

the applicability limitation set forth in section 6(c)(2) of the Nutrition Labeling and Education Act (NLEA), which was not codified. Section 6(c)(2) of the NLEA provided that section 403A of the FD&C Act “shall not be construed to apply to any requirement respecting a statement on the labeling of food that provides for a warning concerning the safety of the food or component of the food” (Pub. L. 101–535, section 6, 104 Stat. 2353 (1990)). FDA clarifies that its past discussions of section 403A of the FD&C Act should have included the language of section 6(c)(2) of the NLEA.

Dated: September 28, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Parts 9 and 721

[EPA–HQ–OPPT–2010–1075; FRL–8880–2]

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 36 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 36 chemical substances for an activity that is designated as a significant new use by this rule to notify EPA at least 90 days before commencing that activity. The required notification will provide EPA with the opportunity to evaluate the intended use and, if necessary, to prohibit or limit that activity before it occurs.

**DATES:** This rule is effective on December 5, 2011. For purposes of judicial review, this rule shall be promulgated at 1 p.m. (E.S.T.) on October 19, 2011.

Written adverse or critical comments, or notice of intent to submit adverse or critical comments, on one or more of these SNURs must be received on or before November 4, 2011 (see Unit VI. of the **SUPPLEMENTARY INFORMATION**).

For additional information on related reporting requirement dates, see Units I.A., VI., and VII. of the **SUPPLEMENTARY INFORMATION**.

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2010–1075, 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–2010–1075. 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–2010–1075. EPA’s policy is that all comments received will be included in the docket without change and may be made available on-line at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through [www.regulations.gov](http://www.regulations.gov) or e-mail. The [www.regulations.gov](http://www.regulations.gov) Web site is an “anonymous access” system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through [www.regulations.gov](http://www.regulations.gov), your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

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

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

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

## SUPPLEMENTARY INFORMATION:

### I. General Information

#### A. Does this action apply to me?

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

- Manufacturers, importers, or processors of one or more subject chemical substances (NAICS codes 325 and 324110), e.g., chemical manufacturing and petroleum refineries.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also

be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in § 721.5. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Chemical importers are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements promulgated at 19 CFR 12.118 through 12.127; see also 19 CFR 127.28. Chemical importers must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA. Importers of chemicals subject to these SNURs must certify their compliance with the SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export a chemical substance that is the subject of this rule on or after November 4, 2011 are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)) (see § 721.20), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

#### *B. What should I consider as I prepare my comments for EPA?*

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying

information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

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

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

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

## **II. Background**

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

EPA is promulgating these SNURs using direct final procedures. These SNURs will require persons to notify EPA at least 90 days before commencing the manufacture, import, or processing of a chemical substance for any activity designated by these SNURs as a significant new use. Receipt of such notices allows EPA to assess risks that may be presented by the intended uses and, if appropriate, to regulate the proposed use before it occurs. Additional rationale and background to these rules are more fully set out in the preamble to EPA's first direct final SNUR published in the **Federal Register** of April 24, 1990 (55 FR 17376). Consult that preamble for further information on the objectives, rationale, and procedures for SNURs and on the basis for significant new use designations, including provisions for developing test data.

### *B. What is the agency's authority for taking this action?*

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a "significant new use." EPA must make this determination by rule after considering all relevant factors, including the four bulleted TSCA section 5(a)(2) factors listed in Unit III. Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1)(B) requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days

before they manufacture, import, or process the chemical substance for that use. Persons who must report are described in § 721.5.

### *C. Applicability of General Provisions*

General provisions for SNURs appear in 40 CFR part 721, subpart A. These provisions describe persons subject to the rule, recordkeeping requirements, exemptions to reporting requirements, and applicability of the rule to uses occurring before the effective date of the rule. Provisions relating to user fees appear at 40 CFR part 700. According to § 721.1(c), persons subject to these SNURs must comply with the same notice requirements and EPA regulatory procedures as submitters of PMNs under TSCA section 5(a)(1)(A). In particular, these requirements include the information submission requirements of TSCA section 5(b) and 5(d)(1), the exemptions authorized by TSCA section 5(h)(1), (h)(2), (h)(3), and (h)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUN, EPA may take regulatory action under TSCA section 5(e), 5(f), 6, or 7 to control the activities for which it has received the SNUN. If EPA does not take action, EPA is required under TSCA section 5(g) to explain in the **Federal Register** its reasons for not taking action.

## **III. Significant New Use Determination**

Section 5(a)(2) of TSCA states that EPA's determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors, including:

- The projected volume of manufacturing and processing of a chemical substance.
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.
- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.
- The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

In addition to these factors enumerated in TSCA section 5(a)(2), the statute authorized EPA to consider any other relevant factors.

To determine what would constitute a significant new use for the 36 chemical substances that are the subject of these SNURs, EPA considered relevant information about the toxicity of the chemical substances, likely human exposures and environmental releases associated with possible uses, taking into consideration the four bulleted

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

#### IV. Substances Subject to This Rule

EPA is establishing significant new use and recordkeeping requirements for 36 chemical substances in 40 CFR part 721, subpart E. In this unit, EPA provides the following information for each chemical substance:

- PMN number.
- Chemical name (generic name, if the specific name is claimed as CBI).
- Chemical Abstracts Service (CAS) number (if assigned for non-confidential chemical identities).
- Basis for the TSCA section 5(e) consent order or, for non-section 5(e) SNURs, the basis for the SNUR (*i.e.*, SNURs without TSCA section 5(e) consent orders).
- Toxicity concerns.
- Tests recommended by EPA to provide sufficient information to evaluate the chemical substance (see Unit VIII. for more information).
- CFR citation assigned in the regulatory text section of this rule.

The regulatory text section of this rule specifies the activities designated as significant new uses. Certain new uses, including production volume limits (*i.e.*, limits on manufacture and importation volume) and other uses designated in this rule may be claimed as CBI. Unit IX. discusses a procedure companies may use to ascertain whether a proposed use constitutes a significant new use.

This rule includes 4 PMN substances (P-06-36, P-06-37, P-09-146 and P-09-147) for which EPA determined, pursuant to TSCA section 5(e), that uncontrolled manufacture, import, processing, distribution in commerce, use, and disposal may present an unreasonable risk of injury to human health or the environment. Accordingly, these substances are subject to “risk-based” consent orders under TSCA section 5(e)(1)(A)(ii)(I). Those consent orders require protective measures to limit exposures or otherwise mitigate the potential unreasonable risk. The so-called “5(e) SNURs” on these PMN substances are promulgated pursuant to § 721.160, and are based on and consistent with the provisions in the underlying consent orders. The 5(e) SNURs designate as a “significant new use” the absence of the protective measures required in the corresponding consent orders.

Where EPA determined that the PMN substance may present an unreasonable risk of injury to human health via inhalation exposure, the underlying TSCA section 5(e) consent order usually requires, among other things, that

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

This rule also includes SNURs on 32 PMN substances that are not subject to consent orders under TSCA section 5(e). In these cases, for a variety of reasons, EPA did not find that the use scenario described in the PMN triggered the determinations set forth under TSCA section 5(e). However, EPA does believe that certain changes from the use scenario described in the PMN could result in increased exposures, thereby constituting a “significant new use.” These so-called “non-5(e) SNURs” are promulgated pursuant to § 721.170. EPA has determined that every activity designated as a “significant new use” in all non-5(e) SNURs issued under § 721.170 satisfies the two requirements stipulated in § 721.170(c)(2), *i.e.*, these significant new use activities, “(i) Are different from those described in the premanufacture notice for the substance, including any amendments, deletions, and additions of activities to the premanufacture notice, and (ii) may be accompanied by changes in exposure or release levels that are significant in relation to the health or environmental concerns identified” for the PMN substance.

PMN Numbers P-06-36 and P-06-37

*Chemical names:* (P-06-36) Rutile, tin zinc, calcium-doped and (P-06-37) Rutile, tin zinc, sodium-doped.

*CAS numbers:* (P-06-36) 389623-01-2 and (P-06-37) 389623-07-8.

*Effective date of TSCA section 5(e) consent order:* February 17, 2009.

*Basis for TSCA section 5(e) consent order:* The PMN states that the substances will be used as colorants for polymers and industrial coatings. The order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) based on a finding that the substances may present an unreasonable risk of injury to human health. To protect against these risks, the consent order requires: Use of personal respiratory equipment, including a National Institute for Occupational Safety and Health (NIOSH)-certified respirator with an Assigned Protection Factor (APF) of at least 10, or compliance with a NCEL of 1.5 mg/m<sup>3</sup> as an 8-hour time weighted average; establishment of a hazard communication program; and restricts the company from manufacturing the PMN substances with a d10 particle size less than 100 nanometers, where d10 particle size presents the particle size, as determined by laser light scattering, at which 10 percent by weight of the substance measured is smaller; and corresponding recordkeeping. The SNUR designates as a “significant new use” the absence of these protective measures.

*Toxicity concern:* Based on structural activity relationship analysis derived from test data on structurally similar respirable, poorly soluble particulates, the PMN substances may cause lung overload and fibrosis in workers exposed to the PMN substances by the inhalation route.

*Recommended testing:* EPA has determined that the following test would help characterize the human health effects of the PMN substances: A 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) in rats. The testing should include a 60-day recovery period to assess the progression or regression of any lesions; and include special attention to histopathology (inflammation and cell proliferation) of the lung tissues and to various parameters of the bronchoalveolar lavage fluid (BALF), *e.g.*, marker enzyme activities, total protein content, total cell count, cell differential, and cell viability. The order does not require submission of the aforementioned information at any specified time or production volume. However, the order’s restrictions on manufacturing, import, processing, distribution in

commerce, use, and disposal of the PMN substances will remain in effect until the order is modified or revoked by EPA based on submission of that or other relevant information.

*CFR citations:* 40 CFR 721.10230 (P-06-36) and 40 CFR 721.10231 (P-06-37).

PMN Number P-08-694

*Chemical name:* N-arylamino-phenol-formaldehyde condensate (generic).

*CAS number:* Not available.

*Basis for action:* The PMN states that the generic (non-confidential) uses of the substance will be as a curative to be used with epoxy resin; a curative to be used with isocyanates in urethane systems; and an intermediate for synthesis of epoxy resins. Based on ecological structure-activity relationship (EcoSAR) analysis of test data on analogous phenols, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 part per billion (ppb) of the PMN substance in surface waters. As described in the PMN, releases of the substance are not expected to result in surface water concentrations that exceed 1 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 1 ppb may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(ii).

*Recommended testing:* EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test, tiers I and II (OPPTS Test Guideline 850.5400) would help characterize the 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. EPA recommends that the special considerations for conducting laboratory studies (OPPTS Test Guideline 850.1000) be followed to facilitate solubility in the test media, because of the PMN's low water solubility. Test reports should include protocols approved by EPA, certificate of analysis for the test substance, raw data, and results.

*CFR citation:* 40 CFR 721.10232.

PMN Number P-08-704

*Chemical name:* Linear alkyl epoxide (generic).

*CAS number:* Not available.

*Basis for action:* The PMN states that the generic (non-confidential) uses of the substance will be as site-limited intermediates for personal care ingredients and foam control agents. Based on EcoSAR analysis of test data on analogous epoxides, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PMN substance in surface waters. As described in the PMN, releases of the PMN substance are not expected to result in surface water concentrations that exceed 1 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 1 ppb may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(ii).

*Recommended testing:* EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test, tiers I and II (OPPTS Test Guideline 850.5400) would help characterize the 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. Test reports should include protocols approved by EPA, certificate of analysis for the test substance, raw data, and results.

*CFR citation:* 40 CFR 721.10233.

PMN Number P-09-61

*Chemical name:* Hydroxy-chloro-cyclopropyl-heteromonocyclic carboxylic acid (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 the PMN substance, and EcoSAR analysis of test data on analogous phenols, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 6 ppb of the PMN substance in surface waters. As described in the PMN, releases of the PMN substance are not expected to result in surface water concentrations

that exceed 6 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 6 ppb may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(i) and (b)(4)(ii).

*Recommended testing:* EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400) and a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300) would help characterize the environmental effects of the PMN substance. Testing should be performed using the flow-through method with measured concentrations. Test reports should include protocols approved by EPA, certificate of analysis for the test substance, raw data, and results.

*CFR citation:* 40 CFR 721.10234.

PMN Number P-09-72

*Chemical name:* Phenol, 2-ethoxy-4-(ethoxymethyl)-.

*CAS number:* 71119-07-8.

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

*Recommended testing:* EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test, tiers I and II (OPPTS Test Guideline 850.5400) would help characterize the 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. Test reports should include protocols approved by EPA, certificate of analysis for the test substance, raw data, and results.

*CFR citation:* 40 CFR 721.10235.

PMN Number P-09-139

*Chemical name:* 1-Propanamine, 3-[2-(2-methoxyethoxy)ethoxy]-.

*CAS number:* 91933-40-3.

*Basis for action:* The PMN states that the generic (non-confidential) use of the substance will be as a dispersant. Based on test data on an analogous substance submitted under TSCA section 8(e), EPA identified the following toxicity concerns from exposure to the PMN substance: Irritation to eyes; sensitization and corrosion to skin; and irritation to mucous membranes, lungs, and the gastrointestinal tract. For the uses described in the PMN, worker exposure and general population exposure are limited. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. However, EPA has determined that use of the substance other than as described in the PMN, or use of the substance in a consumer product, may result in significant human exposures. 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 an acute oral toxicity test (OPPTS Test Guideline 870.1100 or Organisation for Economic Co-operation and Development (OECD) Test Guideline 425); a bacterial reverse mutation test (OPPTS Test Guideline 870.5100); a mammalian erythrocyte micronucleus test (OPPTS Test Guideline 870.5395) via the intraperitoneal route; and a repeated dose 28-day oral toxicity study in rodents (OPPTS Test Guideline 870.3050 or OECD Test Guideline 407) would help characterize the human health effects of the PMN substance. Testing should be performed on the neutralized PMN substance. Test reports should include protocols approved by EPA, certificate of analysis for the test substance, raw data, and results.

*CFR citation:* 40 CFR 721.10236.

PMN Numbers P-09-146 and P-09-147

*Chemical names:* (P-09-146)

Formaldehyde, polymers with acetone-phenol reaction products and phenol, sodium salts and (P-09-147)

Formaldehyde, polymers with acetone-phenol reaction products and phenol, potassium sodium salts.

*CAS numbers:* (P-09-146) 1065544-88-8 and (P-09-147) 1072227-60-1.

*Effective date of TSCA section 5(e) consent order:* May 26, 2010.

*Basis for TSCA section 5(e) consent order:* The PMNs state that the generic (non-confidential) use of the substances will be as adhesives. The order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) based on a finding that the substances may present an unreasonable risk of injury to human health. To protect against these risks, the consent order requires: Restrictions on formaldehyde residuals and polymer composition in the PMN substances; testing of representative samples at new manufacturing facilities; development and implementation of a written control plan for analysis and compliance with specified chemical composition limits; use only as listed in the consent order; no processing or distribution of the PMNs except when processed under specified conditions, where the PMNs are irreversibly cured into a thermoset polymer matrix; and maintaining certain records. The SNUR designates as a "significant new use" the absence of these protective measures.

*Toxicity concern:* Based on physical-chemical properties, the PMN substances are expected to be absorbed from the lung and low molecular weight fractions are expected to be poorly absorbed from the gastrointestinal tract. Further, the PMN substances are not expected to be absorbed through the skin. EPA identified concerns for respiratory tract irritation, coughing; skin irritation and redness; eye irritation, watering, and redness; sensitization and severe allergic reactions. Further, based on test data on formaldehyde, a component of the PMN substances and regarded by EPA and International Agency for Research on Cancer (IARC) to be a carcinogen, EPA predicts human carcinogenicity.

*Recommended testing:* EPA has determined that the following test would help characterize the human health effects of the PMN substances: Determining formaldehyde concentration in air from wood products, using a large scale chamber (American Society for Testing and Materials International (ASTM) Test Guideline E1333-10 or its equivalent) to demonstrate that formaldehyde emissions are equal to or less than 0.04 parts per million (ppm). The order does not require submission of the aforementioned information at any specified time or production volume. However, the order's restrictions on manufacturing, import, processing, distribution in commerce, use, and disposal of the PMN substances will

remain in effect until the order is modified or revoked by EPA based on submission of that or other relevant information.

*CFR citations:* 40 CFR 721.10237 (P-09-146) and 40 CFR 721.10238 (P-09-147).

PMN Numbers P-09-152 and P-09-153

*Chemical names:* Trivalent chromium complexes of a substituted beta-naphthol amine azo dye (generic).

*CAS numbers:* Not available.

*Basis for action:* The PMNs state that the use of the substances will be as acid dyes for coloring anodized aluminum. Based on test data on analogous substances including Beta-naphthylamine and chromium, EPA determined that the PMN substances may cause blood toxicity (methemoglobinemia), male reproductive toxicity, developmental toxicity to workers and the general public exposed to the PMN substances via the lung or gastrointestinal tract. For the use described in the PMNs, worker inhalation exposure is unlikely, as the substances are imported, processed, and used as a wet press cake (greater than 30 percent water). Significant general population exposure is unlikely, as significant inhalation and drinking water exposures are not expected. Therefore, EPA has not determined that the proposed import, processing, or use of the substances may present an unreasonable risk. EPA has determined, however, that domestic manufacture, use of the substances other than as described in the PMNs, or the import, processing, or use of the substances in a powder or solid form (other than as a wet press cake that is comprised of greater than 30 percent water), may cause serious health effects. Based on this information, the PMN substances meet 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 Test Guideline 870.5100) with the prival modification with a concurrent positive control; and an unscheduled DNA synthesis in mammalian cells in culture (OPPTS Test Guideline 870.5550) in rat hepatocytes on the Beta-naphthylamine reduction product would help characterize the human health effects of the PMN substances. Test reports should include protocols approved by EPA, certificate of analysis for the test substance, raw data, and results.

*CFR citation:* 40 CFR 721.10239.

PMN Numbers P-09-154, P-09-155, and P-09-156

*Chemical names:* (P-09-154) Olefinic carbocycle, reaction products with alkoxy silane (generic); (P-09-155) olefinic carbocycle, reaction products with alkoxy silane, sulfurized (generic); and (P-09-156) olefinic carbocycle, reaction products with alkoxy silane, polysulfurized (generic).

*CAS numbers:* (P-09-154) Not available; (P-09-155) not available; and (P-09-156) not available.

*Basis for action:* The PMNs state that the generic (non-confidential) uses of the substances will be as a processing additive intermediate (P-09-154 and P-09-155) and as a processing additive (P-09-156). Based on EcoSAR analysis of test data on analogous alkoxy silanes, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PMN substance (P-09-154) and 6 ppb of the PMN substance (P-09-156) in surface waters. Based on test data on analogous alkoxy silanes and thiols, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PMN substance (P-09-155) in surface waters. As described in the PMNs, the substances will not be 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 any use 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 ready biodegradability—CO<sub>2</sub> in sealed vessels test (OPPTS Test Guideline 835.3140); a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test, tiers I and II (OPPTS Test Guideline 850.5400) would help characterize the environmental effects of the PMN substance. 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. EPA recommends that the fate testing be performed first as the results may mitigate the need for further toxicity testing or change the testing recommendations. Testing should be performed on P-09-155. Test reports

should include protocols approved by EPA, certificate of analysis for the test substance, raw data, and results.

*CFR citations:* 40 CFR 721.10240 (P-09-154); 40 CFR 721.10241 (P-09-155); and 40 CFR 721.10242 (P-09-156).

PMN Numbers P-09-193 and P-09-195

*Chemical names:* (P-09-193) Phosphonic acid, P-[2-[bis(2-hydroxyethyl)amino]ethyl]-, bis(2-chloroethyl) ester and (P-09-195) Phosphonic acid, P-[2-[bis(2-hydroxyethyl)amino]ethyl]-, 2-[bis(2-chloroethoxy)phosphinyl]ethyl 2-chloroethyl ester.

*CAS numbers:* (P-09-193) 55088-28-3 and (P-09-195) 1094213-37-2.

*Basis for action:* The PMNs state that the substances will be used as intermediates in the manufacture of a polyurethane flame retardant. Based on the alkylating activity of the PMN substances, EPA has concerns for oncogenicity, mutagenicity, developmental toxicity, dermal and respiratory sensitization, and irritation to all tissues. Additionally, the Agency has concern for liver toxicity, kidney toxicity, heart toxicity, developmental toxicity, and neurotoxicity based on test data for analog substances submitted to the Agency under TSCA section 8(e). Based on EcoSAR analysis of test data on structurally similar aliphatic amines, EPA predicts toxicity to aquatic organisms at concentrations that exceed 8 ppb in surface waters. As described in the PMN, significant worker dermal and inhalation exposure is unlikely for the use described in the PMN due to the use of personal protective equipment and engineering controls. Further, significant general population and environmental exposure is unlikely as the substances are not released to water. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of these substances may present an unreasonable risk. EPA has determined, however, that use of the substances other than as intermediates in the manufacture of a polyurethane flame retardant, use of the substances without the use of impervious gloves where there is potential for dermal exposure, or any use of the substances resulting in release to surface waters may cause significant adverse health or environmental effects. Based on this information, the PMN substances meet 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 a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465); a fish acute toxicity test, freshwater and marine

(OPPTS Test Guideline 850.1075); an aquatic invertebrate, acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test, tiers I and II (OPPTS Test Guideline 850.5400) would help characterize the human health and environmental effects of the PMN substances. 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 concentration. Testing should be performed on P-09-193. Test reports should include protocols approved by EPA, certificate of analysis for the test substance, raw data, and results.

*CFR citations:* 40 CFR 721.10243 (P-09-193) and 40 CFR 721.10244 (P-09-195).

PMN Number P-09-207

*Chemical name:* Branched and linear fatty alcohol ethoxylate (generic).

*CAS number:* Not available.

*Basis for action:* The PMN states that the substance will be used as an intermediate in the manufacture of nonionic surfactants. Based on EcoSAR analysis of test data on analogous nonionic surfactants, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 14 ppb of the PMN substance in surface waters. For the use described in the PMN, releases of the PMN substance are not expected to result in surface water concentrations that exceed 14 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 an intermediate in the manufacture of nonionic surfactants may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(ii).

*Recommended testing:* EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test, tiers I and II (OPPTS Test Guideline 850.5400) would help characterize the environmental effects of the PMN substance. 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. EPA recommends that the special considerations for conducting laboratory

studies (OPPTS Test Guideline 850.1000) be followed to facilitate solubility in the test media, because of the PMN's low water solubility. Test reports should include protocols approved by EPA, certificate of analysis for the test substance, raw data, and results.

*CFR citation:* 40 CFR 721.10245.

PMN Number P-09-234

*Chemical name:* Alkylpolyhydroxy polymer (generic).

*CAS number:* Not available.

*Basis for action:* The PMN states that the generic (non-confidential) use of the substance will be as a drilling fluid additive. Based on EcoSAR analysis of test data on analogous alkyl ethoxylate nonionic surfactants, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 56 ppb of the PMN substance in surface waters. As described in the PMN, the substance is not released to surface waters. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in release to surface waters may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(ii).

*Recommended testing:* EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test, tiers I and II (OPPTS Test Guideline 850.5400) would help characterize the environmental effects of the PMN substance. 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. Test reports should include protocols approved by EPA, certificate of analysis for the test substance, raw data, and results.

*CFR citation:* 40 CFR 721.10246.

PMN Number P-09-258

*Chemical name:* Bis-phenoxyethanol fluorene diacrylate (generic).

*CAS number:* Not available.

*Basis for action:* The PMN states that the substance will be used as a raw material in ultra violet (UV) curable inks and coatings. EPA 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 for more than two months and estimates a bioaccumulation factor of greater than or equal to 5,000. Also, based on test data on analogous acrylates, EPA believes exposure to the PMN substance may cause systemic human health effects and predicts toxicity to aquatic organisms. As described in the PMN, significant worker exposure is unlikely and the substance is not released to surface waters. Therefore, EPA has not determined that the proposed 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 environmental effects, since the PMN substance has been characterized by EPA as a PBT. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(3)(ii), (b)(4)(ii), and (b)(4)(iii).

*Recommended testing:* EPA has determined that the results of the tiered testing described in the New Chemicals Program's PBT Category would help characterize the PBT attributes of the PMN substance. Test reports should include protocols approved by EPA, certificate of analysis for the test substance, raw data, and results.

*CFR citation:* 40 CFR 721.10247.

PMN Number P-09-259

*Chemical name:* Aromatic bromide (generic).

*CAS number:* Not available.

*Basis for action:* The PMN states that the substance will be used as a synthetic intermediate. EPA identified health and environmental concerns because the substance may be a PBT chemical, based on physical/chemical properties of the PMN substance, as described in the New Chemical Program's PBT category (64 FR 60194; November 4, 1999). EPA estimates that the PMN substance will persist in the environment more than six months and estimates a bioaccumulation factor of greater than or equal to 5,000. Also, based on test data on analogous brominated aromatics and neutral organics (aryl halides), EPA believes exposure to the PMN substance may cause systemic human health effects and predicts toxicity to aquatic organisms. As described in the PMN, significant worker exposure is unlikely

and the substance is not released to surface waters. Therefore, EPA has not determined that the proposed 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 or any predictable or purposeful release containing the PMN substance into the waters of the United States may cause serious health effects and significant environmental effects, since the PMN substance has been characterized by EPA as a PBT. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(3)(ii), (b)(4)(ii), and (b)(4)(iii).

*Recommended testing:* EPA has determined that the results of the tiered testing described in the New Chemicals Program's PBT Category would help characterize the PBT attributes of the PMN substance. Test reports should include protocols approved by EPA, certificate of analysis for the test substance, raw data, and results.

*CFR citation:* 40 CFR 721.10248.

PMN Number P-09-316

*Chemical name:* Disubstituted phenol (generic).

*CAS number:* Not available.

*Basis for action:* The PMN states that the generic (non-confidential) use of the substance will be as a chemical intermediate. Based on test data on analogous anilines and phenols, as well as on test data submitted to the Agency under TSCA section 8(e), EPA identified concerns for liver toxicity, mutagenicity, carcinogenicity, developmental toxicity, neurotoxicity, and male reproductive system toxicity to workers from inhalation exposure to the PMN substance. Additionally, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 6 ppb of the PMN substance in surface waters. For the use described in the PMN, significant worker exposure is unlikely due to the use of personal protective equipment. Furthermore, significant environmental exposure is unlikely as the substance is not released to surface water resulting in surface water concentrations that exceed 6 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 other than as a chemical intermediate, or exceedance of the manufacture and import limit of 100 kg per year may cause serious health effects and significant adverse environmental effects. Based on this information, the PMN substance meets the concern

criteria at § 721.170(b)(1)(i)(C), (b)(3)(ii), and (b)(4)(ii).

*Recommended testing:* EPA has determined that the results of a combined chronic toxicity/carcinogenicity test (OPPTS Test Guideline 870.4300); a bacterial reverse mutation test (OPPTS Test Guideline 870.5100); a mammalian erythrocyte micronucleus test (OPPTS Test Guideline 870.5395); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300) prolonged exposure; a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400) using rainbow trout and a 60-day minimum duration; and an algal toxicity test, tiers I and II (OPPTS Test Guideline 850.5400) would help characterize the 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. Test reports should include protocols approved by EPA, certificate of analysis for the test substance, raw data, and results.

*CFR citation:* 40 CFR 721.10249.

PMN Number P-09-356

*Chemical name:* Zirconium lysine complex (generic).

*CAS number:* Not available.

*Basis for action:* The PMN states that the generic (non-confidential) use of the substance will be as an adhesion promoter and corrosion inhibitor. Based on EcoSAR analysis of test data on analogous inorganic zirconium compounds, EPA predicts toxicity to aquatic organisms at concentrations that exceed 120 ppb of the PMN substance in surface waters. As described in the PMN, releases of the substance are not expected to result in surface water concentrations that exceed 120 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 120 ppb may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(ii).

*Recommended testing:* EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test, tiers I and II (OPPTS Test Guideline 850.5400) would help characterize the environmental

effects of the PMN substance. 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. Test reports should include protocols approved by EPA, certificate of analysis for the test substance, raw data, and results.

*CFR citation:* 40 CFR 721.10250.

PMN Number P-09-366

*Chemical name:* Fatty acids, reaction products with alkanolamine (generic).

*CAS number:* Not available.

*Basis for action:* The PMN states that the substance will be used as an intermediate for a product used as a component of a multipurpose additive in gasoline. Based on test data on the PMN substance, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 400 ppb of the PMN substance in surface waters. As described in the PMN, releases of the PMN substance are not expected to result in surface water concentrations that exceed 400 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 an intermediate 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)(i).

*Recommended testing:* EPA has determined that the results of an aerobic and anaerobic transformation in aquatic sediment systems (OECD Test Guideline 308); a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); and a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300) would help characterize the environmental effects of the PMN substance. Fish and daphnid testing should be performed using the flow-through method with measured concentrations. EPA recommends that the special considerations for conducting laboratory studies (OPPTS Test Guideline 850.1000) be followed to facilitate solubility in the test media, because of the PMN's low water solubility. EPA also recommends performing the fate testing first as the results may mitigate the need for further toxicity testing or change the testing requirements. Test reports should include protocols approved by EPA, certificate of analysis for the test substance, raw data, and results.

*CFR citation:* 40 CFR 721.10251.

PMN Number P-09-373

*Chemical name:* Thiosulfuric acid (H<sub>2</sub>S<sub>2</sub>O<sub>3</sub>), manganese(2+) salt (1:1).

*CAS number:* 1033050-53-1.

*Basis for action:* The PMN states that the substance will be used as a micronutrient manganese source for selected agricultural crops. Based on EcoSAR analysis of test data on analogous manganese salts, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 400 ppb of the PMN substance in surface waters. As described in the PMN, releases of the substance are not expected to result in surface water concentrations that exceed 400 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 400 ppb may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(ii).

*Recommended testing:* EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test, tiers I and II (OPPTS Test Guideline 850.5400) would help characterize the environmental effects of the PMN substance. Fish and daphnid testing should be performed using the flow-through method with mean measured concentrations. Algal testing should be performed using the static method with mean measured concentrations. Test reports should include protocols approved by EPA, certificate of analysis for the test substance, raw data, and results.

*CFR citation:* 40 CFR 721.10252.

PMN Number P-09-388

*Chemical name:* Butanedioic acid, 2-methylene-, polymer with 2,5 furanedione, copper(2+) manganese(2+) sodium zinc salt, hydrogen peroxide-initiated.

*CAS number:* 1134078-27-5.

*Basis for action:* The PMN states that the generic (non-confidential) use of the substance will be as a seed coating to provide micronutrients. Based on EcoSAR analysis of test data on analogous soluble complexes of zinc, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 34 ppb of the PMN substance in surface waters. As described in the PMN, releases of the

substance are not expected to result in surface water concentrations that exceed 34 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 34 ppb may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(ii).

*Recommended testing:* EPA has determined that the results of a ready biodegradability-CO<sub>2</sub> in sealed vessels (headspace test) (OECD Test Guideline 310); a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test, tiers I and II (OPPTS Test Guideline 850.5400) would help characterize the environmental effects of the PMN substance. 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. EPA recommends performing the fate testing first as the results may mitigate the need for further toxicity testing or change the testing requirements. Test reports should include protocols approved by EPA, certificate of analysis for the test substance, raw data, and results.

*CFR citation:* 40 CFR 721.10253.

PMN Number P-09-390

*Chemical name:* Substituted acrylamide (generic).

*CAS number:* Not available.

*Basis for action:* The PMN states that the generic (non-confidential) use of the substance will be as a raw material. Based on test data on the PMN substance and EcoSAR analysis of test data on analogous amides and acrylamides, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 21 ppb of the PMN substance in surface waters. As described in the PMN, releases of the substance are not expected to result in surface water concentrations that exceed 21 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 21 ppb may cause significant adverse environmental effects. Based on this information, the PMN substance meets

the concern criteria at § 721.170(b)(4)(i) and (b)(4)(ii).

*Recommended testing:* EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075) using the flow-through method with measured concentrations, and an algal toxicity test, tiers I and II (OPPTS Test Guideline 850.5400) using the static method with measured concentrations would help characterize the environmental effects of the PMN substance. Test reports should include protocols approved by EPA, certificate of analysis for the test substance, raw data, and results.

*CFR citation:* 40 CFR 721.10254.

PMN Number P-09-400

*Chemical name:* Vinyl carboxylic acid ester (generic).

*CAS number:* Not available.

*Basis for action:* The PMN states that the generic (non-confidential) use of the substance will be as a monomer. Based on test data on the PMN substance and analogous vinyl esters, EPA identified concerns for dermal sensitization; dermal irritation; mutagenicity; neurotoxicity; and blood, liver, kidney, spleen, brain, testes, developmental, and reproductive toxicity to the general population if exposed to the PMN substance. In addition, based on test data on the PMN substance, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 15 ppb of the PMN substance in surface waters. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(3)(ii) and (b)(4)(i). At the production volume stated in the PMN, general population exposure is limited. Further, as described in the PMN, releases of the PMN substance are not expected to result in surface water concentrations that exceed 15 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk under TSCA section 5(e). However, EPA has determined that annual manufacture (including importation) of this PMN substance at volumes greater than 100,000 kilograms per year may result in significant human exposures. Further, EPA has determined that any use of the substance resulting in surface water concentrations exceeding 15 ppb may cause significant adverse environmental effects.

*Recommended testing:* EPA has determined that the results of a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465); a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); and a daphnid

chronic toxicity test (OPPTS Test Guideline 850.1300) would help characterize the human health and environmental effects of the PMN substance. Aquatic toxicity testing should be performed using the flow-through method with measured concentrations. Test reports should include protocols approved by EPA, certificate of analysis for the test substance, raw data, and results.

*CFR citation:* 40 CFR 721.10255.

PMN Number P-09-479

*Chemical name:* Benzoic acid, 4-(dimethylamino)-, 1,1'-[[methylimino]di-2,1-ethanediy] ester.

*CAS number:* 925246-00-0.

*Basis for action:* The PMN states that the substance will be used as a co-photoinitiator for UV-curable pigmentation inks; co-photoinitiator for photoresists, optical fibers, and printed plates; co-photoinitiator for UV-curable coatings; and co-photoinitiator for UV-curable adhesives and other coatings. Based on test data on the PMN substance and EcoSAR analysis of test data on analogous aliphatic amines and esters, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 2 ppb of the PMN substance in surface waters. As described in the PMN, the substance is not released to surface waters. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in release to surface waters may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(i) and (b)(4)(ii).

*Recommended testing:* EPA has determined that the results of a ready biodegradability test (OPPTS Test Guideline 835.3100); a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); and a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300) would help characterize the environmental effects of the PMN substance. Testing should be performed using the flow-through method with mean measured concentrations. EPA recommends that the special considerations for conducting laboratory studies (OPPTS Test Guideline 850.1000) be followed to facilitate solubility in the test media, because of the PMN's low water solubility. EPA also recommends that the fate testing be performed first as the results may mitigate the need for further toxicity testing or change the testing recommendations. Test reports should

include protocols approved by EPA, certificate of analysis for the test substance, raw data, and results.

*CFR citation:* 40 CFR 721.10256.

PMN Number P-09-532

*Chemical name:* Butyl aromatic bisurea (generic).

*CAS number:* Not available.

*Basis for action:* The PMN states that the generic (non-confidential) use of the substance will be as a sealant. Based on EcoSAR analysis of test data on analogous substituted urea, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PMN substance in surface waters. As described in the PMN, the substance will not be released to surface waters. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in release to surface waters may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(ii).

*Recommended testing:* EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test, tiers I and II (OPPTS Test Guideline 850.5400) would help characterize the environmental effects of the PMN substance. 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. EPA recommends that the special considerations for conducting laboratory studies (OPPTS Test Guideline 850.1000) be followed to facilitate solubility in the test media, because of the PMN's low water solubility. Test reports should include protocols approved by EPA, certificate of analysis for the test substance, raw data, and results.

*CFR citation:* 40 CFR 721.10257.

PMN Numbers P-09-535 and P-09-540

*Chemical names:* (P-09-535) Aromatic hydrocarbon (generic) and (P-09-540) Halogenated aromatic hydrocarbon (generic).

*CAS numbers:* (P-09-535) Not available and (P-09-540) not available.

*Basis for action:* The PMNs state that the substances will be used as synthetic intermediates. EPA has identified health and environmental concerns because

the substances may be PBT chemicals, based on physical/chemical properties of the PMN substances, as described in the New Chemicals Program's PBT Category (64 FR 60194; November 4, 1999). EPA estimates that the PMN substances will persist in the environment more than two months and estimates bioaccumulation factors that are greater than or equal to 5,000. Also, based on test data on analogous polyaromatic hydrocarbons, EPA predicts chronic adverse human health effects. As described in the PMNs, significant worker exposure is unlikely and 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 any predictable or purposeful release containing the PMN substances into the waters of the United States may cause serious health effects and significant adverse environmental effects, since the PMN substances have been characterized by EPA as PBT. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(3)(ii) and (b)(4)(iii).

*Recommended testing:* EPA has determined that the results of the tiered testing described in the New Chemicals Program's PBT Category would help characterize the PBT attributes of the PMN substances. Test reports should include protocols approved by EPA, certificate of analysis for the test substance, raw data, and results.

*CFR citations:* 40 CFR 721.10258 (P-09-535) and 40 CFR 721.10259 (P-09-540).

PMN Number P-09-552

*Chemical name:* Benzene, 1,3-bis(1-chloro-1-methylethyl)-.

*CAS number:* 37133-18-9.

*Basis for action:* The PMN states that the substance will be used as a site-limited starting material in novel polymer synthesis reactions. EPA has identified health and environmental concerns because the substance may be a PBT chemical, based on physical/chemical properties of the PMN substance, as described in the New 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. In addition, based on the potential for the PMN to be an alkylating agent, EPA identified concerns for oncogenicity, developmental toxicity, sensitivity, and corrosion to all tissues from dermal and

respiratory exposure. Further, based on EcoSAR analysis of test data on analogous benzyl halides, EPA predicts toxicity to aquatic organisms at concentrations that exceed 1 ppb of the PMN substance in surface waters. As described in the PMN, significant worker exposure is unlikely due to the use of adequate dermal and respiratory protection and the substance is not expected to be released to surface waters. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any 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), (b)(4)(ii), and (b)(4)(iii).

*Recommended testing:* EPA has determined that the results of the tiered testing described in the New Chemicals Program's PBT Category (64 FR 60914; November 4, 1999) should help characterize the PBT attributes of the PMN substance. Test reports should include protocols approved by EPA, certificate of analysis for the test substance, raw data, and results.

*CFR citation:* 40 CFR 721.10260.

PMN Numbers P-09-589 and P-09-590

*Chemical names:* (P-09-589) Oxime, di-Me silane (generic) and (P-09-590) Oxime, Me vinyl silane (generic).

*CAS numbers:* (P-09-589) Not available and (P-09-590) not available.

*Basis for action:* The PMNs state that the generic (non-confidential) use of the substances will be as chain extenders. Based on test data on the PMN substances and the expected hydrolysis product, EPA identified concerns for carcinogenicity, dermal sensitization, blood effects, reproductive toxicity, and neurotoxicity to workers and the general population exposed dermally or by inhalation to the PMN substances. In addition, based on EcoSAR analysis of test data on analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 2 ppb of the PMN substances in surface waters. As described in the PMNs, worker exposure will be minimal due to the use of adequate personal protective equipment, general population inhalation and dermal exposure is not expected, and 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 any use of the substances without the use of impervious gloves where there is potential for dermal exposure, annual manufacture (including importation) of each of the PMN substances at volumes greater than 20,000 kilograms, or any use of the substances resulting in release to surface waters may cause serious health effects and/or significant adverse environmental effects. Based on this information, the PMN substances meet 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 two-generation reproduction toxicity test (OECD Test Guideline 416); a ready biodegradability test (OPPTS Test Guideline 835.3110); a porous pot test (OPPTS Test Guideline 835.3220); a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); a fish acute toxicity mitigated by humic acid test (OPPTS Test Guideline 850.1085); an aquatic invertebrate acute toxicity test; freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test, tiers I and II (OPPTS Test Guideline 850.5400) would help characterize the human health and environmental effects of the PMN substances. 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. Testing should be performed on P-09-589. EPA recommends that the fate testing be performed first as the results may mitigate the need for further testing or change the testing requirements. Test reports should include protocols approved by EPA, certificate of analysis for the test substance, raw data, and results.

*CFR citations:* 40 CFR 721.10261 (P-09-589) and 40 CFR 721.10262 (P-09-590).

PMN Number P-09-634

*Chemical name:* Phenol, 4-(1,1-dimethylethyl)-2-nitro-

*CAS number:* 3279-07-0.

*Basis for action:* The PMN states that the substance will be used as a raw material (reactant) for production of intermediate for a photographic chemical. Based on test data on the PMN substance, and test data submitted under TSCA section 8(e) on analogous aminophenols, EPA identified concerns

for irritation to the eye and skin, mutagenicity, neurotoxicity, developmental, liver, blood, and reproductive toxicities to workers and members of the general population if exposed to the PMN substance. In addition, based on EcoSAR analysis of test data on analogous phenols, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PMN substance in surface waters. For the uses described in the PMN, significant worker exposure is unlikely, as dermal/inhalation exposure is not expected; the substance is not released to surface waters; and the substance is not expected to result in significant exposure to the general population. 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 or any use of the substance resulting in release 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 combined repeated dose toxicity with the reproduction/development toxicity screening test (OPPTS Test Guideline 870.3650); a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test; freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test, tiers I and II (OPPTS Test Guideline 850.5400) would help characterize the 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. Test reports should include protocols approved by EPA, certificate of analysis for the test substance, raw data, and results.

*CFR citation:* 40 CFR 721.10263.

PMN Number P-10-343

*Chemical name:* Polycarbocyclic methacrylate (generic).

*CAS number:* Not available.

*Basis for action:* The PMN states that the generic (non-confidential) use of the substance will be as a polymeric component. Based on EcoSAR analysis of test data on analogous methacrylates, EPA predicts toxicity to aquatic organisms may occur at concentrations

that exceed 8 ppb of the PMN substance in surface waters. As described in the PMN, the substance is not released to surface waters. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in release to surface waters may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(ii).

*Recommended testing:* EPA has determined that the results of a ready biodegradability test (OPPTS Test Guidelines 835.3110); a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test (OPPTS Test Guideline 850.1010); and an algal toxicity test, tiers I and II (OPPTS Test Guideline 850.5400) would help characterize the environmental effects of the PMN substance. 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. EPA recommends that the special considerations for conducting laboratory studies (OPPTS Test Guideline 850.1000) be followed to facilitate solubility in the test media, because of the PMN's low water solubility. Test reports should include protocols approved by EPA, certificate of analysis for the test substance, raw data, and results.

*CFR citation:* 40 CFR 721.10264.

## V. Rationale and Objectives of the Rule

### A. Rationale

During review of the PMNs submitted for the chemical substances that are subject to these SNURs, EPA concluded that for 4 of the 36 chemical substances, regulation was warranted under TSCA section 5(e), pending the development of information sufficient to make reasoned evaluations of the health or environmental effects of the chemical substances. The basis for such findings is outlined in Unit IV. Based on these findings, TSCA section 5(e) consent orders requiring the use of appropriate exposure controls were negotiated with the PMN submitters. The SNUR provisions for these chemical substances are consistent with the provisions of the TSCA section 5(e) consent orders. These SNURs are promulgated pursuant to § 721.160 (see Unit II.).

In the other 32 cases, where the uses are not regulated under a TSCA section

5(e) consent order, EPA determined that one or more of the criteria of concern established at § 721.170 were met, as discussed in Unit IV.

#### B. Objectives

EPA is issuing these SNURs for specific chemical substances which have undergone premanufacture review because the Agency wants to achieve the following objectives with regard to the significant new uses designated in this rule:

- EPA will receive notice of any person's intent to manufacture, import, or process a listed chemical substance for the described significant new use before that activity begins.
- EPA will have an opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing, importing, or processing a listed chemical substance for the described significant new use.
- EPA will be able to regulate prospective manufacturers, importers, or processors of a listed chemical substance before the described significant new use of that chemical substance occurs, provided that regulation is warranted pursuant to TSCA sections 5(e), 5(f), 6, or 7.
- EPA will ensure that all manufacturers, importers, and processors of the same chemical substance that is subject to a TSCA section 5(e) consent order are subject to similar requirements.

Issuance of a SNUR for a chemical substance does not signify that the chemical substance is listed on the TSCA Inventory. Guidance on how to determine if a chemical substance is on the TSCA Inventory is available on the Internet at <http://www.epa.gov/opptintr/newchems/pubs/invntory.htm>.

#### VI. Direct Final Procedures

EPA is issuing these SNURs as a direct final rule, as described in § 721.160(c)(3) and § 721.170(d)(4). In accordance with § 721.160(c)(3)(ii) and § 721.170(d)(4)(i)(B), the effective date of this rule is December 5, 2011 without further notice, unless EPA receives written adverse or critical comments, or notice of intent to submit adverse or critical comments before November 4, 2011.

If EPA receives written adverse or critical comments, or notice of intent to submit adverse or critical comments, on one or more of these SNURs before November 4, 2011, EPA will withdraw the relevant sections of this direct final rule before its effective date. EPA will then issue a proposed SNUR for the chemical substance(s) on which adverse or critical comments were received,

providing a 30-day period for public comment.

This rule establishes SNURs for a number of chemical substances. Any person who submits adverse or critical comments, or notice of intent to submit adverse or critical comments, must identify the chemical substance and the new use to which it applies. EPA will not withdraw a SNUR for a chemical substance not identified in the comment.

#### VII. Applicability of Rule to Uses Occurring Before Effective Date of the Rule

Significant new use designations for a chemical substance are legally established as of the date of publication of this direct final rule, October 5, 2011.

To establish a significant "new" use, EPA must determine that the use is not ongoing. The chemical substances subject to this rule have undergone premanufacture review. TSCA section 5(e) consent orders have been issued for 4 chemical substances and the PMN submitters are prohibited by the TSCA section 5(e) consent orders from undertaking activities which EPA is designating as significant new uses. In cases where EPA has not received a notice of commencement (NOC) and the chemical substance has not been added to the TSCA Inventory, no other person may commence such activities without first submitting a PMN. For chemical substances for which an NOC has not been submitted at this time, EPA concludes that the uses are not ongoing. However, EPA recognizes that prior to the effective date of the rule, when chemical substances identified in this SNUR are added to the TSCA Inventory, other persons may engage in a significant new use as defined in this rule before the effective date of the rule. However, 23 of the 36 chemical substances contained in this rule have CBI chemical identities, and since EPA has received a limited number of post-PMN *bona fide* submissions (per §§ 720.25 and 721.11), the Agency believes that it is highly unlikely that any of the significant new uses described in the regulatory text of this rule are ongoing.

As discussed in the **Federal Register** of April 24, 1990 (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 effective, and then argue that the use was ongoing before the effective date of the rule. Thus, persons who begin commercial manufacture, import, or processing of the chemical substances regulated through this SNUR will have to cease any such activity before the effective date of this rule. To resume their activities, these persons would have to comply with all applicable SNUR notice requirements and wait until the notice review period, including all extensions, expires.

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

#### VIII. Test Data and Other Information

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

1. Development of test data is required where the chemical substance subject to the SNUR is also subject to a test rule under TSCA section 4 (see TSCA section 5(b)(1)).

2. Development of test data may be necessary where the chemical substance has been listed under TSCA section 5(b)(4) (see TSCA section 5(b)(2)).

In the absence of a TSCA section 4 test rule or a TSCA section 5(b)(4) listing covering the chemical substance, persons are required only to submit test data in their possession or control and to describe any other data known to or reasonably ascertainable by them (see § 720.50). However, upon review of PMNs and SNUNs, the Agency has the authority to require appropriate testing. In cases where EPA issued a TSCA section 5(e) consent order that requires or recommends certain testing, Unit IV lists those tests. Unit IV also lists recommended testing for non-5(e) SNURs. Descriptions of tests are provided for informational purposes. EPA strongly encourages persons, before performing any testing, to consult with the Agency pertaining to protocol selection. To access the harmonized test guidelines referenced in this document electronically, please go to <http://www.epa.gov/ocspp> and select "Test Methods and Guidelines." The Organisation for Economic Co-operation and Development (OECD) test guidelines are available from the OECD Bookshop at <http://www.oecdbookshop.org> or SourceOECD at <http://www.sourceoecd.org>. The American Society for Testing and

Materials International (ASTM) standards are available at <http://www.astm.org/Standard/index.shtml>.

In the TSCA section 5(e) consent orders for four of the chemical substances regulated under this rule, EPA has established restrictions 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 restrictions will not be removed until EPA determines that the unrestricted use will not present an unreasonable risk of injury or result in significant or substantial exposure or environmental release. This determination is usually made based on the results of the required or recommended toxicity tests.

The recommended tests specified in Unit IV. may not be the only means of addressing the potential risks of the chemical substance. However, submitting a SNUN without any test data may increase the likelihood that EPA will take action under TSCA section 5(e), particularly if satisfactory test results have not been obtained from a prior PMN or SNUN submitter. EPA recommends that potential SNUN submitters contact EPA early enough so that they will be able to conduct the appropriate tests.

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

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

#### IX. Procedural Determinations

By this rule, EPA is establishing certain significant new uses which have been claimed as CBI subject to Agency confidentiality regulations at 40 CFR part 2 and 40 CFR part 720, subpart E. Absent a final determination or other disposition of the confidentiality claim under 40 CFR part 2 procedures, EPA is required to keep this information confidential. EPA promulgated a procedure to deal with the situation where a specific significant new use is CBI, at 40 CFR 721.1725(b)(1). Today's rules cross-reference § 721.1725(b)(1) (which is similar to the procedure in § 721.11, for situations where the chemical identity of the chemical substance subject to a SNUR is CBI) in each SNUR that includes specific significant new uses that are CBI.

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

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

#### X. SNUN Submissions

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

#### XI. Economic Analysis

EPA has evaluated the potential costs of establishing SNUN requirements for

potential manufacturers, importers, and processors of the chemical substances subject to this rule. EPA's complete economic analysis is available in the docket under docket ID number EPA-HQ-OPPT-2010-1075.

#### XII. Statutory and Executive Order Reviews

##### A. Executive Order 12866

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

##### B. Paperwork Reduction Act

According to the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, an Agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable. EPA is amending the table in 40 CFR part 9 to list the OMB approval number for the information collection requirements contained in this rule. This listing of the OMB control numbers and their subsequent codification in the CFR satisfies the display requirements of PRA and OMB's implementing regulations at 5 CFR part 1320. This Information Collection Request (ICR) was previously subject to public notice and comment prior to OMB approval, and given the technical nature of the table, EPA finds that further notice and comment to amend it is unnecessary. As a result, EPA finds that there is "good cause" under section 553(b)(3)(B) of the Administrative Procedure Act, 5 U.S.C. 553(b)(3)(B), to amend this table without further notice and comment.

The information collection requirements related to this action have already been approved by OMB pursuant to PRA under OMB control number 2070-0012 (EPA ICR No. 574). This action does not impose any burden requiring additional OMB approval. If an entity were to submit a SNUN to the Agency, the annual burden is estimated to average between 30 and 170 hours per response. This burden estimate includes the time needed to review instructions, search existing data sources, gather and maintain the data

needed, and complete, review, and submit the required SNUN.

Send any comments about the accuracy of the burden estimate, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques, to the Director, Collection Strategies Division, Office of Environmental Information (2822T), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. Please remember to include the OMB control number in any correspondence, but do not submit any completed forms to this address.

### C. Regulatory Flexibility Act

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 this SNUR will not have a significant adverse economic impact on a substantial number of small entities. 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 final 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 SNURs covering over 1,000 chemicals, the Agency receives only a handful of notices per year. For example, the number of SNUNs was four in Federal fiscal year 2005, eight in FY2006, six in FY2007, eight in FY2008, and seven in FY2009. During this five-year period, three small entities submitted a SNUN. In addition, the estimated reporting cost for submission of a SNUN (*see* Unit XI.) is minimal regardless of the size of the firm. Therefore, EPA believes that the potential economic impacts of complying with this SNUR are not expected to be significant or adversely impact a substantial number of small entities. In a SNUR that published in the **Federal Register** of June 2, 1997 (62 FR 29684) (FRL-5597-1), the Agency presented its general determination that final SNURs are not expected to have a significant economic impact on a substantial number of small entities, which was provided to the Chief

Counsel for Advocacy of the Small Business Administration.

### D. Unfunded Mandates Reform Act

Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reasons to believe that any State, local, or Tribal government will be impacted by this rule. As such, EPA has determined that this rule does not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the requirements of sections 202, 203, 204, or 205 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4).

### E. Executive Order 13132

This action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999).

### F. Executive Order 13175

This rule does not have Tribal implications because it is not expected to have substantial direct effects on Indian Tribes. This rule does not significantly nor uniquely affect the communities of Indian Tribal governments, nor does it involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000), do not apply to this rule.

### G. Executive Order 13045

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

### H. Executive Order 13211

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

or use and because this action is not a significant regulatory action under Executive Order 12866.

### I. National Technology Transfer and Advancement Act

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

### J. Executive Order 12898

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

## XIII. Congressional Review Act

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

### List of Subjects

#### 40 CFR Part 9

Environmental protection, Reporting and recordkeeping requirements.

#### 40 CFR Part 721

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

Dated: September 23, 2011.

**Wendy C. Hamnett,**

*Director, Office of Pollution Prevention and Toxics.*

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

## PART 9—[AMENDED]

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

**Authority:** 7 U.S.C. 135 *et seq.*, 136-136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601-2671; 21 U.S.C. 331j, 346a, 348; 31 U.S.C. 9701; 33 U.S.C. 1251 *et seq.*, 1311, 1313d, 1314, 1318, 1321, 1326, 1330, 1342, 1344, 1345 (d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971-1975 Comp. p. 973; 42 U.S.C. 241,

242b, 243, 246, 300f, 300g, 300g-1, 300g-2, 300g-3, 300g-4, 300g-5, 300g-6, 300j-1, 300j-2, 300j-3, 300j-4, 300j-9, 1857 *et seq.*, 6901-6992k, 7401-7671q, 7542, 9601-9657, 11023, 11048.

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

**§ 9.1 OMB approvals under the Paperwork Reduction Act.**

40 CFR citation	OMB control No.
* * * * *	
* * * * *	
<b>Significant New Uses of Chemical Substances</b>	
* * * * *	
721.10230 .....	2070-0012
721.10231 .....	2070-0012
721.10232 .....	2070-0012
721.10233 .....	2070-0012
721.10234 .....	2070-0012
721.10235 .....	2070-0012
721.10236 .....	2070-0012
721.10237 .....	2070-0012
721.10238 .....	2070-0012
721.10239 .....	2070-0012
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721.10256 .....	2070-0012
721.10257 .....	2070-0012
721.10258 .....	2070-0012
721.10259 .....	2070-0012
721.10260 .....	2070-0012
721.10261 .....	2070-0012
721.10262 .....	2070-0012
721.10263 .....	2070-0012
721.10264 .....	2070-0012
* * * * *	
* * * * *	

**PART 721—[AMENDED]**

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

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

■ 4. Add § 721.10230 to subpart E to read as follows:

**§ 721.10230 Rutile, tin zinc, calcium-doped.**

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

(1) The chemical substance identified as rutile, tin zinc, calcium-doped (PMN P-06-36; CAS No. 389623-01-2) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this rule do not apply to quantities of the PMN substance that have been incorporated into a polymer, glass, dispersion, cementitious matrix, or a similar incorporation.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(4), (a)(5), (a)(6)(i), (b) (concentration set at 1.0 percent), and (c). The following National Institute for Occupational Safety and Health (NIOSH)-certified respirators with an assigned protection factor (APF) of 10 meet the minimum requirements for § 721.63(a)(5):

(A) NIOSH-certified air-purifying, tight-fitting half-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters;

(B) NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters;

(C) NIOSH-certified powered air-purifying respirator equipped with a loose-fitting hood or helmet and high efficiency particulate air (HEPA) filters;

(D) NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (either half-face or full-face) and HEPA filters; or

(E) NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (either half-face or full-face).

(1) As an alternative to the respiratory requirements listed in paragraph (a)(2)(i), a manufacturer, importer, or processor may choose to follow the new chemical exposure limit (NCEL) provisions listed in the TSCA section 5(e) consent order for these substances. The NCEL is 1.5 mg/m<sup>3</sup> as an 8-hour time-weighted-average for both chemical substances combined. Persons who wish to pursue NCELs as an alternative to the § 721.63 respirator requirements may request to do so under § 721.30. Persons whose § 721.30 requests to use the NCELs approach are approved by EPA will receive NCELs provisions comparable to those contained in the corresponding section 5(e) consent order.

(2) [Reserved]

(ii) *Hazard communication program.* Requirements as specified in

§ 721.72(a), (b), (c), (d), (e) (concentration set at 1.0 percent), (f), (g)(1)(ii), (g)(2)(ii), (g)(2)(iv) (use respiratory protection or maintain workplace airborne concentrations at or below an 8-hour time-weighted average of 1.5 mg/m<sup>3</sup>), and (g)(5).

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k) (manufacture of the substances with a particle size less than 100 nanometers, where d10 particle size presents the particle size, as determined by laser light scattering, at which 10 percent by weight of the substance measured is smaller).

(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.

■ 5. Add § 721.10231 to subpart E to read as follows:

**§ 721.10231 Rutile, tin zinc, sodium-doped.**

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

(1) The chemical substance identified as rutile, tin zinc, sodium-doped (PMN P-06-37; CAS No. 389623-07-8) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this rule do not apply to quantities of the PMN substance that have been incorporated into a polymer, glass, dispersion, cementitious matrix, or a similar incorporation.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(4), (a)(5), (a)(6)(i), (b) (concentration set at 1.0 percent), and (c). The following National Institute for Occupational Safety and Health (NIOSH)-certified respirators with an assigned protection factor (APF) of 10 meet the minimum requirements for § 721.63(a)(5):

(A) NIOSH-certified air-purifying, tight-fitting half-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters;

(B) NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters;

(C) NIOSH-certified powered air-purifying respirator equipped with a

loose-fitting hood or helmet and high efficiency particulate air (HEPA) filters;

(D) NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (either half-face or full-face) and HEPA filters; or

(E) NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (either half-face or full-face).

(1) As an alternative to the respiratory requirements listed in paragraph (a)(2)(i), a manufacturer, importer, or processor may choose to follow the new chemical exposure limit (NCEL) provisions listed in the TSCA section 5(e) consent order for these substances. The NCEL is 1.5 mg/m<sup>3</sup> as an 8-hour time-weighted-average for both chemical substances combined. Persons who wish to pursue NCELS as an alternative to the § 721.63 respirator requirements may request to do so under § 721.30. Persons whose § 721.30 requests to use the NCELS approach are approved by EPA will receive NCELS provisions comparable to those contained in the corresponding section 5(e) consent order.

(2) [Reserved]

(ii) *Hazard communication program.* Requirements as specified in § 721.72(a), (b), (c), (d), (e) (concentration set at 1.0 percent), (f), (g)(1)(ii), (g)(2)(ii), (g)(2)(iv) (use respiratory protection or maintain workplace airborne concentrations at or below an 8-hour time-weighted average of 1.5 mg/m<sup>3</sup>), and (g)(5).

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k) (manufacture of the substances with a particle size less than 100 nanometers, where d<sub>10</sub> particle size presents the particle size, as determined by laser light scattering, at which 10 percent by weight of the substance measured is smaller).

(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.

■ 6. Add § 721.10232 to subpart E to read as follows:

**§ 721.10232 N-arylamino-phenol-formaldehyde condensate (generic).**

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

(1) The chemical substance identified generically as n-arylamino-phenol-formaldehyde condensate (PMN P-08-694) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

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

(ii) [Reserved]

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

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

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

■ 7. Add § 721.10233 to subpart E to read as follows:

**§ 721.10233 Linear alkyl epoxide (generic).**

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

(1) The chemical substance identified generically as linear alkyl epoxide (PMN P-08-704) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

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

(ii) [Reserved]

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

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

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

■ 8. Add § 721.10234 to subpart E to read as follows:

**§ 721.10234 Hydroxy-chloro-cyclopropyl-heteromonocyclic carboxylic acid (generic).**

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

(1) The chemical substance identified generically as hydroxy-chloro-cyclopropyl-heteromonocyclic

carboxylic acid (PMN P-09-61) 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 = 6).

(ii) [Reserved]

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

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

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

■ 9. Add § 721.10235 to subpart E to read as follows:

**§ 721.10235 Phenol, 2-ethoxy-4-(ethoxymethyl)-.**

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

(1) The chemical substance identified as phenol, 2-ethoxy-4-(ethoxymethyl)- (PMN P-09-72; CAS No. 71119-07-8) 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)(4), (b)(4), and (c)(4) (N = 1).

(ii) [Reserved]

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

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

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

■ 10. Add § 721.10236 to subpart E to read as follows:

**§ 721.10236 1-Propanamine, 3-[2-(2-methoxyethoxy)ethoxy]-.**

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

(1) The chemical substance identified as 1-propanamine, 3-[2-(2-methoxyethoxy)ethoxy]- (PMN P-09-139; CAS No. 91933-40-3) 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(j) and (o).

(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. Add § 721.10237 to subpart E to read as follows:

**§ 721.10237 Formaldehyde, polymers with acetone-phenol reaction products and phenol, sodium salts.**

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

(1) The chemical substance identified as formaldehyde, polymers with acetone-phenol reaction products and phenol, sodium salts (PMN P-09-146; CAS No. 1065544-88-8) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this rule do not apply to quantities of the PMN substance that have been completely reacted (cured).

(2) The significant new uses are:

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

(A) Manufacture or import of the PMN substance only where the maximum unbound formaldehyde residual levels and typical polymer weight to weight composition ratios are as specified in the TSCA section 5(e) consent order.

(B) Upon start-up of manufacture of the PMN at any new facility, conduct the American Society for Testing and Materials International (ASTM) E1333-10 test or its equivalent on a representative sample of the finished cured resin product, demonstrating that formaldehyde emissions are less than or equal to 0.04 ppm.

(C) Development and implementation of a written control plan that includes analysis of representative samples to ensure compliance with (a)(2)(i)(A) and (a)(2)(i)(B) of this section.

(D) Manufacturing, processing, distribution, or use of the PMN substance only as described in the TSCA section 5(e) consent order.

(E) Processing or distribution for processing only under the conditions

described in the TSCA section 5(e) consent order and which are capable of irreversibly curing the PMN substance into a thermoset polymer matrix.

(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. Add § 721.10238 to subpart E to read as follows:

**§ 721.10238 Formaldehyde, polymers with acetone-phenol reaction products and phenol, potassium sodium salts.**

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

(1) The chemical substance identified as formaldehyde, polymers with acetone-phenol reaction products and phenol, potassium sodium salts (PMN P-09-147; CAS No. 1072227-60-1) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this rule do not apply to quantities of the PMN substance that have been completely reacted (cured).

(2) The significant new uses are:

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

(A) Manufacture or import of the PMN substance only where the maximum unbound formaldehyde residual levels and typical polymer weight to weight composition ratios are as specified in the TSCA section 5(e) consent order.

(B) Upon start-up of manufacture of the PMN at any new facility, conduct the American Society for Testing and Materials International (ASTM) E1333-10 test or its equivalent on a representative sample of the finished cured resin product, demonstrating that formaldehyde emissions are less than or equal to 0.04 ppm.

(C) Development and implementation of a written control plan that includes analysis of representative samples to ensure compliance with (a)(2)(i)(A) and (a)(2)(i)(B) of this section.

(D) Manufacturing, processing, distribution, or use of the PMN substance only as described in the TSCA section 5(e) consent order.

(E) Processing or distribution for processing only under the conditions

described in the TSCA section 5(e) consent order and which are capable of irreversibly curing the PMN substance into a thermoset polymer matrix.

(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.

■ 13. Add § 721.10239 to subpart E to read as follows:

**§ 721.10239 Trivalent chromium complexes of a substituted beta-naphthol amine azo dye (generic).**

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

(1) The chemical substance identified generically as trivalent chromium complexes of a substituted beta-naphthol amine azo dye (PMNs P-09-152 and P-09-153) are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f) and (j) (acid dye for coloring anodized aluminum). Also, requirements as specified in § 721.80(v)(1), (v)(2), (w)(1), (w)(2), (x)(1), and (x)(2), except that importing, processing, and use of the PMN substance in the form of a wet press cake containing greater than 30 percent water does not require submission of a SNUN.

(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.

■ 14. Add § 721.10240 to subpart E to read as follows:

**§ 721.10240 Olefinic carbocycle, reaction products with alkoxysilane (generic).**

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

(1) The chemical substance identified generically as olefinic carbocycle, reaction products with alkoxysilane (PMN P-09-154) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

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

(ii) [Reserved]

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

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

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

■ 15. Add § 721.10241 to subpart E to read as follows:

**§ 721.10241 Olefinic carbocycle, reaction products with alkoxysilane, sulfurized (generic).**

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

(1) The chemical substance identified generically as olefinic carbocycle, reaction products with alkoxysilane, sulfurized (PMN P-09-155) 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.

■ 16. Add § 721.10242 to subpart E to read as follows:

**§ 721.10242 Olefinic carbocycle, reaction products with alkoxysilane, polysulfurized (generic).**

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

(1) The chemical substance identified generically as olefinic carbocycle, reaction products with alkoxysilane, polysulfurized (PMN P-09-156) 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.

■ 17. Add § 721.10243 to subpart E to read as follows:

**§ 721.10243 Phosphonic acid, P-[2-[bis(2-hydroxyethyl)amino]ethyl]-, bis(2-chloroethyl) ester.**

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

(1) The chemical substance identified as phosphonic acid, P-[2-[bis(2-hydroxyethyl)amino]ethyl]-, bis(2-chloroethyl) ester (PMN P-09-193; CAS No. 55088-28-3) 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) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i), (a)(3), (b) (concentration set at 0.1 percent), and (c).

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(j) (intermediate in the manufacture of a polyurethane flame retardant).

(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.

■ 18. Add § 721.10244 to subpart E to read as follows:

**§ 721.10244 Phosphonic acid, P-[2-[bis(2-hydroxyethyl)amino]ethyl]-, 2-[bis(2-chloroethoxy)phosphinyl]ethyl 2-chloroethyl ester.**

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

(1) The chemical substance identified as phosphonic acid, P-[2-[bis(2-hydroxyethyl)amino]ethyl]-, 2-[bis(2-chloroethoxy)phosphinyl]ethyl 2-chloroethyl ester (PMN P-09-195; CAS No. 1094213-37-2) 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) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i), (a)(3), (b) (concentration set at 0.1 percent), and (c).

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(j) (intermediate in the manufacture of a polyurethane flame retardant).

(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.

■ 19. Add § 721.10245 to subpart E to read as follows:

**§ 721.10245 Branched and linear fatty alcohol ethoxylate (generic).**

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

(1) The chemical substance identified generically as branched and linear fatty alcohol ethoxylate (PMN P-09-207) 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) (site-limited, isolated, chemical intermediate).

(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. Add § 721.10246 to subpart E to read as follows:

**§ 721.10246 Alkylpolyhydroxy polymer (generic).**

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

(1) The chemical substance identified generically as alkylpolyhydroxy polymer (PMN P-09-234) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

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

■ 21. Add § 721.10247 to subpart E to read as follows:

**§ 721.10247 Bis-phenoxyethanol fluorene diacrylate (generic).**

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

(1) The chemical substance identified generically as bis-phenoxyethanol fluorene diacrylate (PMN P-09-258) 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.

■ 22. Add § 721.10248 to subpart E to read as follows:

**§ 721.10248 Aromatic bromide (generic).**

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

(1) The chemical substance identified generically as aromatic bromide (PMN P-09-259) 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) (synthetic intermediate).

(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.

■ 23. Add § 721.10249 to subpart E to read as follows:

**§ 721.10249 Disubstituted phenol (generic).**

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

(1) The chemical substance identified generically as disubstituted phenol (PMN P-09-316) 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) and (s) (100 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.

■ 24. Add § 721.10250 to subpart E to read as follows:

**§ 721.10250 Zirconium lysine complex (generic).**

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

(1) The chemical substance identified generically as zirconium lysine complex (PMN P-09-356) 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 = 120).

(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.

■ 25. Add § 721.10251 to subpart E to read as follows:

**§ 721.10251 Fatty acids, reaction products with alkanolamine (generic).**

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

(1) The chemical substance identified generically as fatty acids, reaction products with alkanolamine (PMN P-09-366) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

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

(ii) [Reserved]

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

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

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

■ 26. Add § 721.10252 to subpart E to read as follows:

**§ 721.10252 Thiosulfuric acid (H<sub>2</sub>S<sub>2</sub>O<sub>3</sub>), manganese(2+) salt (1:1).**

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

(1) The chemical substance identified as thiosulfuric acid (H<sub>2</sub>S<sub>2</sub>O<sub>3</sub>), manganese(2+) salt (1:1) (PMN P-09-373; CAS No. 1033050-53-1) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) (N = 400).

(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.

■ 27. Add § 721.10253 to subpart E to read as follows:

**§ 721.10253 Butanedioic acid, 2-methylene-, polymer with 2,5 furanedione, copper(2+) manganese(2+) sodium zinc salt, hydrogen peroxide-initiated.**

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

(1) The chemical substance identified as butanedioic acid, 2-methylene-, polymer with 2,5 furanedione, copper(2+) manganese(2+) sodium zinc salt, hydrogen peroxide-initiated (PMN P-09-388; CAS No. 1134078-27-5) 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) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) (N = 34).

(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.

■ 28. Add § 721.10254 to subpart E to read as follows:

**§ 721.10254 Substituted acrylamide (generic).**

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

(1) The chemical substance identified generically as substituted acrylamide (PMN P-09-390) 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 = 21).

(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. Add § 721.10255 to subpart E to read as follows:

**§ 721.10255 Vinyl carboxylic acid ester (generic).**

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

(1) The chemical substance identified generically as vinyl carboxylic acid ester (PMN P-09-400) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(s) (100,000 kilograms).

(ii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) (N = 15).

(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.

■ 30. Add § 721.10256 to subpart E to read as follows:

**§ 721.10256 Benzoic acid, 4-(dimethylamino)-, 1,1'-[(methylimino)di-2,1-ethanediy] ester.**

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

(1) The chemical substance identified as benzoic acid, 4-(dimethylamino)-, 1,1'-[(methylimino)di-2,1-ethanediy] ester (PMN P-09-479; CAS No. 925246-00-0) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

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

(ii) [Reserved]

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

(1) *Recordkeeping.* 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. Add § 721.10257 to subpart E to read as follows:

**§ 721.10257 Butyl aromatic bisurea (generic).**

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

(1) The chemical substance identified generically as butyl aromatic bisurea (PMN P-09-532) 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. Add § 721.10258 to subpart E to read as follows:

**§ 721.10258 Aromatic hydrocarbon (generic).**

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

(1) The chemical substance identified generically as aromatic hydrocarbon (PMN P-09-535) 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.

■ 33. Add § 721.10259 to subpart E to read as follows:

**§ 721.10259 Halogenated aromatic hydrocarbon (generic).**

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

(1) The chemical substance identified generically as halogenated aromatic hydrocarbon (PMN P-09-540) 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.

■ 34. Add § 721.10260 to subpart E to read as follows:

**§ 721.10260 Benzene, 1,3-bis(1-chloro-1-methylethyl)-.**

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

(1) The chemical substance identified as benzene, 1,3-bis(1-chloro-1-methylethyl)- (PMN P-09-552; CAS No. 37133-18-9) 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. Add § 721.10261 to subpart E to read as follows:

**§ 721.10261 Oxime, di-Me silane (generic).**

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

(1) The chemical substance identified generically as oxime, di-Me silane (PMN P-09-589) 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), (b) (concentration set at 0.1 percent), and (c).

(ii) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(s) (20,000 kilograms).

(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.

■ 36. Add § 721.10262 to subpart E to read as follows:

**§ 721.10262 Oxime, Me vinyl silane (generic).**

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

(1) The chemical substance identified generically as oxime, Me vinyl silane (PMN P-09-590) 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), (b) (concentration set at 0.1 percent), and (c).

(ii) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(s) (20,000 kilograms).

(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.

■ 37. Add § 721.10263 to subpart E to read as follows:

**§ 721.10263 Phenol, 4-(1,1-dimethylethyl)-2-nitro-.**

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

(1) The chemical substance identified as phenol, 4-(1,1-dimethylethyl)-2-nitro- (PMN P-09-634; CAS No. 3279-07-0) 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(j) (raw material (reactant) for production of intermediate for a photographic chemical).

(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.

■ 38. Add § 721.10264 to subpart E to read as follows:

**§ 721.10264 Polycarbocyclic methacrylate (generic).**

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

(1) The chemical substance identified generically as polycarbocyclic methacrylate (PMN P-10-343) 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.

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2011-0053; FRL-8884-2]

### Prothioconazole; Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of prothioconazole in or on multiple commodities which are identified and discussed later in this document. Bayer CropScience requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective October 5, 2011. Objections and requests for hearings must be received on or before December 5, 2011, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2011-0053. 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., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only

available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:** Tawanda Maignan, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; *telephone number:* (703) 308-8050; *e-mail address:* [maignan.tawanda@epa.gov](mailto:maignan.tawanda@epa.gov).

### SUPPLEMENTARY INFORMATION:

#### I. General Information

##### A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather to provide 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. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

##### B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at [http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl).

##### C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection

or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2011-0053 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before December 5, 2011. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-OPP-2011-0053, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.
- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

#### II. Summary of Petitioned-For Tolerance

In the **Federal Register** of March 29, 2011 (76 FR 17375) (FRL-8867-4), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PPs 0F7714 and 0F7715) by Bayer CropScience, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.626 be amended by establishing tolerances for residues of the fungicide prothioconazole, 2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione and its desthio metabolite, in or on the raw or processed agricultural commodity rice,