guideline 422). EPA has also determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400);

and a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300) would help characterize the environmental effects of the PMN substance. The consent order does not require submission of this testing at any specified time or production volume. However, the consent order's restrictions on manufacture, processing, distribution in commerce, use, and disposal of the PMN will remain in effect until the consent order is modified or revoked by EPA based on submission of that or other relevant information.

*CFR citation:* 40 CFR 721.10774.

*PMN Number P-13-495*

*Chemical name:* Metal hydroxide, treated with alkenyl alkoxy silane (generic).

*CAS number:* Claimed confidential.

*Basis for action:* The PMN states that the use of the substance will be as a filler in fire resistant silicone rubber blends. Based on SAR analysis of test data on analogous respirable poorly soluble particulates, EPA identified human health concerns for lung toxicity and oncogenicity from exposure to the PMN substance via inhalation. As described in the PMN, occupational inhalation exposures are not expected as the substance is not handled in the form of a powder. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance in the form of a powder may result in serious health effects. Based on this information, the PMN substance meets the concern criteria at § 721.170 (b)(1)(i)(C) and (b)(3)(ii).

*Recommended testing:* EPA has determined that the results of a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) with a 60-day holding period would help characterize the human health effects of the PMN substance.

*CFR citation:* 40 CFR 721.10775.

*PMN Number P-13-793*

*Chemical name:* Functionalized carbon nanotubes (generic).

*CAS number:* Claimed confidential.

*Basis for action:* The PMN states that the substance will be used as a thin film for electronic device applications. Based on SAR analysis of test data on analogous carbon nanotubes and other respirable poorly soluble particulates, EPA identified potential lung effects, developmental toxicity, and dermal toxicity from exposure to the PMN substance via inhalation, dermal, and oral routes. Further, EPA predicts

toxicity to aquatic organisms via releases of the PMN substance to surface water. As described in the PMN, EPA does not expect significant occupational exposures due to the use of impervious gloves, where there is potential for dermal exposure, and because the PMN is used in liquid form and is not spray applied. Further, EPA does not expect environmental releases during the use identified in the PMN submission. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk human health or the environment. EPA has determined, however, that any use of the substance without the use of impervious gloves, where there is a potential for dermal exposure; manufacturing the PMN substance for use other than as a thin film for electronic device applications; manufacturing, processing, or using the PMN substance in a form other than a liquid; use of the PMN substance involving an application method that generates a mist, vapor, or aerosol; or any release of the PMN substance into surface waters may cause serious health effects or significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria in § 721.170 (b)(3)(ii) and (b)(4)(ii).

*Recommended testing:* EPA has determined that the results of an oral and inhalation pharmacokinetic test (OPPTS Test Guideline 870.7485); a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465); a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); an algal toxicity test (OCSPP Test Guideline 850.4500); and a surface charge by electrophoresis by either the (ASTM Test Guideline E2865-12) or measuring the zeta potential of nanoparticles (Nanotechnology Characterization Library (NCL) Method PCC-2) (located in the Docket under Docket ID number EPA-HQ-OPPT-2014-0390); would help characterize the human health and environmental effects of the PMN substance.

*CFR citation:* 40 CFR 721.10776.

*PMN Numbers P-13-945 and P-13-946*

*Chemical names:* (P-13-945) 2,4-Hexadienoic acid, 3-(trimethoxysilyl)propyl ester; and (P-13-946) 2,4-Hexadienoic acid, 3-(trimethoxysilyl)propyl ester (2E,4E)-.

*CAS numbers:* (P-13-945) 3090-13-9 and (P-13-946) 163802-53-7.

*Basis for action:* The PMNs state that the generic (non-confidential) use of the substances will be as industrial

thermoplastic additives. Based on test data on the PMN substances, as well as SAR analysis of test data on analogous alkoxysilanes, EPA identified concerns for respiratory irritation and chronic lung toxicity from inhalation exposures. Further, based on test data on the PMN substances, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 58 ppb of the substances in surface waters. As described in the PMNs, inhalation exposures are not expected, and releases to surface waters are not expected to result in surface water concentrations that exceed 58 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substances may present an unreasonable risk. However, EPA has determined that any use of the substances involving an application method that generates a vapor, mist, or aerosol; or any use of the substances resulting in surface water concentrations exceeding 58 ppb may result in serious health effects and significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(3)(i), (b)(3)(ii), and (b)(4)(i).

*Recommended testing:* EPA has determined that the results of a 90-day toxicity test in rodents (OPPTS Test Guideline 870.3100) via the inhalation route; a hydrolysis test (OPPTS Test Guideline 835.2120); a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); and a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300) on PMN substance P-13-946 would help characterize the human health and environmental effects of the PMN substances.

*CFR citation:* 40 CFR 721.10777 (P-13-945) and 40 CFR 721.10778 (P-13-946).

*PMN Number P-14-28*

*Chemical name:* Substituted alkene, reaction products with isophoronediamine (generic).

*CAS number:* Claimed confidential.

*Basis for action:* The PMN states that the use of the substance will be as a site-limited intermediate for coating resin manufacture. Based on SAR analysis of test data on analogous organonitriles and cyanides, EPA identified human health concerns for acute oral toxicity and developmental toxicity from exposure to the PMN substance via inhalation. Further, based on ecological SAR analysis of test data on analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 49 ppb of the PMN substance in surface waters. As described in the PMN, occupational

exposures are expected to be minimal as the substance is used as a site-limited intermediate by an application method that does not generate a dust, mist, vapor, or aerosol. In addition, releases of the substance are not expected to result in surface water concentrations that exceed 49 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance other than as a site-limited intermediate; any use of the substance involving an application method that generates a dust, vapor, mist, or aerosol; or any use of the substance resulting in surface water concentrations exceeding 49 ppb may result in serious human health or significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(3)(ii) and (b)(4)(ii).

**Recommended testing:** EPA has determined that the results of prenatal developmental toxicity test (OPPTS Test Guideline 870.3700) in rats; a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); a fish acute toxicity mitigated by humic acid (OPPTS Test Guideline 850.1085); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the human health and environmental effects of the PMN substance.

**CFR citation:** 40 CFR 721.10779.

#### PMN Number P-14-72

**Chemical name:** Propaneperoxoic acid, 2,2-dimethyl-, 1,1,3,3-tetramethylbutyl ester.

**CAS number:** 22288-41-1.

**Basis for action:** The PMN states that the use of the substance will be as a polymerization initiator for the production of polyvinyl chloride (PVC) and polyethylene resin. Based on test data on the PMN substance, as well as ecological SAR analysis of test data on analogous peroxy esters, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 3 ppb of the PMN substance in surface waters. As described in the PMN, releases of the substance are not expected to result in surface water concentrations that exceed 3 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface waters concentrations exceeding 3 ppb may result in significant adverse

environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(i) and (b)(4)(ii).

**Recommended testing:** EPA has determined that the results of a ready biodegradability test (OECD Test Guideline 301C) with product-specific chemical analytics to validate the degradation products (including intermediate products) and the rates of degradation (including intermediate degradation rates); and a hydrolysis as a function of pH and temperature test (OPPTS Test Guideline 835.2130) would help characterize the environmental effects of the PMN substance.

**CFR citation:** 40 CFR 721.10780.

#### PMN Numbers P-14-89, P-14-90, P-14-91, and P-14-92

**Chemical names:** Fatty acid amide hydrochlorides (generic).

**CAS numbers:** Claimed confidential.

**Basis for action:** The consolidated PMN states that the substances will be used as surfactants for use in asphalt emulsions. Based on ecological SAR analysis of test data on analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed the following values of the PMN substances in surface waters:

PMN No.	Concentration of concern (ppb)
P-14-89, P-14-92 .....	110
P-14-90 .....	240
P-14-91 .....	53

For the use described in the PMNs, releases of the substances are not expected to result in surface water concentrations that exceed these values. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substances resulting in surface water concentrations exceeding the aforementioned concentrations of concern may result in significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(ii).

**Recommended testing:** EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of

the PMN substances. EPA also recommends that the guidance document on aquatic toxicity testing of difficult substances and mixtures (OECD Test Guideline 23) be followed.

**CFR citation:** 40 CFR 721.10781.

#### PMN Numbers P-14-158, P-14-159, P-14-161, P-14-162, and P-14-163

**Chemical names:** Fatty acid amides (generic).

**CAS numbers:** Claimed confidential.

**Basis for action:** The consolidated PMN states that the substances will be used as chemical intermediates and additives for flotation products. Based on ecological SAR analysis of test data on analogous amides and aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed the following values of the PMN substances in surface waters:

PMN No.	Concentration of concern (ppb)
P-14-158, P-14-159, P-14-161, P-14-163	1
P-14-162 .....	140

For the use described in the PMNs, releases of the substances are not expected to result in surface water concentrations that exceed these values. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substances resulting in surface water concentrations exceeding the aforementioned concentrations of concern may result in significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(ii).

**Recommended testing:** EPA has determined that the results of (1) a water solubility: Column elution method; shake flask method test (OPPTS Test Guideline 830.7840) or a water solubility generator column method test (OPPTS Test Guideline 830.7860); and (2) a determination of the partition coefficient (n-octanol/water) by shake flask method (OPPTS Test Guideline 830.7550), or generator column method (OPPTS Test Guideline 830.7560), or estimation by liquid chromatography (OPPTS Test Guideline 830.7570) would help characterize the physical/chemical properties of the PMN substances. Depending upon the results of these data, the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); and an algal toxicity test (OCSPP Test

Guideline 850.4500) may be recommended to help characterize the environmental effects of the PMN substances.

*CFR citation:* 40 CFR 721.10782.

*PMN Numbers* P-14-173, P-14-175, P-14-176, P-14-177, P-14-178, P-14-179, P-14-180, P-14-181, P-14-182, P-14-183, P-14-184, P-14-185, P-14-186, P-14-187, P-14-188, P-14-190, P-14-191, P-14-192 and P-14-193

*Chemical names:* Fatty acid amide acetates (generic).

*CAS numbers:* Claimed confidential.

*Basis for action:* The PMNs state that the substances will be used as flotation additives for use in mineral processing. Based on ecological SAR analysis of test data on analogous amides and aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed the following values of the PMN substances in surface waters:

PMN No.	Concentration of concern (ppb)
P-14-173, P-14-175, P-14-178, P-14-179, P-14-181, P-14-183, P-14-184, P-14-192, P-14-193 .....	1
P-14-176, P-14-180, P-14-185, P-14-186, P-14-187, P-14-190 .....	2
P-14-177, P-14-188 .....	3
P-14-191 .....	4
P-14-182 .....	140

For the use described in the PMNs, releases of the substances are not expected to result in surface water concentrations that exceed these values. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substances resulting in surface water concentrations exceeding the aforementioned concentrations of concern may result in significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(ii).

*Recommended testing:* EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) on P-14-184, and any one of the remaining PMN substances, would help characterize the environmental effects of the PMN substances. Further, EPA determined

that the results of a fish acute toxicity mitigated by humic acid test (OPPTS Test Guideline 850.1085) on PMN P-14-184 would help characterize the environmental effects of the PMN substance. EPA also recommends that the guidance document on aquatic toxicity testing of difficult substances and mixtures (OECD Test Guideline 23) be followed.

*CFR citation:* 40 CFR 721.10783.

*PMN Numbers* P-14-216, P-14-217, P-14-218, and P-14-231

*Chemical names:* (P-14-216, P-14-217, and P-14-218) Mixed butyltin mercaptoester sulfides (generic) and (P-14-231) Mixed methyltin mercaptoester sulfides (generic).

*CAS numbers:* Claimed confidential.

*Basis for action:* The PMNs state that the substances will be used as stabilizers in polyvinyl chloride. Based on the physical-chemical properties of the PMN substances and their anticipated degradation products, as well as SAR analysis of test data on analogous organotin compounds, EPA identified concerns for immunotoxicity, neurotoxicity, developmental and reproductive toxicity, asthma and skin sensitization from dermal and inhalation exposures to the PMN substances, and toxicity to aquatic organisms at concentrations that exceed 0.5 ppb of the PMN substances in surface waters. For the use described in the PMNs (including waste handling and hazard communication), EPA does not expect significant occupational or general population exposures, nor significant releases to the aquatic environment due to

1. Use of impervious gloves, where there is a potential for dermal exposures.

2. Maintaining workplace airborne concentrations of the PMN substances not to exceed the OSHA PEL for organotins of 0.1 micrograms/m<sup>3</sup> by percent tin (% Sn).

3. Labeling transport containers and providing hazard communication.

4. Use of the substance only as described in the PMN. and

5. Releases of any waste stream into the waters of the United States not to exceed 0.5 ppb.

Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance without dermal protection, where there is a potential for dermal exposures; any use of the PMN substances without maintaining workplace airborne concentrations exceeding the OSHA PEL of 0.1

micrograms/m<sup>3</sup> by percent tin; use of the substance without container labeling and appropriate hazard communication; or any use of the substances other than as stabilizers in polyvinyl chloride at concentrations not to exceed 2%, or any use of the substance resulting in releases to surface waters exceeding concentrations of 0.5 ppb of the PMN substances may result in serious health effects and significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(3)(ii), (b)(3)(iii), (b)(4)(ii), and (b)(4)(iv).

*Recommended testing:* EPA has determined that the results of the following testing on either P-14-216, P-14-217, or P-14-218; and P-14-231 would help characterize the human health and environmental effects of the PMN substances: A 90-day toxicity test (OPPTS Test Guideline 870.3100) in rats, by the oral route, with special attention to lymphoid organs (thymus, spleen, peripheral lymph nodes) and bone marrow; a neurotoxicity test (OPPTS Test Guideline 870.6200) to include motor activity, functional observational battery, and neuropathology with special attention to lesions in the hippocampus; a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an acute invertebrate toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); an algal toxicity test (OCSPP Test Guideline 850.4500); an aerobic ready biodegradability test (OECD Test Guideline 301); a fish early life stage toxicity test (OPPTS Test Guideline 850.1400); and a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300). In addition, Further, EPA had determined that a leaching from PVC pipe study on PMN substances P-14-216, P-14-217, or P-14-218 (or model dibutyltin mercaptoester sulfide); and a leaching from PVC pipe study on PMN substance P-14-231 (or model dimethyltin mercaptoester sulfide) would be helpful in characterizing the PMN substances.

*CFR citation:* 40 CFR 721.10784 (P-14-216, P-14-217, and P-14-218) and 40 CFR 721.10785 (P-14-231).

*PMN Number* P-14-234

*Chemical name:* Trisubstituted ethoxylated carbomonocycle (generic).

*CAS number:* Claimed confidential.

*Basis for action:* The PMN states that the generic (non-confidential) use of the substance is as a dispersant. Based on test data on the PMN substance, as well as ecological SAR analysis of test data on analogous nonionic surfactants, EPA predicts toxicity to aquatic organisms

may occur at concentrations that exceed 24 ppb of the PMN substance in surface waters. As described in the PMN, releases of the substance are not expected to result in surface water concentrations that exceed 24 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 24 ppb may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(i) and (b)(4)(ii).

**Recommended testing:** EPA has determined that the results of an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substance.

**CFR citation:** 40 CFR 721.10786.

#### PMN Number P-14-270

**Chemical name:** Multi-functional novolac type epoxy resin (generic).

**CAS number:** Claimed confidential.

**Basis for action:** The PMN states that the substance will be used as a monomer for polyamides and as an ingredient to produce metamethylene 1,5 diisocyanate. Based on ecological SAR analysis of test data on analogous polyepoxides, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PMN substance in surface waters. As described in the PMN, releases of the substance are not expected to result in surface water concentrations that exceed 1 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 1 ppb may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(ii).

**Recommended testing:** EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substance.

**CFR citation:** 40 CFR 721.10787.

#### PMN Number P-14-357

**Chemical name:** Alkanedioic acids, polymer with substituted propanediol, alkanediols, polyethylene glycol and MDI (generic).

**CAS number:** Claimed confidential.

**Basis for action:** The PMN states that the use of the substance will be with lamination of plastic sheets and textiles. Based on SAR analysis of test data on analogous diisocyanates, EPA identified concerns for irritation to the eye, skin, and mucous membranes; and dermal and respiratory sensitization. As described in the PMN, EPA does not expect significant occupational exposures due to the use of a NIOSH-certified respirator with an APF of at least 10, where there is a potential for inhalation exposures; and the substance is applied by a method that does not generate a vapor, mist, or aerosol. Further, consumer inhalation exposures are not expected as the PMN is not being used in consumer products. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance without a NIOSH-certified organic vapor respirator with an APF of at least 10, where there is a potential for inhalation exposure; any use in consumer products; or any use of the substance involving an application method that generates a vapor, mist, or aerosol may cause serious health effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(3)(ii).

**Recommended testing:** EPA has determined that the results of a skin sensitization test (OPPTS Test Guideline 870.2600) and a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) would help characterize the human health effects of the PMN substance.

**CFR citation:** 40 CFR 721.10788.

### 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 9 of the 52 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) consent orders requiring the use of appropriate exposure controls were negotiated with the PMN submitters. The SNUR

provisions for these chemical substances are consistent with the provisions of the TSCA section 5(e) consent orders. These SNURs are promulgated pursuant to § 721.160 (see Unit VI.).

In the other 43 cases, where the uses are not regulated under a TSCA section 5(e) consent order, EPA determined that one or more of the criteria of concern established at § 721.170 were met, as discussed in Unit IV.

#### 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 regulate prospective manufacturers or processors of a listed chemical substance before the described significant new use of that chemical substance occurs, provided that regulation is warranted pursuant to TSCA sections 5(e), 5(f), 6, or 7.
- EPA will ensure that all manufacturers and processors of the same chemical substance that is subject to a TSCA section 5(e) consent order are subject to similar requirements.

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 a direct final rule, as described in § 721.160(c)(3) and § 721.170(d)(4). In accordance with § 721.160(c)(3)(ii) and § 721.170(d)(4)(i)(B), the effective date of this rule is December 26, 2014 without further notice, unless EPA receives written adverse or critical comments, or notice of intent to submit adverse or critical comments before November 26, 2014.

If EPA receives written adverse or critical comments, or notice of intent to

submit adverse or critical comments, on one or more of these SNURs before November 26, 2014, EPA will withdraw the relevant sections of this direct final rule before its effective date. EPA will then issue a proposed SNUR for the chemical substance(s) on which adverse or critical comments were received, providing a 30-day period for public comment.

This rule establishes SNURs for a number of chemical substances. Any person who submits adverse or critical comments, or notice of intent to submit adverse or critical 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) consent orders have been issued for 9 of the 52 chemical substances, and the PMN submitters are prohibited by the TSCA section 5(e) consent orders from undertaking activities which would be designated as significant new uses. The identities of 46 of the 52 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). 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 October 27, 2014 as the cutoff date for determining whether the new use is ongoing. Persons who begin commercial manufacture or processing of the chemical substances for a significant new use identified as of that date would have to cease any such activity upon the effective date of the final rule. To resume their activities,

these persons would have to first comply with all applicable SNUR notification requirements and wait until the notice review period, including any extensions, expires. If such a person met the conditions of advance compliance under § 721.45(h), the person would be considered exempt from the requirements of the SNUR. Consult the **Federal Register** document of April 24, 1990 for a more detailed discussion of the cutoff date for ongoing uses.

#### VIII. Test Data and Other Information

EPA recognizes that TSCA section 5 does not require developing any particular test data before submission of a SNUN. The two exceptions are:

1. Development of test data is required where the chemical substance subject to the SNUR is also subject to a test rule under TSCA section 4 (see TSCA section 5(b)(1)).
2. Development of test data may be necessary where the chemical substance has been listed under TSCA section 5(b)(4) (see TSCA section 5(b)(2)).

In the absence of a TSCA section 4 test rule or a TSCA section 5(b)(4) listing covering the chemical substance, persons are required only to submit test data in their possession or control and to describe any other data 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. In cases where EPA issued a TSCA section 5(e) consent order that requires or recommends certain testing, Unit IV. lists those tests. Unit IV. also lists recommended testing for TSCA non-section 5(e) SNURs. Descriptions of tests are provided for informational purposes. EPA strongly encourages persons, before performing any testing, to consult with the Agency pertaining to protocol selection. To access the OCSPP test guidelines referenced in this document electronically, please go to <http://www.epa.gov/ocspp> and select "Test Methods and Guidelines." The Organisation for Economic Co-operation and Development (OECD) test guidelines are available from the OECD Bookshop at <http://www.oecdbookshop.org> or SourceOECD at <http://www.sourceoecd.org>. ASTM International standards are available at <http://www.astm.org/Standard/index.shtml>.

In the TSCA section 5(e) consent orders for several of 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 toxicity tests that would permit a reasoned evaluation of the potential risks posed by these chemical substances. Under recent TSCA section 5(e) consent orders, each PMN submitter is required to submit each study before reaching the specified production limit. Listings of the tests specified in the TSCA section 5(e) consent orders are included in Unit IV. The SNURs contain the same production volume limits as the TSCA section 5(e) consent 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.

The recommended tests specified 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 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 conduct the appropriate tests.

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

- Human exposure and environmental release that may result from the significant new use of the chemical substances.
- Potential benefits of the chemical substances.
- Information on risks posed by the chemical substances compared to risks posed by potential substitutes.

#### IX. Procedural Determinations

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

Under these procedures a manufacturer or processor may request EPA to determine whether a proposed use would be a significant new use

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

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

## X. SNUN Submissions

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

## XI. Economic Analysis

EPA has evaluated the potential costs of establishing SNUN requirements for potential manufacturers and processors of the chemical substances subject to this rule. EPA's complete economic analysis is available in the docket under docket ID number EPA–HQ–OPPT–2014–0390.

## XII. Statutory and Executive Order Reviews

### A. Executive Order 12866

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

### B. Paperwork Reduction Act (PRA)

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

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

- A significant number of SNUNs would not be submitted by small entities in response to the SNUR.
- Submission of the SNUN would not cost any small entity significantly more than \$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 rule. As such, EPA has determined that this rule does not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the requirements of UMRA sections 202, 203, 204, or 205 (2 U.S.C. 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 rule does not have Tribal implications because it is not expected to have substantial direct effects on Indian Tribes. This rule 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 rule.

#### G. Executive Order 13045

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

#### H. Executive Order 13211

This 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).

#### XIV. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller

General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

#### List of Subjects

##### 40 CFR Part 9

Environmental protection, Reporting and recordkeeping requirements.

##### 40 CFR Part 721

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

Dated: October 9, 2014.

**Maria J. Doa,**

*Director, Chemical Control Division, 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.
* * * * *	
<b>Significant New Uses of Chemical Substances</b>	
* * * * *	
721.10766 .....	2070–0012
721.10767 .....	2070–0012
721.10768 .....	2070–0012
721.10769 .....	2070–0012
721.10770 .....	2070–0012
721.10771 .....	2070–0012
721.10772 .....	2070–0012
721.10773 .....	2070–0012
721.10774 .....	2070–0012
721.10775 .....	2070–0012
721.10776 .....	2070–0012
721.10777 .....	2070–0012

40 CFR citation	OMB control No.
721.10778 .....	2070–0012
721.10779 .....	2070–0012
721.10780 .....	2070–0012
721.10781 .....	2070–0012
721.10782 .....	2070–0012
721.10783 .....	2070–0012
721.10784 .....	2070–0012
721.10785 .....	2070–0012
721.10786 .....	2070–0012
721.10787 .....	2070–0012
721.10788 .....	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 § 721.10766 to subpart E to read as follows:

##### § 721.10766 Pyridine, 4-decyl-.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as pyridine, 4-decyl- (PMN P–10–235; CAS No. 1815–99–2) 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(j).

(ii) *Release to water.* Requirements as specified in § 721.90(a)(4) and (b)(4) (N=1).

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

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

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

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

■ 5. Add § 721.10767 to subpart E to read as follows:

##### § 721.10767 Fluoroether (generic).

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

(1) The chemical substance identified

generically as fluoroether (PMN P-11-224) 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 completely reacted (cured).

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k) (a significant new use is any manufacturing, processing, or use other than as an electrolyte for electrical/electronic equipment) and (q).

(ii) [Reserved]

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

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

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

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

■ 6. Add § 721.10768 to subpart E to read as follows:

**§ 721.10768 N-(2-hydroxyethyl) alkenamide (generic).**

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

(1) The chemical substance identified generically as N-(2-hydroxyethyl) alkenamide (PMN P-11-226) 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 completely 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), (a)(4), (a)(6)(ii), (a)(6)(vi), (b), and (c). 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) The following gloves have been demonstrated to meet the requirements of § 721.63(a)(3): North Silver Shield

Gloves, Ansell Barrier Gloves, North Butyl Gloves, Ansell Chemi Pro Gloves, Ansell Neoprene Gloves, Ansell So-Vex, and Ansell Cannerns.

(B) The following National Institute for Occupational Safety and Health (NIOSH)-certified respirators with an Assigned Protection Factor (APF) of at least 1,000 meet the requirements of § 721.63(a)(4):

(1) NIOSH-certified power air-purifying respirator with a hood or helmet and with appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridges in combination with HEPA filters.

(2) NIOSH-certified continuous flow supplied-air respirator equipped with a loose fitting face piece, hood, or helmet.

(3) NIOSH-certified negative pressure (demand) supplied-air respirator with a full face piece.

(C) As an alternative to the respiratory requirements listed here, a manufacturer or processor may choose to follow the New Chemical Exposure Limit (NCEL) provisions listed in the section TSCA 5(e) consent order for this substance. The NCEL is 0.03 mg/m<sup>3</sup> as an 8-hour time weighted average verified by actual monitoring data.

(ii) *Hazard communication program.* Requirements as specified in § 721.72(a), (b), (c), (d), (e), (f), (g)(1)(i), (g)(1)(iii), (g)(1)(iv), (g)(1)(vi), (g)(1)(vii), (g)(1)(viii), (g)(1)(ix), (g)(2)(i), (g)(2)(ii), and (g)(2)(iv) (use respiratory protection, or maintain workplace airborne concentrations at or below an 8-hour time-weighted average of 0.03 mg/m<sup>3</sup>), (g)(2)(v), (g)(3), and (g)(4). A significant new use of this substance is any manner or method of manufacture or processing associated with any use of this substance without providing risk notification as follows under § 721.72(c):

(A) If as a result of the test data required under the TSCA section 5(e) consent order for this substance, the employer becomes aware that this substance may present a risk of injury to human health or the environment, the employer must incorporate this new information, and any information on methods for protecting against such risk, into a MSDS as described in § 721.72(c) within 90 days from the time the employer becomes aware of the new information. If this substance is not being manufactured, processed, or used in the employer's workplace, the employer must add the new information to a MSDS before the substance is reintroduced into the workplace.

(B) The employer must ensure that persons who will receive the PMN substance from the employer, or who have received the PMN substance from

the employer within 5 years from the date the employer becomes aware of the new information described in paragraph (a)(2)(i)(A) of this section, are provided an MSDS containing the information required under paragraph (a)(2)(i)(A) of this section within 90 days from the time the employer becomes aware of the new information.

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

(iv) *Disposal.* Requirements as specified in § 721.85(a)(1) (destruction and removal efficiency of 99.99%), (a)(3) (underground injection control (class 1 well, deep well injection hazardous waste)), (b)(1) (destruction and removal efficiency of 99.99%), (b)(3) (underground injection control (class 1 well, deep well injection hazardous waste)), (c)(1) (destruction and removal efficiency of 99.99%), (c)(3) (underground injection control (class 1 well, deep well injection hazardous waste)).

(v) *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 (k) are applicable to manufacturers and processors of these substances.

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

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

■ 7. Add § 721.10769 to subpart E to read as follows:

**§ 721.10769 1-Octadecanaminium, N,N-dimethyl-N-[3-(triethoxysilyl)propyl]-, chloride (1:1), reaction products with ethylene glycol.**

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

(1) The chemical substance identified as 1-octadecanaminium, N,N-dimethyl-N-[3-(triethoxysilyl)propyl]-, chloride (1:1), reaction products with ethylene glycol (PMN P-12-41; CAS No. 1314035-96-5) 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 completely reacted (cured).

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f), (k) (a significant new use is import, processing and use of the PMN substance other than for waterproofing inorganic substrates, an asphalt binder modifier, and waterproofing of soil), and (q) (839,000 kilograms).

(ii) [Reserved]

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

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

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

■ 8. Add § 721.10770 to subpart E to read as follows:

**§ 721.10770 Fluoroalkyl sulfonamide derivatives (generic).**

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

(1) The chemical substances identified generically as fluoroalkyl sulfonamide derivatives (PMN P-12-404, P-12-405, and P-12-406) are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses for P-12-404 and P-12-406 are:

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

(ii) *Hazard communication program.* Requirements as specified in § 721.72(a), (b), (c), (e), (f), (g)(1) (The PMN substances may: Cause serious eye damage; and suspected of damaging fertility or the unborn child), and (g)(2) (When using these substances: Wear eye/face protection; avoid breathing dust/fume/gas/mist/vapors/spray; and wear protective gloves). A significant new use of these substances is any manner or method of manufacture or processing associated with any use of these substances without providing risk notification as follows under § 721.72(c):

(A) If as a result of the test data required under the TSCA section 5(e) consent order for these substances, the employer becomes aware that this substance may present a risk of injury to human health or the environment, the employer must incorporate this new information, and any information on methods for protecting against such risk, into a MSDS as described in § 721.72(c) within 90 days from the time the employer becomes aware of the new information. If these substances are not being manufactured, processed, or used in the employer's workplace, the employer must add the new information to a MSDS before the substances are reintroduced into the workplace.

(B) The employer must ensure that persons who will receive the PMN substances from the employer, or who have received the PMN substances from the employer within 5 years from the date the employer becomes aware of the new information described in paragraph (a)(2)(i)(A) of this section, are provided an MSDS containing the information required under paragraph (a)(2)(i)(A) of this section within 90 days from the time the employer becomes aware of the new information.

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

(3) The significant new uses for P-12-405 are:

(i) *Protection in the workplace.* (A) Requirements as specified in § 721.63(a)(1), (a)(2)(i), (a)(3), (a)(4), (a)(6)(v), (a)(6)(vi), (b), and (c). 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. The following National Institute for Occupational Safety and Health (NIOSH)-certified respirators with an Assigned Protection Factor (APF) of at least 10 meet the requirements of § 721.63(a)(4):

(1) NIOSH-certified power air-purifying respirator with a hood or helmet and with appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridges in combination with HEPA filters.

(2) NIOSH-certified continuous flow supplied-air respirator equipped with a loose fitting face piece, hood, or helmet.

(3) NIOSH-certified negative pressure (demand) supplied-air respirator with a full face piece.

(B) As an alternative to the respiratory requirements listed here, a manufacturer or processor may choose to follow the New Chemical Exposure Limit (NCEL) provisions listed in the section TSCA 5(e) consent order for these substances. The NCEL is 0.7 mg/m<sup>3</sup> as an 8-hour time weighted average verified by actual monitoring data.

(ii) *Hazard communication program.* Requirements as specified in § 721.72(a), (b), (c), (e), (f), (g)(1) (The PMN substance may: Cause serious eye damage; and suspected of damaging fertility or the unborn child), and (g)(2) (When using this substance: Wear eye/face protection; avoid breathing dust/fume/gas/mist/vapors/spray; use respiratory protection, or maintain workplace airborne concentrations at or below an 8-hour time-weighted average of 0.70 mg/m<sup>3</sup>; and wear protective gloves). A significant new use of this substance is any manner or method of manufacture or processing associated with any use of this substance without providing risk notification as follows under § 721.72(c):

(A) If as a result of the test data required under the TSCA section 5(e) consent order for this substance, the employer becomes aware that this substance may present a risk of injury to human health or the environment, the employer must incorporate this new information, and any information on methods for protecting against such risk, into a MSDS as described in § 721.72(c) within 90 days from the time the employer becomes aware of the new information. If this substance is not being manufactured, processed, or used in the employer's workplace, the employer must add the new information to a MSDS before the substance is reintroduced into the workplace.

(B) The employer must ensure that persons who will receive the PMN substance from the employer, or who have received the PMN substance from the employer within 5 years from the date the employer becomes aware of the new information described in paragraph (a)(2)(i)(A) of this section, are provided an MSDS containing the information required under paragraph (a)(2)(i)(A) of this section within 90 days from the time the employer becomes aware of the new information.

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

(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) and (a)(3)(iii) of this section.

■ 9. Add § 721.10771 to subpart E to read as follows:

**§ 721.10771 Hexane, 1,6-diisocyanato-, homopolymer, .alpha.-[1-[[[3-[[3-(dimethylamino)propyl]amino]propyl]amino]carbonyl]-1,2,2,2-tetrafluoroethyl]-.omega.-(1,1,2,2,3,3,3-heptafluoropropoxy)poly[oxy(trifluoro(trifluoromethyl)-1,2-ethanediyl)]-blocked.**

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

(1) The chemical substance identified as hexane, 1,6-diisocyanato-, homopolymer, .alpha.-[1-[[[3-[[3-(dimethylamino)propyl]amino]propyl]amino]carbonyl]-1,2,2,2-tetrafluoroethyl]-.omega.-(1,1,2,2,3,3,3-heptafluoropropoxy)poly[oxy(trifluoro(trifluoromethyl)-1,2-ethanediyl)]-blocked (PMN P-13-175; CAS No. 1279108-20-1) 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) *Hazard communication program.* A significant new use of this substance is any manner or method of manufacture or processing associated with any use of this substance without providing risk notification as follows:

(A) If as a result of the test data required under the TSCA section 5(e) consent order for this substance, the employer becomes aware that this substance may present a risk of injury to human health or the environment, the employer must incorporate this new information, and any information on methods for protecting against such risk, into a MSDS as described in § 721.72(c) within 90 days from the time the employer becomes aware of the new information. If this substance is not being manufactured, processed, or used in the employer's workplace, the employer must add the new information to a MSDS before the substance is reintroduced into the workplace.

(B) The employer must ensure that persons who will receive the PMN substance from the employer, or who have received the PMN substance from the employer within 5 years from the date the employer becomes aware of the new information described in paragraph (a)(2)(i)(A) of this section, are provided an MSDS containing the information

required under paragraph (a)(2)(i)(A) of this section within 90 days from the time the employer becomes aware of the new information.

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k) 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), (b), (c), and (i) are applicable to manufacturers and processors of this substance.

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

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

■ 10. Add § 721.10772 to subpart E to read as follows:

**§ 721.10772 Fluorinated oxirane polymer (generic).**

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

(1) The chemical substance identified generically as fluorinated oxirane polymer (PMN P-13-176) 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 completely reacted (cured).

(2) The significant new uses are:

(i) *Hazard communication program.* A significant new use of this substance is any manner or method of manufacture or processing associated with any use of this substance without providing risk notification as follows:

(A) If as a result of the test data required under the TSCA section 5(e) consent order for this substance, the employer becomes aware that this substance may present a risk of injury to human health or the environment, the employer must incorporate this new information, and any information on methods for protecting against such risk, into a MSDS as described in § 721.72(c) within 90 days from the time the employer becomes aware of the new information. If this substance is not being manufactured, processed, or used in the employer's workplace, the employer must add the new information to a MSDS before the substance is reintroduced into the workplace.

(B) The employer must ensure that persons who will receive the PMN substance from the employer, or who

have received the PMN substance from the employer within 5 years from the date the employer becomes aware of the new information described in paragraph (a)(2)(i)(A) of this section, are provided an MSDS containing the information required under paragraph (a)(2)(i)(A) of this section within 90 days from the time the employer becomes aware of the new information.

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k) 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), (b), (c), and (i) are applicable to manufacturers and processors of this substance.

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

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

■ 11. Add § 721.10773 to subpart E to read as follows:

**§ 721.10773 Methylene bisacetophenone derivative (generic).**

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

(1) The chemical substance identified generically as methylene bisacetophenone derivative (PMN P-13-223) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i), (a)(3), and (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) The following National Institute for Occupational Safety and Health (NIOSH)-certified respirators with an Assigned Protection Factor (APF) of at least 10 meet the requirements of § 721.63(a)(4):

(1) NIOSH-certified power air-purifying respirator with a hood or helmet and with appropriate gas/vapor (acid gas, organic vapor, or substance

specific) cartridges in combination with HEPA filters.

(2) NIOSH-certified continuous flow supplied-air respirator equipped with a loose fitting face piece, hood, or helmet.

(3) NIOSH-certified negative pressure (demand) supplied-air respirator with a full face piece.

(B) [Reserved]

(ii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) (N=5).

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

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

■ 12. Add § 721.10774 to subpart E to read as follows:

**§ 721.10774 Amine adduct (generic).**

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

(1) The chemical substance identified generically as amine adduct (PMN P-13-239) 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 completely reacted (cured).

(2) The significant new uses are:

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

(ii) [Reserved]

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

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

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

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

■ 13. Add § 721.10775 to subpart E to read as follows:

**§ 721.10775 Metal hydroxide, treated with alkenyl alkoxy silane (generic).**

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

(1) The chemical substance identified generically as metal hydroxide, treated with alkenyl alkoxy silane (PMN P-13-495) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(v)(1), (w)(1), and (x)(1).

(ii) [Reserved]

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

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

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

■ 14. Add § 721.10776 to subpart E to read as follows:

**§ 721.10776 Functionalized carbon nanotubes (generic).**

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

(1) The chemical substance identified generically as functionalized carbon nanotubes (PMN P-13-793) 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 completely reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.*

Requirements as specified in § 721.63(a)(1), (a)(2)(i), and (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.

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(j) (a significant new use is use other than as a thin film for electronic device applications), (v)(1), (v)(2), (w)(1), (w)(2), (x)(1), (x)(2), and (y)(1).

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

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

apply to this section except as modified by this paragraph (b).

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

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

■ 15. Add § 721.10777 to subpart E to read as follows:

**§ 721.10777 2,4-Hexadienoic acid, 3-(trimethoxysilyl)propyl ester.**

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

(1) The chemical substance identified as 2,4-hexadienoic acid, 3-(trimethoxysilyl)propyl ester (PMN P-13-945; CAS No. 3090-13-9) 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(y)(1).

(ii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) (N = 58).

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

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

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

■ 16. Add § 721.10778 to subpart E to read as follows:

**§ 721.10778 2,4-Hexadienoic acid, 3-(trimethoxysilyl)propyl ester (2E,4E)-.**

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

(1) The chemical substance identified as 2,4-hexadienoic acid, 3-(trimethoxysilyl)propyl ester (2E,4E)- (PMN P-13-946; CAS No. 163802-53-7) 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(y)(1).

(ii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) (N=58).

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

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

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

■ 17. Add § 721.10779 to subpart E to read as follows:

**§ 721.10779 Substituted alkene, reaction products with isophoronediamine (generic).**

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

(1) The chemical substance identified generically as substituted alkene, reaction products with isophoronediamine (PMN P-14-28) 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(h), (y)(1), and (y)(2).

(ii) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) (N=49).

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

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

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

■ 18. Add § 721.10780 to subpart E to read as follows:

**§ 721.10780 Propaneperoxoic acid, 2,2-dimethyl-, 1,1,3,3-tetramethylbutyl ester.**

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

(1) The chemical substance identified as propaneperoxoic acid, 2,2-dimethyl-, 1,1,3,3-tetramethylbutyl ester (PMN P-14-72; CAS No. 22288-41-1) 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) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) (N=3).

(ii) [Reserved]

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

(1) *Recordkeeping*. Recordkeeping requirements as specified in

§ 721.125(a), (b), (c), and (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.

■ 19. Add § 721.10781 to subpart E to read as follows:

**§ 721.10781 Fatty acid amide hydrochlorides (generic).**

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

(1) The chemical substances identified generically as fatty acid amide hydrochlorides (PMNs P-14-89, P-14-90, P-14-91 and P-14-92) are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) (where N=110 for PMNs P-14-89 and P-14-92; N=240 for PMN P-14-90; N=53 for PMN P-14-91).

(ii) [Reserved]

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

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

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

■ 20. Add § 721.10782 to subpart E to read as follows:

**§ 721.10782 Fatty acid amides (generic).**

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

(1) The chemical substances identified generically as fatty acid amides (PMN P-14-158, P-14-159, P-14-161, P-14-162, and P-14-163) are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Release to water*. Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) (where N=1 for PMNs P-14-158, P-14-159, P-14-161, and P-14-163; N=140 for PMN P-14-162).

(ii) [Reserved]

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

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

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

■ 21. Add § 721.10783 to subpart E to read as follows:

**§ 721.10783 Fatty acid amide acetates (generic).**

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

(1) The chemical substances identified generically as fatty acid amide acetates (PMNs P-14-173, P-14-175, P-14-176, P-14-177, P-14-178, P-14-179, P-14-180, P-14-181, P-14-182, P-14-183, P-14-184, P-14-185, P-14-186, P-14-187, P-14-188, P-14-190, P-14-191, P-14-192 and P-14-193) are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Release to water*. Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) (where N = concentration of concern as follows):

PMN No.	Concentration of concern (ppb)
P-14-173, P-14-175, P-14-178, P-14-179, P-14-181, P-14-183, P-14-184, P-14-192, P-14-193	1
P-14-176, P-14-180, P-14-185, P-14-186, P-14-187, P-14-190	2
P-14-177, P-14-188	3
P-14-191	4
P-14-182	140

(ii) [Reserved]

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

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

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

■ 22. Add § 721.10784 to subpart E to read as follows:

**§ 721.10784 Mixed butyltin mercaptoester sulfides (generic).**

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

(1) The chemical substances identified generically as mixed butyltin mercaptoester sulfides (PMNs P-14-216, P-14-217, and P-14-218) are subject to reporting under this section for the significant new uses described in

paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the PMN substances after they have been completely reacted (cured) or permanently entrained into a solid polyvinyl chloride matrix.

(2) The significant new uses are:

(i) *Protection in the workplace.*

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

(ii) *Hazard communication program.*

Requirements as specified in § 721.72(a) through (e)(concentration set at 1.0 percent), (f), (g)(1)(i), (g)(1)(ii), (g)(1)(iii), (g)(1)(iv), (g)(1)(v), (g)(1)(viii), (g)(1)(ix), (g)(2)(i), (g)(2)(ii), (g)(2)(iii), (g)(2)(v), (g)(3)(i), (g)(3)(ii), (g)(4)(i), and (g)(5).

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80. A significant new use is any use other than as a stabilizer in polyvinyl chloride (PVC) at a concentration of no greater than 2 percent.

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) (N=0.5).

(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 these substances.

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

■ 23. Add § 721.10785 to subpart E to read as follows:

**§ 721.10785 Mixed methyltin mercaptoester sulfides (generic).**

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

(1) The chemical substance identified generically as mixed methyltin mercaptoester sulfides (PMN P-14-231) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the PMN substance after it has been completely reacted (cured) or permanently

entrained into a solid polyvinyl chloride matrix.

(2) The significant new uses are:

(i) *Protection in the workplace.*

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

(ii) *Hazard communication program.*

Requirements as specified in § 721.72(a) through (e)(concentration set at 1.0 percent), (f), (g)(1)(i), (g)(1)(ii), (g)(1)(iii), (g)(1)(iv), (g)(1)(v), (g)(1)(viii), (g)(1)(ix), (g)(2)(i), (g)(2)(ii), (g)(2)(iii), (g)(2)(v), (g)(3)(i), (g)(3)(ii), (g)(4)(i), and (g)(5).

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80. A significant new use is any use other than as a stabilizer in polyvinyl chloride at a concentration of no greater than 2 percent.

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) (N=0.5).

(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.

■ 24. Add § 721.10786 to subpart E to read as follows:

**§ 721.10786 Trisubstituted ethoxylated carbomonocycle (generic).**

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

(1) The chemical substance identified generically as trisubstituted ethoxylated carbomonocycle (PMN P-14-234) 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) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) (N=24).

(ii) [Reserved]

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

(1) *Recordkeeping.* Recordkeeping requirements as specified in

§ 721.125(a), (b), (c), and (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.

■ 25. Add § 721.10787 to subpart E to read as follows:

**§ 721.10787 Multi-functional novolac type epoxy resin (generic).**

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

(1) The chemical substance identified generically as multi-functional novolac type epoxy resin (PMN P-14-270) 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) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) (N=1).

(ii) [Reserved]

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

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a), (b), (c), and (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.

■ 26. Add § 721.10788 to subpart E to read as follows:

**§ 721.10788 Alkanedioic acids, polymer with substituted propanediol, alkanediols, and polyethylene glycol and MDI (generic).**

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

(1) The chemical substance identified generically as alkanedioic acids, polymer with substituted propanediol, alkanediols, and polyethylene glycol and MDI (PMN P-14-357) 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)(4), (a)(6)(ii), (a)(6)(v), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. The following National Institute for Occupational

Safety and Health (NIOSH)-certified respirators with an Assigned Protection Factor (APF) of at least 10 meet the requirements of § 721.63(a)(4):

(A) NIOSH-certified power air-purifying respirator with a hood or helmet and with appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridges in combination with HEPA filters.

(B) NIOSH-certified continuous flow supplied-air respirator equipped with a loose fitting face piece, hood, or helmet.

(C) NIOSH-certified negative pressure (demand) supplied-air respirator with a full face piece.

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o) 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), (b), (c), (d), 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.

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