ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[EPA–HQ–OPPT–2008–0251; FRL–8371–3]

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 56 chemical substances which were the subject of premanufacture notices (PMNs). Four 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 56 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 January 5, 2009 without further notice, unless EPA receives written adverse or critical comments, or notice of intent to submit adverse or critical comments before December 5, 2008. This rule shall be promulgated for purposes of judicial review at 1 p.m. (e.s.t.) on November 19, 2008.

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 December 5, 2008, 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.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2008–0251, 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–2008–0251. 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–2008–0251. EPA's policy is that all comments received will be included in the public 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 or e-mail. The 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, your e-mail address will be automatically captured and included as part of the comment that is placed in the public 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. For additional information about EPA's public docket, visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm*.

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 Federal 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 Pennington, 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: *pennington.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

40 CFR 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. Persons who import any chemical substance governed by a final SNUR are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements and the corresponding regulations at 19 CFR 12.118 through 12.127 and 19 CFR 127.28. Those persons must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA, including any SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export a chemical substance that is the subject of this rule on or after [*December 5, 2008*] are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)) (see 40 CFR 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 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 rulemaking 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. Additional rationale and background to this rule 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 40 CFR 721.5.

C. Applicability of General Provisions

General provisions for SNURs appear under 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 final rule. Provisions relating to user fees appear at 40 CFR part 700. According to 40 CFR 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 on 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.

Persons who export or intend to export a chemical substance identified in a proposed or final SNUR are subject to the export notification provisions of TSCA section 12(b). The regulations that interpret TSCA section 12(b) appear at 40 CFR part 707, subpart D. Persons who import a chemical substance identified in a final SNUR are subject to the TSCA section 13 import certification requirements, codified at 19 CFR 12.118 through 12.127 and 19 CFR 127.28. Such persons must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA, including any SNUR requirements. The EPA policy statement in support of the import certification appears at 40 CFR part 707, subpart B.

III. Substances Subject to this Rule

EPA is establishing significant new use and recordkeeping requirements for 56 chemical substances under 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.
- Toxicity concerns.
- Tests recommended by EPA to provide sufficient information to evaluate the chemical substance (see Unit VI. for more information).
- CFR citation assigned in the regulatory text section of this rule.

The specific activities designated as significant new uses are specified in the regulatory text section of this document. Certain new uses, including production limits and other uses designated in the

rule, are claimed as CBI. The procedure for obtaining confidential information is set out in Unit VII.

This rule includes SNURs on 3 PMN substances that are subject to ''risk-based'' consent orders under TSCA section 5(e)(1)(A)(ii)(I) wherein EPA determined that activities associated with the PMN substances may present unreasonable risk to 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 substances are promulgated pursuant to 40 CFR 721.160, and are based on and consistent with the provisions in the underlying consent orders. In addition, the rule includes one SNUR on a PMN substance that is subject to an ''exposure-based'' consent order under section 5(e)(1)(A)(ii)(II) wherein EPA determined that the PMN substance is expected to be produced in substantial quantities, there may be significant or substantial human exposure, and the substance may enter the environment in substantial quantities. That consent order requires submission of certain test data to EPA before the manufacturer may exceed a specified production volume. These SNURs designate as a ''significant new use'' the absence of the protective measures or exceedance of the production volume limit required in the 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 must 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 NCELs provisions currently exist in 40 CFR part 721, subpart B for SNURs. Therefore, for these cases, the individual SNURs in 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 40 CFR 721.30. Persons whose § 721.30 requests to use the NCELs approach for SNURs are approved by EPA will receive NCELs provisions comparable to those contained in the corresponding TSCA section 5(e) consent order for the same chemical substance.

This rule also includes SNURs on 52 PMN substances that are not subject to consent orders under TSCA section 5(e). In these cases, 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 40 CFR 721.170. EPA has determined that every activity designated as a ''significant new use'' in all non-5(e) SNURs issued under 40 CFR 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–00–552

Chemical name: Modified salicylic acid, zirconium complex (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as a photocopying chemical. EPA has identified health and environmental concerns because the substance may be a persistent, bio-accumulative, and toxic (PBT) chemical, based on physical/chemical properties of the PMN substance, as described in the New Chemical Program's PBT category (64 FR 60194; November 4, 1999) (FRL–6097–7). EPA estimates that the PMN substance will persist in the environment more than two months and estimates a bioaccumulation factor of greater than or equal to 5,000. Also, based on test data on the PMN substance and analogous substances, EPA believes exposure to the PMN substance may cause systemic human health effects and 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 manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any predictable or purposeful release containing the PMN substance into the waters of the United States may cause 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)(i), (b)(3)(ii), (b)(4)(i), and (b)(4)(ii).

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. EPA has determined that the results of a fish early-life stage toxicity test (OPPTS 850.1400 test guideline (public draft)) and a daphnid chronic toxicity test (OPPTS 850.1300 test guideline (public draft)) would help characterize the environmental effects of the PMN substance. Fish testing should be performed with rainbow trout for a 90-day period. Daphnid testing should be performed for a 21-day period.

CFR citation: 40 CFR 721.10089.

PMN Number P–01–595

Chemical name: Tertiary amine salt of glycol succinate (generic).

CAS number: Not available.

Effective date of section 5(e) consent order: July 26, 2004.

Basis for section 5(e) consent order: The PMN states that the generic (non-confidential) use of the substance will be as a pigment additive. The order was issued under section 5 (e)(1)(A)(i) and (e)(1)(A)(ii)(I) of TSCA based on a finding that this substance may present an unreasonable risk of injury to the environment. To protect against this risk, the consent order requires that the PMN substance be manufactured from specified feedstocks containing limited impurities. To ensure compliance, the consent order also requires that the feedstock is analyzed first at the time of initial commencement, then annually thereafter. The SNUR designates as a ''significant new use'' the absence of these protective measures.

Toxicity concern: Based on test data on analogous anionic substances, the Agency has concerns for toxicity to aquatic organisms at concentrations that exceed 20 parts per billion (ppb) in surface waters. EPA predicts higher toxicity to aquatic organisms could occur if the PMN substance is manufactured with feedstocks other than specified in the PMN submission. A manufacturing process other than that specified in the PMN could produce a product which is resistant to microbial biodegradation, resistant to removal in

sewage treatment, and more persistent in the aquatic environment.
Recommended testing: EPA has determined that the results of a Zahn-Wellens/EMPA test (OPPTS 835.3200 test guideline); a fish acute toxicity test, freshwater and marine (OPPTS 850.1075 test guideline (public draft)); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS 850.1010 test guideline (public draft)); and an algal toxicity test, tiers I and II (OPPTS 850.5400 test guideline (public draft)) would help characterize possible effects of the PMN substance. The order does not require 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 chemical 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 721.10090.

PMN Number P–02–135
Chemical name: 2(1H)-Pyrimidinone, tetrahydro-1,3-dimethyl-.
CAS number: 7226–23–5.
Basis for action: The PMN states that the substance will be used as an aprotic solvent and a catalyst. Based on test data on the PMN substance, EPA identified concerns for acute neurotoxicity, developmental toxicity and systemic effects to workers exposed dermally to the PMN substance. As described in the PMN, worker inhalation exposure is not expected and dermal exposure will be minimal due to the use of adequate personal protective equipment. Therefore, EPA has not determined that the proposed import, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that domestic manufacture, exceedence of the 20,000 kilogram annual import volume, use other than as described in the PMN, or use of the substance without the use of impervious gloves where there is a potential for dermal exposure, may cause serious health effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(3)(i).

Recommended testing: EPA has determined that the results of a 90-day oral toxicity in rodents (OPPTS 870.3100 test guideline) and a reproduction and fertility effects test (OPPTS 870.3800 test guideline) would help characterize the human health effects of the PMN substance.
CFR citation: 40 CFR 721.10091.

PMN Number P–02–421
Chemical name: Poly(oxy-1,2-ethanediyl), .alpha.-sulfo-.omega.-[[1-[(2-propen-1-yloxy)methyl]undecyl]oxy]-, ammonium salt (1:1); Poly(oxy-1,2-ethanediyl), .alpha.-sulfo-.omega.-[[1-[(2-propen-1-yloxy)methyl]tridecyl]oxy]-, ammonium salt (1:1).
CAS numbers: 352661–91–7 and 224646–44–0.
Effective date of section 5(e) consent order: September 12, 2003.
Basis for section 5(e) consent order: The PMN states that the generic (non-confidential) use of the substance will be as an emulsifier. The order was issued under section 5 (e)(1)(A)(i) and (e)(1)(A)(ii)(I) of TSCA based on a finding that this substance may present an unreasonable risk of injury to the environment. To protect against this risk, the consent order requires the company not to manufacture or import the PMN substance unless: (1) The mean number of moles of the ethoxy group is equal to or greater than 8 or (2) the average molecular weight is greater than 721 daltons. To ensure compliance, the consent order also requires that the substance is analyzed first at the time of initial commencement, then annually thereafter. The SNUR designates as a ''significant new use'' the absence of these protective measures.
Toxicity concern: Based on test data on analogous anionic surfactants, EPA predicts toxicity to aquatic organisms to occur at concentrations that exceed 3 ppb in surface waters. PMN substances with fewer ethoxy groups could have higher toxicity.
Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS 850.1075 test guideline (public draft)); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS 850.1010 test guideline (public draft)); and an algal toxicity test, tiers I and II (OPPTS 850.5400 test guideline (public draft)) would help characterize the environmental effects of the PMN substance.

CFR citation: 40 CFR 721.10092.

PMN Numbers P–03–12 and P–03–13
Chemical name: Alkylamides, ethoxylated (generic).
CAS number: Not available.
Basis for action: The PMNs state that the generic (non-confidential) use of the substances will be as surfactants. Based on test data on structurally similar aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 20 ppb in surface waters. As described in the amended PMNs, the substances are not released to surface waters. 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 other uses of the substances resulting in release to surface waters may cause significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(ii).

Recommended testing: EPA has determined that a fish acute toxicity test, freshwater and marine (OPPTS 850.1075 test guideline (public draft)); a fish acute toxicity test mitigated by humic acid (OPPTS 850.1085 test guideline (public draft)); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS 850.1010 test guideline (public draft)); and an algal toxicity test, tiers I and II (OPPTS 850.5400 test guideline (public draft)) would help characterize the environmental effects of the PMN substances. All aquatic toxicity tests should use the static method and nominal concentrations. EPA recommends that only the PMN substance described in P–03–13 needs to be tested. The chloride salt of the PMN substance should be tested at pH 7. The fish acute toxicity test mitigated by humic acid should be done twice with 20 mg humic acid/liter and 10 mg humic acid/liter. Fish 96-hour LC50 values should be determined in the fish acute toxicity tests mitigated by humic acid. Dilution water hardness in the fish and daphnid toxicity tests should be less than 180 mg/liter as CaCO3. Dilution water and growth medium total organic carbon (TOC) concentrations should be measured just prior to testing and should be less than 2.0 mg TOC/liter. The TOC in the dilution water of the humic acid controls should be measured at the start of the tests and reported.

CFR citation: 40 CFR 721.10093.

PMN Number P–03–272
Chemical name: Decene, branched and linear.
CAS number: 833482–31–8.
Basis for action: The PMN states that the substance will be used as a chemical intermediate. Based on test data on structurally similar neutral organic chemicals, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 2 ppb 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 other uses 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, freshwater and marine (OPPTS 850.1075 test guideline (public draft)); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS 850.1010 test guideline (public draft)); and an algal toxicity test, tiers I and II (OPPTS 850.5400 test guideline (public draft)) would help characterize the environmental effects of the PMN substance. All testing should be performed using the static method with measured concentrations in a closed vessel with no head space.
CFR citation: 40 CFR 721.10094.

PMN Number P–03–471

Chemical name: Oxetane, 3,3′-[oxybis(methylene)] bis[3-ethyl-.
CAS number: 18934–00–4.
Effective date of section 5(e) consent order: November 18, 2004.
Basis for section 5(e) consent order: The PMN states that the generic (non-confidential) use of the substance is an additive for industrial applications. The order was issued under section 5 (e)(1)(A)(i) and (e)(1)(A)(ii)(I) of TSCA 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 use of gloves demonstrated by testing to be impervious (Polyvinyl Alcohol gloves with a thickness of no less than 31.3 mils or Silvershield/4H sleeves with a thickness of no less than 2.7 mils have satisfied this requirement for up to 8 hours), a hazard communication program, and an aggregate production volume limit for manufacture or import. The SNUR designates as a ''significant new use'' the absence of these protective measures.

Toxicity concern: Based on a 28-day repeated dose study on the PMN substance, the Agency has concerns for male reproductive toxicity and systemic toxicity.
Recommended testing: EPA has determined that the results of a combined repeated dose toxicity study with a reproductive/developmental toxicity screening test (OPPTS 870.3650 test guideline) in rats by gavage would help characterize possible effects of the PMN substance. The PMN submitter has agreed not to exceed the production volume limit without performing these tests.
CFR citation: 40 CFR 721.10095.

PMN Number P–03–614

Chemical name: Benzene, 1,4-bis (methoxymethyl)-.
CAS number: 6770–38–3.
Effective date of section 5(e) consent order: April 21, 2004.
Basis for section 5(e) consent order: The PMN states that the generic (non-confidential) use of the substance will be as an electronic chemical. The exposure based 5(e) order was issued under section 5 (e)(1)(A)(i) and (e)(1)(A)(ii)(II) of TSCA based on a finding that the PMN substance is expected to be produced in substantial quantities, there may be significant or substantial human exposures, and the substance may enter the environment in substantial quantities. To protect against possible human health and environmental effects, the order requires submission of testing by a specified production volume.
Recommended testing: EPA has determined that the results of an acute oral toxicity test (OPPTS 870.1100 test guideline); a bacterial reverse mutation test (OPPTS 870.5100 test guideline); a mammalian erythrocyte micronucleus test (intraperitoneal route) (OPPTS 870.5395 test guideline); a repeated dose 28-day oral toxicity in rodents (OPPTS 870.3050 test guideline), including for all test doses a neurotoxicity functional observational battery, as described in OPPTS 870.6200 (test guideline); a fish acute toxicity test (OPPTS 850.1075 guideline (public draft)); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS 850.1010 test guideline (public draft)); an algal toxicity test, tiers I and II (OPPTS 850.5400 test guideline (public draft)); and a ready biodegradability test (OPPTS 835.3110 test guideline) would help characterize possible human health and environmental effects of the PMN substance. Fish and daphnid testing should be performed using the flow-through method with measured concentrations. Algal testing should be performed using the static method with measured concentrations. The PMN submitter has agreed not to exceed the production volume limit without performing these tests.
CFR citation: 40 CFR 721.10096.

PMN Numbers P–03–642 and P–03–643

Chemical names: (P–03–642) Disubstituted benzenesulfonic acid, alkali metal salt (generic) and (P–03–643) Disubstituted benzoic acid, alkali metal salt (generic).
CAS numbers: Not available.
Basis for action: The PMNs state that the generic (non-confidential) use of the substances will be as starting materials for the manufacture of agrochemicals. Based on test data on the PMN substances and structurally similar analogs, EPA has concerns for irritation and possible corrosion to eyes, mucous membranes and lungs, as well as concerns for liver and male reproductive system toxicity. As described in the PMNs, significant inhalation exposure is unlikely. 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 other uses of the substances other than as described in the PMNs may result in serious health effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(3)(i) and (b)(3)(ii).
Recommended testing: EPA has determined that the results of a bacterial reverse mutation test (OPPTS 870.5100 test guideline); a mammalian erythrocyte micronucleus assay (OPPTS 870.5395 test guideline); a repeated dose 28-day oral toxicity study in rodents (OPPTS 870.3050 test guideline); an acute oral toxicity (OPPTS 870.1100 test guideline); and a prenatal developmental toxicity study (OPPTS 870.3700 test guideline) would help characterize the human health effects of the PMN substances. The prenatal developmental toxicity study should be performed on P–03–643, while all remaining tests should be performed on P–03–642.
CFR citations: 40 CFR 721.10097 (P–03–642) and 40 CFR 721.10098 (P–03–643).

PMN Numbers P–03–715 and P–03–716

Chemical names: (P–03–715) Dialkyl dimethyl ammonium carbonate (1:1) (generic) and (P–03–716) Dialkyl dimethyl ammonium carbonate (2:1) (generic).

CAS numbers: Not available.
Basis for action: The PMNs state that the substances will be used as metal treatment chemicals, and surfactants in hard surface cleaning applications. Based on test data on structurally similar substances, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 5 ppb in surface waters. As described in the PMNs, releases of the PMN substances are not expected to result in surface water concentrations that exceed 5 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substances may present an unreasonable risk. EPA has determined, however, that other uses of the substances resulting in surface water concentrations that exceed 5 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 850.1400 test guideline (public draft)) and a porous pot test (OPPTS 835.3220 test guideline) would help characterize the environmental effects of the PMN substances.

CFR citations: 40 CFR 721.10099 (P–03–715) and 40 CFR 721.10100 (P–03–716).
PMN Number P–03–755
Chemical name: Copolymer of alkyl acrylate and ethyleneglycol dimethacrylate (generic).
CAS number: Not available.
Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as an additive for paints and coatings. Based on test data for structurally similar polynonionic polymers, EPA has concerns for lung fibrosis if the substance is inhaled, due to its high molecular weight. As described in the PMN, worker inhalation exposure to the PMN substance will be minimal due to adequate personal protective equipment, and worker dermal exposure is not expected. Therefore, EPA has not determined that the proposed import, processing, or use of the substance may cause significant adverse effects. EPA has determined, however, that domestic manufacture or where there is potential inhalation exposure without the use of a National Institute for Occupational Safety and Health (NIOSH)-approved respirator with an assigned protection factor (APF) of at least 10, may result in 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 90-day inhalation toxicity test (OPPTS 870.3465 test guideline) with a 60-day holding period in rats would help characterize the human health effects of the PMN substance.
CFR citation: 40 CFR 721.10101.
PMN Number P–04–126
Chemical name: Diphosphoric acid, compd. with piperazine (1:1).
CAS number: 66034–17–1.
Basis for action: The PMN states that the substance will be used as a flame retardant. Based on test data on analogous amines and inorganic phosphates, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 10 ppb in surface waters. As described in the PMN, the substance is not released to surface water. Therefore, EPA has not determined that the proposed manufacturing 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 fish acute toxicity test, freshwater and marine (OPPTS 850.1075 test guideline (public draft)); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS 850.1010 test guideline (public draft)); and an algal toxicity test, tiers I and II (OPPTS 850.5400 test guideline (public draft)) would help characterize the environmental effects of the PMN substance. All tests should be performed using the static method with nominal concentrations.

CFR citation: 40 CFR 721.10102.
PMN Number P–04–235
Chemical name: Naphtha (Fischer-Tropsch), C4-11-alkane, branched and linear.

CAS number: 849101–58–2.
Basis for action: The PMN states that the substance will be used as an olefin manufacturing feed stock, specialty solvent, alcohol denaturant, and fuel blendstock. Based on test data on analogous neutral organic chemicals, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 6 ppb in surface waters. As described in the PMN, all waste streams containing the substance will be incinerated and not released to surface waters or landfilled. 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 disposal of the substance without incineration may result in release to surface waters and 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 850.1075 test guideline (public draft)); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS 850.1010 test guideline (public draft)); and an algal toxicity test, tiers I and II (OPPTS 850.5400 test guideline (public draft)) would help characterize the environmental effects of the PMN substance. Testing should be performed using the static method with measured concentrations in a closed vessel with no head space.
CFR citation: 40 CFR 721.10103.
PMN Number P–04–254
Chemical name: Halophosphate mixed metal complex (generic).
CAS number: Not available.
Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as a coating additive. Based on test data on structurally similar substances, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 10 ppb in surface waters. As described in the PMN, releases of the PMN substance are not expected to result in surface water concentrations that exceed 10 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or uses of the substance may present an unreasonable risk. EPA has determined, however, that other uses of the substance resulting in release to surface waters at concentrations that exceed 10 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 850.1075 test guideline (public draft)); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS 850.1010 test guideline (public draft)); and an algal toxicity test, tiers I and II (OPPTS 850.5400 test guideline (public draft)) would help characterize the environmental effects of the PMN substance. The fish and daphnid tests should be performed using the flow-through method with measured concentrations. The algae test should be performed using the static method with measured concentrations.
CFR citation: 40 CFR 721.10104.
PMN Number P–04–417
Chemical name: Polyfluoroalkylether (generic).

CAS number: Not available.
Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as source material for coating plastic parts. Based on test data on structurally similar chemicals, EPA has concerns for lung toxicity if the substance is inhaled, due to its reactivity with lung membranes. As described in the PMN, dermal and inhalation exposures to workers 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 the use of the PMN substance involving an application method that generates a vapor, mist, or aerosol may result in 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 90-day inhalation toxicity (OPPTS 870.3465 test guideline) with a 60-day holding period would help characterize the health effects of the substance.
CFR citation: 40 CFR 721.10105.

PMN Number P–04–419

Chemical name: Silica, [(ethenylsilylidyne)tris(oxy)] - modified.
CAS number: 649574–37–8.
Basis for action: The PMN states that the substance will be used as filler. Based on test data on analogous crystalline silica and other high molecular weight polymers, EPA has concerns for lung toxicity, lung overload, and cancer. As described in the PMN, significant worker inhalation 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 manufacture, processing, or use of the substance in a powder form 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 test (OPPTS 870.3465 test guideline) in rats with special attention to histopathology (inflammation and cell proliferation) of the lung tissues and to various parameters of the bronchoalveolar lavage fluid (BALF) with a recovery period of 60 days; and a carcinogenicity test (OPPTS 870.4200 test guideline) in rats would help characterize the human health concerns of the PMN substance.
CFR citation: 40 CFR 721.10106.

PMN Number P–04–495

Chemical name: Naphthalenedisulfonic acid, [amino-hydroxy-[(substituted)azo-sulfo-naphthaleneyl]azo]-hydroxy-[(methoxy-sulfophenyl)azo], metal salt (generic).

CAS number: Not available.
Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as a dye. Based on test data on structurally similar beta-N-substituted naphthalene-based azo reduction products, EPA has concerns for carcinogenicity, mutagenicity, and developmental toxicity from exposure to the PMN substance. As described in the PMN, the substance is imported so domestic worker exposure is not expected. Although there is potential for short-term, infrequent consumer dermal exposure, based on physical-chemical properties of the PMN substance, dermal absorption of the intact dye is not expected. Therefore, EPA has not determined that the proposed importation or use of the substance may present an unreasonable risk. EPA has determined, however, that domestic manufacturing, or use other than that listed in the PMN, could result in serious health effects. Based on this information, the PMN substance meets the concern criteria at § 721.170 (b)(1)(i)(C) and (b)(3)(ii).
Recommended testing: EPA has determined that the results of a bacterial reverse mutation test (OPPTS 870.5100 test guideline) with the Prival modification and a concurrent positive control; and an unscheduled DNA synthesis in mammalian cells in culture (OPPTS 870.5550 test guideline) would help characterize the human health effects of the PMN substance.
CFR citation: 40 CFR 721.10107.

PMN Number P–04–498

Chemical name: Naphthalenedisulfonic acid, hydrozy-[[[(hydroxyl-disulfo-naphthaleneyl)azo]-alkyl(C=1-5)-(sulfoalkoxy)cyclic]azo]-substituted azo-, metal salt (generic).
CAS number: Not available.
Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as a dye. Based on test data on structurally similar beta-N-substituted naphthalene-based azo reduction products, EPA has concerns for carcinogenicity, mutagenicity, and developmental toxicity from exposure to the PMN substance. As described in the PMN, the substance is imported so domestic worker exposure is not expected. Although there is potential for short-term, infrequent consumer dermal exposure, based on physical-chemical properties of the PMN substance, dermal absorption of the intact dye is not expected. Therefore, EPA has not determined that the proposed importation or use of the substance may present an unreasonable risk. EPA has determined, however, that domestic manufacturing, or use other than that listed in the PMN, could result in serious health effects. Based on this information, the PMN substance meets the concern criteria at § 721.170 (b)(1)(i)(C) and (b)(3)(ii).
Recommended testing: EPA has determined that the results of a bacterial reverse mutation test (OPPTS 870.5100 test guideline) with the Prival modification with a concurrent positive control; and an unscheduled DNA synthesis in mammalian cells in culture (OPPTS 870.5550 test guideline) would help characterize the human health effects of the PMN substance.
CFR citation: 40 CFR 721.10108.

PMN Numbers P–04–508, P–04–509, and P–04–510

Chemical names: (P–04–508) Hexanoic acid, 2-ethyl-, mixed triesters with benzoic acid and trimethylolpropane; (P–04–509) Hexanoic acid, 2-ethyl-, mixed diesters with benzoic acid and neopentyl glycol; and (P–04–510) Hexanoic acid, 2-ethyl-, mixed diesters with benzoic acid and diethylene glycol.
CAS numbers: (P–04–508) 610787–76–3; (P–04–509) 610787–77–4; and (P–04–510) 610787–78–5.
Basis for action: The PMNs state that the substances will be used as plasticizers for products manufactured from polyvinyl chloride (PVC). Based on test data on structurally similar esters, EPA predicts chronic toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb in surface waters. Based on test data on the PMN substance, EPA has concerns for liver toxicity, reproductive toxicity, developmental toxicity, and a marginal concern for cancer. Also, if any diethylene glycol is released from ester hydrolysis of P–04–510, there is concern for acute poisoning (lethality) at high doses. As described in the PMNs, the substances are not be released to surface waters and worker inhalation and dermal exposures are not of concern. Consumer exposure to the PMN substances are not expected as the substances are compounded with other nonvolatile substances and are not expected to volatilize, leach, or otherwise be separated from the final product under normal conditions of use. Therefore, EPA has not determined that the proposed import, processing, or use of the substances may present an unreasonable risk to human health or the environment. EPA has determined, however, that domestic manufacture or any other uses resulting in release of the substances to surface waters may cause serious health effects and significant adverse environmental effects. Based on this information, the PMN substances meets the concern criteria at § 721.170 (b)(1)(i)(C), (b)(3)(i), and (b)(4)(ii).
Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OPPTS 850.1400 test guideline (public draft)); a daphnid chronic toxicity test (OPPTS

850.1300 test guideline (public draft)); an algal toxicity test, tiers I and II (OPPTS 850.5400 test guideline (public draft)); a Zahn-Wellens/EMPA test (OPPTS 835.3200 test guideline); a fish BCF (OPPTS 850.1730 test guideline (public draft)); and a reproduction/developmental toxicity screening test (OPPTS 870.3550 test guideline) would help characterize the environmental effects, environmental fate, and human health effects of the PMN substances. Testing for P–04–508, P–04–509, and P–04–510 should be tiered. Testing should first be completed on P–04–510. If the results indicate toxicity, then the testing should be repeated for P–04–509. If the results for P–04–509 indicate toxicity, then the testing should be repeated for P–04–508.

CFR citations: 40 CFR 721.10109 (P–04–508), 40 CFR 721.10110 (P–04–509); and 40 CFR 721.10111 (P–04–510).

PMN Number P–04–530

Chemical name: Ethanone, 2-chloro-1-(1-chlorocyclopropyl)-.

CAS number: 120983–72–4.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as an intermediate. Based on test data on the PMN substance, EPA has human health concerns for mutagenicity, acute toxicity, systemic toxicity (liver and kidney effects), lung toxicity, and dermal sensitization. Based on test data on structural analogs, EPA has health concerns for reproductive toxicity and systemic toxicity (cardiotoxicity and spleen effects). In addition, there is concern for carcinogenicity based on the results of the mutagenicity studies and the potential for the chemical to be an alkylating agent. Based on test data on structurally similar alpha-halo ketones, EPA predicts toxicity to aquatic organisms at concentrations that exceed 1 ppb in surface waters. Since significant worker dermal and inhalation exposure is unlikely for the use described in the PMN due to adequate personal protective equipment and engineering controls, and since significant general population and environmental exposure is unlikely as the substance is not released to surface waters, 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 an intermediate or other uses of the substance resulting in release of the PMN substance to surface water may cause serious health effects or significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170 (b)(1)(i)(C), (b)(3)(i), (b)(3)(ii), and (b)(4)(ii).

Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OPPTS 850.1400 test guideline (public draft)) and a daphnid chronic toxicity test (OPPTS 850.1300 test guideline (public draft)) would help characterize the environmental effects of the PMN substance. These tests should be performed using the flow-through method with measured concentrations. EPA also has determined that the results of the following test would characterize the human health effects of the PMN substance: Combined repeated dose toxicity study with the reproduction/developmental screening (OPPTS 870.3650 test guideline).

CFR citation: 40 CFR 721.10112.

PMN Number P–04–547

Chemical name: Thioether epoxy (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as an epoxy monomer. Based on test data on structurally similar epoxides, EPA has health concerns for carcinogenicity, mutagenicity, sensitization, male reproductive effects, and severe irritation to all exposed tissues. As described in the PMN, 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 substance may present an unreasonable risk of injury to human health. EPA has determined, however, that use other than that listed in the PMN could result in serious health effects. Based on this information the PMN substance meets the concern criteria at § 721.170 (b)(1)(i)(C) and (b)(3)(ii). Also, based on structural analogy to epoxides, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 30 ppb in surface waters. As described in the PMN, the substance is not released to water. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk of injury to the environment. EPA has determined, however, that any other uses of the substance resulting in release of the PMN substance 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 90-day inhalation toxicity test (OPPTS 870.3465 test guideline); a fish acute toxicity test, freshwater and marine (OPPTS 850.1075 test guideline (public draft)); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS 850.1010 test guideline (public draft)); an algal toxicity test, tiers I and II (OPPTS 850.5400 test guideline (public draft)); and a ready biodegradability study (OPPTS 835.3110 test guideline) would help characterize the human health and environmental effects of the PMN substance.

CFR citation: 40 CFR 721.10113.

PMN Numbers P–04–578, P–04–579, P–04–580, P–04–581, P–04–582, and–P–04–583

Chemical name: Polyhydroxyaminoether salts (generic).

CAS number: Not available.

Basis for action: The PMNs state that the generic (non-confidential) use of the substances will be for coated plastic bottle and film. Based on test data on analogous polycationic polymers, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 10 ppb in surface waters. As described in the PMNs, the substances are not released into surface waters. 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 other uses resulting in release of the PMN substances to surface water may cause significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(ii).

Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS 850.1075 test guideline (public draft)); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS 850.1010 test guideline (public draft)); and an algal toxicity test, tiers I and II (OPPTS 850.5400 test guideline (public draft)) would help characterize the environmental effects of the PMN substances. Any of the consolidated chemicals may be used to conduct the testing. All studies should be performed using the static method with nominal concentrations.

CFR citation: 40 CFR 721.10114.

PMN Number P–04–625

Chemical name: 1-Hexadecanaminium, N,N-dibutyl-N-(2-hydroxyethyl)-, bromide (1:1).

CAS number: 160653–08–7.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as a crude oil additive for downhole applications. Based on test data on structurally similar substances, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 4 ppb 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 other uses of the substance resulting in release of the PMN substance to surface water 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 850.1075 test guideline (public draft)); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS 850.1010 test guideline (public draft)); and an algal toxicity test, tiers I and II (OPPTS 850.5400 test guideline (public draft)) would help characterize the environmental effects of the PMN substance. All studies should be performed using the static method with nominal concentrations.

CFR citation: 40 CFR 721.10115.

PMN Number P–04–758

Chemical name: Blocked polymeric isocyanate (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as a coating. Based on test data on analogous small and medium molecular-weight isocyanates, EPA has concerns for pulmonary sensitization and mutagenicity for the PMN material. As described in the PMN, significant worker exposure is unlikely, as neither dermal nor inhalation exposure is 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 PMN substance other than as described in the PMN 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 90-day inhalation toxicity test (OPPTS 870.3465 test guideline) with a 60-day holding period would help characterize the health effects of the substance.

CFR citation: 40 CFR 721.10116.

PMN Number P–04–776

Chemical name: Heteromonocyclo-beta-(2,4-dichlorophenyl)-1-propanol (generic).

CAS number: Not available.

Basis for action: The PMN states that the substance will be used as an industrial intermediate. Based on test data on structurally analogous chemicals, EPA expects toxicity to aquatic organisms at surface water concentrations that exceed 100 ppb in surface waters. Also, based on test data on the PMN substance, EPA has concerns for liver toxicity and effects on the lungs, kidneys, and the GI tract. In addition, based on test data on structurally analogous chemicals, EPA has concerns for developmental toxicity. As described in the PMN, environmental releases are not expected as the substance is not released to surface waters. Although there is potential for inhalation and dermal exposures from use, based on analog data, the margin of exposure (MOE) of 100 is considered adequate. 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 other uses of the substance resulting in release of the PMN substance to surface waters 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), (b)(3)(ii), and (b)(4)(ii).

Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OPPTS 850.1400 test guideline (public draft)); a daphnid chronic toxicity test (OPPTS 850.1300 test guideline (public draft)); an algal toxicity test, tiers I and II (OPPTS 850.5400 test guideline (public draft)); and a prenatal developmental toxicity study (OPPTS 870.3700 test guideline) in rats would help characterize the human health and environmental effects of the PMN substance. All ecotox studies should be performed using the flow-through method with measured concentrations.

CFR citation: 40 CFR 721.10117.

PMN Number P–05–35

Chemical name: Substituted aryl acetonitrile (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as an intermediate. Based on test data on analogous nitriles, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 5 ppb in surface waters. As described in the PMN, the substance is not released into 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 other uses 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, freshwater and marine (OPPTS 850.1075 test guideline (public draft)); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS 850.1010 test guideline (public draft)); and an algal toxicity test, tiers I and II (OPPTS 850.5400 test guideline (public draft)) would help characterize the environmental effects of the PMN substance. The fish and daphnid tests should be performed using the flow thorough method with measured concentrations. The algal test should be preformed using the static method with measured concentrations.

CFR citation: 40 CFR 721.10118.

PMN Number P–05–673

Chemical name: Siloxane modified silica nanoparticles (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as an additive. Based on test data on analogous respirable, poorly soluble, particulates, EPA has concerns for lung effects for the PMN substance. Based on physical properties, EPA has concerns for potential systemic effects from dermal exposure to the PMN substance. As described in the PMN, dermal and inhalation exposures are not expected. 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 use without impervious gloves or a NIOSH-approved respirator with an APF of at least 10; the manufacture, process, or use of the substance as a powder; or uses of the substance other than as described in the PMN 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 90-day inhalation toxicity test (OPPTS 870.3465 test guideline) would help characterize the human health effects of the PMN substance.

CFR citation: 40 CFR 721.10119.

PMN Number P–05–687

Chemical name: Siloxane modified alumina nanoparticles (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as an additive. Based on test data on analogous respirable, poorly soluble, particulates, EPA has concerns for lung effects for the PMN substance. Based on physical properties, EPA has concerns for potential systemic effects from inhalation and dermal exposure to the PMN substance. As described in the PMN, worker inhalation exposure to the PMN substance will be minimal due to adequate personal protective equipment, and worker dermal 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 without impervious gloves or a NIOSH-approved respirator with an APF of at least 10; the manufacture, process or use of the substance as a powder; or uses of the substance other than as described in the PMN 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 90-day inhalation toxicity test (OPPTS 870.3465 test guideline) would help characterize the human health effects of the PMN substance.

CFR citation: 40 CFR 721.10120.

PMN Number P–05–766

Chemical name: Poly[oxy(methyl-1,2-ethanediyl)], .alpha.-methyl-.omega.-(4-nonylphenoxy)-, branched.

CAS number: 858944–25–9.

Basis for action: The PMN states that the generic (non-confidential use) of the substance will be as a polyalkylene glycol lubricant basefluid and additive. Based on test data on structurally similar chemicals, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb 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 substances may present an unreasonable risk. EPA has determined, however, that other uses 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 early-life stage toxicity test (OPPTS 850.1400 test guideline (public draft)); a daphnid chronic toxicity test (OPPTS 850.1300 test guideline (public draft)); and an algal toxicity test, tiers I and II (OPPTS 850.5400 test guideline (public draft)) would help characterize the environmental effects of the PMN substance. The fish and daphnid testing should be performed using the flow-through method with measured concentrations. The algal testing should be performed using the static method with measured concentrations.

CFR citation: 40 CFR 721.10121.

PMN Number P–06–151

Chemical name: 2-Propenoic acid, 2-methyl-, 1,1′-[2-ethyl-2-[[(2-methyl-1-oxo-2-propen-1-yl)oxy]methyl]- 1,3-propanediyl] ester, polymer with 1,3-butadiene, ethenylbenzene and 2-hydroxyethyl 2-methyl-2-propenoate.

CAS number: 849925–18–4.

Basis for action: The PMN states that the substance will be used as an additive in rubber, i.e. as a reinforcing agent. Based on test data on analogous respirable, poorly soluble, particulates, EPA has concerns for lung effects for the PMN substance. Based on physical properties, EPA has concerns for potential systemic effects from dermal exposure to the PMN substance. As 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, that use of the substance other than as described in the PMN 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 90-day inhalation toxicity test (OPPTS 870.3465 test guideline) with a 60 day holding period would help characterize the human health effects of the PMN substance. This study should include observation of the entire body, rather than just the lungs.

CFR citation: 40 CFR 721.10122.

PMN Number P–06–554

Chemical name: [1,2,4-Triazolo[1,5-a]pyrimidin-2-amine, 5,7-dimethoxy-].

CAS number: 13223–43–3.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as a process intermediate. Based on test data on structurally similar substances, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 5 ppb in surface waters. As described in the PMN, releases of the substance are not expected to result in surface water concentrations that exceed 5 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that other uses of the substance resulting in surface water concentrations that exceed 5 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 an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS 850.1010 test guideline (public draft)) using the flow-through method with measured concentrations would help characterize the environmental effects of the PMN substance.

CFR citation: 40 CFR 721.10123.

PMN Number P–06–617

Chemical name: Brominated polyaromatic compound (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 polybrominated diphenyls and polybrominated diphenylethers, the Agency identified human health concerns for liver and kidney toxicity, mutagenicity, carcinogenicity, developmental toxicity, neurotoxicity, reproductive toxicity, and possible chloracne from inhalation or dermal exposure to the PMN substance. In addition, EPA has identified health and environmental concerns because the substance may be a persistent, bio-accumulative, and toxic (PBT) chemical, based on physical/chemical properties of the PMN substance, as described in the New Chemical Program's PBT category (64 FR 60194; November 4, 1999). EPA estimates that the PMN substance will persist in the environment more than two months and estimates a bioaccumulation factor of greater than or equal to 1,000. As described in the PMN, significant worker exposure is unlikely due to adequate dermal protection and negligible inhalation exposure, and environmental exposure is unlikely as 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 PMN substance without

the use of impervious gloves, any use of the PMN substance other than as an intermediate, 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)(1)(i)(C), (b)(3)(ii), and (b)(4)(ii).

Recommended testing: EPA has determined that the results of tiered testing as described in the New Chemicals Program's PBT Category (64 FR 60194; November 4, 1999); a fish acute toxicity test (OPPTS 850.1075 test guideline (public draft)); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS 850.1010 test guideline (public draft)); an algal toxicity test, tiers I and II (OPPTS 850.5400 test guideline (public draft)); an acute oral toxicity (OPPTS 870.1100 test guideline); a bacterial reverse mutation test (OPPTS 870.5100 test guideline); a mammalian erythrocyte micronucleus test by the intraperitoneal route (OPPTS 870.5395 test guideline); a 90-day oral toxicity test in rodents (OPPTS 870.3100 test guideline); and a prenatal developmental toxicity study (OPPTS 870.3700 test guideline) would help characterize the PBT, health, and environmental effects of the PMN substance.

CFR citation: 40 CFR 721.10124.

PMN Numbers P–06–665, P–06–666, P–06–667, P–06–668, P–06–669, and P–06–670

Chemical name: Alkenedioic acid, dialkyl ester, reaction products with polyaminocarbomonocycle and alkenoic acid alkyl ester (generic).

CAS number: Not available.

Basis for action: The consolidated PMN states that the generic (non-confidential) use of the substances will be as a component of an automotive coating. Based on test data on analogous chemicals, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb in surface waters. As described in the consolidated PMN, the substances are not released to surface waters. 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 other uses of the substances resulting in release to surface waters may cause significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(ii).

Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS 850.1075 test guideline (public draft)); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS 850.1010 test guideline (public draft)); an algal toxicity test, tiers I and II (OPPTS 850.5400 test guideline (public draft)); and a ready biodegradability test (OPPTS 835.3100 test guideline) would help characterize the environmental effects of the PMN substances. The fish and daphnid tests should be performed using the flow-through method with measured concentrations. The algal test should be performed using the static method with measured concentrations. The fish, daphnid, and algal studies should be conducted with a stock solution neutralized to pH 7 by HCl.

CFR citation: 40 CFR 721.10125.

PMN Number P–06–689

Chemical name: Alkyl amino substituted triazine amino substituted benezenesulfonic acid reaction product with naphthalenesulfonato azo substituted phenyl azo substituted benzenesulfonic acid copper compound (generic).

CAS number: Not available.

Basis for action: The PMN states that the substance will be used as a dye for cellulosic fabric. Based on test data on analogous substances, EPA has concerns for carcinogenicity and mutagenicity for the PMN substance. As 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 processing or use of the substance may present an unreasonable risk. EPA has determined, however, that domestic manufacture of the PMN substance 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 bacterial reverse mutation test with the Prival modification (OPPTS 870.5100 test guideline); a mammalian erythrocyte micronucleus test in mice through the oral route of exposure (OPPTS 870.5395 test guideline); and a carcinogenicity test (OPPTS 870.4200 test guideline) pending positive results on either of the first two tests would help characterize the human health effects of the PMN substance.

CFR citation: 40 CFR 721.10126.

PMN Number P–06–693

Chemical name: Alkenyl dimethyl betaine (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as a crude oil production chemical. Based on test data on structurally similar analogs, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 50 ppb in surface waters. As described in the PMN, releases of the PMN substance are not expected to result in surface water concentrations that exceed 50 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 surface water concentrations that exceed 50 ppb 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 fish acute toxicity test, freshwater and marine (OPPTS 850.1075 test guideline (public draft)); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS 850.1010 test guideline (public draft)); and an algal toxicity test, tiers I and II (OPPTS 850.5400 test guideline (public draft)) would help characterize the environmental effects of the PMN substance.

CFR citation: 40 CFR 721.10127.

PMN Number P–06–752

Chemical name: Modified imidazole (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as an adhesive for electrical parts. Based on test data for imidazoles and esters, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 4 ppb 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 substances may present an unreasonable risk. EPA has determined, however, that other uses of the substances 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, freshwater and marine (OPPTS 850.1075 test guideline (public draft)); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS 850.1010 test guideline (public draft)); an algal toxicity test, tiers I and II (OPPTS 850.5400 test guideline (public draft)); and a ready biodegradability test (OPPTS 835.3110 test guideline) would help characterize the environmental effects of the PMN substance. The fish and daphnid testing should be performed using the flow-through method with measured concentrations. The algal testing should be conducted using the static method with measured concentrations.
CFR citation: 40 CFR 721.10128.

PMN Number P–07–24

Chemical name: Alkylamine ethoxylated (generic).
CAS number: Not available.
Basis for action: The PMN states that the use of the substance will be as an emulsifier for oilfield application. Based on test data on the PMN substance and on structurally similar analogs, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 3 ppb in surface waters. As described in the PMN, releases of the PMN substance are not expected to result in surface water concentrations that exceed 3 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that use of the substance other than as described in the PMN could result in surface water concentrations that exceed 3 ppb which 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 ready biodegradability test (OPPTS 835.3110 test guideline); a fish acute toxicity test (OPPTS 850.1075 test guideline (public draft)); a fish acute toxicity test mitigated by humic acid (OPPTS 850.1085 test guideline (public draft)); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS 850.1010 test guideline (public draft));and an algal toxicity test, tiers I and II (OPPTS 850.5400 test guideline (public draft)) would help characterize the environmental effects of the PMN substance. The ready biodegradability test should be conducted first. The results of this test may mitigate the need for further testing. For the fish, daphnid and algal testing, the substance should be tested as the chloride salt at pH 7.
CFR citation: 40 CFR 721.10129.

PMN Number P–07–140

Chemical name: Quino[2,3-b]acridine-7,14-dione, 5,12-dihydro-ar-[4-[[2-(sulfooxy)ethyl]substituted]phenyl]-, monosodium salt (generic).
CAS number: Not available.
Basis for action: The PMN states that the generic (non-confidential) use of this substance will be as a colorant raw material. Based on test data on analogous respirable, poorly soluble, particulates, EPA predicts the PMN substance may cause lung effects. As described in the PMN, significant worker exposure is unlikely, as dermal exposure is not expected and significant inhalation exposure to the PMN substance 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 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 90-day inhalation toxicity test (OPPTS 870.3465 test guideline) with observations for a cancer potential would help characterize the human health effects of the PMN substance.
CFR citation: 40 CFR 721.10130.

PMN Number P–07–205

Chemical name: Isononanamide, N-(2-ethylhexyl)-.
CAS number: 93820–33–8.
Basis for action: The PMN states that the use of the substance will be as a defoamer for cement additives in oilfield applications. Based on test data on the PMN substance and on structurally similar analogous neutral organic compounds, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb in surface waters. For the use described in the PMN, releases of the PMN substance to surface waters are not expected to result in concentrations exceeding 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 use of the substance other than as described in the PMN could result in surface water concentrations that exceed 1 ppb which 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 early life-stage toxicity test (OPPTS 850.1400 test guideline (public draft)); a daphnid chronic toxicity test (OPPTS 850.1300 test guideline (public draft)); and an algal toxicity test, tiers I and II (OPPTS 850.5400 test guideline (public draft)) would help characterize the environmental effects of the PMN substance. The fish and daphnid testing should be performed using the flow-through method with measured concentrations. The algal testing should be performed using the static method with measured concentrations.
CFR citation: 40 CFR 721.10131.

PMN Number P–07–269

Chemical name: Phosphoramidic acid, carbomonocyclic-, diphenylester (generic).

CAS number: Not available.
Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as a flame-resisting material used in cars. Based on test data on the PMN substance, EPA has concerns for liver toxicity in humans for the PMN material. Also, based on test data on analogous triphenyl phosphates, EPA believes the PMN substance may cause delayed neurotoxicity in humans. As described in the PMN, significant worker or consumer 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, increased importation or production volumes, or uses other than as described in the PMN may result in increased exposure to the PMN substance which may cause serious health effects. Based on this information, the PMN substance meets the concern criteria at § 721.170 (b)(3)(i) and (b)(3)(ii).
Recommended testing: EPA has determined that the results of a 90-day oral toxicity study in rodents (OPPTS 870.3100 test guideline) via the oral-gavage route and an acute and 28-day delayed neurotoxicity of organophosphorus substances study (OPPTS 870.6100 test guideline) in hens would help characterize the human health effects of the PMN substance.
CFR citation: 40 CFR 721.10132.

PMN Number P–07–401

Chemical name: 2-Propenoic acid, 2-methyl, 2-hydroxyethyl ester, homopolymer.

CAS number: 25249–16–5.
Basis for action: The PMN states that the generic (non-confidential) use of the

substance will be as a matrix for an analysis device. Based on test data on analogous high molecular weight polymers, the PMN substance may cause lung toxicity and cancer. As described in the PMN, worker inhalation exposure will be minimal due to adequate personal protective equipment. 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, use without workers wearing a NIOSH-approved respirator with an assigned protection factor (APF) of 1,000 or greater, or use without an appropriate hazard communication program 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 870.3465 test guideline) with a 60-day holding period would help characterize the health effects of the PMN substance.

CFR citation: 40 CFR 721.10133.

IV. Objectives and Rationale 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 4 of the 56 chemical substances, regulation was warranted under section 5(e) of TSCA, 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 III. 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 listed in this document are consistent with the provisions of the TSCA section 5(e) consent orders. These SNURs are promulgated pursuant to 40 CFR 721.160.

In the other 52 cases for which the proposed 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 40 CFR 721.170 were met, as discussed in Unit III.

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:

1. 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.

2. 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.

3. 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.

4. 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 substance is on the TSCA Inventory is available on the Internet at *http://www.epa.gov/opptintr/newchems/pubs/invntory.htm*.

V. Direct Final Procedures

EPA is issuing these SNURs as a direct final rule, as described in 40 CFR 721.160(c)(3) and 721.170(d)(4)(B). In accordance with 40 CFR 721.160(c)(3)(ii) and 721.170(d)(4)(i)(B), this rule will be effective [*January 5, 2009*], unless EPA receives a written notice by [*December 5, 2008*] of adverse or critical comments, or notice of intent to submit adverse or critical comments, on EPA's action. If EPA receives such a notice, EPA will publish a document to withdraw the direct final SNUR for the specific chemical substance(s) to which the adverse or critical comments apply. EPA will then propose a SNUR for the specific chemical substance providing a 30-day comment period.

This action 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 a notice.

VI. Test Data and Other Information

EPA recognizes that TSCA section 5 does not require developing any particular test data before submission of a SNUN. 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. 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 III. lists those tests. Unit III. 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 test guidelines are now available on the Internet at *http://www.epa.gov/opptsfrs/home/guidelin.htm*.

In the TSCA section 5(e) consent orders for several of the chemical substances regulated under this rule, EPA has established production 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 production 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 consent orders, each PMN submitter is required to submit each study at least 14 weeks (earlier 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 III. The SNURs contain the same production volume limits as the 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.

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 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:

1. Human exposure and environmental release that may result from the significant new use of the chemical substances.

2. Potential benefits of the chemical substances.

3. Information on risks posed by the chemical substances compared to risks posed by potential substitutes.

VII. Procedural Determinations

EPA is establishing through this rule certain significant new uses which have been claimed as CBI subject to Agency confidentiality regulations at 40 CFR part 2. EPA is required to keep this information confidential to protect the CBI of the original PMN submitter. EPA promulgated a procedure to deal with the situation where a specific significant new use is CBI. This procedure appears in 40 CFR 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 of these SNURs that include specific significant new uses that are CBI.

A manufacturer, importer, or processor may request EPA to determine whether a proposed use would be a significant new use under this rule. Under the procedure in § 721.1725(b)(1), a 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 a manufacturer, importer, or processor is told that the production volume identified in the *bona fide* submission would not be a significant new use, i.e., it is below the level that would be a significant new use, that person can manufacture, import, or process the chemical substance as long as the aggregate amount does not exceed that identified in the *bona fide* submission to EPA. 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. EPA is considering whether to adopt a special procedure for use when CBI production volume is designated as a significant new use. Under such a procedure, a person showing a *bona fide* intent to manufacture, import, or process the chemical substance, under the procedure described in § 721.11, would automatically be informed of the production volume that would be a significant new use. Thus, the person would not have to make multiple *bona fide* submissions to EPA for the same chemical substance to remain in compliance with the SNUR, as could be the case under the procedures in § 721.1725(b)(1).

VIII. Applicability of Rule to Uses Occurring Before Effective Date of the Final Rule

To establish a significant ''new'' use, EPA must determine that the use is not ongoing. The chemical substances subject to this rule have recently undergone premanufacture review. TSCA section 5(e) consent orders have been issued for 4 chemical substances and notice 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 an 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 has concluded that the uses are not ongoing. However, EPA recognizes in cases when chemical substances identified in this SNUR are added to the TSCA Inventory prior to the effective date of the rule, the chemical substances may be manufactured, imported, or processed by other persons for a significant new use as defined in this rule before the effective date of the rule. However, 38 of the 56 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 following regulatory text are ongoing. EPA solicits comments on whether any of the uses described as significant new uses are ongoing.

As discussed in the **Federal Register** of April 24, 1990 (55 FR 17376), 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 final, and then argue that the use was ongoing as of the effective date of the final 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.

EPA has promulgated provisions to allow persons to comply with this SNUR before the effective date. If a person were to meet the conditions of advance compliance under § 721.45(h), the person would be considered to have met the requirements of the final SNUR for those activities.

IX. SNUN Submissions

EPA recommends that submitters consult with the Agency prior to submitting a SNUN to discuss what data may be useful in evaluating a significant new use. Discussions with the Agency prior to submission can afford ample time to conduct any tests that might be helpful in evaluating risks posed by the substance. According to 40 CFR 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 40 CFR 721.25 and 720.40). Forms and information are also available electronically at *http://www.epa.gov/opptintr/newchems/pubs/pmnforms.htm*.

X. 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 public docket.

XI. Statutory and Executive Order Reviews

A. Executive Order 12866

Under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), the Office of Management and Budget (OMB) has determined that proposed or final SNURs are not a ''significant regulatory action'' subject to review by OMB, because they do not meet the criteria in section 3(f) of the Executive order.

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.

The information collection requirements related to this action have already been approved by OMB pursuant to the 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 as follows. 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 2005–2007, none appear to be from small entities. In addition, the estimated reporting cost for submission of a SNUN (see Unit IX.), are 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 on June 2, 1997 (62 FR 29684) (FRL–5597–1), the Agency presented its general determination that proposed and 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 rulemaking. As such, EPA has determined that this regulatory action does not impose any enforceable duty, contain any unfunded mandate, or otherwise have any affect 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 rule 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.

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).

K. Executive Order 12630

EPA has complied with Executive Order 12630, entitled *Governmental Actions and Interference with Constitutionally Protected Property Rights* (53 FR 8859, March 18, 1988), by examining the takings implications of this rule in accordance with the ''Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings'' issued under the Executive order.

L. Executive Order 12988

In issuing this rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct, as required by section 3 of Executive Order 12988, entitled *Civil Justice Reform* (61 FR 4729, February 7, 1996).

XII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a final rule may take effect, the agency promulgating it must submit a final rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this final 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 final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 721

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

Dated: October 30, 2008.

Charles M. Auer,

Director, Office of Pollution Prevention and Toxics.

■ Therefore, 40 CFR part 721 is amended as follows:

PART 721—[AMENDED]

■ 1. The authority citation for part 721 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

■ 2. By adding new § 721.10089 to subpart E to read as follows:

§ 721.10089 Modified salicylic acid, zirconium complex (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as modified salicylic acid, zirconium complex (PMN P–00–552) 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.

■ 3. By adding new § 721.10090 to subpart E to read as follows:

§ 721.10090 Tertiary amine salt of glycol succinate (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as tertiary amine salt of glycol succinate (PMN P–01–595) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

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

(A) Restricting the manufacture of the PMN substance with only those feedstocks specified in the PMN submission.

(B) Manufacture, import, or processing of the PMN substance without analyzing representative samples of the chemical substance to determine compliance with the requirements in § 721.10090(a)(2)(i)(A). To ensure compliance, the PMN substance must be analyzed (1) at the time of initial commencement of non-exempt commercial manufacture of the chemical substance, and (2) at least annually thereafter during every year in which the substance is manufactured.

(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.

■ 4. By adding new § 721.10091 to subpart E to read as follows:

§ 721.10091 2(1H)-Pyrimidinone, tetrahydro-1,3-dimethyl-.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 2(1H)-pyrimidinone, tetrahydro-1,3-dimethyl- (PMN P–02–135; CAS No. 7226–23–5) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(1), (a)(2)(i), (a)(3)(i), (b), and (c). Best's Viton model #890, Best's Butyl model #874, and Best's Butyl #878 have been demonstrated to satisfy § 721.63(a)(3)(i). Other demonstrated impervious gloves that satisfy § 721.63(a)(3)(i) are permissible.

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80 (f), (j) (aprotic solvent and catalyst), and (s) (20,000 kg).

(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), 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.

■ 5. By adding new § 721.10092 to subpart E to read as follows:

§ 721.10092 Poly(oxy-1,2-ethanediyl), .alpha.-sulfo-.omega.-[[1-[(2-propen-1-yloxy)methyl]undecyl]oxy]-, ammonium salt (1:1); Poly(oxy-1,2-ethanediyl), .alpha.-sulfo-.omega.-[[1-[(2-propen-1-yloxy)methyl]tridecyl]oxy]-, ammonium salt (1:1).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as poly(oxy-1,2-ethanediyl), .alpha.-sulfo-.omega.-[[1-[(2-propen-1-yloxy)methyl]undecyl]oxy]-, ammonium salt (1:1); poly(oxy-1,2-ethanediyl), .alpha.-sulfo-.omega.-[[1-[(2-propen-1-yloxy)methyl]tridecyl]oxy]-, ammonium salt (1:1) (PMN P–02–421; CAS Nos. 352661–91–7 and 224646–44–0) 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(k) (no manufacture or import of the PMN substance unless: (1) The mean number of moles of the ethoxy group is equal to or greater than 8 or (2) the average molecular weight is greater than 721 daltons). Representative samples of the PMN substance must be analyzed and determined to comply with these requirements both at the time of initial commencement and annually thereafter.

(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.

■ 6. By adding new § 721.10093 to subpart E to read as follows:

§ 721.10093 Alkylamides, ethoxylated (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substances identified generically as alkylamides, ethoxylated (PMNs P–03–12 and P–03–13) are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Release to water.* Requirements as specified in § 721.90 (a)(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 these substances.

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

■ 7. By adding new § 721.10094 to subpart E to read as follows:

§ 721.10094 Decene, branched and linear.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as decene, branched and linear (PMN P–03–272; CAS No. 833482–31–8) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

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

(ii) [Reserved]

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

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

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

■ 8. By adding new § 721.10095 to subpart E to read as follows:

§ 721.10095 Oxetane, 3,3′-[oxybis(methylene)] bis[3-ethyl-.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as oxetane, 3,3′-[oxybis(methylene)] bis[3-ethyl- (PMN P–03–471; CAS No. 18934–00–4) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(1), (a)(2)(i), (a)(2)(iii), and (a)(3) (polyvinyl alcohol gloves with a thickness of no less than 31.3 mils or silvershield/4H sleeves with a thickness of no less than 2.7 mils have satisfied § 721.63(a)(3)(i) for up to 8 hours.

(ii) *Hazard communication program.* Requirements as specified in § 721.72 (a), (b), (c), (d), (e), (f), (g)(1)(iv), (g)(1)(v), and (g)(2)(v).

(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), (b), (c), (d), (e), (f), (g), (h), 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.

■ 9. By adding new § 721.10096 to subpart E to read as follows:

§ 721.10096 Benzene, 1,4-bis (methoxymethyl)-.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as benzene, 1,4-bis (methoxymethyl)- (PMN P–03–614; CAS No. 6770–38–3) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

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

(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 § 721.10097 to subpart E to read as follows:

§ 721.10097 Disubstituted benzenesulfonic acid, alkali metal salt (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as disubstituted benzenesulfonic acid, alkali metal salt (PMN P–03–642) 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.

■ 11. By adding new § 721.10098 to subpart E to read as follows:

§ 721.10098 Disubstituted benzoic acid, alkali metal salt (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as disubstituted benzoic acid, alkali metal salt (PMN P–03–643) 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.

■ 12. By adding new § 721.10099 to subpart E to read as follows:

§ 721.10099 Dialkyl dimethyl ammonium carbonate (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as dialkyl dimethyl ammonium carbonate (1:1) (PMN P–03–715) 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 = 5).

(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. By adding new § 721.10100 to subpart E to read as follows:

§ 721.10100 Dialkyl dimethyl ammonium carbonate (2:1) (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as dialkyl dimethyl ammonium carbonate (2:1) (PMN P–03–716) 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 = 5).

(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 § 721.10101 to subpart E to read as follows:

§ 721.10101 Copolymer of alkyl acrylate and ethyleneglycol dimethacrylate (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as copolymer of alkyl acrylate and ethyleneglycol dimethacrylate (PMN P–03–755) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(4), (a)(5), (a)(6)(i), (a)(6)(ii), (b), and (c). The following National Institute for Occupational Safety and Health (NIOSH)-approved respirators with an assigned protection factor (APF) of 10-25 meet the minimum requirements for § 721.63(a)(4): Air-purifying, tight-fitting respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters (either half- or full-face); powered air-purifying respirator equipped with a loose-fitting hood or helmet and High Efficiency Particulate Air (HEPA) filters; powered air-purifying respirator equipped with a tight-fitting facepiece (either half- or full-face) and HEPA filters; and supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (either half- or full-face).

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

(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), 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.

■ 15. By adding new § 721.10102 to subpart E to read as follows:

§ 721.10102 Diphosphoric acid, compd. with piperazine (1:1).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as diphosphoric acid, compd. with piperazine (1:1) (PMN P–04–126; CAS No. 66034–17–1) 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(j) (flame retardant).

(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.

■ 16. By adding new § 721.10103 to subpart E to read as follows:

§ 721.10103 Naphtha (Fischer-Tropsch), C4-11-alkane, branched and linear.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as naphtha (fischer-tropsch), C4-11-alkane, branched and linear (PMN P–04–235; CAS No. 849101–58–2) 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) *Disposal.* Requirements as specified in § 721.85 (a)(1), (b)(1) and (c)(1).

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

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

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

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

■ 17. By adding new § 721.10104 to subpart E to read as follows:

§ 721.10104 Halophosphate mixed metal complex (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as halophosphate mixed metal complex (PMN P–04–254) 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=10).

(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.

■ 18. By adding new § 721.10105 to subpart E to read as follows:

§ 721.10105 Polyfluoroalkylether (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as polyfluoroalkylether (PMN P–04–417) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

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

(ii) [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. By adding new § 721.10106 to subpart E to read as follows:

§ 721.10106 Silica , [(ethenylsilylidyne)tris(oxy)] - modified.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as silica , [(ethenylsilylidyne)tris(oxy)] - modified (PMN P–04–419; CAS No. 649574–37–8) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

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

(ii) [Reserved]

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

(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.

■ 20. By adding new § 721.10107 to subpart E to read as follows:

§ 721.10107 Naphthalenedisulfonic acid, [amino-hydroxy-[(substituted)azo-sulfo-naphthaleneyl]azo]-hydroxy-[(methoxy-sulfophenyl)azo], metal salt (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as naphthalenedisulfonic acid, [amino-hydroxy-[(substituted)azo-sulfo-naphthaleneyl]azo]-hydroxy-[(methoxy-sulfophenyl)azo], metal salt (PMN P–04–495) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

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

■ 21. By adding new § 721.10108 to subpart E to read as follows:

§ 721.10108 Naphthalenedisulfonic acid, hydrozy-[[[(hydroxyl-disulfo-naphthaleneyl)azo]-alkyl(C=1-5)-(sulfoalkoxy)cyclic]azo]-substituted azo-, metal salt (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as naphthalenedisulfonic acid, hydrozy-[[[(hydroxyl-disulfo-naphthaleneyl)azo]-alkyl(C=1-5)-(sulfoalkoxy)cyclic]azo]-substituted azo-, metal salt (PMN P–04–498) 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 (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.

■ 22. By adding new § 721.10109 to subpart E to read as follows:

§ 721.10109 Hexanoic acid, 2-ethyl-, mixed triesters with benzoic acid and trimethylolpropane.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as hexanoic acid, 2-ethyl-, mixed triesters with benzoic acid and trimethylolpropane (PMN P–04–508; CAS No. 610787–76–3) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

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

■ 23. By adding new § 721.10110 to subpart E to read as follows:

§ 721.10110 Hexanoic acid, 2-ethyl-, mixed diesters with benzoic acid and neopentlyl glycol.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as hexanoic acid, 2-ethyl-, mixed diesters with benzoic acid and neopentlyl glycol (PMN P–04–509; CAS No. 610787–77–4) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

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

■ 24. By adding new § 721.10111 to subpart E to read as follows:

§ 721.10111 Hexanoic acid, 2-ethyl-, mixed diesters with benzoic acid and diethylene glycol.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as hexanoic acid, 2-ethyl-, mixed diesters with benzoic acid and diethylene glycol (PMN P–04–510; CAS No. 610787–78–5) 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) *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.

■ 25. By adding new § 721.10112 to subpart E to read as follows:

§ 721.10112 Ethanone, 2-chloro-1-(1-chlorocyclopropyl)-.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as ethanone, 2-chloro-1-(1-chlorocyclopropyl)- (PMN P–04–530; CAS No. 120983–72–4) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

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

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

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

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

■ 26. By adding new § 721.10113 to subpart E to read as follows:

§ 721.10113 Thioether epoxy (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as thioether epoxy (PMN P–04–547) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

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

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

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

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

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

■ 27. By adding new § 721.10114 to subpart E to read as follows:

§ 721.10114 Polyhydroxyaminoether salts (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substances identified generically as polyhydroxyaminoether salts (PMNs P–04–578, P–04–579, P–04–580, P–04–581, P–04–582, and-P–04–583) are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Release to water.* Requirements as specified in § 721.90 (a)(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 those substances.

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

■ 28. By adding new § 721.10115 to subpart E to read as follows:

§ 721.10115 1-Hexadecanaminium, N,N-dibutyl-N-(2-hydroxyethyl)-, bromide (1:1).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 1-hexadecanaminium, N,N-dibutyl-N-(2-hydroxyethyl)-, bromide (1:1) (PMN P–04–625; CAS No. 160653–08–7) 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)(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.

■ 29. By adding new § 721.10116 to subpart E to read as follows:

§ 721.10116 Blocked polymeric isocyanate (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as blocked polymeric isocyanate (PMN P–04–758) 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.

■ 30. By adding new § 721.10117 to subpart E to read as follows:

§ 721.10117 Heteromonocyclo-beta-(2,4-dichlorophenyl) -1-propanol (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as heteromonocyclo-beta-(2,4-dichlorophenyl) -1-propanol (PMN P–04–776) 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.

■ 31. By adding new § 721.10118 to subpart E to read as follows:

§ 721.10118 Substituted aryl acetonitrile (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as substituted aryl acetonitrile (PMN P–05–35) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *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.

■ 32. By adding new § 721.10119 to subpart E to read as follows:

§ 721.10119 Siloxane modified silica nanoparticles (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as siloxane modified silica nanoparticles (PMN P–05–673) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(1), (a)(2)(i), (a)(3), (a)(4), (a)(5), (a)(6)(ii), (b) (concentration set at 1 percent), and (c). The following National Institute for Occupational Safety and Health (NIOSH)-approved respirators with an APF of 10-25 meet the minimum requirements for § 721.63(a)(4): Air-purifying, tight-fitting respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters (either half- or full-face); powered air-purifying respirator equipped with a loose-fitting hood or helmet and High Efficiency Particulate Air (HEPA) filters; powered air-purifying respirator equipped with a tight-fitting facepiece (either half- or full-face) and HEPA filters; supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (either half- or full-face).

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

■ 33. By adding new § 721.10120 to subpart E to read as follows:

§ 721.10120 Siloxane modified alumina nanoparticles (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as siloxane modified alumina nanoparticles (PMN P–05–687) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(1), (a)(2)(i), (a)(3), (a)(4), (a)(5), (a)(6)(ii), (b) (concentration set at 1 percent), and (c). The following National Institute for Occupational Safety and Health (NIOSH)-approved respirators with an APF of 10-25 meet the minimum requirements for § 721.63(a)(4): Air-purifying, tight-fitting respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters (either half- or full-face); powered air-purifying respirator equipped with a loose-fitting hood or helmet and High Efficiency Particulate Air (HEPA) filters; powered air-purifying respirator equipped with a tight-fitting facepiece (either half- or full-face) and HEPA filters; supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (either half- or full-face).

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

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

(1) *Recordkeeping.* Requirements as specified in § 721.125 (a), (b), (c), (d), (e), 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.

■ 34. By adding new § 721.10121 to subpart E to read as follows:

§ 721.10121 Poly[oxy(methyl-1,2-ethanediyl)], .alpha.-methyl-.omega.-(4-nonylphenoxy)-, branched.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as poly[oxy(methyl-1,2-ethanediyl)], .alpha.-methyl-.omega.-(4-nonylphenoxy)-, branched (PMN P–05–766; CAS No. 858944–25–9) 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) *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.

■ 35. By adding new § 721.10122 to subpart E to read as follows:

§ 721.10122 2-Propenoic acid, 2-methyl-, 1,1′-[2-ethyl-2-[[(2-methyl-1-oxo-2-propen-1-yl)oxy]methyl]- 1,3-propanediyl] ester, polymer with 1,3-butadiene, ethenylbenzene and 2-hydroxyethyl 2-methyl-2-propenoate.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 2-propenoic acid, 2-methyl-, 1,1′-[2-ethyl-2-[[(2-methyl-1-oxo-2-propen-1-yl)oxy]methyl]- 1,3-propanediyl] ester, polymer with 1,3-butadiene, ethenylbenzene and 2-hydroxyethyl 2-methyl-2-propenoate (PMN P–06–151; CAS No. 849925–18–4) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(j) (additive in rubber, i.e. as reinforcing agent; additive in plastics, i.e. as polymeric plasticizer; and additive in polyurethane, i.e. to improve low temperature flexibility).

(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 these substances.

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

■ 36. By adding new § 721.10123 to subpart E to read as follows:

§ 721.10123 [1,2,4-Triazolo[1,5-a]pyrimidin-2-amine, 5,7-dimethoxy-].

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as [1,2,4-triazolo[1,5-a]pyrimidin-2-amine, 5,7-dimethoxy-] (PMN P–06–554; CAS No. 13223–43–3) 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)(4), (b)(4), and (c)(4) (N = 5).

(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.

■ 37. By adding new § 721.10124 to subpart E to read as follows:

§ 721.10124 Brominated polyaromatic compound (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as brominated polyaromatic compound (PMN P–06–617) 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.* Impervious gloves: Requirements as specified in § 721.63 (a)(1), (a)(2)(i), (a)(3), (b), and (c).

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

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

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

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

■ 38. By adding new § 721.10125 to subpart E to read as follows:

§ 721.10125 Alkenedioic acid, dialkyl ester, reaction products with polyaminocarbomonocycle and alkenoic acid alkyl ester (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substances identified generically as alkenedioic acid, dialkyl ester, reaction products with polyaminocarbomonocycle and alkenoic acid alkyl ester (PMNs P–06–665, P–06–666, P–06–667, P–06–668, P–06–669, and P–06–670) are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Release to water.* Requirements as specified in § 721.90 (a)(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 these substances.

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

■ 39. By adding new § 721.10126 to subpart E to read as follows:

§ 721.10126 Alkyl amino substituted triazine amino substituted benezenesulfonic acid reaction product with naphthalenesulfonato azo substituted phenyl azo substituted benzenesulfonic acid copper compound (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as alkyl amino substituted

triazine amino substituted benezenesulfonic acid reaction product with naphthalenesulfonato azo substituted phenyl azo substituted benzenesulfonic acid copper compound (PMN P–06–689) 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) [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.

■ 40. By adding new § 721.10127 to subpart E to read as follows:

§ 721.10127 Alkenyl dimethyl betaine (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as alkenyl dimethyl betaine (PMN P–06–693) 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.

■ 41. By adding new § 721.10128 to subpart E to read as follows:

§ 721.10128 Modified imidazole (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as modified imidazole (PMN P–06–752) 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.

■ 42. By adding new § 721.10129 to subpart E to read as follows:

§ 721.10129 Alkylamine ethoxylated (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as alkylamine ethoxylated (PMN P–07–24) 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) (emulsifier for oilfield application).

(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.

■ 43. By adding new § 721.10130 to subpart E to read as follows:

§ 721.10130 Quino[2,3-b]acridine-7,14-dione, 5,12-dihydro-ar-[4-[[2-(sulfooxy)ethyl]substituted]phenyl]-, monosodium salt (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as quino[2,3-b]acridine-7,14-dione, 5,12-dihydro-ar-[4-[[2-(sulfooxy)ethyl]substituted]phenyl]-, monosodium salt (PMN P–07–140) 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.

■ 44. By adding new § 721.10131 to subpart E to read as follows:

§ 721.10131 Isononanamide, N-(2-ethylhexyl)-.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as isononanamide, N-(2-ethylhexyl)- (PMN P–07–205: CAS No. 93820–33–8) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(j) (defoamer for cement additives in oilfield applications).

(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.

■ 45. By adding new § 721.10132 to subpart E to read as follows:

§ 721.10132 Phosphoramidic acid, carbomonocyclic-, diphenylester (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as phosphoramidic acid, carbomonocyclic-, diphenylester (PMN P–07–269) 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) and (s) (100,000 kilograms).

(ii) [Reserved]

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

(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.

■ 46. By adding new § 721.10133 to subpart E to read as follows:

§ 721.10133 2-Propenoic acid, 2-methyl, 2-hydroxyethyl ester, homopolymer.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 2-propenoic acid, 2-methyl, 2-hydroxyethyl ester, homopolymer (PMN P–07–401; CAS No. 25249–16–5) 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)(4), (a)(5), (a)(6), (b), and (c). Respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 1,000. A NIOSH-certified supplied-air respirator operated in pressure demand or other positive pressure mode and equipped with a tight-fitting full facepiece meets the minimum requirements for § 721.63(a)(4).

(ii) *Hazard communication program.* Requirements as specified in § 721.72 (a), (b), (c), (d), (e) (concentration set at 0.1 percent), (f), (g)(1)(vii), and (g)(2)(iv).

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

(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), (f), (g), (h), 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.

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DEPARTMENT OF LABOR

Veterans' Employment and Training Service

41 CFR Part 61–250

RIN 1293–AA16

Annual Report From Federal Contractors

AGENCY: Veterans' Employment and Training Service (VETS), Labor.

ACTION: Final Rule.

SUMMARY: This final rule revises the regulations in 41 CFR Part 61–250 implementing the requirement under the Vietnam Era Veterans' Readjustment Assistance Act of 1974, as amended, (''VEVRAA'') that Government contractors track and annually report the number of employees in their workforces who are veterans covered under the law. Today's final rule revises the regulations in 41 CFR Part 61–250 to incorporate the amendment to VEVRAA made by the Veterans' Benefit and Health Care Improvement Act of 2000 (''VBHCIA''). The VBHCIA amendment extended the protections of VEVRAA to a category of veterans called ''recently separated veterans.'' In addition, the final rule published today clarifies that the regulations in 41 CFR Part 61–250 implement the reporting requirements under VEVRAA prior to their amendment in 2002 by the Jobs for Veterans Act (''JVA''), and apply to Government contracts entered into before December 1, 2003. The final rule also makes clear that the regulations in 41 CFR Part 61–300 implementing the JVA amendments to VEVRAA's reporting requirements, apply if a contract entered into before December 1, 2003, is modified on or after that date and the contract as modified is for $100,000 or more.

DATES: These regulations are effective December 5, 2008.

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SUPPLEMENTARY INFORMATION:

Background

The Vietnam Era Veterans' Readjustment Assistance Act of 1974, as amended, (''VEVRAA''), 38 U.S.C. 4212(d), requires that Federal contractors report annually to the Secretary of Labor the number of employees and new hires that belong to the categories of veterans protected under the statute. The Veterans' Employment and Training Service (VETS) has promulgated two sets of regulations to implement the reporting requirements under VEVRAA. The regulations in 41 CFR Part 61–250 implement the reporting requirements under VEVRAA prior to the amendments made by the JVA in 2002, and apply to Government contracts of $25,000 or more that were entered into before December 1, 2003. The regulations in part 61–250 require contractors to use the VETS–100 Report form to provide information on the number of covered veterans in their workforces.

The recently published regulations in 41 CFR Part 61–300 implement the JVA amendments to the reporting requirements under VEVRAA (73 FR 28710, May 19, 2008), and apply to contracts entered into or modified on/or after December 1, 2003. The JVA amendments increased from $25,000 to $100,000, the dollar amount of the contract that subjects a Government contractor to the requirement to report the number of employees in their workforces who are covered veterans. In addition, the JVA amendments changed the categories of covered veterans under VEVRAA and thus the categories of veterans that contractors are required to track and report on annually. The regulations in part 61–300 require contractors to use the VETS–100A Report form to provide the required information on their employment of covered veterans.

Today's final rule revises the part 61–250 regulations to incorporate the amendment to VEVRAA that was made by the Veterans' Benefit and Health Care Improvement Act of 2000 (VBHCIA). Prior to amendment by the VBHCIA, VEVRAA required contractors with a contract of $25,000 or more to report at least annually to the Secretary the number of employees, by job category and hiring location, who are ''special disabled veterans, veterans of the Vietnam era, and other protected