

Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

7. Taking of Private Property

This rule will not cause a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

8. Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

9. Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

10. Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

11. Energy Effects

This action is not a "significant energy action" under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use.

12. Technical Standards

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

13. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023-01 and Commandant Instruction M16475.ID, which guide the Coast Guard in

complying with the National Environmental Policy Act of 1969 (NEPA)(42 U.S.C. 4321-4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves establishment of a safety zone, and, therefore, it is categorically excluded from further review under paragraph 34(g) of Figure 2-1 of the Commandant Instruction. An environmental analysis checklist supporting this determination and a Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this rule.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping, Security measure, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

- 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05-1, 6.04-1, 6.04-6 and 160.5; Pub. L. 107-295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

- 2. Add § 165.T09-0729 to read as follows:

§ 165.T09-0729 Safety Zone; Superior Bay, Duluth, MN.

(a) *Location.* The following area is a temporary safety zone: All waters of the Duluth Harbor Basin, Northern Section, including the Duluth Entry encompassed in an imaginary line beginning at point 46 46'36.1236" N 092 06'06.987" W, running southeast to 46 46'32.7534" N 092 06'01.7382" W, running northeast to 46 46'45.9228" N 092 05'45.1818" W, running northwest to 46 46'49.4718" N 092 05'49.349" W and finally running southwest to the original point.

(b) *Effective and Enforcement Period.* This rule will be effective and enforced from 6 a.m. to 8:30 a.m. on August 26, 2012.

(c) *Regulations.* (1) In accordance with the general regulations in § 165.23, entry into, transiting or anchoring within this safety zone is prohibited unless authorized by the Captain of the Port, Marine Safety Unit Duluth, or his designated representative.

(2) This safety zone is closed to all vessel traffic, except as may be permitted by the Captain of the Port, Marine Safety Unit Duluth or his designated representative.

(3) The "on-scene representative" of the Captain of the Port is any Coast Guard commissioned, warrant or petty officer who has been designated by the Captain of the Port to act on his behalf. The on-scene representative will be aboard either a Coast Guard or Coast Guard auxiliary vessel. The Captain of the Port representative may be contacted via VHF channel 16.

(4) Vessel operators desiring to enter or operate within the safety zone shall contact the Captain of the Port, Marine Safety Unit Duluth or his on-scene representative to request permission to do so. Vessel operators must comply with all directions given to them by the Captain of the Port, Marine Safety Unit Duluth or his on-scene representative.

Dated: July 27, 2012.

K.R. Bryan,

Commander, U.S. Coast Guard, Captain of the Port Marine Safety Unit Duluth.

[FR Doc. 2012-20004 Filed 8-14-12; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 721

[EPA-HQ-OPPT-2012-0450; FRL-9358-1]

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 25 chemical substances which were the subject of premanufacture notices (PMNs). Fourteen of these chemical substances are subject to TSCA section 5(e) consent orders issued by EPA. This action requires persons who intend to manufacture, import, or process any of these 25 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 October 15, 2012. For purposes of judicial

review, this rule shall be promulgated at 1 p.m. (e.s.t.) on August 29, 2012.

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 September 14, 2012 (see Unit VI. of the **SUPPLEMENTARY INFORMATION**).

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-2012-0450, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments.

- *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:* OPPT Document Control Office (DCO), EPA East, Rm. 6428, 1201 Constitution Ave. NW., Washington, DC. Attention: Docket ID Number EPA-HQ-OPPT-2012-0450. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564-8930. Such deliveries are only accepted during the DCO's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to docket ID number EPA-HQ-OPPT-2012-0450. EPA's policy is that all comments received will be included in the docket without change and may be made available online at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through [regulations.gov](http://www.regulations.gov) or email. The [regulations.gov](http://www.regulations.gov) Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through [regulations.gov](http://www.regulations.gov), your email address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM

you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically at <http://www.regulations.gov>, or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave. NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

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

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

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you manufacture, import, process, or use the chemical substances contained in this rule. Potentially affected entities may include, but are not limited to:

- Manufacturers, importers, or processors of one or more subject

chemical substances (NAICS codes 325 and 324110), e.g., chemical manufacturing and petroleum refineries.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in § 721.5. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Chemical importers are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements promulgated at 19 CFR 12.118 through 12.127 and 19 CFR 127.28. Chemical importers must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA. Importers of chemicals subject to these SNURs must certify their compliance with the SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export a chemical substance that is the subject of this rule 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, import, 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** issue of April 24, 1990 (55 FR 17376) (April 24, 1990 SNUR). 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, import, 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 notice requirements and EPA regulatory procedures as submitters of PMNs under TSCA section 5(a)(1)(A). In particular, these requirements include the information submission requirements of TSCA section 5(b) and 5(d)(1), the exemptions authorized by TSCA sections 5(h)(1), 5(h)(2), 5(h)(3), and 5(h)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUN, EPA may take regulatory action under TSCA section 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 25 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 25 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) number (if assigned for non-confidential chemical identities).
- Basis for the TSCA section 5(e) consent order or, for non-section 5(e) SNURs, the basis for the SNUR (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 and importation 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 14 PMN substances (P-10-405, P-10-485, P-11-48, P-11-63, P-11-160, P-11-181, P-11-203, P-11-247, P-11-384, P-11-557, P-11-646, P-12-30, P-12-31, and P-12-32) 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 "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 5(e) SNURs designate as a "significant new use" the absence of the protective measures required in the corresponding consent orders.

This rule also includes SNURs on 11 PMN substances (P-11-411, P-11-412, P-11-413, P-11-414, P-12-35, P-12-87, P-12-149, P-12-167, P-12-182, P-12-260, and P-12-275) 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 "non-5(e) SNURs" are promulgated pursuant to § 721.170. EPA has determined that every activity designated as a "significant new use" in all non-5(e) SNURs issued under § 721.170 satisfies the two requirements stipulated in § 721.170(c)(2), i.e., these significant new use activities, "(i) 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 (ii) 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-10-405

Chemical name: Perfluorinated alkythio betaine (generic).

CAS number: Not available.

Effective date of TSCA section 5(e) consent order: May 3, 2012.

Basis for TSCA section 5(e) consent order: The PMN states that the generic (non-confidential) use of the substance will be as a surfactant additive for dispersive use in fire fighting foams and vapor suppressing foams. In addition, EPA has concerns for the formation of potential incineration or other decomposition products from the PMN substance. These perfluorinated products may be released to the environment from incomplete incineration of the PMN substance at low temperatures. EPA has preliminary evidence suggesting that, under some conditions, the PMN substance could degrade in the environment. EPA has concerns that the degradation products of the PMN substance will persist in the environment, could bioaccumulate or biomagnify, and could be toxic to people, wild mammals, and birds. These concerns are based on data on analog chemicals, including perfluorooctanoic acid (PFOA) and other perfluorinated carboxylates, such as the presumed environmental degradant of the PMN substance. Toxicity studies on PFOA indicate developmental, reproductive,

and systemic toxicity in various species, as well as cancer. These factors, taken together, raise concerns for potential adverse chronic effects from the presumed degradation product of this PMN substance on humans and wildlife. The consent order was issued under TSCA sections 5(e)(1)(A)(i), 5(e)(1)(A)(ii)(I), and 5(e)(1)(A)(ii)(II), based on a finding that this 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 and its potential degradation products. To protect against these risks, the consent order requires:

1. Manufacture of the PMN substance (a) according to the chemical composition section of the consent order, including analyzing and reporting certain starting raw material impurities to EPA and (b) within the maximum established limits of certain fluorinated impurities of the PMN substances as stated in the consent order.

2. Manufacture of the PMN substance at an annual manufacturing and import volume not to exceed the confidential production volume stated in the consent order.

3. Submission of certain testing prior to exceeding the two confidential production volume limits specified in the consent order.

4. Disposal of manufacturing wastes by incineration.

5. Releases to surface waters not to exceed 50 ppb for the specific processing and use streams identified in the consent order.

6. 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.

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

Recommended testing: EPA has determined that the results of certain fate and physical/chemical property 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 first production limit without performing a modified semi-continuous activated sludge (SCAS) test (OPPTS Test Guideline 835.5045 or

Organisation for Economic Co-operation and Development (OECD) Test Guideline 302A). The PMN submitter has also agreed not to exceed the second production limit without performing a hydrolysis as a function of pH and temperature test (OPPTS Test Guideline 835.3120 or OECD Test Guideline 111); a metabolism and pharmacokinetic test (OPPTS Test Guideline 870.7485 or OECD Test Guideline 417); a modified 1-generation reproduction test (OECD Test Guidelines 421 or 422) in rats or mice); and an avian reproduction test (OECD Test Guideline 206) in mallard ducks. EPA has also determined that the results of certain additional human health, ecotoxicity, and fate testing would help characterize the PMN substance. The consent order does not require submission of the pended testing specified in the consent order at any specified time or production volume. However, the consent order's restrictions on manufacture, import, 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 721.10516.

PMN Numbers P-10-485 and P-11-48

Chemical names: P-10-485: Alkyl methacrylates, polymer with substituted carbomonocycle, hydroxymethyl acrylamide and fluorinatedalkyl acrylate (generic); P-11-48: and Diethylene glycol, polymer with diisocyanatoalkane, polyethylene glycol monomethyl ether- and fluorinatedalkanol -blocked (generic).

CAS numbers: Not available.

Effective date of section 5(e) consent order: January 27, 2012.

Basis for section 5(e) consent order: The PMNs states that the substances will be used as open, non-dispersive textile finishes. EPA has concerns for the formation of potential incineration or other decomposition products from the PMN substances. These perfluorinated products may be released to the environment from incomplete incineration of the PMN substances at low temperatures. EPA has preliminary evidence, including data on some fluorinated polymers, suggesting that, under some conditions, the PMN substances could degrade in the environment. EPA has concerns that the degradation products of the PMN substances will persist in the environment, could bioaccumulate or biomagnify, and could be toxic to people, wild mammals, and birds. These concerns are based on data on analog chemicals, including PFOA and other

perfluorinated carboxylates, which include the presumed environmental degradant of the PMN substances. There is pharmacokinetic and toxicological data in animals on PFOA, as well as epidemiological and blood monitoring data in humans. Toxicity studies on PFOA indicate developmental, reproductive, and systemic toxicity in various species, as well as cancer. These factors, taken together, raise concerns for potential adverse chronic effects from the presumed degradation products of the PMN substances in humans and wildlife. The consent order was issued under TSCA sections 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; 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. Monitoring of the effluent waste water stream during manufacture in addition to the requirements of any existing NPDES permit. Data will be collected on the confidential analytes specified in the consent order and submitted to the Agency quarterly.

2. Manufacture of the PMN substances (a) according to the chemical composition section of the consent order, including analyzing and reporting certain starting raw material impurities to EPA and (b) within the maximum established limits of certain fluorinated impurities of the PMN substances as stated in the consent order.

3. 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 MSDS, within 90 days.

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

Recommended testing: EPA has determined that the results of a modified reproduction/developmental toxicity screening test (OECD Test Guideline 421), an avian reproduction test (OPPTS Test Guideline 850.2300), ready biodegradability test (OPPTS Test Guideline 835.3110), hydrolysis as a function of pH test (OPPTS Test Guideline 835.2110), and indirect photolysis screening test: Sunlight photolysis in waters containing

dissolved humic substances (OPPTS Test Guideline 835.5270) would help characterize possible effects of the substances and their degradation products. The consent order does not require the submission of this testing at any specified time or production volume. However, the consent order’s restrictions on manufacture, import, 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 citations: 40 CFR 721.10517 (P–10–485) and 40 CFR 721.10518 (P–11–98).

PMN Number P–11–63

Chemical name: Perfluoroalkyl acrylate copolymer (generic).

CAS number: Not available.

Effective date of section 5(e) consent order: February 23, 2012.

Basis for section 5(e) consent order: The PMN states that the substance will be used as a coating material for uses in textiles and/or paper. EPA has concerns that the PMN substance under some conditions of use could cause lung effects, based on limited data on some perfluorinated compounds. In addition, EPA has concerns for the formation of potential incineration or other decomposition products from the PMN substance. These perfluorinated products may be released to the environment from incomplete incineration of the PMN substance at low temperatures. EPA has preliminary evidence, including data on some fluorinated polymers, suggesting that, under some conditions, the PMN substance could degrade in the environment. EPA has concerns that the degradation products of the PMN substance will persist in the environment, could bioaccumulate or biomagnify, and could be toxic to people, wild mammals, and birds. These concerns are based on data on analog chemicals, including PFOA and other perfluorinated carboxylates, which include the presumed environmental degradant of the PMN substance. There is pharmacokinetic and toxicological data in animals on PFOA, as well as epidemiological and blood monitoring data in humans. Toxicity studies on PFOA indicate developmental, reproductive, and systemic toxicity in various species, as well as cancer. These factors, taken together, raise concerns for potential adverse chronic effects from the presumed degradation product of the PMN substance on humans and wildlife. The consent order was issued under TSCA sections 5(e)(1)(A)(i),

5(e)(1)(A)(ii)(I), and 5(e)(1)(A)(ii)(II), based on a finding that this 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 and its potential degradation products. To protect against these risks, the consent order requires:

1. Manufacture of the PMN substances (a) according to the chemical composition section of the consent order, including analyzing and reporting certain starting raw material impurities to EPA and (b) within the maximum established limits of certain fluorinated impurities of the PMN substances as stated in the consent order.

2. No use of the PMN substance in consumer products with spray applications.

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

4. 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 MSDS, within 90 days.

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

Recommended testing: EPA has determined that the results of certain fate testing specified in the consent order would help characterize possible effects of the substance and its degradation products. The PMN submitter has agreed not to exceed the confidential production volume limit without performing the following tests which are further specified in the consent order: a combined direct and indirect photolysis with hydrolysis study, a highly modified inherent biodegradability: Zahn-Wellens/EMPA test (OECD Test Guideline 302B), accelerated weathering for textiles with a water component test, and an aerobic and anaerobic transformation in soil test (OECD Test Guideline 307). The consent order does not require submission of the pending testing described in the consent order at any specified time or production volume. However, the consent order’s restrictions on manufacture, import, 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 721.10519.

PMN Number P-11-160

Chemical name: Acetylated fatty acid glycerides (generic).

CAS number: Not available.

Effective date of section 5(e) consent order: February 27, 2012.

Basis for section 5(e) consent order:

The PMN states that the generic (non-confidential) use of the substance will be as a resin. Based on ecological structure activity relationship (EcoSAR) analysis of test data on analogous esters, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 3 ppb for the PMN in surface waters. The consent order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) based on a finding that this substance may present an unreasonable risk of injury to the environment. To protect against this risk, the order requires use of the substance only as described in the order, and submission of certain ecotoxicity testing prior to exceeding the confidential production volume limit specified in the order. The SNUR designates as a "significant new use" the absence of these protective measures.

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. The PMN submitter has agreed not to exceed the confidential production volume limit specified in the order without performing these tests.

CFR citation: 40 CFR 721.10520.

PMN Number P-11-181

Chemical name: Fluorosurfactant (generic).

CAS number: Not available.

Effective date of TSCA section 5(e) consent order: February 17, 2012.

Basis for TSCA section 5(e) consent order:

The PMN states that the generic (non-confidential) use of the substance will be as a surfactant for laboratory use fluid. Based on structure activity relationship (SAR) analysis of test data on analogous high molecular weight polymers, EPA identified concerns for lung toxicity for the PMN substance if respirable droplets are inhaled. In addition, based on SAR analysis of analogous substances, including PFOA and perfluorooctane sulfonate (PFOS), EPA identified concerns for liver

toxicity, acute toxicity, developmental and reproductive toxicity, and cancer, when the mean moles of each perfluoro propylene oxide (PPO) unit is less than 5. Further, EPA expected the PMN substance and the perfluoro degradation products to be highly persistent, and the low molecular weight fraction is expected to be mobile and bioaccumulate in the environment. Although there are no ecological concerns for the PMN substance itself, there is high concern for possible environmental effects to mammals and wild birds from the perfluoro degradation products of the PMN substance. These concerns are based on data on analog chemicals, including PFOA and other perfluorinated carboxylates, which include the presumed environmental degradant of the PMN substance. There is pharmacokinetic and toxicological data in animals on PFOA, as well as epidemiological and blood monitoring data in humans. Toxicity studies on PFOA indicate developmental, reproductive, and systemic toxicity in various species, as well as cancer. These factors, taken together, raise concerns for potential adverse chronic effects from the presumed degradation product of the PMN substance in humans and wildlife. The consent order was issued under TSCA sections 5(e)(1)(A)(i), 5(e)(1)(A)(ii)(I), and 5(e)(1)(A)(ii)(II), based on a finding that this 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 and its potential degradation products. To protect against this exposure and risk, the consent order requires:

1. Manufacture of the PMN substance (a) according to the chemical composition section of the consent order, including analyzing and reporting to EPA the average number molecular weight at each manufacturing facility at the time of initial commencement and annually thereafter, and (b) where the mean number of moles of each PPO unit must be greater than or equal to 5.

2. Manufacture of the PMN substance at an annual manufacturing and import volume not to exceed the confidential production volume limit stated in the consent order.

3. 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 MSDS, within 90 days.

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

Recommended testing: EPA has determined that the results of certain health, fate, and physical/chemical property testing identified in the consent order would help characterize possible effects of the substances and their degradation products. 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, import, 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 721.10521.

PMN Number P-11-203

Chemical name: Perfluoroalkylethyl methacrylate copolymer with dialkylaminoethylmethacrylate (generic).

CAS number: Not available.

Effective date of section 5(e) consent order: March 13, 2012.

Basis for section 5(e) consent order:

The PMN states that the substance will be used as a paper treatment. EPA has concerns for the formation of potential incineration or other decomposition products from the PMN substance. These perfluorinated products may be released to the environment from incomplete incineration of the PMN substance at low temperatures. EPA has preliminary evidence, including data on some fluorinated polymers, suggesting that, under some conditions, the PMN substance could degrade in the environment. EPA has concerns that these degradation products will persist in the environment, could bioaccumulate or biomagnify, and could be toxic to people, wild mammals, and birds. These concerns are based on data on analog chemicals, including PFOA and other perfluorinated carboxylates, which include the presumed environmental degradant of the PMN substance. There is pharmacokinetic and toxicological data in animals on PFOA, as well as epidemiological and blood monitoring data in humans. Toxicity studies on PFOA indicate developmental, reproductive, and systemic toxicity in various species, as well as cancer. These factors, taken together, raise concerns for potential adverse chronic effects from the

presumed degradation product of the PMN substance in humans and wildlife. The consent order was issued under TSCA sections 5(e)(1)(A)(i), 5(e)(1)(A)(ii)(I), and 5(e)(1)(A)(ii)(II), based on a finding that this 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 and its potential degradation products. To protect against these risks, the consent order requires submission of certain fate testing prior to September 30, 2014, and 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 MSDS, within 90 days. The SNUR designates as a "significant new use" the absence of these protective measures.

Recommended testing: EPA has determined that the results of certain fate testing identified in the consent order would help characterize possible effects of the substance and its degradation products. The PMN submitter has agreed not to manufacture or import the PMN substance after September 30, 2014 without performing a modified SCAS test (OPPTS Test Guideline 835.5045 or OECD Test Guideline 302A), a UV/visible absorption test (OPPTS Test Guideline 830.7050), direct photolysis rate in water by sunlight test (OPPTS Test Guideline 835.2210), a hydrolysis as a function of pH and temperature test (OPPTS Test Guideline 835.3120 or OECD Test Guideline 111); an indirect photolysis screening test: sunlight photolysis in waters containing dissolved humic substances (OPPTS Test Guideline 835.5270), a photolysis on soils study using the Phototransformation of Chemicals on Soil Surfaces OECD Test Guideline 2005 Draft (located in the docket under docket ID number EPA-HQ-OPPT-2012-0450), aerobic and anaerobic transformation in aquatic sediment systems (OECD Test Guideline 308), and an anaerobic biodegradability of organic compounds in digested sludge by measurement of gas production test (OECD Test Guideline 311). These tests are further detailed in the consent order. EPA has determined that the results of certain health testing identified in the

consent order would help characterize possible effects of the substances and their degradation products. 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, import, 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 721.10522.

PMN Number P-11-247

Chemical name: Perfluoroalkylethyl methacrylate copolymer with hydroxymethyl acrylamide, vinyl chloride and long chain fatty alkyl acrylate (generic).

CAS number: Not available.

Effective date of section 5(e) consent order: March 13, 2012.

Basis for section 5(e) consent order:

The PMN states that the PMN substance will be used as a treatment for textiles. EPA has concerns for the formation of potential incineration or other decomposition products from the PMN substance. These perfluorinated products may be released to the environment from incomplete incineration of the PMN substance at low temperatures. EPA has preliminary evidence, including data on some fluorinated polymers, suggesting that, under some conditions, the PMN substance could degrade in the environment. EPA has concerns that these degradation products will persist in the environment, could bioaccumulate or biomagnify, and could be toxic to people, wild mammals, and birds. These concerns are based on data on analog chemicals, including PFOA and other perfluorinated carboxylates, which include the presumed environmental degradant of the PMN substance. There is pharmacokinetic and toxicological data in animals on PFOA, as well as epidemiological and blood monitoring data in humans. Toxicity studies on PFOA indicate developmental, reproductive, and systemic toxicity in various species, as well as, cancer. These factors, taken together, raise concerns for potential adverse chronic effects from the presumed degradation product of the PMN substance on humans and wildlife. The consent order was issued under TSCA sections 5(e)(1)(A)(i), 5(e)(1)(A)(ii)(I), and 5(e)(1)(A)(ii)(II), based on a finding that this 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 and its potential degradation products. To protect against these risks, the consent order requires submission of certain fate testing prior to March 31, 2015, and 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 MSDS, within 90 days. The SNUR designates as a "significant new use" the absence of these protective measures.

Recommended testing: EPA has determined that the results of certain fate testing identified in the consent order would help characterize possible effects of the substance and its degradation products. The PMN submitter has agreed not to manufacture or import the PMN substance after March 31, 2015 without performing a modified SCAS test (OPPTS Test Guideline 835.5045 or OECD Test Guideline 302A), a UV/visible absorption test (OPPTS Test Guideline 830.7050), direct photolysis rate in water by sunlight test (OPPTS Test Guideline 835.2210), a hydrolysis as a function of pH and temperature test (OPPTS Test Guideline 835.3120 or OECD Test Guideline 111); an indirect photolysis screening test: sunlight photolysis in waters containing dissolved humic substances (OPPTS Test Guideline 835.5270), a photolysis on soils study using the Phototransformation of Chemicals on Soil Surfaces OECD Test Guideline 2005 Draft (located in the docket under docket ID number EPA-HQ-OPPT-2012-0450), aerobic and anaerobic transformation in aquatic sediment systems (OECD Test Guideline 308), and an anaerobic biodegradability of organic compounds in digested sludge by measurement of gas production test (OECD Test Guideline 311). These tests are further detailed in the consent order. EPA has determined that the results of certain health testing identified in the consent order would help characterize possible effects of the substances and their degradation products. 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, import, 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 721.10523.

PMN Number P-11-384

Chemical name: Fluorinated alkylsulfonamidol urethane polymer (generic).

CAS number: Not available.

Effective date of section 5(e) consent order: January 18, 2012.

Basis for section 5(e) consent order:

The PMN states that the generic (non-confidential) use of the substance will be as a protective treatment. Based on EPA analysis of the potential content of the polymer, EPA is concerned that some perfluorinated substances could be present and if degraded, could be released into the environment. EPA has concerns that the PMN substance and its degradation products will persist in the environment, could bioaccumulate or biomagnify, and could be toxic to various species. These concerns are based on data on analog chemicals, including PFOS and other perfluorinated carboxylates, such as the presumed ultimate perfluorinated degradant of the PMN substance, perfluorobutanesulfonic acid (PFBS). Although some data indicate a different and less toxic toxicological and ecological profile for PFBS than for PFOS and PFOA, EPA believes that, based on the persistence of PFBS, potential intermediate fate products, and the fact that these products may be major substitutes for some uses of PFOS, more information is warranted on the fate and physical/chemical properties of PFBS-derived polymers in the environment. The consent order was issued under TSCA sections 5(e)(1)(A)(i) 5(e)(1)(A)(ii)(I), and 5(e)(1)(A)(ii)(II) based on a finding that this substance may present an unreasonable risk of injury to the environment, the substance may be produced in substantial quantities, and there may be significant (or substantial) human exposure to the substance and its potential degradation products. To protect against this risk, the order requires submission of certain abiotic fate testing prior to exceeding an aggregate manufacturing and import volume of 150,000 kilograms and submission of certain biotic fate testing prior to exceeding an aggregate manufacturing and import volume of 550,000 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

fate testing identified in the consent order would help characterize possible effects of the substances and their degradation products. The PMN submitter has agreed not to exceed the first production volume limit without performing a highly modified indirect photolysis screening test, and not to exceed the second production volume limit without performing a highly modified aerobic activated sludge biodegradation test and a modified aerobic and anaerobic transformation in sludge-amended to soil test. These tests are further detailed in the consent order. EPA has determined that the results of certain health and environmental effects testing identified in the consent order would help characterize possible effects of the substances and their degradation products. 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, import, 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 721.10524.

PMN Numbers P-11-411, P-11-412, P-11-413 and P-11-414

Chemical names: Alkoxy dialkyl aminoalkanol carboxylate (generic).

CAS numbers: Not available.

Basis for action: The PMN states that the generic (non confidential) use of the substances is for contained use in energy production. Based on EcoSAR analysis of test data on analogous cationic surfactants, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 17 ppb of the PMN substances in surface waters. As described in the consolidated PMN, releases to surface waters are not expected to exceed 17 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substances may present an unreasonable risk. EPA has determined, however, that any use of the substances resulting in surface water concentrations exceeding 17 ppb may cause 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.

CFR citation: 40 CFR 721.10525.

PMN Number P-11-557

Chemical name: 2-Propenoic acid, 2-methyl-, 2-hydroxyethyl ester, telomers with C₁₈₋₂₆-alkyl acrylate, 1-dodecanethiol, N-(hydroxymethyl)-2-methyl-2-propenamide, polyfluorooctyl methacrylate and vinylidene chloride, 2,2'-[1,2-diazenediyl]bis(1-methylethylidene)bis[4,5-dihydro-1H-imidazole] hydrochloride (1:2)-initiated (generic).

CAS number: Not available.

Effective date of TSCA section 5(e) consent order: March 22, 2012.

Basis for TSCA section 5(e) consent order: The PMN states that the generic (non-confidential) use of the substance will be as a water and oil repellent. Based on SAR analysis of test data on analogous high molecular weight polymers, EPA identified concerns for lung effects through lung overload if respirable particles of the intact PMN substances are inhaled. In addition, EPA has concerns for the formation of potential incineration or other decomposition products from the PMN substance. These perfluorinated products may be released to the environment from incomplete incineration of the PMN substance at low temperatures. EPA has preliminary evidence, including data on some fluorinated polymers, suggesting that, under some conditions, the PMN substance could degrade in the environment. EPA has concerns that these degradation products will persist in the environment, could bioaccumulate or biomagnify, and could be toxic to people, wild mammals, and birds. These concerns are based on data on analog chemicals, including PFOA and other perfluorinated carboxylates, which include the presumed environmental degradant of the PMN substance. There is pharmacokinetic and toxicological data in animals on PFOA, as well as epidemiological and blood monitoring data in humans. Toxicity studies on PFOA indicate developmental, reproductive, and systemic toxicity in various species, as well as cancer. These factors, taken together, raise concerns for potential adverse chronic effects from the presumed degradation product in humans and wildlife. The consent order was issued under TSCA sections 5(e)(1)(A)(i), 5(e)(1)(A)(ii)(I), and 5(e)(1)(A)(ii)(II), based on a finding that this 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 and its potential degradation products. To protect against these risks, the consent order requires:

1. Manufacture of the PMN substance (a) according to the chemical composition section of the consent order, including analyzing and reporting certain starting raw material impurities to EPA and (b) within the maximum established limits of certain fluorinated impurities of the PMN substances as stated in the consent order.

2. Manufacture of the PMN substance at an annual manufacturing and import volume not to exceed the confidential production volume stated in the consent order.

3. No use of the PMN substance in consumer products with spray applications.

4. 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 MSDS, within 90 days.

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

Recommended testing: EPA has determined that the results of certain health and environmental effects, fate, and physical/chemical property testing identified in the consent order would help characterize possible effects of the substances and their degradation products. 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, import, 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 721.10526.

PMN Number P-11-646

Chemical name: Perfluoroalkylethyl methacrylate copolymer (generic).

CAS number: Not available.

Effective date of section 5(e) consent order: March 23, 2012.

Basis for section 5(e) consent order: The PMN states that the substance will be used as a fabric treatment. EPA identified concerns for the formation of potential incineration or other

decomposition products from the PMN substance. These perfluorinated products may be released to the environment from incomplete incineration of the PMN substance at low temperatures. EPA has preliminary evidence, including data on some fluorinated polymers, suggesting that, under some conditions, the PMN substance could degrade in the environment. EPA has concerns that these degradation products will persist in the environment, could bioaccumulate or biomagnify, and could be toxic to people, wild mammals, and birds. These concerns are based on data on analog chemicals, including PFOA and other perfluorinated carboxylates, which include the presumed environmental degradant of the PMN substance. There is pharmacokinetic and toxicological data in animals on PFOA, as well as epidemiological and blood monitoring data in humans. Toxicity studies on PFOA indicate developmental, reproductive, and systemic toxicity in various species, as well as, cancer. These factors, taken together, raise concerns for potential adverse chronic effects from the presumed degradation product of the PMN substance in humans and wildlife. The consent order was issued under TSCA sections 5(e)(1)(A)(i), 5(e)(1)(A)(ii)(I), and 5(e)(1)(A)(ii)(II), based on a finding that this 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 and its potential degradation products. To protect against these risks, the consent order requires submission of certain fate testing prior to March 31, 2015, and 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 MSDS, within 90 days. The SNUR designates as a "significant new use" the absence of these protective measures.

Recommended testing: EPA has determined that the results of certain fate testing identified in the consent order would help characterize possible effects of the substance and its degradation products. The PMN submitter has agreed not to manufacture or import the PMN substance after

March 31, 2015 without performing a modified SCAS test (OPPTS Test Guideline 835.5045 or OECD Test Guideline 302A), a UV/visible absorption test (OPPTS Test Guideline 830.7050), direct photolysis rate in water by sunlight test (OPPTS Test Guideline 835.2210), a hydrolysis as a function of pH and temperature test (OPPTS Test Guideline 835.3120 or OECD Test Guideline 111); an indirect photolysis screening test: sunlight photolysis in waters containing dissolved humic substances (OPPTS Test Guideline 835.5270), a photolysis on soils study using the Phototransformation of Chemicals on Soil Surfaces OECD Test Guideline 2005 Draft (located in the docket under docket ID number EPA-HQ-OPPT-2012-0450), aerobic and anaerobic transformation in aquatic sediment systems (OECD Test Guideline 308), and an anaerobic biodegradability of organic compounds in digested sludge by measurement of gas production test (OECD Test Guideline 311). EPA has also determined that the results of certain additional human health and environmental effects testing would help characterize the PMN substance. The consent order does not require submission of the pended testing specified in the consent order at any specified time or production volume. However, the consent order's restrictions on manufacture, import, 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 721.10527.

PMN Numbers P-12-30, P-12-31, and P-12-32

Chemical names: Modified fluorinated acrylates (generic).

CAS numbers: Not available.

Effective date of section 5(e) consent order: April 18, 2012.

Basis for section 5(e) consent order: The PMN states that the substances will be used as an open, non-dispersive textile finish. EPA has concerns for the formation of potential incineration or other decomposition products from the PMN substances. These perfluorinated products may be released to the environment from incomplete incineration of the PMN substances at low temperatures. EPA has preliminary evidence, including data on some fluorinated polymers, suggesting that, under some conditions, the PMN substances could degrade in the environment. EPA has concerns that these degradation products will persist

in the environment, could bioaccumulate or biomagnify, and could be toxic to people, wild mammals, and birds. These concerns are based on data on analog chemicals, including PFOA and other perfluorinated carboxylates, which include the presumed environmental degradant of the PMN substances. There is pharmacokinetic and toxicological data in animals on PFOA, as well as epidemiological and blood monitoring data in humans. Toxicity studies on PFOA indicate developmental, reproductive, and systemic toxicity in various species, as well as cancer. These factors, taken together, raise concerns for potential adverse chronic effects from the presumed degradation product in humans and wildlife. The consent order was issued under TSCA sections 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, the 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. Monitoring of the effluent waste water stream during manufacture in addition to the requirements of any existing NPDES permit. Data will be collected on the confidential analytes specified in the consent order and submitted to the Agency quarterly.

2. Manufacture of the PMN substances (a) according to the chemical composition section of the consent order, including analyzing and reporting certain starting raw material impurities to EPA, and (b) within the maximum established levels of certain fluorinated impurities of the PMN substances as stated in the consent order.

2. 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 MSDS, within 90 days.

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

Recommended testing: EPA has determined that the results of an aerobic and anaerobic transformation in soil test (OECD Test Guideline 307), fish short-term reproduction test (OPPTS Test Guideline 890.1350), ready

biodegradability test (OPPTS Test Guideline 835.3110), hydrolysis as a function of pH test (OPPTS Test Guideline 835.2110), and indirect photolysis screening test: sunlight photolysis in waters containing dissolved humic substances (OPPTS Test Guideline 835.5270) would help characterize possible effects of the substance and its degradation products. The consent order does not require the submission of this testing at any specified time or production volume. However, the consent order's restrictions on manufacture, import, 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 721.10528.

PMN Number P-12-35

Chemical name: Cobalt iron manganese oxide, carboxylic acid-modified (generic).

CAS number: Not available.

Basis for action: The PMN states that the substance will be used as a ferrite dispersion ink additive to ensure magnetic performance characteristics. Based on test data on analogous respirable, poorly soluble particulates (subcategory: lithium manganese oxide), EPA identified concerns for lung effects to workers exposed to the PMN substance. EPA also identified concerns for mutagenicity based on the amount of cobalt and manganese in the PMN substance and neurotoxicity for manganese. For the uses described in the PMN, significant exposures to workers or the general population is unlikely. 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 the following may cause serious health effects:

1. Domestic manufacture.
2. Use of the substance other than as described in the PMN.
3. Use in a consumer product.
4. Processing or use of the substance in a solid form.
5. Manufacturing, processing, or use of the PMN substance without an appropriate material safety data sheet that warns to not release to water.
6. Any use of the substance resulting in surface water release.

Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(3)(ii).

Recommended testing: EPA has determined that the results of a 90-day inhalation toxicity test (OPPTS Test

Guideline 870.3465) with 60-day holding period; workplace exposure monitoring; characterization of the mobility of the particles in soil using a modified version of the leaching test (OPPTS Test Guideline 835.1240) and/or an adsorption/desorption (batch equilibrium) test (OPPTS Test Guideline 835.1230); a ready biodegradability (OECD Test Guideline 301) to characterize the persistence of the functional groups; and physical-chemical characterization data including particle size distribution by count, surface area, morphology, shape, and size; aggregation and agglomeration states using transmission electron microscopy, scanning-transmission and electron microscopy atomic force microscopy, porosity using mercury intrusion, surface chemistry including elemental composition using electron-energy loss spectroscopy, X-ray photoelectron spectroscopy, auger electron spectroscopy, or atomic force microscopy; surface charge using zetasizer, water solubility (OECD Test Guideline 105), and density of liquids and solids (OECD Test Guideline 109) would help characterize the health effects of the PMN substance.

CFR citation: 40 CFR 721.10529.

PMN Number P-12-87

Chemical name: Acrylate manufacture byproduct distillation residue (generic).

CAS number: Not available.

Basis for action: The PMN states that the uses of the substance are as a viscosity modifier/flow enhancer for crude oil and in boiler fuels as a burn promoter for fuel value. Based on test data on the PMN substance, and EcoSAR analysis of test data on analogous acrylates, 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 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 substance.

CFR citation: 40 CFR 721.10530.

PMN Number P-12-149

Chemical name: Distillation bottoms from manufacture of brominated cycloalkanes (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be for destructive use in bromine recovery. Based on EcoSAR analysis of test data on analogous neutral organic chemicals, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 2 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 2 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 2 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 Guidelines 850.1400); a daphnid chronic toxicity study (OPPTS Test Guidelines 850.1300); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substance. When testing the PMN substance, if difficulty is encountered in dissolving the chemical in the test media, consult the special consideration for conducting aquatic laboratory studies (OPPTS Test Guideline 850.1000).

CFR citation: 40 CFR 721.10531.

PMN Number P-12-167

Chemical name: Tar, brown coal.

CAS number: 101316-83-0.

Basis for action: The PMN states that the substance will be used for blending existing tar oil with petroleum oil for feed to refineries. EPA has identified health and environmental concerns because the substance may be a persistent, bio-accumulative, and toxic (PBT) chemical, based on physical/chemical properties of the PMN substance, as described in the New Chemical Program's PBT category (64

FR 60194; November 4, 1999) (FRL-6097-7). EPA estimates that the PMN substance will persist in the environment more than two months and estimates a bioaccumulation factor of greater than or equal to 1,000. Also, based on SAR analysis of test data on analogous polycyclic aromatic hydrocarbons, EPA identified concerns for irritation and possible corrosion to all exposed tissues, solvent neurotoxicity, liver and kidney toxicity, effects to the pancreas and spleen, photosensitization, and oncogenicity. These concerns are for workers exposed via inhalation or dermal contact with the PMN substance. Additionally, based on EcoSAR analysis of test data on analogous neutral organic chemicals, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PMN substance in surface waters. For the uses described in the PMN, significant exposures to workers or the general population is unlikely and the substance is not released to surface waters. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk to the human health or the environment. EPA has determined, however, that any predictable or purposeful release containing the PMN substance into the waters of the United States may cause serious health effects and significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170 (b)(1)(i)(C), (b)(3)(ii), (b)(4)(ii), and (b)(4)(iii).

Recommended testing: EPA has determined that the results of the aerobic and anaerobic transformation in aquatic sediment systems test (OECD Test Guideline 308) and the bioconcentration: flow-through fish test (OECD Test Guideline 305) would help characterize the persistent and bioaccumulative attributes of the PMN substance. In addition, 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. When testing the PMN substance, if difficulty is encountered in dissolving the chemical in the test media, consult the special considerations for conducting aquatic laboratory studies (OPPTS Test Guideline 850.1000).

CFR citation: 40 CFR 721.10532.

PMN Number P-12-182

Chemical name: Amine-modified urea-formaldehyde polymer (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as a mining chemical. Based on EcoSAR analysis of test data on analogous polycationic polymers, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 56 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 56 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 56 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 acute toxicity mitigated by humic acid test (OPPTS Test Guidelines 850.1085); 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 substance.

CFR citation: 40 CFR 721.10533.

PMN Number P-12-260

Chemical name: Brominated aliphatic alcohol (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be for destructive use. Based on EcoSAR analysis of test data on analogous halo-alcohols, 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 water concentrations exceeding 3 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 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 algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substance. EPA also recommends that the special considerations for conducting aquatic laboratory studies (OPPTS Test Guideline 850.1000) be followed.

CFR citation: 40 CFR 721.10534.

PMN Number P-12-275

Chemical name: Phosphonium, tributyltetradecyl-, chloride (1:1).

CAS number: 81741-28-8.

Basis for action: The PMN states that the substance will be used as reactant for the production of proprietary chemicals in the electronics industry. EPA has identified environmental concerns because the substance may be a PBT chemical, based on physical/chemical properties of the PMN substance, as described in the New Chemical Program's PBT category. EPA estimates that the PMN substance will persist in the environment more than two months and estimates a bioaccumulation factor of greater than or equal to 1,000. Additionally, based on EcoSAR analysis of test data on analogous cationic surfactants, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 11 ppb of the PMN substance in surface waters. As described in the PMN, the substance is not released to surface waters. 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 predictable or purposeful release containing the PMN substance into the waters of the United States may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(ii) and (b)(4)(iii).

Recommended testing: EPA has determined that the results of the aerobic and anaerobic transformation in aquatic sediment systems test (OECD Test Guideline 308) and the bioconcentration: Flow-through fish test (OECD Test Guideline 305) would help characterize the persistent and bioaccumulative attributes of the PMN substance. In addition, 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 environmental effects of the PMN substance. When testing the PMN substance, if difficulty is encountered in dissolving the chemical in the test media, consult the special considerations for conducting aquatic laboratory studies (OPPTS Test Guideline 850.1000).

CFR citation: 40 CFR 721.10535.

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 14 of the 25 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 II.).

In the other 11 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, import, 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, importing, or processing a listed chemical substance for the described significant new use.
- EPA will be able to regulate prospective manufacturers, importers, 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, importers, 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 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 October 15, 2012 without further notice, unless EPA receives written adverse or critical comments, or notice of intent to submit adverse or critical comments before September 14, 2012.

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 September 14, 2012, 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 Rule to Uses Occurring Before Effective Date of the Rule

Significant new use designations for a chemical substance are legally established as of the date of publication of this direct final rule August 15, 2012.

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. TSCA section 5(e) consent orders have been issued for 14 chemical substances and the PMN

submitters are prohibited by the TSCA section 5(e) consent orders from undertaking activities which EPA is designating as significant new uses. 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 other person may commence such activities without first submitting a PMN. For chemical substances for which an NOC has not been submitted at this time, EPA concludes that the uses are not ongoing. However, EPA recognizes that prior to the effective date of the rule, when chemical substances identified in this SNUR are added to the TSCA Inventory, other persons may engage in a significant new use as defined in this rule before the effective date of the rule. However, 23 of the 25 chemical substances contained in this rule have CBI chemical identities, and since EPA has received a limited number of post-PMN *bona fide* submissions (per §§ 720.25 and 721.11), 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.

As discussed in the April 24, 1990 SNUR, EPA has decided that the intent of TSCA section 5(a)(1)(B) is best served by designating a use as a significant new use as of the date of publication of this direct final rule rather than as of the effective date of the rule. If uses begun after publication were considered ongoing rather than new, it would be difficult for EPA to establish SNUR notice requirements because a person could defeat the SNUR by initiating the significant new use before the rule became effective, and then argue that the use was ongoing before the effective date of the rule. Thus, persons who begin commercial manufacture, import, or processing of the chemical substances regulated through this SNUR will have to cease any such activity before the effective date of this rule. To resume their activities, these persons would have to comply with all applicable SNUR notice requirements and wait until the notice review period, including any extensions expires.

EPA has promulgated provisions to allow persons to comply with this SNUR before the effective date. If a person meets the conditions of advance compliance under § 721.45(h), the person is considered exempt from the requirements of the SNUR.

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 § 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 non-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" or for guidelines that are not currently available on the Web site, EPA has placed a copy of that guideline in the public docket. The Organization 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>.

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, import, 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, importer, or processor may request EPA to determine whether a proposed use would be a significant new use under the rule. The manufacturer, importer, or processor must show that it has a *bona fide* intent to manufacture, import, or process the chemical substance and must identify the specific use for which it intends to manufacture, import, or process the chemical substance. If EPA concludes that the person has shown a *bona fide* intent to manufacture, import, 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, importers, 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, import, 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 notice requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in § 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 §§ 721.25 and 720.40. 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, importers, 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–2012–0450.

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 and, in some cases, 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

According to the Paperwork Reduction Act (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

On February 18, 2012, EPA certified pursuant to section 605(b) of the Regulatory Flexibility Act (RFA) (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 SNUN submitted by any small entity would not cost significantly more than \$8300. 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 \$8300.

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

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 sections 202, 203, 204, or 205 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4).

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

In addition, since this action does not involve any technical standards, section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note), does not apply to this action.

J. Executive Order 12898

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

XIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. 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 rule 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: August 9, 2012.

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. The table in § 9.1 is amended by adding 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. |
|-----------------|-----------------|
| 721.10516 | 2070-0012 |
| 721.10517 | 2070-0012 |
| 721.10518 | 2070-0012 |
| 721.10519 | 2070-0012 |
| 721.10520 | 2070-0012 |
| 721.10521 | 2070-0012 |
| 721.10522 | 2070-0012 |
| 721.10523 | 2070-0012 |
| 721.10524 | 2070-0012 |
| 721.10525 | 2070-0012 |
| 721.10526 | 2070-0012 |
| 721.10527 | 2070-0012 |
| 721.10528 | 2070-0012 |

| 40 CFR citation | OMB control No. |
|-----------------|-----------------|
| 721.10529 | 2070-0012 |
| 721.10530 | 2070-0012 |
| 721.10531 | 2070-0012 |
| 721.10532 | 2070-0012 |
| 721.10533 | 2070-0012 |
| 721.10534 | 2070-0012 |
| 721.10535 | 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 § 721.10516 to subpart E to read as follows:

§ 721.10516 Perfluorinated alkylthio betaine (generic).

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

(1) The chemical substance identified generically as perfluorinated alkylthio betaine (PMN P-10-405) 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, import, 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 company becomes aware that this substance may present a risk of injury to human health, the employer must incorporate this new information, and any information on methods for protecting against such risk, into a Material Safety Data Sheet (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, imported, 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 this substance from the employer are provided a MSDS as described in § 721.72(c) 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) (analysis, reporting, and limitation of maximum impurity levels of certain fluorinated impurities as described in the chemical composition section of the consent order), (q), and (t).

(iii) *Disposal.* Requirements as specified in § 721.85(a)(1).

(iv) *Release to water.* Requirements as specified in § 721.90(b)(4) and (c)(4) (N=50 for the specific release waste streams specified in the consent order).

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

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

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

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

■ 5. Add § 721.10517 to subpart E to read as follows:

§ 721.10517 Alkyl methacrylates, polymer with substituted carbomonocycle, hydroxymethyl acrylamide and fluorinatedalkyl acrylate (generic).

(a) Chemical substances and significant new uses subject to reporting. (1) The chemical substance identified generically as alkyl methacrylates, polymer with substituted carbomonocycle, hydroxymethyl acrylamide and fluorinatedalkyl acrylate (PMN P-10-485) 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, import, 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, the employer must incorporate this new information, and any information on methods for protecting against such risk, into a Material Safety Data Sheet (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, imported, 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 this substance from the employer are provided a MSDS as described in § 721.72(c) 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) (Monitoring of the effluent waste water stream during manufacture in addition to any existing NPDES permit. Monitoring data will be collected on the confidential analytes and submitted to the Agency quarterly. Analysis, reporting, and limitation of maximum impurity levels of certain fluorinated impurities.).

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

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

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

(3) *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.

■ 6. Add § 721.10518 to subpart E to read as follows:

§ 721.10518 Diethylene glycol, polymer with diisocyanatoalkane, polyethylene glycol monomethyl ether- and fluorinatedalkanol-blocked (generic).

(a) Chemical substances and significant new uses subject to reporting. (1) The chemical substance identified generically as diethylene glycol, polymer with diisocyanatoalkane, polyethylene glycol monomethyl ether- and fluorinatedalkanol-blocked (PMN P-11-48) 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, import, 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, the employer must incorporate this new information, and any information on methods for protecting against such risk, into a Material Safety Data Sheet (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, imported, 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 this substance from the employer are provided a MSDS as described in § 721.72(c) 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) (Monitoring of the effluent waste water stream during manufacture in addition to any existing NPDES permit. Monitoring data will be collected on the confidential analytes and submitted to the Agency quarterly. Analysis, reporting, and limitation of maximum impurity levels of certain fluorinated impurities.).

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

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

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

(3) *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.

■ 7. Add § 721.10519 to subpart E to read as follows:

§ 721.10519 Perfluoroalkyl acrylate copolymer (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as perfluoroalkyl acrylate copolymer (PMN P-11-63) 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, import, 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, the employer must incorporate this new information, and any information on methods for protecting against such risk, into a Material Safety Data Sheet (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, imported, 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 this substance from the employer are provided a MSDS as described in § 721.72(c) 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) (analysis and reporting and limitations of maximum impurity levels of certain fluorinated impurities), (o)(use in a consumer product that could be spray applied), and (q).

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

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

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

(3) *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.

■ 8. Add § 721.10520 to subpart E to read as follows:

§ 721.10520 Acetylated fatty acid glycerides (generic).

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

(1) The chemical substance identified generically as acetylated fatty acid glycerides (PMN P-11-160) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this rule do not apply to quantities of the PMN substance after it has been completely reacted (cured) or entrained in a film.

(2) The significant new uses are:

(i) *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.

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

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

(3) *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.

■ 9. Add § 721.10521 to subpart E to read as follows:

§ 721.10521 Fluorosurfactant (generic).

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

(1) The chemical substance identified generically as fluorosurfactant (PMN P-11-181) 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, import, 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, the employer must incorporate this new information, and any information on methods for protecting against such risk, into a Material Safety Data Sheet (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, imported, 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 this substance from the employer are provided a MSDS as described in § 721.72(c) 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) (manufacture of the PMN substance according to the chemical composition section of the consent order, including analyzing and reporting to EPA the average number molecular weight at each manufacturing facility at the time of initial commencement and annually thereafter, and where the mean number of moles of each PPO unit must be greater than or equal to 5) and (t).

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

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

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

(3) *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 § 721.10522 to subpart E to read as follows:

§ 721.10522 Perfluoroalkylethyl methacrylate copolymer with dialkylaminoethylmethacrylate (generic).

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

(1) The chemical substance identified generically as perfluoroalkylethyl methacrylate copolymer with dialkylaminoethylmethacrylate (PMN P-11-203) 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, import, 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, the employer must

incorporate this new information, and any information on methods for protecting against such risk, into a Material Safety Data Sheet (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, imported, 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 this substance from the employer are provided a MSDS as described in § 721.72(c) 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(p) (any amount after September 30, 2014).

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

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

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

(3) *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 § 721.10523 to subpart E to read as follows:

§ 721.10523 Perfluoroalkylethyl methacrylate copolymer with hydroxymethyl acrylamide, vinyl chloride and long chain fatty alkyl acrylate (generic).

(a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as perfluoroalkylethyl methacrylate copolymer with hydroxymethyl acrylamide, vinyl chloride and long chain fatty alkyl acrylate (PMN P-11-247) 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, import, 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, the employer must incorporate this new information, and any information on methods for protecting against such risk, into a Material Safety Data Sheet (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, imported, 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 this substance from the employer are provided a MSDS as described in § 721.72(c) 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(p) (any amount after March 31, 2015).

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

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

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

(3) *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.

■ 12. Add § 721.10524 to subpart E to read as follows:

§ 721.10524 Fluorinated alkylsulfonamidol urethane polymer (generic).

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

(1) The chemical substance identified generically as fluorinated alkylsulfonamidol urethane polymer (PMN P-11-384) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(p) (production limits set at 150,000 kilograms and at 550,000 kilograms).

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

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

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

■ 13. Add § 721.10525 to subpart E to read as follows:

§ 721.10525 Alkoxy dialkyl aminoalkanol carboxylate (generic).

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

(1) The chemical substances identified generically as alkoxy dialkyl aminoalkanol carboxylate (PMNs P-11-411, P-11-412, P-11-413 and P-11-414) 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)(N = 17).

(ii) [Reserved]

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

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

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

■ 14. Add § 721.10526 to subpart E to read as follows:

§ 721.10526 2-Propenoic acid, 2-methyl-, 2-hydroxyethyl ester, telomers with C₁₈₋₂₆ alkyl acrylate, 1-dodecanethiol, N-(hydroxymethyl)-2-methyl-2-propenamide, polyfluorooctyl methacrylate and vinylidene chloride, 2,2'-[1,2-diazenediyl]bis(1-methylethylidene)bis[4,5-dihydro-1H-imidazole] hydrochloride (1:2)-initiated (generic).

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

(1) The chemical substance identified generically as 2-propenoic acid, 2-methyl-, 2-hydroxyethyl ester, telomers with C₁₈₋₂₆-alkyl acrylate, 1-dodecanethiol, N-(hydroxymethyl)-2-methyl-2-propenamide, polyfluorooctyl methacrylate and vinylidene chloride, 2,2'-[1,2-diazenediyl]bis(1-methylethylidene)bis[4,5-dihydro-1H-imidazole] hydrochloride (1:2)-initiated

(PMN P-11-557) 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, import, 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, the employer must incorporate this new information, and any information on methods for protecting against such risk, into a Material Safety Data Sheet (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, imported, 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 this substance from the employer are provided a MSDS as described in § 721.72(c) 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) (Manufacture of the PMN substance according to the chemical composition section of the consent order, where the company must analyze and report certain starting raw material impurities, and within the maximum established levels of certain fluorinated impurities of the PMN substances), (j) (use in a consumer product that could be spray applied), and (t).

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

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

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

(3) *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.

■ 15. Add § 721.10527 to subpart E to read as follows:

§ 721.10527 Perfluoroalkylethyl methacrylate copolymer (generic).

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

(1) The chemical substance identified generically as perfluoroalkylethyl methacrylate copolymer (PMN P-11-646) 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, import, 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, the employer must incorporate this new information, and any information on methods for protecting against such risk, into a Material Safety Data Sheet (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, imported, 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 this substance from the employer are provided a MSDS as described in § 721.72(c) 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(p) (any amount after March 31, 2015).

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

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

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

(3) *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.

■ 16. Add § 721.10528 to subpart E to read as follows:

§ 721.10528 Modified fluorinated acrylates (generic).

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

(1) The chemical substances identified generically as modified fluorinated acrylates (PMNs P-12-30, P-12-31, and P-12-32) 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) *Hazard communication program.* A significant new use of this substance is any manner or method of manufacture, import, 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, the employer must incorporate this new information, and any information on methods for protecting against such risk, into a Material Safety Data Sheet (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, imported, 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 this substance from the employer are provided a MSDS as described in § 721.72(c) 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) (Monitoring of the effluent waste water stream during manufacture in addition to the existing NPDES permit. Monitoring data will be collected on the confidential analytes and submitted to the Agency quarterly. Analysis, reporting, and limitation of maximum impurity levels of certain fluorinated impurities.).

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

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

applicable to manufacturers, importers, and processors of this substance.

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

(3) *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.

■ 17. Add § 721.10529 to subpart E to read as follows:

§ 721.10529 Cobalt iron manganese oxide, carboxylic acid-modified (generic).

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

(1) The chemical substance identified generically as cobalt iron manganese oxide, carboxylic acid-modified (PMN P-12-35) 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.* Requirements as specified in § 721.72(c) and (g) (do not release to water).

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f), (j) (ferrite dispersion ink additive to ensure magnetic performance characteristics), (o), (v)(2), and (x)(2).

(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.

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

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

■ 18. Add § 721.10530 to subpart E to read as follows:

§ 721.10530 Acrylate manufacture byproduct distillation residue (generic).

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

(1) The chemical substance is identified generically as acrylate manufacture byproduct distillation residue (PMN P-12-87) 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.

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

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

■ 19. Add § 721.10531 to subpart E to read as follows:

§ 721.10531 Distillation bottoms from manufacture of brominated cycloalkanes (generic).

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

(1) The chemical substance identified generically as distillation bottoms from manufacture of brominated cycloalkanes (PMN P-12-149) 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 = 2).

(ii) [Reserved]

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

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

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

■ 20. Add § 721.10532 to subpart E to read as follows:

§ 721.10532 Tar, brown coal.

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

(1) The chemical substance identified as tar, brown coal (PMN P-12-167, CAS No. 101316-83-0) 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)(1), (b)(1), and (c)(1).

(ii) [Reserved]

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

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

§ 721.125(a), (b), (c), and (k) are applicable to manufacturers, importers, and processors of this substance.

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

■ 21. Add § 721.10533 to subpart E to read as follows:

§ 721.10533 Amine-modified urea-formaldehyde polymer (generic).

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

(1) The chemical substance identified generically as amine-modified urea-formaldehyde polymer (PMN P-12-182) 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 = 56).

(ii) [Reserved]

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

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

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

■ 22. Add § 721.10534 to subpart E to read as follows:

§ 721.10534 Brominated aliphatic alcohol (generic).

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

(1) The chemical substance identified generically as brominated aliphatic alcohol (PMN P-12-260) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *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.

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

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

■ 23. Add § 721.10535 to subpart E to read as follows:

§ 721.10535 Phosphonium, tributyltetradecyl-, chloride (1:1).

(a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as phosphonium, tributyltetradecyl-, chloride (1:1) (PMN P-12-275; CAS No. 81741-28-8) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

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

(ii) [Reserved]

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

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

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

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 49

[EPA-R08-OAR-2012-0479; FRL-9710-4]

Approval and Promulgation of Federal Implementation Plan for Oil and Natural Gas Well Production Facilities; Fort Berthold Indian Reservation (Mandan, Hidatsa, and Arikara Nations), ND

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is taking final action to promulgate a Reservation-specific Federal Implementation Plan in order to regulate emissions from oil and natural gas production facilities located on the Fort Berthold Indian Reservation located in North Dakota. The Federal Implementation Plan includes basic air quality regulations for the protection of communities in and adjacent to the Fort Berthold Indian Reservation. The Federal Implementation Plan requires owners and operators of oil and natural gas production facilities to reduce emissions of volatile organic compounds emanating from well

completions, recompletions, and production and storage operations. This Federal Implementation Plan will be implemented by EPA, or a delegated Tribal Authority, until replaced by a Tribal Implementation Plan. EPA is proposing a Reservation-specific Federal Implementation Plan concurrently with this final rule.

DATES: This rule is effective in the CFR on August 15, 2012. This rule is effective with actual notice by EPA to the owners and operators for purposes of enforcement beginning at 5 p.m. (eastern daylight time) on August 3, 2012.

Public Hearing: EPA will hold a public hearing on the following date: September 12, 2012. The hearing will start at 1 p.m. local time and continue until 4 p.m. or until everyone has had a chance to speak. Additionally, an evening session will be held from 6 p.m. until 8 p.m. The hearing will be held at the 4 Bears Casino & Lodge, 202 Frontage Rd, New Town, ND 58763, (701) 627-4018.

ADDRESSES:

Docket: All documents in the docket are listed in the <http://www.regulations.gov> index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly-available docket materials are available either electronically in <http://www.regulations.gov> or in hard copy at the following locations: Air Program, U.S. Environmental Protection Agency (EPA), Region 8, Mailcode 8P-AR, 1595 Wynkoop, Denver, Colorado 80202-1129; and Environmental Division, Three Affiliated Tribes, 204 West Main, New Town, North Dakota 58763-9404. EPA requests that if at all possible, you contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section to view the hard copy of the docket. You may view the hard copy of the docket Monday through Friday, 8 a.m. to 4 p.m., excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Deirdre Rothery, U. S. Environmental Protection Agency, Region 8, Air Program, Mail Code 8P-AR, 1595 Wynkoop Street, Denver, Colorado 80202-1129, (303) 312-6431, rothery.deirdre@epa.gov.

SUPPLEMENTARY INFORMATION:

Throughout this document, “we,” “us” and “our” refer to the EPA.

Definitions

For the purpose of this document, we are giving meaning to certain words or initials as follows:

- (i) The initials *APA* mean or refer to the Administrative Procedure Act.
- (ii) The words or initials *Act* or *CAA* mean or refer to the Clean Air Act, unless the context indicates otherwise.
- (iii) The initials *BTU* mean or refer to British Thermal Unit.
- (iv) The initials *CAFOs* mean or refer to Consent Agreement Final Orders.
- (v) The initials *CDPHE* mean or refer to Colorado Department of Public Health and Environment Air Pollution Control Division.
- (vi) The initials *CO* mean or refer to carbon monoxide.
- (vii) The words *EPA*, *we*, *us* or *our* mean or refer to the United States Environmental Protection Agency.
- (viii) The words *Reservation* or the initials *FBIIR* mean or refer to the Fort Berthold Indian Reservation.
- (ix) The initials *FIP* mean or refer to Federal Implementation Plan.
- (x) The initials *GOR* mean or refer to gas-to-oil ratio.
- (xi) The initials *LACT* mean or refer to lease automatic custody transfer.
- (xii) The initials *MDEQ* mean or refer to Montana Department of Environmental Quality.
- (xiii) The initials *NAAQS* mean or refer to the National Ambient Air Quality Standards.
- (xiv) The initials *NAICS* mean or refer to the North American Industry Classification System.
- (xv) The initials *NDDoH* mean or refer to the North Dakota Department of Health.
- (xvi) The initials *NDIC* mean or refer to the North Dakota Industrial Commission.
- (xvii) The initials *NESHAP* mean or refer to National Emission Standards for Hazardous Air Pollutants.
- (xviii) The initials *NMED* mean or refer to New Mexico Environment Department Air Quality Bureau.
- (xix) The initials *NO_x* mean or refer to nitrogen oxides.
- (xx) The initials *NO₂* mean or refer to nitrogen dioxide.
- (xxi) The initials *NSPS* mean or refer to New Source Performance Standards.
- (xxii) The initials *NSR* mean or refer to new source review.
- (xxiii) The initials *ODEQ* mean or refer to Oklahoma Department of Environmental Quality Air Quality Division.
- (xxiv) The initials *PM* mean or refer to particulate matter.
- (xxv) The initials *PSD* mean or refer to prevention of significant deterioration.
- (xxvi) The initials *PTE* mean or refer to potential to emit.
- (xxvii) The initials *RCT* mean or refer to Railroad Commission of Texas, Oil and Gas Division.
- (xxviii) The initials *SCADA* mean or refer to Supervisory Control and Data Acquisition.
- (xxix) The initials *SIP* mean or refer to State Implementation Plan.
- (xxx) The initials *SO₂* mean or refer to sulfur dioxide.