

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

Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023-01 and Commandant Instruction M16475.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321-4370f), and have concluded this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded, under figure 2-1, paragraph (34)(g), of the Instruction. This rule involves the establishment of a safety zone.

An environmental analysis checklist and a categorical exclusion determination are available in the docket where indicated under

ADDRESSES.

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05-1, 6.04-1, 6.04-6, and 160.5; Public Law 107-295; 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add a new temporary section § 165.T11-233 to read as follows:

§ 165.T11-233 Safety Zone; Naval Training October and November; San Clemente Island, CA.

(a) *Location.* The limits of the safety zone will be the navigable waters of the Pacific Ocean at the north end of San Clemente Island bounded by the following coordinates:

33°01.09' N, 118°36.34' W;
32°59.95' N, 118°39.77' W;
running parallel to the shoreline at approximately 3 NM to 33°02.81' N, 118°30.65' W; 33°01.29' N, 118°33.88' W; along the shoreline to 33°01.09' N, 118°36.34' W.

(b) *Enforcement Period.* This section will be enforced from October 1, 2009

through November 30, 2009 during naval training exercises. If the training is concluded prior to the scheduled termination time, the COTP will cease enforcement of this safety zone and will announce that fact via Broadcast Notice to Mariners.

(c) *Definitions.* The following definitions apply to this section: *Designated representative*, means any Commissioned, Warrant, or Petty Officers of the Coast Guard, Coast Guard Auxiliary, or local, state, and federal law enforcement vessels who have been authorized to act on the behalf of the COTP; *non-authorized personnel and vessels*, means any civilian vessels, fishermen, divers, and swimmers.

(d) *Regulations.* (1) Entry into, transit through or anchoring within this safety zone is prohibited unless authorized by the COTP San Diego or his designated representative.

(2) Non-authorized personnel and vessels requesting permission to transit through the safety zone may request authorization to do so from the COTP San Diego or his designated representative. They may be contacted on VHF-FM Channel 16, or at telephone number (619) 278-7033.

(3) Naval units involved in the exercise are allowed in confines of the established safety zone.

(4) All persons and vessels shall comply with the instructions of the Coast Guard COTP or his designated representative.

(5) Upon being hailed by U.S. Coast Guard or other official personnel by siren, radio, flashing light, or other means, the operator of a vessel shall proceed as directed.

(6) The Coast Guard may be assisted by other federal, state, or local agencies including the U.S. Navy.

Dated: August 31, 2009.

T.H. Farris,

Captain, U.S. Coast Guard, Captain of the Port San Diego.

[FR Doc. E9-22463 Filed 9-17-09; 8:45 am]

BILLING CODE 4910-15-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 721

[EPA-HQ-OPPT-2009-0729; FRL-8430-3]

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 section 5(a)(2) of the Toxic Substances Control Act (TSCA) for 12 chemical substances which were the subject of premanufacture notices (PMNs). Two of these chemical substances are subject to TSCA section 5(e) consent orders issued by EPA. This action requires persons who intend to manufacture, import, or process any of these 12 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: The effective date of this rule is November 17, 2009 without further notice, unless EPA receives written adverse or critical comments, or notice of intent to submit adverse or critical comments before October 19, 2009. This rule shall be promulgated for purposes of judicial review at 1 p.m. (e.s.t.) on October 2, 2009.

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 October 19, 2009, 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.

Significant new use designations for a chemical substance are legally established as of the date of publication of this direct final rule September 18, 2009. See the discussion in Unit VII. for more specific details.

Any persons intending to import or export a chemical substance that is the subject of this rule on or after October 19, 2009 are subject to the TSCA section 13 import certification requirements and the export notification provisions of TSCA section 12(b). See the discussion in Unit I.A. and Unit II.C. for more specific details.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2009-0729, by one of the following methods:

• *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the on-line 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-2009-0729. 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-2009-0729. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through [regulations.gov](http://www.regulations.gov) or e-mail. The [regulations.gov](http://www.regulations.gov) website 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 e-mail comment directly to EPA without going through [regulations.gov](http://www.regulations.gov), your e-mail 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 general information contact:* Colby Lintner, Regulatory Coordinator, Environmental Assistance Division (7408M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 554-1404; e-mail address: TSCA-Hotline@epa.gov.

For technical information contact: Tracey Klosterman, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-2209; e-mail address: klosterman.tracey@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 (the corresponding EPA policy appears at 40 CFR part 707, subpart B). 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. In addition, any persons who export or intend to export a chemical substance that is the subject of this rule on or after October 19, 2009 are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)) (see § 721.20), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through [regulations.gov](http://www.regulations.gov) or e-mail. 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** of April 24, 1990 (55 FR 17376). 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 those listed in TSCA section 5(a)(2). 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. The mechanism for reporting under this requirement is established under § 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 section 5(h)(1), (h)(2), (h)(3), and (h)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUN, EPA may take regulatory action under TSCA 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.

Chemical importers are subject to the TSCA section 13 (15 U.S.C. 1612) import certification requirements promulgated at 19 CFR 12.118 through 12.127, and 19 CFR 127.28 (the corresponding EPA policy appears at 40 CFR part 707, subpart B). Chemical importers must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA. Importers of chemical substances subject to a final SNUR must certify their compliance with the SNUR requirements. In addition, any persons who export or intend to export a chemical substance identified in a final SNUR are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2612 (b)) (see § 721.20), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

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 12 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 factors listed in TSCA section 5(a)(2) and this unit.

IV. Substances Subject to this Rule

EPA is establishing significant new use and recordkeeping requirements for 12 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).
- 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).
- Toxicity concerns.
- 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 2 PMN substances 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 10 PMN substances that are not subject to consent orders under TSCA section 5(e). In these cases, for a variety of reasons, EPA did not find that the use scenario described in the PMN triggered the determinations set forth under TSCA section 5(e). EPA, however, does believe that certain changes from the use scenario described in the PMN could result in increased exposures, thereby constituting a "significant new use." These so-called "non-5(e) SNURs" are promulgated pursuant to § 721.170. EPA has determined that every activity designated as a "significant new use" in all non-5(e) SNURs issued under § 721.170 satisfies the two requirements stipulated in § 721.170(c)(2), i.e., these significant new use activities, "(i) are different from those described in the premanufacture notice for the substance, including any amendments, deletions, and additions of activities to

the premanufacture notice, and (ii) may be accompanied by changes in exposure or release levels that are significant in relation to the health or environmental concerns identified" for the PMN substance.

PMN Number P-05-775

Chemical name: Benzeneethanol, halo-, halocycloalkyl-, hydrazinealkyl- (generic).

CAS number: Not available.

Effective date of TSCA section 5(e)

consent order: May 8, 2008.

Basis for TSCA section 5(e) consent

order: The PMN states that the generic (non-confidential) use of the substance will be as an intermediate used in a closed process. The order was issued under sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) of TSCA based on a finding that this substance may present an unreasonable risk of injury to human health and the environment. To protect against this risk, the consent order requires dermal protection, hazard communication, and water release restrictions. The SNUR designates as a "significant new use" the absence of these protective measures.

Toxicity concern: Based on test data on the PMN substance, analogous hydrazines and other (confidential) moieties of the PMN substance, EPA identified concerns for mutagenicity, skin sensitization, liver toxicity, kidney toxicity, neurotoxicity, and eye irritation from dermal exposure. Further, based on test data for analogous hydrazines, EPA predicts aquatic toxicity at concentrations that exceed 0.1 parts per billion (ppb) from releases of the PMN substance to the environment.

Recommended testing: EPA has determined that the results of the following tests would help characterize the human health and environmental effects of the PMN substance: A fish early-life stage toxicity test (OPPTS Harmonized Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Harmonized Test Guideline 850.1300); an algal toxicity test, tiers I and II (OPPTS Harmonized Test Guideline 850.5400); a repeated dose oral toxicity in rodents with reproductive, developmental and neurotoxicity screening (Organisation for Economic Co-operation and Development (OECD) 422 test guideline) for a duration of 90-days; a bacterial reverse mutation test (OPPTS Harmonized Test Guideline 870.5100); and a mammalian erythrocyte micronucleus test (OPPTS Harmonized Test Guideline 870.5395) via the intraperitoneal route. Depending upon the results of mutagenicity testing, a two year carcinogenicity study (OPPTS Harmonized Test Guideline

870.4200) may be warranted. Further, a certificate of analysis should be provided for the test substance. The order does not require the submission of the aforementioned information 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 substance will remain in effect until the order is modified or revoked by EPA based on submission of that or other relevant information.

CFR citation: 40 CFR 721.10157.

PMN Number P-06-16

Chemical name: 2-Pentanone, 3,5-dichloro-.

CAS number: 58371-98-5.

Effective date of TSCA section 5(e)

consent order: May 8, 2008.

Basis for TSCA section 5(e) consent

order: The PMN states that the generic (non-confidential) use of the substance will be as an intermediate used in a closed process. The order was issued under sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) of TSCA based on a finding that this substance may present an unreasonable risk of injury to human health and the environment. To protect against this risk, the consent order requires dermal and respiratory protection, hazard communication, and water release restrictions. The SNUR designates as a "significant new use" the absence of these protective measures.

Toxicity concern: Based on test data on the PMN substance and analogous haloketones, EPA identified concerns for acute inhalation toxicity, mutagenicity, developmental toxicity, skin sensitization, systemic toxicity, and neurotoxicity from inhalation or dermal exposure. Further, based on test data on analogous neutral organic chemicals and haloketones, and potential excess toxicity due to reactivity (hydrolysis), EPA predicts aquatic toxicity at concentrations that exceed 0.1 ppb resulting from releases of the PMN substance to the environment.

Recommended testing: EPA has determined that the results of the following tests would help characterize possible human health and environmental effects of the PMN substance: A fish early-life stage toxicity test (OPPTS Harmonized Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Harmonized Test Guideline 850.1300); an algal toxicity test, tiers I and II (OPPTS Harmonized Test Guideline 850.5400); a repeated dose oral toxicity in rodents with reproductive, developmental and neurotoxicity screening (OECD 422 test guideline) for a duration of 90-days; a

bacterial reverse mutation test (OPPTS Harmonized Test Guideline 870.5100); and a mammalian erythrocyte micronucleus test (OPPTS Harmonized Test Guideline 870.5395) via the intraperitoneal route. Depending upon the results of mutagenicity testing, a 2-year carcinogenicity study (OPPTS Harmonized Test Guideline 870.4200) may be warranted. Further, a certificate of analysis should be provided for the test substance. The order does not require the submission of the aforementioned information 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 substance will remain in effect until the order is modified or revoked by EPA based on submission of that or other relevant information.

CFR citation: 40 CFR 721.10158.

PMN Number P-07-587

Chemical name: 1-Docosamine, N,N-dimethyl-.

CAS number: 21542-96-1.

Basis for action: 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 analogous aliphatic amines, 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 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 release to surface waters may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170 (b)(4)(i) and (b)(4)(ii).

Recommended testing: EPA has determined that the results of a fish acute toxicity test mitigated by humic acid (OPPTS Harmonized Test Guideline 850.1085) would help characterize the environmental effects of the PMN substance. The test substance should be the chloride salt of the PMN substance at pH 7. Further, a certificate of analysis should be provided for the test substance.

CFR citation: 40 CFR 721.10159.

PMN Number P-07-629

Chemical name: Poly(oxy-1,2-ethanediyl), .alpha.-[[13Z]-1-oxo-13-docosen-1-yl]-.omega.-[[13Z]-1-oxo-13-docosen-1-yl]oxy]-.

CAS number: 56565-72-1.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as a polymer additive. Based on test data on analogous nonionic surfactants, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 20 ppb of the PMN substance in surface waters. For the use described in the PMN, releases of the substance are not expected to result in surface water concentrations that exceed 20 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that use of the substance other than as described in the PMN could result in exposures which 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 Harmonized Test Guideline 835.3110); a fish acute toxicity test (OPPTS Harmonized Test Guideline 850.1075); an aquatic invertebrate acute toxicity test with freshwater daphnids (OPPTS Harmonized Test Guideline 850.1010); and an algal toxicity test, tiers I and II (OPPTS Harmonized Test Guideline 850.5400) would help characterize the environmental effects of the PMN substance. Aquatic toxicity testing should be performed using the static method with nominal concentrations. Further, a certificate of analysis should be provided for the test substance.

CFR citation: 40 CFR 721.10160.

PMN Number P-08-3

Chemical name: Substituted silyl methacrylate (generic).

CAS number: Not available.

Basis for action: The PMN states that the substance will be used as an intermediate for a paint binder. Based on test data on analogous acrylates and neutral organic chemicals, 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 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 release to surface waters 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 hydrolysis as a function of pH test (OPPTS Harmonized Test Guideline 835.2120) and a ready biodegradability test (OPPTS Harmonized Test Guideline 835.3110) would help characterize the possible fate attributes of the PMN substance. If the results of the ready biodegradation test demonstrate that the hydrolysis product remains intact, then a shake-flask die-away test (OPPTS Harmonized Test Guideline 835.3170) and a fish bioconcentration test (OPPTS Harmonized Test Guideline 850.1730) may be warranted. Further, a certificate of analysis should be provided for the test substance.

CFR citation: 40 CFR 721.10161.

PMN Number P-08-24

Chemical name: 1,3 Dioxolane-4-butanol, 2-ethenyl-.

CAS number: 2421-08-1.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as a crosslinking agent to be ultimately used in the manufacture of automotive and aircraft coating materials. Based on test data on an expected hydrolysis product for an analogous chemical, EPA has concerns for mutagenicity, oncogenicity, developmental toxicity, liver toxicity, kidney toxicity, and skin sensitization and irritation for the PMN substance. As described in the PMN, significant worker exposure is 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 use of the substance other than as described in the PMN could result in exposures which 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 the results of a repeated dose 28-day oral toxicity study (OPPTS Harmonized Test Guideline 870.3050) in rodents would help characterize the human health effects of the PMN substance.

CFR citation: 40 CFR 721.10162.

PMN Number P-08-33

Chemical name: Chloro fluoro alkane (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as a chemical intermediate. EPA identified health and environmental concerns because the substance may be a persistent, bioaccumulative, and toxic (PBT) chemical, based on physical/chemical properties of the PMN substance, as

described in the New Chemicals Program's PBT Category (64 FR 60194; November 4, 1999) (FRL-6097-7). EPA estimates that the PMN substance will persist in the environment for more than six months and estimates a bioaccumulation factor of greater than or equal to 1,000. Also, based on test data on analogous haloalkanes, EPA predicts toxicity to aquatic organisms. As described in the PMN, significant worker exposure is unlikely and the substance is not released to surface waters. Therefore, EPA has not determined that the proposed processing or use of the substance may present an unreasonable risk. EPA has determined, however, that domestic manufacture, exceedance of the annual import volume limit of 50,000 kilograms, or any predictable or purposeful release containing the PMN substance into the waters of the United States may cause serious health effects and significant adverse environmental effects, since the PMN substance has been characterized by EPA as a PBT. Based on this information, the PMN substance meets the concern criteria at § 721.170 (b)(3)(ii), (b)(4)(ii), and (b)(4)(iii).

Recommended testing: EPA has determined that the results of the tiered testing as described in the New Chemicals Program's PBT Category would help characterize the PBT attributes of the PMN substance. The fish bioconcentration factor (BCF) test should be conducted using the flow through method with measured concentrations and include a certificate of analysis for the test substance showing percentage and level of impurities; measured BCF should be based on 100% active ingredient and measured concentrations.

CFR citation: 40 CFR 721.10163.

PMN Number P-08-36

Chemical name:

Benzenecarboximidamide, N-hydroxy-4-nitro-

CAS number: 1613-86-1.

Basis for action: The PMN states that the substance will be used as a chemical intermediate. Based on test data on analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 400 ppb of the PMN substance in surface waters. As described in the PMN, the substance is not expected to be 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 release to surface waters 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 Harmonized Test Guideline 850.1075); an aquatic invertebrate acute toxicity test with freshwater daphnids (OPPTS Harmonized Test Guideline 850.1010); and an algal toxicity test, tiers I and II (OPPTS Harmonized Test Guideline 850.5400) would help characterize the environmental effects of the PMN substance. Fish and daphnia testing should be performed using the flow through method with measured concentrations. Algal testing should be performed using the static method with measured concentrations. Further, a certificate of analysis should be provided for the test substance.

CFR citation: 40 CFR 721.10164.

PMN Number P-08-138

Chemical name: Carbonotrithioic acid, bis(phenylmethyl) ester.

CAS number: 26504-29-0.

Basis for action: The PMN states that the substance will be used as a chain transfer agent. EPA identified health and environmental concerns because the substance may be a PBT chemical, based on physical/chemical properties of the PMN substance, as described in the New Chemicals Program's PBT Category (64 FR 60194, November 4, 1999). EPA estimates that the PMN substance will persist in the environment for more than two months and estimates a bioaccumulation factor of greater than or equal to 5,000. Also, based on test data for analogous esters, EPA predicts toxicity to aquatic organisms. As described in the PMN, significant worker exposure is unlikely and the substance is not released to surface waters. Therefore, EPA has not determined that the proposed processing or use of the substance may present an unreasonable risk. EPA has determined, however, that domestic manufacture or any predictable or purposeful release containing the PMN substance into the waters of the United States may cause serious health effects and significant adverse environmental effects, since the PMN substance has been characterized by EPA as a PBT. Based on this information, the PMN substance meets the concern criteria at § 721.170 (b)(3)(ii), (b)(4)(ii), and (b)(4)(iii).

Recommended testing: EPA has determined that the results of the tiered testing described in the New Chemicals Program's PBT Category would help characterize the PBT attributes of the PMN substance. Further, a certificate of

analysis should be provided for the test substance.

CFR citation: 40 CFR 721.10165.

PMN Number P-08-180

Chemical name: 1,3-Cyclohexanedione, 2-[2-chloro-4-(methylsulfonyl)-3-[(2,2,2-trifluoroethoxy)methyl]benzoyl]-, ion(1-), potassium salt (1:1).

CAS number: 1121649-70-4.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as a precursor to another chemical substance. Based on test data on the PMN substance, EPA has concerns for developmental and systemic toxicity in humans. EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 0.1 ppb of the PMN substance in surface waters. As described in the PMN, significant worker exposure is not expected for the use described and the substance will not be released to surface waters in amounts resulting in surface water concentrations that exceed 0.1 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface waters concentrations that exceed 0.1 ppb may cause serious health effects and significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170 (b)(3)(i) and (b)(4)(i).

Recommended testing: EPA has determined that the results of the following tests would help characterize the human health and environmental effects of the PMN substance: A porous pot test (OPPTS Harmonized Test Guideline 835.3220); and either (1) a sediment/water microcosm biodegradation test (OPPTS Harmonized Test Guideline 835.3180), (2) a site-specific aquatic microcosm test, laboratory (OPPTS Harmonized Test Guideline 850.1925), or (3) a field testing for aquatic organisms (OPPTS Harmonized Test Guideline 850.1950).

CFR citation: 40 CFR 721.10166.

PMN Number P-08-212

Chemical name: Tetrafluoro nitrotoluene (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as a chemical intermediate. Based on test data on analogous neutral organic chemicals, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 200 ppb of the PMN substance in surface waters. As described in the PMN, the substance is not expected to be 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 release to surface waters 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 Harmonized Test Guideline 850.1075); an aquatic invertebrate acute toxicity test with freshwater daphnids (OPPTS Harmonized Test Guideline 850.1010); and an algal toxicity test, tiers I and II (OPPTS Harmonized Test Guideline 850.5400) would help characterize the environmental effects of the PMN substance. Fish and daphnia testing should be performed using the flow-through method with measured concentrations. Algal testing should be performed using the static method with measured concentrations. Further, a certificate of analysis should be provided for the test substance.
CFR citation: 40 CFR 721.10167.

PMN Number P-08-275

Chemical name: Cesium tungsten oxide.
CAS number: 52350-17-1.

Basis for action: The PMN states that the substance will be used as a component of infrared absorption material. Based on test data on analogous crystalline respirable, poorly soluble particulates, EPA has concerns for lung overload and lung cancer for the PMN substance. As described in the PMN, significant worker exposure is unlikely as dermal absorption is not expected and inhalation exposures are expected to be negligible because the PMN substance is used in aqueous form. 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 manufacturing, processing, or use of the substance as a solid may cause serious health effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(1)(i)(C) and (b)(3)(ii).

Recommended testing: EPA has determined that the results of a 90-day inhalation toxicity study (OPPTS Harmonized Test Guideline 870.3465) with a 60-day holding period in rats and with special attention to the histopathology of the lungs would help characterize the human health effects of the PMN substance. Depending on the results of this testing, a 2-year inhalation carcinogenicity study

(OPPTS Harmonized Test Guideline 870.4200) may be warranted.

CFR citation: 40 CFR 721.10168.

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 2 of the 12 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.

In the other 10 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/newchems/pubs/invntory.htm>.

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 November 17, 2009 without further notice, unless EPA receives written adverse or critical comments, or notice of intent to submit adverse or critical comments before October 19, 2009.

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 October 19, 2009, 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

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 2 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, 4 of the 12 chemical substances contained in this rule have CBI chemical identities, and since EPA has received a limited number of post-PMN *bona fide* submissions (per § 720.25 and § 721.11), the Agency believes that it is highly unlikely that any of the significant new uses described in the regulatory text of this rule are ongoing.

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

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, except where the chemical substance subject to the SNUR is also subject to a test rule under TSCA section 4 (see TSCA section 5(b)). Persons are required only to submit test data in their possession or control and to describe any other data known to or reasonably ascertainable by them (see § 720.50). However, upon review of PMNs and SNUNs, the Agency has the authority to require appropriate testing. In cases where EPA issued a TSCA section 5(e) consent order that requires or recommends certain testing, Unit IV. lists those tests. Unit IV. also lists recommended testing for non-5(e) SNURs. Descriptions of tests are

provided for informational purposes. EPA strongly encourages persons, before performing any testing, to consult with the Agency pertaining to protocol selection. Many OPPTS Harmonized Test Guidelines are now available on the Internet at <http://www.epa.gov/opptsfrs/home/guidelin.htm>. 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>.

In the TSCA section 5(e) consent orders for several of the chemical substances regulated under this rule, EPA has established production volume limits in view of the lack of data on the potential health and environmental risks that may be posed by the significant new uses or increased exposure to the chemical substances. These limits cannot be exceeded unless the PMN submitter first submits the results of toxicity tests that would permit a reasoned evaluation of the potential risks posed by these chemical substances. Under recent TSCA section 5(e) consent orders, each PMN submitter is required to submit each study at least 14 weeks (earlier TSCA section 5(e) consent orders required submissions at least 12 weeks) before reaching the specified production limit. Listings of the tests specified in the TSCA section 5(e) consent orders are included in Unit IV. The SNURs contain the same production volume limits as the TSCA section 5(e) consent orders. Exceeding these production limits is defined as a significant new use. Persons who intend to exceed the production limit must notify the Agency by submitting a SNUN at least 90 days in advance of commencement of non-exempt commercial manufacture, import, or processing.

The recommended tests may not be the only means of addressing the potential risks of the chemical substance. However, SNUNs submitted for significant new uses 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. This rule cross-references § 721.1725(b)(1) and is similar to that in § 721.11 for situations where the chemical identity of the chemical substance subject to a SNUR is CBI. This procedure is cross-referenced in each SNUR that includes specific significant new uses that are CBI.

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

As stated in Unit II.C., 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 mailed to the Environmental Protection Agency, OPPT Document Control Office (7407M), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. Information must be submitted in the form and manner set forth in EPA Form No. 7710-25. This form is available from the Environmental Assistance Division (7408M), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001 (see § 721.25 and § 720.40). Forms and information are also available electronically at <http://www.epa.gov/opptintr/newchems/pubs/pmnforms.htm>.

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.

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 the 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

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency hereby certifies that promulgation of these SNURs will not have a significant adverse economic impact on a substantial number of small entities. The rationale supporting this conclusion is discussed in this unit. The requirement to submit a SNUN applies to any person (including small or large entities) who intends to engage in any activity described in the rule as a "significant new use." Because these

uses are "new," based on all information currently available to EPA, it appears that no small or large entities presently engage in such activities. A SNUR requires that any person who intends to engage in such activity in the future must first notify EPA by submitting a SNUN. Although some small entities may decide to pursue a significant new use in the future, EPA cannot presently determine how many, if any, there may be. However, EPA's experience to date is that, in response to the promulgation of over 1,000 SNURs, the Agency receives on average only 5 notices per year. Of those SNUNs submitted from 2006-2008, only one appears to be from a small entity. In addition, the estimated reporting cost for submission of a SNUN (see Unit XI.) is minimal regardless of the size of the firm. Therefore, EPA believes that the potential economic impacts of complying with these SNURs are not expected to be significant or adversely impact a substantial number of small entities. In a SNUR that published in the **Federal Register** of June 2, 1997 (62 FR 29684) (FRL-5597-1), the Agency presented its general determination that final SNURs are not expected to have a significant economic impact on a substantial number of small entities, which was provided to the Chief Counsel for Advocacy of the Small Business Administration.

D. Unfunded Mandates Reform Act

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) (Public Law 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 does not significantly or uniquely affect the communities of Indian Tribal governments, nor does it involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000), do not apply to this rule.

G. Executive Order 13045

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

H. Executive Order 13211

This action is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply, distribution, or use and because this action is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act

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

J. Executive Order 12898

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

XIII. Congressional Review Act

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

report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects

40 CFR Part 9

Environmental protection, Reporting and recordkeeping requirements.

40 CFR Part 721

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

Dated: September 11, 2009.

Wendy C. Hamnett,

Acting Director, Office of Pollution Prevention and Toxics.

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

PART 9—[AMENDED]

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

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

■ 2. The table in § 9.1 is amended by adding the following sections in numerical order under the undesignated center heading "Significant New Uses of Chemical Substances" to read as follows:

§ 9.1 OMB approvals under the Paperwork Reduction Act.

* * * * *

40 CFR citation	OMB control No.
*	*

Significant New Uses of Chemical Substances

* * * * *

721.10157	2070-0012
721.10158	2070-0012
721.10159	2070-0012
721.10160	2070-0012
721.10161	2070-0012
721.10162	2070-0012
721.10163	2070-0012
721.10164	2070-0012
721.10165	2070-0012

40 CFR citation	OMB control No.
721.10166	2070-0012
721.10167	2070-0012
721.10168	2070-0012
* * * * *	* * * * *

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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. By adding new § 721.10157 to subpart E to read as follows:

§ 721.10157 Benzeneethanol, halo-,halocycloalkyl-,hydrazinealkyl-(generic).

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

(1) The chemical substance identified generically as benzeneethanol,halo-,halocycloalkyl-,hydrazinealkyl (PMN P-05-775) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:
(i) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(1), (a)(2)(i), (a)(2)(ii), (a)(3), (b) (concentration set at 1.0%), and (c).

(ii) *Hazard communication program.* Requirements as specified in § 721.72 (a), (b), (c), (d), (e) (concentration set at 1.0%), (f), (g)(1)(i) (eye irritation), (g)(1)(iii), (g)(1)(iv), (g)(1)(viii) (sensitization), (g)(1)(ix), (g)(2)(i), (g)(2)(v), (g)(3)(i), (g)(3)(ii), (g)(4) (resulting in receiving stream levels exceeding 0.1 parts per billion (ppb)), and (g)(5).

(iii) *Release to water.* Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) (N=0.1).

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

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d), (e), (f), (g), (h), 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.

■ 5. By adding new § 721.10158 to subpart E to read as follows:

§ 721.10158 2-Pentanone, 3,5-dichloro-

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

(1) The chemical substance identified as 2-pentanone, 3,5-dichloro- (PMN P-06-16; CAS No. 58371-98-5) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.*

Requirements as specified in § 721.63 (a)(1), (a)(2)(i), (a)(2)(ii), (a)(3), (a)(4), (a)(5), (a)(6), (b) (concentration set at 1.0%), and (c). Respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 50. The following NIOSH-approved respirator with an APF of 50 meets the minimum requirements for § 721.63(a)(4): NIOSH-approved air-purifying, tight-fitting full facepiece respirator equipped with combination organic gas/vapor P100 cartridges (organic vapor, acid gas, or substance-specific).

(ii) *Hazard communication program.* Requirements as specified in § 721.72 (a), (b), (c), (d), (e) (concentration set at 1.0%), (f), (g)(1)(i), (g)(1)(ii), (g)(1)(iii), (g)(1)(iv), (g)(1)(viii), (g)(1)(ix), (g)(2)(i), (g)(2)(ii), (g)(2)(iii), (g)(2)(iv), (g)(2)(v), (g)(3)(i), (g)(3)(ii), (g)(4) (resulting in receiving stream levels exceeding 0.1 parts per billion (ppb)), and (g)(5).

(iii) *Release to water.* Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) (N=0.1).

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

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d), (e), (f), (g), (h), 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.

■ 6. By adding new § 721.10159 to subpart E to read as follows:

§ 721.10159 1-Docosanamine, N,N-dimethyl-

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 1-docosanamine, N,N-dimethyl- (PMN P-07-587; CAS No. 21542-96-1) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

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

(ii) [Reserved]

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

(1) *Recordkeeping.* 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.

■ 7. By adding new § 721.10160 to subpart E to read as follows:

§ 721.10160 Poly(oxy-1,2-ethanediyl), .alpha.-[(13Z)-1-oxo-13-docosen-1-yl]-.omega.-[[[(13Z)-1-oxo-13-docosen-1-yl]oxy]-

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

(1) The chemical substance identified as poly(oxy-1,2-ethanediyl), .alpha.-[(13Z)-1-oxo-13-docosen-1-yl]-.omega.-[[[(13Z)-1-oxo-13-docosen-1-yl]oxy]- (PMN P-07-629; CAS No. 56565-72-1) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

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

■ 8. By adding new § 721.10161 to subpart E to read as follows:

§ 721.10161 Substituted silyl methacrylate (generic).

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

(1) The chemical substance identified generically as substituted silyl methacrylate (PMN P-08-3) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

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

(ii) [Reserved]

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

apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* 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.

■ 9. By adding new § 721.10162 to subpart E to read as follows:

§ 721.10162 1,3 Dioxolane-4-butanol, 2-ethenyl-

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

(1) The chemical substance identified as 1,3 dioxolane-4-butanol, 2-ethenyl- (PMN P-08-24; CAS No. 2421-08-1) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

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

■ 10. By adding new § 721.10163 to subpart E to read as follows:

§ 721.10163 Chloro fluoro alkane (generic).

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

(1) The chemical substance identified generically as chloro fluoro alkane (PMN P-08-33) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80 (f) and (s) (50,000 kilograms).

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

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

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

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

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

■ 11. By adding new § 721.10164 to subpart E to read as follows:

§ 721.10164 Benzenecarboximidamide, N-hydroxy-4-nitro-

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

(1) The chemical substance identified as benzenecarboximidamide, N-hydroxy-4-nitro- (PMN P-08-36; CAS No. 1613-86-1) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

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

(ii) [Reserved]

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

(1) *Recordkeeping.* 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. By adding new § 721.10165 to subpart E to read as follows:

§ 721.10165 Carbonotrithioic acid, bis(phenylmethyl) ester.

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

(1) The chemical substance identified as carbonotrithioic acid, bis(phenylmethyl) ester (PMN P-08-138; CAS No. 26504-29-0) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

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

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

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

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

(2) *Limitations or revocation of certain notification requirements.* The

provisions of § 721.185 apply to this section.

■ 13. By adding new § 721.10166 to subpart E to read as follows:

§ 721.10166 1,3-Cyclohexanedione, 2-[2-chloro-4-(methylsulfonyl)-3-[(2,2,2-trifluoroethoxy)methyl]benzoyl]-, ion(1-), potassium salt (1:1).

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

(1) The chemical substance identified as 1,3-cyclohexanedione, 2-[2-chloro-4-(methylsulfonyl)-3-[(2,2,2-trifluoroethoxy)methyl]benzoyl]-, ion(1-), potassium salt (1:1) (PMN P-08-180; CAS No. 1121649-70-4) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Release to water.* Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) (N= 0.1).

(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.

■ 14. By adding new § 721.10167 to subpart E to read as follows:

§ 721.10167 Tetrafluoro nitrotoluene (generic).

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

(1) The chemical substance identified generically as tetrafluoro nitrotoluene (PMN P-08-212) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

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

(ii) [Reserved]

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

(1) *Recordkeeping.* 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.

■ 15. By adding new § 721.10168 to subpart E to read as follows:

§ 721.10168 Cesium tungsten oxide.

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

(1) The chemical substance identified as cesium tungsten oxide (PMN P-08-275; CAS No. 52350-17-1) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80 (v)(2), (w)(2), and (x)(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 (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.

[FR Doc. E9-22533 Filed 9-17-09; 8:45 am]

BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R08-OAR-2005-0463; FRL-8957-3]

Approval and Promulgation of State Implementation Plans; State of Colorado; Revisions to the Denver Emergency Episode Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct Final Rule.

SUMMARY: EPA is taking direct final action approving State Implementation Plan (SIP) revisions to the Denver Emergency Episode Plan submitted by the State of Colorado on September 16, 1997. EPA has determined that the Denver Emergency Episode Plan revisions meet the requirements for the prevention of air pollution emergency episodes with ambient concentrations of air pollutants that may endanger public health and welfare. The intended effect of this action is to make Federally enforceable those provisions that EPA is approving. This action is being taken under section 110 of the Clean Air Act.

DATES: This rule is effective on November 17, 2009 without further notice, unless EPA receives adverse