interfering with its special function as a naval ship: Annex I, paragraph 3(a), pertaining to the horizontal distance between the forward and after masthead lights; and Annex I, paragraph 2(k) as described in Rule 30 (a)(i), pertaining to the vertical separation between anchor lights. The DAJAG (Admiralty and Maritime Law) has also certified that the lights involved are located in closest possible compliance with the applicable 72 COLREGS requirements.

Moreover, it has been determined, in accordance with 32 CFR parts 296 and 701, that publication of this amendment for public comment prior to adoption is impracticable, unnecessary, and contrary to public interest since it is based on technical findings that the placement of lights on this vessel in a manner differently from that prescribed herein will adversely affect the vessel's ability to perform its military functions.

List of Subjects in 32 CFR Part 706

Marine safety, Navigation (water), and Vessels.

For the reasons set forth in the preamble, amend part 706 of title 32 of the CFR as follows:

PART 706—CERTIFICATIONS AND EXEMPTIONS UNDER THE INTERNATIONAL REGULATIONS FOR PREVENTING COLLISIONS AT SEA, 1972

■ 1. The authority citation for part 706 continues to read:

Authority: 33 U.S.C. 1605.

■ 2. Section 706.2 is amended as follows:

■ A. In Table Three by adding, in alpha numerical order, by vessel number, an entry for USS ASHLAND (LSD 48); and

■ B. In Table Five by revising the entry for USS ASHLAND (LSD 48).

§ 706.2 Certifications of the Secretary of the Navy under Executive Order 11964 and 33 U.S.C. 1605.

* * * * *

TABLE THREE

Vessel	Number	Masthead lights arc of visibility; rule 21(a)	Side lights arc of visibility; rule 21(b)	Stern light arc of visibility; rule 21(c)	Side lights distance inboard of ship's sides in meters 3(b) Annex 1	Stern light, distance forward of stern in meters; Rule 21(c)	Forward anchor light, height above hull in meters; 2(k) Annex 1	Anchor lights relation-ship of aft light to forward light in meters 2(k) Annex 1
*	*	*	*	*	*	*	*	
USS ASHLAND ...	LSD 48 ...	.....	.....	.....	.....	.....	.....	2.60 below.
*	*	*	*	*	*	*	*	

* * * * *

TABLE FIVE

Vessel	Number	Masthead lights not over all other lights and obstructions. Annex I,sec. 2(f)	Forward masthead light not in forward quarter of ship. Annex I, sec. 3(a)	After masthead light less than 1/2 ship's length aft of forward masthead light. Annex I, sec. 3(a)	Percentage horizontal separation attained
*	*	*	*	*	*
USS ASHLAND	LSD 48	.....	.....	X	63.6
*	*	*	*	*	*

Approved: April 16, 2012.

C.J. Spain,

Deputy Assistant Judge Advocate, General (Admiralty and Maritime Law), Acting.

Dated: April 18, 2012.

J.M. Beal,

Lieutenant Commander, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. 2012–9928 Filed 4–24–12; 8:45 am]

BILLING CODE 3810–FF–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 721

[EPA–HQ–OPPT–2012–0182; FRL–9345–4]

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 23 chemical substances which were the subject of premanufacture notices (PMNs). Nine of these chemical substances are subject to TSCA consent orders issued by EPA. This action requires persons who intend to manufacture, import, or process any of these 23 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 June 25, 2012. For purposes of judicial review, this rule shall be promulgated at 1 p.m. (e.s.t.) on May 9, 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 May 25, 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–2012–0182, 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–2012–0182. 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–2012–0182. 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 or email. The 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, 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 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 23 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 23 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 nine PMN substances (P–07–537, P–07–706, P–10–135, P–10–358, P–11–264, P–11–561, P–11–567, P–11–568, and P–11–569) 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.

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

This rule also includes SNURs on 14 PMN substances (P–05–714, P–11–128, P–11–338, P–11–481, P–11–594, P–11–654, P–12–22, P–12–23, P–12–24, P–12–25, P–12–26, P–12–33, P–12–51, and P–12–52) 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 or releases, 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–05–714

Chemical name: Polyether ester acid compound with a polyamine amide (generic).

CAS number: Not available.

Basis for action: The PMN states that the substance will be used as an additive for industrial paints, industrial coatings, and architectural coatings. Based on test data on the PMN substance, EPA predicts toxicity to aquatic organisms may occur if releases of the PMN substance to surface water, from uses other than described in the PMN, exceed the releases expected from the use described in the PMN. For the use described in the PMN, significant environmental releases are not expected. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance other than as described in the PMN may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(i).

Recommended testing: EPA has determined that the results of a fish acute toxicity mitigated by humic acid test (Office of Pollution Prevention, Pesticides and Toxic Substances (OPPTS) Test Guideline 850.1085) would help characterize the environmental effects of the PMN substance.

CFR citation: 40 CFR 721.10410.

PMN Number P–07–537

Chemical name: Alkanenitrile, bis(cyanoalkyl)amino (generic).

CAS number: Not available.

Effective date of TSCA section 5(e) consent order: June 19, 2009.

Basis for TSCA section 5(e) consent order: The PMN states that the generic (non-confidential) use of the PMN substance will be as a chemical intermediate. Based on test data on the PMN substance, EPA identified concerns for neurotoxicity to workers from dermal and inhalation exposures. The NCEL is 70 microgram/cubic meter ($\mu g/m^3$) as an 8-hour time-weighted average. In addition, based on ecological structure-activity relationship (EcoSAR) analysis of test data on structurally similar aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 700 parts per billion (ppb). 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 human health and the environment. To protect against these risks, the consent order requires:

1. Use of personal protective equipment including impervious gloves (when there is potential dermal exposure) and either a National Institute for Occupational Safety and Health (NIOSH)-certified respirator with an assigned protection factor (APF) of at least 5, or compliance with a NCEL of 70 $\mu g/m^3$ as an 8-hour time-weighted average (when there is potential inhalation exposure).

2. Establishment and use of a hazard communication program.

3. Manufacture and use of the PMN substance only as a site-limited intermediate.

4. Submission of certain human health testing prior to exceeding the confidential production volume limit specified in the consent order.

5. Disposal of the PMN substance only by incineration or landfill.

6. No release of the PMN substance into the waters of the United States.

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

Recommended testing: EPA has determined that the results of a neurotoxicity study in rodents (Organisation for Economic Co-operation and Development (OECD) Test Guideline 424); a fish early-life stage toxicity test (OPPTS Test Guideline 850.1085); and a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300) would help characterize the human health and environmental effects of the PMN substance. The PMN submitter has agreed not to exceed the confidential production volume limit specified in the consent order without performing the neurotoxicity test. The consent order does not require the submission of the fish and daphnid testing at any specified time or production volume. However, the 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 721.10411.

PMN Number P–07–706

Chemical name: Phosphonic acid ester (generic).

CAS number: Not available.

Effective date of TSCA section 5(e) consent order: April 8, 2009.

Basis for TSCA section 5(e) consent order: The PMN states that the generic (non-confidential) use of the substance will be as a chemical intermediate. Based on test data on the PMN substance and an analogous chemical, EPA identified concerns for oncogenicity, mutagenicity, reproductive/developmental toxicity, skin irritation, and sensitization to workers from dermal and inhalation exposures. The NCEL is 1.0 milligram (mg)/m^3 as an 8-hour time-weighted average. 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 human health. To protect against this risk, the consent order requires:

1. Use of personal protective equipment including dermal protection (when there is potential dermal exposure) and a NIOSH-certified respirator with an assigned protection factor (APF) of at least 15, or compliance with a NCEL of 1.0 mg/m^3 as an 8-hour time-weighted average (when there is potential inhalation exposure).

2. Establishment and use of a hazard communication program.

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

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

Recommended testing: EPA has determined that the results of a combined repeated dose toxicity with the reproduction/developmental toxicity screening test (OECD Test Guideline 422) and a mammalian erythrocyte micronucleus test (OECD Test Guideline 474) would help characterize possible human health risks of the PMN substance. The PMN submitter has agreed not to exceed the confidential production volume limit specified in the consent order without performing these tests. The consent order does not require the submission of a genetic toxicology: rodent dominant lethal assay test (OECD Test Guideline 478) 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 721.10412.

PMN Number P–10–135

Chemical name: Fluorinated dialkyl ketone (generic).

CAS number: Not available.

Effective date of TSCA section 5(e) consent order: October 21, 2011.

Basis for TSCA section 5(e) consent order: The PMN states that the generic (non-confidential) use of the substance will be as a heat transfer fluid. Based on test data on the PMN substance and analogs, EPA identified concerns for oncogenicity and liver effects from dermal and inhalation exposures. 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 human health. To protect against this risk, the consent order prohibits exceedance of the confidential annual production volume limit specified in the consent order. The SNUR designates as a ''significant new use'' the absence of this protective measure.

Recommended testing: EPA has determined that a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) and a reproduction/developmental toxicity screening test (OECD Test Guideline 421, with modifications) would help characterize the human health effects of the PMN substance. 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 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 721.10413.

PMN Number P–10–358

Chemical name: Iron(1+), chloro[rel-1,5-dimethyl (1R,2S,4R,5S)- 9,9-dihydroxy-3-methyl-2,4-di(2-pyridinyl-.kappa.N)-7-[(2-pyridinyl-.kappa.N)methyl]-3,7-diazabicyclo[3.3.1]nonane-1,5-dicarboxylate-.kappa.N3,.kappa.N7]-, chloride (1:1), (OC-6–63)-.

CAS number: 478945–46–9.

Effective date of TSCA section 5(e) consent order: February 7, 2011.

Basis for TSCA section 5(e) consent order: The PMN states that the generic (non-confidential) use of the substance will be as a coatings additive at concentrations not to exceed 1.0 percent. Based on test data on the PMN substance, EPA identified concerns for systemic toxicity, neurotoxicity, dermal sensitization, acute toxicity and immunotoxicity from dermal exposure. 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 human health. To protect against these risks, the consent order requires:

1. Use of personal protective equipment including dermal protection (when there is potential dermal exposure).

2. Establishment and use of a hazard communication program.

3. Use of the PMN substance only as described in the PMN.

4. That annual manufacture and importation volume not exceed the confidential limit specified in the consent order.

5. No manufacture, processing, or use of the PMN substance in the form of a powder or a solid.

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

Recommended testing: EPA has determined that the results of an acute oral toxicity test (OPPTS Test Guideline 870.1100) in rabbits would help characterize the human health effects of the substance. 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 721.10414.

PMN Number P–11–128

Chemical name: 3H-indolium, 2-[2-[3-[2-(1,3-dihydro-1,3,3-trimethyl-2H-indol-2-ylidene)ethylidene]-2-[(1-phenyl-1H-tetrazol-5-yl)thio]-1-cyclohexen-1-yl]ethenyl]-1,3, 3-trimethyl-, chloride (1:1).

CAS number: 440102–72–7.

Basis for action: The PMN states that the substance will be used as a dye used in the manufacture of imaging media/products. Based on EcoSAR analysis of test data on cationic dyes, EPA predicts toxicity to aquatic organisms may occur as a result of releases of the PMN substance to surface water from manufacture or import in quantities greater than the 10,000 kilograms (kg) per year production volume stated in the PMN. At the annual production volume of 10,000 kg stated in the PMN,

there were no significant environmental concerns. 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 exceeding an annual manufacturing and importation volume of 10,000 kg may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(ii).

Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); and an algal toxicity test, tiers I and II (OPPTS Test Guideline 850.5400) would help characterize the environmental effects of the PMN substance.

CFR citation: 40 CFR 721.10415.

PMN Number P–11–264

Chemical name: Brominated polyphenyl ether (generic).

CAS number: Not available.

Effective date of TSCA section 5(e) consent order: November 22, 2011.

Basis for TSCA section 5(e) consent order: The PMN states that the generic (non-confidential) use of the PMN substance will be as a flame retardant. EPA expects that brominated dibenzodioxins (BDD) and dibenzofurans (BDF) may be generated during manufacture of the PMN substance and may be potential decomposition products of the PMN substance in the environment. Human health concerns from exposure to BDD and BDF include cancer, reproductive and developmental toxicity, and immunotoxicity. EPA expects the PMN to be highly persistent in the environment and that it may be bioavailable based on data on related substances. EPA also has environmental concerns based on the high degree of bromination of the PMN substance and the potential presence of BDD/BDF impurities that may form during manufacturing and may be decomposition products in the environment. Current knowledge of the ecotoxicity of BDD and BDF indicate adverse effects may occur in the parts per trillion range in rainbow trout embryos and juveniles. 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 and potential impurities and degradants may present an unreasonable risk of injury to human health and the environment, the substance may be produced in substantial quantities and may reasonably be anticipated to enter the environment in substantial quantities, and there may be significant (or substantial) human exposure to the substance. To protect against these risks the consent order requires:

1. No exceedance of the maximum levels of BDD and BDF in the PMN substance as specified in the consent order.

2. Manufacture of the PMN substance only at the site specified in the PMN and only using the process described in the PMN unless the dioxin/furan testing required in the consent order is conducted and the test results submitted to EPA within 16 months of commencement of manufacture at the additional site or process.

3. The molecular weight of the manufactured PMN substance be equal to or greater than the weight reported in the PMN.

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

Recommended testing: EPA has determined that the results of the following tests would help characterize the possible health and environmental effects of the PMN substance, its impurities and its degradation products. The consent order contains two (confidential) production limits. The PMN submitter has agreed not to exceed the first production limit without performing an anaerobic aquatic metabolism test (OPPTS Test Guideline 835.4400) and an amphibian metamorphosis assay (OECD Test Guideline 231). The PMN submitter has also agreed not to exceed a second production limit without performing a dietary exposure bioaccumulation fish test (OECD Test Guideline 305, draft dated October 14, 2011) and a test of the PMN substance for BDD and BDF content by high-resolution gas chromatography/high-resolution mass spectrometry (HRGC/HRMS) (EPA Test Method 8290A). EPA has also determined that the following tests would help characterize the environmental effects of the PMN substance. The consent order does not require the submission of the following information at any specified time or production volume: 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, tiers I and II test (OPPTS Test Guideline 850.5400). 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 721.10416.

PMN Number P–11–338

Chemical name: Biphenyl alkyl morpholino ketone (generic).

CAS number: Not available.

Basis for action: The PMN states that the substance will be used as a photo initiator. Based on EcoSAR analysis of test data on analogous aliphatic amines, 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, 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 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 ready biodegradability test (OPPTS Test Guideline 835.3110); 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, tiers I and II test (OPPTS Test Guideline 850.5400) would help characterize the environmental effects of the PMN substance. EPA also recommends that the special considerations for conducting laboratory studies (OPPTS Test Guideline 850.1000) be followed to facilitate solubility in the test media, because of the PMN's low water solubility.

CFR citation: 40 CFR 721.10417.

PMN Number P–11–481

Chemical name: 1,2-Cyclohexanedicarboxylic acid, 1-butyl 2-(phenylmethyl) ester.

CAS number: 1200806–67–2.

Basis for action: The PMN states that the generic (non-confidential) use of the substance is as an additive for polymers. Based on EcoSAR analysis of test data on analogous esters, 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

manufacture, 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 acute toxicity test (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test, tiers I and II (OPPTS Test Guideline 850.5400) would help characterize the environmental effects of the PMN substance.

CFR citation: 40 CFR 721.10418.

PMN Number P–11–561

Chemical name: Tetrafluoroethylene chlorotrifluoroethylene copolymer (generic).

CAS number: Not available.

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

Basis for TSCA section 5(e) consent order: The PMN states that the substance will be used as a polymer used in automotive fuel hoses. Based on EPA analysis of the potential content of the polymer, EPA is concerned that some long-chain perfluorinated substances could be present and if degraded, especially under thermal conditions, could be released into the environment. EPA has concerns that the PMN substance and its thermal degradation products will persist in the environment, could bioaccumulate or biomagnify, and could be toxic to humans, wild mammals, and birds. These concerns are based on data on analog chemicals, including perfluorooctanoic acid (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 this exposure and risk, the consent order requires the PMN substance be manufactured, processed, distributed in commerce, and used only as a polymer in automotive fuel hoses and the submitter has agreed to analyze, report, and limit specific fluorinated impurities of the PMN substance where the carbon chain meets or exceeds a specified length. 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 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 721.10419.

PMN Numbers P–11–567, P–11–568, and P–11–569

Chemical name: Fluoropolymers (generic).

CAS number: Not available.

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

Basis for TSCA section 5(e) consent order: The PMNs state that the generic (non-confidential) use of the PMN substances will be in the manufacture of elastomer containing materials (P–11–567 and P–11–569), and a component of film, wire, and cable (P–11–568). 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 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 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 the submitter has agreed to analyze, report, and limit specific fluorinated impurities of the PMN substances where the carbon chain meets or exceeds a specified length and risk notification. 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 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 721.10420.

PMN Number P–11–594

Chemical name: Mercaptoalkoxysilane (generic).

CAS number: Not available.

Basis for action: The PMN states that the substance will be used as an epoxy catalyst. Based on EcoSAR analysis of test data on analogous alkoxysilanes, esters, and phenols, 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, the substance will not be released to water. 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 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, tiers I and II (OPPTS Test Guideline 850.5400) would help characterize the environmental effects of the PMN substance.

CFR citation: 40 CFR 721.10421.

PMN Number P–11–654

Chemical name: Phenol, 2-[[[3-(1H-imidazol-1-yl)propyl]imino]phenylmethyl]-5-(octyloxy)-.

CAS number: 1332716–20–7.

Basis for action: The PMN states that the substance will be used as an epoxy catalyst. Based on EcoSAR analysis of test data on analogous Schiff bases and phenols, 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, the substance will not be released to water. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 1 ppb may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(ii).

Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); and an algal toxicity test, tiers I and II (OPPTS Test Guideline 850.5400) would help characterize the environmental effects of the PMN substance.

CFR citation: 40 CFR 721.10422.

PMN Numbers: P–12–22, P–12–23, P–12–24, P–12–25, and P–12–26

Chemical names: Complex strontium aluminum, rare earth doped (generic).

CAS numbers: Not available.

Basis for action: The PMNs state that the PMN substances will be used as dye used in the manufacture of imaging media/products. Based on analogous respirable and poorly soluble substances, in particular, titanium dioxide, EPA identified concerns for potential lung overload to workers from inhalation exposure to the PMN substances. Specifically, the Agency predicts potential toxicity to workers from inhalation when more than 5% of the PMN substances particles are less than 10 microns. For the uses described in the PMNs, significant worker exposure is unlikely, when no more than 5% of particles are less than 10 microns. 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 other than as described in the PMNs may cause serious health effects. Based on this information, the PMN substances meets the concern criteria at § 721.170(b)(3)(ii).

Recommended testing: EPA has determined that a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) would help characterize the human health effects of the PMN substances.

CFR citation: 40 CFR 721.10423.

PMN Number P–12–33

Chemical name: Benzoic acid, 4-(1,1-dimethylethyl)-, methyl.

CAS number: 26537–19–9.

Basis for action: The PMN states that the substance will be used as an intermediate in the manufacture of an imaging product. Based on submitted test data on p-tert-butyl benzoic acid, EPA identified concerns for neurotoxicity; reproductive toxicity (male); and adverse effects to the liver, kidney, and lung. In addition, based on data on benzoic acid, EPA identified concerns for developmental toxicity and hypersensitivity. These concerns are for effects to workers from inhalation and dermal exposures to the PMN substance. For the chemical intermediate use described in the PMN, significant worker exposure is unlikely, as dermal and inhalation exposures are not expected. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, use of the substance other than as an intermediate may cause serious health effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(3)(ii).

Recommended testing: EPA has determined that a combined repeated dose toxicity with the reproduction/developmental toxicity screening test (OPPTS Test Guideline 870.3650) would help characterize the human health effects of the PMN substance.

CFR citation: 40 CFR 721.10424.

PMN Numbers: P–12–51 and P–12–52

Chemical names: Substituted alkylamides (generic).

CAS numbers: Not available.

Basis for action: The PMNs state that the generic (non-confidential) use of the substances will be as polymer foam additives. Based on test data on analogous chemical substances and information on the Material Safety Data Sheet (MSDS), the Agency identified concerns for irritation to all exposed tissues, solvent irritation, and solvent neurotoxicity to workers from dermal exposure to the PMN substances. For the use described in the PMNs, significant worker exposure is unlikely, as dermal exposure is not expected. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substances may present an unreasonable risk. EPA has determined, however, use of the substances other than as described in the PMNs may cause serious health effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(3)(ii).

Recommended testing: EPA has determined that the results of a combined repeated dose toxicity with the reproduction/developmental toxicity screening test (OPPTS Test Guideline 870.3650); a bacterial reverse mutation test (OPPTS Test Guideline 870.5100); and a mammalian erythrocyte micronucleus test (OPPTS Test Guideline 870.5395) would help characterize the human health effects of the PMN substances.

CFR citation: 40 CFR 721.10425.

V. Rationale and Objectives of the Rule

A. Rationale

During review of the PMNs submitted for the chemical substances that are subject to these SNURs, EPA concluded that for 9 of the 23 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 14 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 June 25, 2012 without further notice, unless EPA receives written adverse or critical comments, or notice of intent to submit adverse or critical comments before May 25, 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 May 25, 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 April 25, 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 9 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, 19 of the 23 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 40 CFR 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. 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 40 CFR 720.50). However, upon review of PMNs and SNUNs, the Agency has the authority to require appropriate testing. In cases where EPA issued a TSCA section 5(e) consent order that requires or recommends certain testing, Unit IV. describes 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 and test reporting. To access the harmonized test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select ''Test Methods and Guidelines.'' The Organisation for Economic Co-operation and Development (OECD) test guidelines are available from the OECD Bookshop at *http://www.oecdbookshop.org* or SourceOECD at *http://www.sourceoecd.org.* To access EPA Method 8290A, please go to *http://www.epa.gov/osw/hazard/testmethods/sw846/pdfs/8290a.pdf.*

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. Listings of the tests specified in the TSCA section 5(e) consent orders are included in Unit IV. The SNURs contain the same production 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 § 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 40 CFR 720.50. SNUNs must be submitted on EPA Form No. 7710–25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in § 721.25 and 40 CFR 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–2012–0182.

XII. Statutory and Executive Order Reviews

A. Executive Order 12866

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

B. Paperwork Reduction Act

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 $8,300. Therefore, the promulgation of the SNUR would not have a significant economic impact on a substantial number of small entities.

D. Unfunded Mandates Reform Act

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

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

List of Subjects

40 CFR Part 9

Environmental protection, Reporting and recordkeeping requirements.

40 CFR Part 721

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

Dated: April 19, 2012.

Ward Penberthy,

Acting Director, Chemical Control Division, Office of Pollution Prevention and Toxics.

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

PART 9—[AMENDED]

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

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

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

§ 9.1 OMB approvals under the Paperwork Reduction Act.

* * * * *

40 CFR Citation	OMB Control No.
Significant New Uses of Chemical Substances	
721.10410	2070–0012
721.10411	2070–0012
721.10412	2070–0012
721.10413	2070–0012
721.10414	2070–0012
721.10415	2070–0012
721.10416	2070–0012
721.10417	2070–0012
721.10418	2070–0012
721.10419	2070–0012
721.10420	2070–0012
721.10421	2070–0012
721.10422	2070–0012
721.10423	2070–0012
721.10424	2070–0012
721.10425	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 § 721.10410 to subpart E to read as follows:

§ 721.10410 Polyether ester acid compound with a polyamine amide (generic) (P–05–714).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as polyether ester acid compound with a polyamine amide (PMN P–05–714) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(j) (additive for industrial paints, industrial coatings, and architectural coatings).

(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 (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.

■ 5. Add § 721.10411 to subpart E to read as follows:

§ 721.10411 Alkanenitrile, bis(cyanoalkyl)amino (generic) (P–07–537).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as alkanenitrile, bis(cyanoalkyl)amino (PMN P–07–537) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the PMN substance after it has been completely reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i), (a)(3), (a)(4), (a)(5), (a)(6)(i), (a)(6)(ii), (a)(6)(v), (a)(6)(vi), (b) (concentration set at 1.0 percent), and (c). The following National Institute for Occupational Safety and Health (NIOSH)-certified respirator with an assigned protection factor (APF) of at least 5 meets the minimum requirements for § 721.63(a)(4): NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters; NIOSH-certified powered air-purifying respirator equipped with a loose- fitting hood or helmet and high efficiency particulate air (HEPA) filters; NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (full-face) and HEPA filters; or NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (full-face) and HEPA filters.

(A) As an alternative to the respiratory requirements listed in paragraph (a)(2)(i), a manufacturer, importer, or processor may choose to follow the new chemical exposure limit (NCEL) provisions listed in the TSCA section 5(e) consent order for this substance. The NCEL is 70 microgram/cubic meter (μg/m^3) as an 8-hour time-weighted average. Persons who wish to pursue NCELs as an alternative to the § 721.63 respirator requirements may request to do so under § 721.30. Persons whose § 721.30 requests to use the NCELs approach are approved by EPA will receive NCELs provisions comparable to those contained in the corresponding TSCA section 5(e) consent order.

(B) [Reserved]

(ii) *Hazard communication program.* Requirements as specified in § 721.72(a), (b), (c), (d), (e)(concentration set at 1.0 percent), (f), (g)(1)(i), (g)(1)(ii), (g)(1)(iii), (g)(1)(iv), (g)(2)(i), (g)(2)(ii), (g)(2)(iii), (g)(2)(iv) (use respiratory protection, or maintain workplace airborne concentrations at or below an 8-hour time-weighted average of 70 μg/m^3), (g)(2)(v), (g)(3)(i), (g)(3)(ii), (g)(4)(i), (g)(4)(iii), and (g)(5).

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

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

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

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

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (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 paragraph (a)(2)(iii) of this section.

■ 6. Add § 721.10412 to subpart E to read as follows:

§ 721.10412 Phosphonic acid ester (generic) (P–07–706).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as phosphonic acid ester (PMN P–07–706) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the PMN substance after it has been completely reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2), (a)(3), (a)(4), (a)(5), (a)(6)(i), (a)(6)(v), (a)(6)(i), (a)(6)(ii), (a)(6)(v), (a)(6)(vi), (b) (concentration set at 0.1 percent) and (c). The following National Institute for Occupational Safety and Health (NIOSH)-approved respirators with an assigned protection

factor (APF) of 15 meet the minimum requirements for § 721.63 (a)(4): NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with the appropriate gas/vapor cartridges (organic vapor, acid gas, or substance-specific); NIOSH-certified powered air-purifying respirator equipped with a loose-fitting hood or helmet and the appropriate gas/vapor cartridges (organic vapor, acid gas, or substance-specific); NIOSH-certified powered air-purifying respirator with a tight-fitting facepiece (full-face) and equipped with the appropriate gas/vapor cartridges (organic vapor, acid gas, or substance-specific); NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (full-face); or NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a loose-fitting hood or helmet or a tight-fitting facepiece (full-face) if no cartridge service life testing is available.

(A) As an alternative to the respiratory requirements listed in paragraph (a)(2)(i), a manufacturer, importer, or processor may choose to follow the new chemical exposure limit (NCEL) provisions listed in the TSCA section 5(e) consent order for this substance. The NCEL is 1.0 millgram/cubic meter (mg/m^3) as an 8-hour time-weighted-average. Persons who wish to pursue NCELs as an alternative to the § 721.63 respirator requirements may request to do so under § 721.30. Persons whose § 721.30 requests to use the NCELs approach are approved by EPA will receive NCELs provisions comparable to those contained in the corresponding TSCA section 5(e) consent order.

(B) [Reserved]

(ii) *Hazard communication program.* Requirements as specified in § 721.72(a), (b), (c), (d), (e) (concentration set at 0.1 percent), (f), (g)(1)(i), (g)(1)(vi), (g)(1)(vii), (g)(1)(ix), (g)(2)(i), (g)(2)(ii), (g)(2)(iii), (g)(2)(iv) (use respiratory protection or maintain workplace airborne concentrations at or below an 8-hour time-weighted average of 1.0 mg/m^3), and (g)(5).

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

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

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

■ 7. Add § 721.10413 to subpart E to read as follows:

§ 721.10413 Fluorinated dialkyl ketone (generic) (P–10–135).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as fluorinated dialkyl ketone (PMN P–10–135) 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(t).

(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 (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.

■ 8. Add § 721.10414 to subpart E to read as follows:

§ 721.10414 Polycyclic polyamine diester organometallic compound (generic) (P–10–358).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as iron(1+), chloro[rel-1,5-dimethyl (1R,2S,4R,5S)-9,9-dihydroxy-3-methyl-2,4-di(2-pyridinyl-.kappa.N)-7-[(2-pyridinyl-.kappa.N)methyl]-3,7-diazabicyclo[3.3.1]nonane-1,5-dicarboxylate-.kappa.N3,.kappa.N7]-, chloride (1:1), (OC–6–63)-(PMN P–10–358, CAS No. 478945–46–9) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the PMN substance after it has been completely reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2), (a)(3), (a)(6)(i), (a)(6)(ii), (a)(6)(iv), (a)(6)(v), (a)(6)(vi), (b) (concentration set at 1.0 percent), and (c).

(ii) *Hazard communication program.* Requirements as specified in § 721.72(a), (b), (c), (d), (e) (concentration set at 1.0 percent), (g)(1)(i), (g)(1)(iii), (g)(1)(iv), (g)(1)(viii), (g)(2)(i), (g)(2)(v), (g)(3)(i), (g)(3)(ii), and (g)(5).

(iii) *Industrial, commercial, and consumer activities. R*equirements as specified in § 721.80(j), (t), (v)(1), (v)(2), (w)(1), (w)(2), (x)(1), and (x)(2).

(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) through (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)(iii) of this section.

■ 9. Add § 721.10415 to subpart E to read as follows:

§ 721.10415 3H-indolium, 2-[2-[3-[2-(1,3-dihydro-1,3,3-trimethyl-2H-indol-2-ylidene)ethylidene]-2-[(1-phenyl-1H-tetrazol-5-yl)thio]-1-cyclohexen-1-yl]ethenyl]-1, 3, 3-trimethyl-, chloride (1:1).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 3H-indolium, 2-[2-[3-[2-(1,3-dihydro-1,3,3-trimethyl-2H-indol-2-ylidene)ethylidene]-2-[(1-phenyl-1H-tetrazol-5-yl)thio]-1-cyclohexen-1-yl]ethenyl]-1, 3, 3-trimethyl-, chloride (1:1) (PMN P–11–128, CAS No. 440102–72–7) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(s) (10,000 kilogram (kg)).

(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 (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.

■ 10. Add § 721.10416 to subpart E to read as follows:

§ 721.10416 Brominated polyphenyl ether (generic) (P–11–264).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as brominated polyphenyl ether (PMN P–11–264) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the PMN substance after it has been completely reacted (cured).

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(j) (manufacture of the substance at a molecular weight greater than or equal to that described in PMN P–11–264), § 721.80 (k) (manufacture at the facility described in PMN P–11–264 or by the process described in PMN P–11–264 (changes in manufacturing processes include, but are not limited to, changes in feedstock, reaction conditions, and/or product isolation and purification) unless the brominated dibenzodioxin (BDD)/brominated dibenzofuran (BDF) testing (EPA Test Method 8290A) required in the consent order is conducted at the new facility or for the new manufacturing method and the test results submitted to EPA within 16 months of changing the manufacturing process or commencement of manufacture at a different facility; manufacture of the substance where levels of the fifteen BDD/BDF congeners are detected at or below the Levels of Quantification (LOQs) published in EPA's Dioxin test rule (40 CFR 766.27)).

(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 (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.

■ 11. Add § 721.10417 to subpart E to read as follows:

§ 721.10417 Biphenyl alkyl morpholino ketone (generic) (P–11–338).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as biphenyl alkyl morpholino ketone (PMN P–11–338) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *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.

■ 12. Add § 721.10418 to subpart E to read as follows:

§ 721.10418 1,2-Cyclohexanedicarboxylic acid, 1-butyl 2-(phenylmethyl) ester.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance is identified as 1,2-cyclohexanedicarboxylic acid, 1-butyl 2-(phenylmethyl) ester (PMN P–11–481, CAS No. 1200806–67–2) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *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.

■ 13. Add § 721.10419 to subpart E to read as follows:

§ 721.10419 Tetrafluoroethylene chlorotrifluoroethylene copolymer (generic) (P–11–561).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as tetrafluoroethylene chlorotrifluoroethylene copolymer (PMN P–11–561) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the PMN substance after it has been completely reacted (cured).

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k) (manufacture, processing, distribution in commerce, and use of PMN P–11–561 substance only as a polymer in automotive fuel hoses; analysis and reporting and limitations of maximum impurity levels of certain fluorinated impurities).

(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 (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.

■ 14. Add § 721.10420 to subpart E to read as follows:

§ 721.10420 Fluoropolymers (generic) (P–11–567, P–11–568, and P–11–569).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substances identified generically as fluoropolymers (PMNs P–11–567, P–11–568, and P–11–569) are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the PMN substances after it has been completely reacted (cured). These PMN substances, which have been molded into final articles and which are recycled into non-virgin raw material are again subject to the requirements 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).

(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.

■ 15. Add § 721.10421 to subpart E to read as follows:

§ 721.10421 Mercaptoalkoxysilane (generic) (P–11–594).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as mercaptoalkoxysilane (PMN P–11–594) 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.

■ 16. Add § 721.10422 to subpart E to read as follows:

§ 721.10422 Phenol, 2-[[[3-(1H-imidazol-1-yl)propyl]imino]phenylmethyl]-5-(octyloxy)-.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as phenol, 2-[[[3-(1H-imidazol-1-yl)propyl]imino]phenylmethyl]-5-(octyloxy)- (PMN P–11–654, CAS No. 1332716–20–7) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *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.

■ 17. Add § 721.10423 to subpart E to read as follows:

§ 721.10423 Complex strontium aluminum, rare earth doped (generic) (P–12–22, P–12–23, P–12–24, P–12–25, and P–12–26).

(a) *Chemical substances and significant new uses subject to reporting.* (1) The chemical substances identified generically as complex strontium aluminum, rare earth doped (PMNs P–12–22, P–12–23, P–12–24, P–12–25, and P–12–26) 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) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(j) (manufacture, processing, or use where no more than 5% of particles are less than 10 microns).

(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 (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.

■ 18. Add § 721.10424 to subpart E to read as follows:

§ 721.10424 Benzoic acid, 4-(1,1-dimethylethyl)-, methyl.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as benzoic acid, 4-(1,1-dimethylethyl)-, methyl (PMN P–12–33, CAS No. 26537–19–9) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

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

(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 (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.

■ 19. Add § 721.10425 to subpart E to read as follows:

§ 721.10425 Substituted alkylamides (generic) (P–12–51 and P–12–52).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substances identified generically as substituted alkylamides (PMNs P–12–51 and P–12–52) 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) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(j).

(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 (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.

[FR Doc. 2012–9965 Filed 4–24–12; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket No. CDC–2011–0010]

42 CFR Part 88

RIN 0920–AA45

World Trade Center Health Program Requirements for the Addition of New WTC-Related Health Conditions

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Final rule.

SUMMARY: Title I of the James Zadroga 9/11 Health and Compensation Act of 2010 amended the Public Health Service Act (PHS Act) to establish the World Trade Center (WTC) Health Program. Sections 3311, 3312, and 3321 of Title XXXIII of the PHS Act require that the WTC Program Administrator develop regulations to implement portions of the WTC Health Program established within the Department of Health and Human Services (HHS). The WTC Health Program, which is administered by the Director of the National Institute for Occupational Safety and Health (NIOSH), within the Centers for Disease Control and Prevention (CDC), provides medical monitoring and treatment to eligible firefighters and related personnel, law enforcement officers, and rescue, recovery and cleanup workers who responded to the September 11, 2001, terrorist attacks in New York City, Shanksville, PA, and at the Pentagon, and to eligible survivors of the New York City attacks. This final rule establishes the processes by which the WTC Program Administrator may add a new condition to the list of WTC-related health conditions through rulemaking, including a process for considering petitions by interested parties to add a new condition.

DATES: This final rule is effective May 25, 2012.

FOR FURTHER INFORMATION CONTACT: Roy M. Fleming, Sc.D., Senior Science Advisor, World Trade Center Health Program, Office of the Director, National Institute for Occupational Safety and Health, 1600 Clifton Road NE., MS–E74, Atlanta, GA 30329; telephone 866–426–3673 (this is a toll-free number). Information requests may also be submitted by email to *wtcpublicinput@cdc.gov.*

SUPPLEMENTARY INFORMATION: This preamble is organized as follows:

I. Public Participation

HHS received comments from six individuals and organizations on the notice of proposed rulemaking published in the **Federal Register** on July 1, 2011 (76 FR 38938). One anonymous commenter expressed anger about the WTC Health Program's cost to American taxpayers; another individual asked that leukemia and other blood cancers be added to the list of WTC-related health conditions; and a physician experienced with treating WTC-related health conditions requested that a mental disorder be added to the list of WTC-related health conditions. Those comments are outside the scope of this rulemaking and could not be considered. HHS received substantive comments from the New York State Laborers' Health & Safety Trust Fund, the Communication Workers of America, and the WTC Health Program Survivor Steering Committee. Those comments are described and addressed below.

II. Background

A. WTC Health Program Statutory Authority

Title I of the James Zadroga 9/11 Health and Compensation Act of 2010 (Pub. L. 111–347), amended the Public Health Service Act (PHS Act) to add Title XXXIII [1] establishing the WTC Health Program within HHS. HHS issued an interim final rule on July 1, 2011 (76 FR 38914), which codified the Program in 42 CFR Part 88. Sections 88.1 through 88.16 were included in that rulemaking; this final rule establishing § 88.17 was developed in a separate rulemaking.

The WTC Health Program provides medical monitoring and treatment benefits to eligible firefighters and related personnel, law enforcement officers, and rescue, recovery and cleanup workers (including those who are Federal employees) who responded to the September 11, 2001, terrorist attacks, and to eligible survivors of the New York City attacks. The WTC Health Program will expand to include eligible firefighters and related personnel, law enforcement officers, and rescue, recovery and cleanup workers who responded to the September 11, 2001, terrorist attacks at the Pentagon and Shanksville, PA. The WTC Program Administrator has gathered information that may serve as a basis for such enrollment, and is working to develop eligibility criteria for these responder groups.

All references to the WTC Program Administrator in this notice mean the NIOSH Director or his or her designee.

Title XXXIII of the PHS Act authorizes the WTC Program Administrator to establish a process by which health conditions, including cancer, may be considered for addition to the list of WTC-related health conditions. This final rule establishes this process.

B. Addition of New Health Conditions for Coverage in the WTC Health Program

The list of WTC-related health conditions defined in sections 3312 and 3322 of Title XXXIII of the PHS Act may be amended in the future to add other conditions for which exposure to airborne toxins, any other hazard, or any other adverse condition resulting from the September 11, 2001, terrorist attacks, based on an examination by a medical professional with experience in treating or diagnosing the health conditions included in the applicable list of WTC-related health conditions, is substantially likely to be a significant factor in aggravating, contributing to, or causing the illness or condition (Title XXXIII, Sec. 3312(a)(1)(A)(i)).

Procedures for the addition of a new condition are established in this final rule. The addition of a new condition

[1] Title XXXIII of the Public Health Service Act is codified at 42 U.S.C. 300mm to 300mm–61. Those portions of the Zadroga Act found in Titles II and III of Public Law 111–347 do not pertain to the World Trade Center Health Program and are codified elsewhere.