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40 CFR Part 721

[OPPTS–50623; FRL–4964–3]

RIN 2070–AB27

Significant New Uses of Certain Chemical Substances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is promulgating significant new use rules (SNURs) under section 5(a)(2) of the Toxic Substances Control Act (TSCA) for certain chemical substances which were the subject of premanufacture notices (PMNs) and subject to TSCA section 5(e) consent orders issued by EPA. Today's action requires persons who intend to manufacture, import, or process these substances for a significant new use to notify EPA at least 90 days before commencing the manufacturing or processing of the substance for a use designated by this SNUR as a significant new use. The required notice will provide EPA with the opportunity to evaluate the intended use, and if necessary, to prohibit or limit that activity before it occurs. EPA is promulgating this SNUR using direct final procedures.

DATES: The effective date of this rule is January 31, 1997. This rule shall be promulgated for purposes of judicial review at 1 p.m. (e.s.t.) on December 16, 1996.

If EPA receives notice before January 2, 1997 that someone wishes to submit adverse or critical comments on EPA's action in establishing a SNUR for one or more of the chemical substances subject to this rule, EPA will withdraw the SNUR for the substance for which the notice of intent to comment is received and will issue a proposed SNUR providing a 30-day period for public comment.

ADDRESSES: Each comment or notice of intent to submit adverse or critical comment must bear the docket control number OPPTS–50623 and the name(s) of the chemical substance(s) subject to the comment. All comments should be sent in triplicate to: OPPT Document Control Officer (7407), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M Street, SW., Room G–099, East Tower, Washington, DC 20460.

All comments which are claimed confidential must be clearly marked as such. Three additional sanitized copies of any comments containing confidential business information (CBI) must also be submitted. Nonconfidential versions of comments on this rule will be placed in the rulemaking record and will be available for public inspection. Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: oppt.ncic@epamail.epa.gov. Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

Comments and data will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number 50623. No CBI should be submitted through e-mail. Electronic comments on this final rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found in Unit X of this document.

FOR FURTHER INFORMATION CONTACT: Susan Hazen, Director, Environmental Assistance Division (7408), Office of Toxic Substances, Environmental Protection Agency, Rm. E–543B, 401 M St., SW., Washington, DC 20460, telephone: (202) 554–1404, TDD: (202) 554–0551; e-mail: TSCA-Hotline@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: This SNUR will require persons to notify EPA at least 90 days before commencing manufacturing or processing a substance for any activity designated by this SNUR as a significant new use. The supporting rationale and background to this rule are more fully set out in the preamble to EPA's first direct final SNURs 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 the rules and on the basis for significant new use designations including provisions for developing test data.

I. Authority

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a ''significant new use.'' EPA must make this determination by rule after considering all relevant factors, including those listed in section 5(a)(2). Once EPA determines that a use of a chemical substance is a significant new use, section 5(a)(1)(B) of TSCA requires persons to submit a notice to EPA at least 90 days before they manufacture, import, or process the substance for that use. The mechanism for reporting under this requirement is established under 40 CFR 721.10.

II. Applicability of General Provisions

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

Persons who intend to export a substance identified in a proposed or final SNUR are subject to the export notification provisions of TSCA section 12(b). The regulations that interpret section 12(b) appear at 40 CFR part 707. Persons who intend to import a chemical substance identified in a final SNUR are subject to the TSCA section 13 import certification requirements, which are codified at 19 CFR 12.118 through 12.127 and 127.28. Such persons must certify that they are in compliance with SNUR requirements. The EPA policy in support of the import certification appears at 40 CFR part 707.

III. Substances Subject to This Rule

EPA is establishing significant new use and recordkeeping requirements for the following chemical substances under 40 CFR part 721, subpart E. In this unit, EPA provides a brief description for each substance, including its PMN number, chemical name (generic name if the specific name is claimed as CBI), CAS number (if assigned), basis for the action taken by EPA in the section 5(e) consent order or as a non-section 5(e) SNUR for the substance (including the statutory citation and specific finding), toxicity concern, and the CFR citation assigned in the regulatory text section of this rule. The specific uses which are designated as significant new uses are cited in the regulatory text section of this document by reference to 40 CFR part 721, subpart B where the significant

new uses are described in detail. Certain new uses, including production limits and other uses designated in the rule are claimed as CBI. The procedure for obtaining confidential information is set out in Unit VII of this preamble.

Where the underlying section 5(e) order prohibits the PMN submitter from exceeding a specified production limit without performing specific tests to determine the health or environmental effects of a substance, the tests are described in this unit. As explained further in Unit VI of this preamble, the SNUR for such substances contains the same production limit, and exceeding the production limit is defined as a significant new use. Persons who intend to exceed the production limit must notify the Agency by submitting a significant new use notice (SNUN) at least 90 days in advance. In addition, this unit describes tests that are recommended by EPA to provide sufficient information to evaluate the substance, but for which no production limit has been established in the section 5(e) order. Descriptions of recommended tests are provided for informational purposes.

Data on potential exposures or releases of the substances, testing other than that specified in the section 5(e) order for the substances, or studies on analogous substances, which may demonstrate that the significant new uses being reported do not present an unreasonable risk, may be included with significant new use notification. Persons submitting a SNUN must comply with the same notice requirements and EPA regulatory procedures as submitters of PMNs, as stated in 40 CFR 721.1(c), including submission of test data on health and environmental effects as described in 40 CFR 720.50.

EPA is not publishing SNURs for PMNs P–94–357, P–94–658, P–95–1777, P–94–1779, P–94–1799/1800/1801, P–94–2237, P–95–92, P–95–142, and P–95–143 which are subject to a final TSCA section 5(e) consent order. The section 5(e) consent orders for these substances are derived from an exposure finding based solely on substantial production volume and significant or substantial human exposure and/or release to the environment of substantial quantities. For these cases there were limited or no toxicity data available for the PMN substances. In such cases, EPA regulates the new chemical substances under section 5(e) by requiring certain toxicity tests. For instance, chemical substances with potentially substantial releases to surface waters would be subject to toxicity testing of aquatic organisms and chemicals with potentially substantial human exposures would be subject to health effects testing for mutagenicity, acute effects, and subchronic effects. However, for these substances, the short-term toxicity testing required by the section 5(e) order is usually completed within 1 to 2 years of notice of commencement. EPA's experience with exposure-based SNURs requiring short-term testing is that the SNUR is often revoked within 1 to 2 years when the test results are received. Rather than issue and revoke SNURs in such a short span of time, EPA will defer publication of exposure-based SNURs until either a notice of commencement (NOC) or data demonstrating risk are received unless the toxicity testing required is long-term. EPA is issuing this explanation and notification as required in 40 CFR 721.160(a)(2) as it has determined that SNURs are not needed at this time for these substances which are subject to a final section 5(e) consent order under TSCA.

PMN Numbers P–91–1210 and P–92–714

Chemical name: (generic) Aliphatic polyisocyanates.
CAS number: Not available.
Effective date of section 5(e) consent order: April 26, 1995.
Basis for section 5(e) consent order: The order was issued under section 5(e)(1)(A)(i) and (e)(1)(A)(ii)(I) of TSCA based on a finding that this substance may present an unreasonable risk of injury to human health.
Toxicity concern: Test data on the substances and similar isocyanates have shown them to cause skin sensitization and chronic lung toxicity in test animals.
Recommended testing: EPA has determined that the results of a 90-day chronic inhalation toxicity study (40 CFR 798.3260) would help to characterize the possible human health risks caused by the manufacture, import, processsing, and use of the PMN substances.
CFR citation: 40 CFR 721.4497.

PMN Numbers P–91–1299, P–95–1667, P–95–1298, and P–95–1297

Chemical name: l-Aspartic acid, homopolymer and ammonium and potassium salts.
CAS number: 25608–40–6 (P–91–1299 and P–95–1667) and 64723–18–8 (P–91–1298).
Effective date of section 5(e) consent order: March 29, 1993.
Basis for section 5(e) consent order: The order was issued under section 5 (e)(1)(A)(i), (e)(1)(A)(ii)(I), and (e)(1)(A)(ii)(II), of TSCA based on findings that this substance is expected to be produced in substantial quantities and there may be significant or substantial human exposure to the substances.
Recommended testing: EPA has determined that a 28-day oral study (OECD 407), an acute oral study (OPPTS 870.1100 test guideline), an ames assay (40 CFR 798.5265), a mouse micronucleus assay by the intraperitoneal route (40 CFR 798.5395), and a developmental toxicity study in one species by the oral route (40 CFR 798.4900), would help characterize possible environmental effects of the substance. The PMN submitter of P–91–1297, P–91–1298, and P–91–1299 has agreed not to exceed the production volume limit without performing these tests on one of the PMN substances.
CFR citation: 40 CFR 721.979.

PMN Number P–93–1694

Chemical name: 3-(Dichloroacetyl)-5-(2-furanyl)-2,2-dimethyloxazolidine.
CAS number: 121776–57–6.
Effective date of section 5(e) consent order: November 29, 1994.
Basis for section 5(e) consent order: The order was issued under section 5 (e)(1)(A)(i) and (e)(1)(A)(ii)(I) of TSCA based on a finding that this substance may present an unreasonable risk of injury to human health and the environment.
Toxicity concern: The PMN substance and similar chemicals have been shown to cause oncogenicity, maternal and developmental toxicity, reproductive toxicity, systemic toxicity (liver and thymus), and environmental toxicity in test organisms.
Recommended testing: No testing recommended. Data on potential exposures or releases of the substance, testing other than that specified in the section 5(e) order for the substance, or studies on analogous substances, which may demonstrate that the significant new uses being reported do not present an unreasonable risk, may be included with significant new use notification.
CFR citation: 40 CFR 721.5545.

PMN Number P–94–351

Chemical name: (generic) Halogenated indane.
CAS number: Not available.
Effective date of section 5(e) consent order: January 30, 1995.
Basis for section 5(e) consent order: The order was issued under section 5 (e)(1)(A)(i) and (e)(1)(A)(ii)(I) of TSCA based on a finding that this substance may present an unreasonable risk of injury to health.
Toxicity concern: Similar chemicals have been shown to cause oncogenicity

in test organisms. Laboratory animal and human epidemiological studies of halogenated dibenzodioxins and dibenzofurans have shown mutagenic and oncogenic effects; these may form as a by-product of manufacture of the PMN substance or during the incineration of the polymer matrices that contain the PMN substance.
Recommended testing: (1) Dioxin/Furan contamination study; and (2) incineration simulation testing (protocol guidelines are available in the March 29, 1991, Midwest Research Institute report entitled ''Guidelines for the Determination of Polyhalogenated Dibenzo-para-Dioxins and Dibenzofurans in PMN Substances, Selected Waste Streams, and Simulated Incinerator Emissions'') would help characterize the potential for dioxin and furan formation through incineration of polymer matrices containing the PMN substance. EPA feels a 90-day subchronic toxicity study (40 CFR 798.2650) would help EPA characterize the human health effects of the PMN substance. The PMN submitter has agreed not to exceed the first production volume limit without performing the dioxin/furan contamination study. The PMN submitter has also agreed not to exceed the second and third higher production volume limits without performing incineration simulation testing and the 90-day subchronic toxicity study.
CFR citation: 40 CFR 721.4484.

PMN Number P–94–437

Chemical name: (generic) Polycyclic isocyanate.
CAS number: Not available.
Effective date of section 5(e) consent order: March 14, 1995.
Basis for section 5(e) consent order: The order was issued under section 5 (e)(1)(A)(i) and (e)(1)(A)(ii)(I) of TSCA based on a finding that this substance may present an unreasonable risk of injury to human health and the environment.
Toxicity concern: Similar chemicals have been shown to cause pulmonary sensitization and lung effects in test animals. The PMN substance itself has been shown to cause dermal sensitization in test animals. In addition, based on structure activity relationship (SAR) predictions for isocyanates, there is concern that the substance may cause toxicity to aquatic organisms at concentrations above 5 ppb.
Recommended testing: A 90-day subchronic toxicity study conducted via the inhalation route (rats) as described at 40 CFR 798.2450 and a pulmonary sensitization study conducted either by the Karol method (*Toxicology and Applied Pharmacology* 68:229–241 (1983)) or an equivalent method are needed to help characterize the lung effects and pulmonary sensitization, respectively. An acute algal (40 CFR 797.1050), an acute daphnid (40 CFR 797.1300), and an acute fish (40 CFR 797.1400) study are needed to help characterize the aquatic toxicity effects of the PMN substance. The PMN submitter has agreed not to exceed a production volume limit without performing the 90-day subchronic and pulmonary sensitization studies.
CFR citation: 40 CFR 721.4494.

PMN Number P–94–1557

Chemical name: (generic) Hydrated alkaline earth metal salts of metalloid oxyanions.
CAS number: Not available.
Effective date of section 5(e) consent order: May 12, 1995.
Basis for section 5(e) consent order: The order was issued under section 5 (e)(1)(A)(i), (e)(1)(A)(ii)(I), and (e)(1)(A)(ii)(II) of TSCA based on a finding that this substance may present an unreasonable risk of injury to human health, is expected to be produced in substantial quantities, and may reasonably be expected to enter the environment in substantial quantities.
Toxicity concern: Similar chemicals have been shown to cause acute toxicity, reproductive toxicity, developmental toxicity, kidney and liver effects, and spleen, blood and adrenal toxicity in test animals.
Recommended testing: EPA has determined that a 90-day subchronic toxicity study (OPPTS 870.3100 test guidelines), developmental toxicity study (40 CFR 798.4900), an acute algal study (40 CFR 797.1050), and an activated sludge sorption isotherm study (OPPTS 835.1110 test guideline) would help characterize the human health and environmental effects of the substance. The PMN submitter has agreed not to exceed a specified production volume limit without performing the acute algal and activated sludge adsorption isotherm studies.
CFR citation: 40 CFR 721.4468.

PMN Numbers P–94–1634/1635/1636/1637/1638/1639

Chemical name: Fatty acids, C(14-18)-unsaturated, branched and linear, methyl and butyl esters.
CAS number: Not available.
Effective date of section 5(e) consent order: September 28, 1994.
Basis for section 5(e) consent order: The order was issued under section 5 (e)(1)(A)(i) and (e)(1)(A)(ii)(II), of TSCA based on findings that this substance is expected to be produced in substantial quantities, and may reasonably be expected to enter the environment in substantial quantities.
Recommended testing: EPA has also determined that a one-species developmental toxicity study (40 CFR 798.4900) by the oral route would help characterize possible health effects of the substance. The PMN submitter has agreed not to exceed the production volume limit without performing this test on P–94–1639.
CFR citation: 40 CFR 721.3628.

PMN Number P–94–1744

Chemical name: (generic) Substituted benzotriazole.
CAS number: Not available.
Effective date of section 5(e) consent order: February 3, 1995.
Basis for section 5(e) consent order: The order was issued under section 5 (e)(1)(A)(i) and (e)(1)(A)(ii)(I) of TSCA based on a finding that this substance may present an unreasonable risk of injury to human health.
Toxicity concern: Similar substances have been shown to cause systemic effects and reproductive toxicity in test animals.
Recommended testing: 90-day oral (gavage) subchronic study (as described in 40 CFR 798.2650). The PMN submitter has agreed not to exceed the production limit without performing this test.
CFR citation: 40 CFR 721.1738.

PMN Number P–94–1747

Chemical name: (generic) Halogenated alkane aromatic compound.
CAS number: Not available.
Effective date of section 5(e) consent order: February 8, 1995.
Basis for section 5(e) consent order: The order was issued under section 5 (e)(1)(A)(i), (e)(1)(A)(ii)(I), and (e)(1)(A)(ii)(II) of TSCA based on findings that this substance may present an unreasonable risk of injury to health and the environment, and that the substance will be produced in substantial quantities and there may be significant (or substantial) human exposure to the substance.
Toxicity concern: Similar substances have been shown to cause cancer, developmental toxicity, and reproductive toxicity in test animals, and toxicity to fish.
Recommended testing: Incineration testing (MRI guidelines, or comparable EPA-approved protocol) to help characterize health effects. The PMN submitter has agreed not to exceed the production limit without performing this test.

In addition, EPA has determined that the following tests would be necessary

to evaluate possible aquatic toxicity: (1) fish bioconcentration test (OPPTS 850.1730 test guideline), (2) fish early life stage toxicity test (40 CFR 797.1600), (3) algal acute toxicity test (40 CFR 797.1050), (4) daphnid chronic toxicity test (40 CFR 797.1330), (5) oyster acute toxicity test (OPPTS 850.1025 test guideline), (6) tadpole/sediment subchronic test (OPPTS 850.1800 test guideline), and (7) chironamid sediment invertebrate test (OPPTS 850.1790 test guideline). The above aquatic toxicity tests would be required on the likely photolysis products or, in the absence of degradation, the parent PMN substance. The following information is required to identify the test species to be used in the above aquatic tests before testing commences: Laboratory determination of direct photolysis reaction quantum yield in aqueous solution and sunlight photolysis (OPPTS 835.2210 test guideline) and gas phase absorption spectra and photolysis (OPPTS 835.2310 test guideline).

In addition, a 2-year rodent bioassay (40 CFR 798.3300) would be necessary to evaluate the carcinogenic effects which may be caused by the PMN substance, and a soil/sediment adsorption (adsorption isotherm) test (40 CFR 796.2750) would be required to evaluate potential for leaching of the PMN substance from landfills to ground water sources.
CFR citation: 40 CFR 721.785.

PMN Number P–94–2061

Chemical name: (generic) Benzotriazole derivative.
CAS number: Not available.
Effective date of section 5(e) consent order: February 8, 1995.
Basis for section 5(e) consent order: The order was issued under section 5 (e)(1)(A)(i) and (e)(1)(A)(ii)(I) of TSCA based on a finding that this substance may present an unreasonable risk of injury to human health.
Toxicity concern: Similar chemicals have been shown to cause systemic toxicity (organ effects, immunotoxicity, blood effects) and reproductive toxicity in test animals. Neurotoxicity was indicated by acute studies on this chemical substance.
Recommended testing: A 90-day gavage study in rats (40 CFR 798.2650). The PMN submitter has agreed not to exceed the production volume limit without performing this test.
CFR citation: 40 CFR 721.1737.

PMN Numbers P–95–116/96–1250 and P–96–117/96–1251

Chemical name: (generic) Isothiazolinone derivatives.
CAS number: Not available.
Basis for action: The PMN substances will be used as preservatives. Based on analogy of the substances to isothiazolones, EPA is concerned that toxicity to aquatic organisms may occur at a concentrations as low as 10 ppb of the PMN substances in surface waters. Based on analogy of the substances similar substances, EPA is concerned for acute lethality, corrosion, developmental toxicity, liver toxicity, sensitization, and cancer to exposed workers. EPA determined that use of the substances as described in the PMN did not present an unreasonable risk because the substances would not be released to surface waters above a concentration of 10 ppb and significant worker exposure would not occur because the substance was not manufactured domestically. EPA has determined that other uses of the substances may result in releases to surface waters which exceed the concern concentration and significant worker exposure. Based on this information the PMN substances meet the concern criteria at § 721.170 (b)(3)(ii) and (b)(4)(ii).
Recommended testing: EPA has determined that a fish acute toxicity study (40 CFR 797.1400), a daphnid acute toxicity study (40 CFR 797.1300), and an algal toxicity study (40 CFR 797.1050) would help characterize the environmental effects of the PMN substance. EPA has determined that a developmental toxicity study (40 CFR 798.4900) and a 90-day subchronic study (40 CFR 797.2650) would help characterize the health effects of the PMN substance.
CFR citation: 40 CFR 721.4525.

PMN Number P–95–175

Chemical name: (generic) Substituted purine metal salt.
CAS number: Not available.
Basis for action: The PMN substance will be used as a contained-use component of a manufactured consumer article. Based on analogy to purines and similar chemicals, EPA is concerned that toxicity to aquatic organisms may occur at concentrations as low as 8 ppb of the PMN substance in surface waters. EPA determined that use of the substance did not present an unreasonable risk because because the substance was not released to surface waters above 8 ppb. EPA has determined that releases to surface water above 8 ppb of the substance may result in significant environmental exposure. Based on this information the PMN substance meets the concern criteria at § 721.170(b)(4)(ii).
Recommended testing: EPA has determined that a fish acute toxicity study (40 CFR 797.1400), a daphnid acute toxicity study (40 CFR 797.1300), and an algal acute toxicity study (40 CFR 797.1050) would help characterize the environmental effects of the PMN substance.
CFR citation: 40 CFR 721.4685.

PMN Number P–95–240

Chemical name: (generic) Azo chromium complex dyestuff preparation.
CAS number: Not available.
Basis for action: The PMN substance will be used as described in the PMN. Based on analogy to similar compounds, the PMN substance may cause cancer, neurotoxicity, and kidney toxicity. EPA has determined that persons exposed by inhalation to the PMN substance may be at risk for cancer, neurotoxicity, and kidney toxicity. EPA determined that use of the substance as a liquid did not present an unreasonable risk because there were no significant inhalation exposures. EPA has determined that use of the substance in a solid or powder form may result in significant inhalation exposures. Based on this information the PMN substance meets the concern criteria at § 721.170 (b)(1)(i)(C) and (b)(3)(ii).
Recommended testing: EPA has determined that a 2-year two-species oral bioassay (40 CFR 798.3300) and a 90-day subchronic oral study in rats (40 CFR 798.2650) would help characterize the health effects of the PMN substance.
CFR citation: 40 CFR 721.2097.

PMN Number P–95–241

Chemical name: (generic) Perfluoroalkylethyl acrylate copolymer.
CAS number: Not available.
Basis for action: The PMN substance will be used as a water and oil repellent. Based on analogy to perfluoro compounds, the PMN substance may cause lung toxicity. EPA has determined that persons exposed by inhalation to the PMN substance may be at risk for lung toxicity. EPA determined that use of the substance as described in the PMN did not present an unreasonable risk because there were no significant inhalation exposures. EPA has determined that use of the substance in an application that generates a vapor, mist, or aerosol may result in significant inhalation exposures. Based on this information the PMN substance meets the concern criteria at § 721.170(b)(3)(ii).
Recommended testing: EPA has determined that a 90-day subchronic inhalation study in rats (40 CFR

798.2650) would help characterize the health effects of the PMN substance.
CFR citation: 40 CFR 721.336.

PMN Number P–95–274

Chemical name: (generic) Phenylenebis[imino(chlorotriazinyl) imino(substituted naphthyl)azo(substituted phenyl) azo, sodium salt.
CAS number: Not available.
Basis for action: The PMN substance will be used as a textile dye. Based on analogy to similar substances, EPA is concerned that respiratory sensitization will occur in exposed workers. EPA determined that use of the substance did not present an unreasonable risk because significant worker exposure would not occur since the substance was not manufactured domestically. EPA has determined that domestic manufacture of the substance may result in significant worker exposure. Based on this information the PMN substance meets the concern criteria at § 721.170(b)(3)(ii).
Recommended testing: EPA has determined that a respiratory sensitization study (*Fundamental and Applied Toxicology* 18:107–114) would help characterize the health effects of the PMN substance.
CFR citation: 40 CFR 721.5930.

PMN Number P–95–284

Chemical name: (generic) Phosphoric acid derivative.
CAS number: Not available.
Basis for action: The PMN substance will be used as an intermediate. Based on analogy to aliphatic amines, EPA is concerned that toxicity to aquatic organisms may occur at a concentration as low as 1 ppb of the PMN substance in surface waters. EPA determined that use of the substance as described in the PMN did not present an unreasonable risk because the substance would not be released to surface waters. EPA has determined that other uses of the substance may result in releases to surface waters which exceed the concern concentration. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(ii).
Recommended testing: EPA has determined that a fish acute toxicity study (40 CFR 797.1400), a daphnid acute toxicity study (40 CFR 797.1300) and an algal acute toxicity study (40 CFR 797.1050) would help characterize the environmental effects of the PMN substance.
CFR citation: 40 CFR 721.6097.

PMN Numbers P–95–510/511

Chemical name: (generic) [(Disubstituted phenyl)]azodihydro hydroxyalkyloxoalkyl substituted pyridines.
CAS number: Not available.
Basis for action: The PMN substances will be used as textile dyes. Based on analogy to similar substances and submitted toxicity data, EPA is concerned that liver toxicity, kidney toxicity, cancer, and reproductive toxicity will occur in exposed workers. EPA determined that use of the substances did not present an unreasonable risk because significant worker exposure would not occur because the substances were not manufactured domestically. EPA has determined that domestic manufacture of the substances may result in significant worker exposure. Based on this information the PMN substance meets the concern criteria at § 721.170 (b)(1)(i)(B), (b)(1)(i)(C), (b)(3)(i), and (b)(3)(ii).
Recommended testing: EPA has determined that a 2-year two-species oral bioassay (40 CFR 798.3300), a two-generation reproduction study (40 CFR 798.4700), and a 90-day subchronic oral study in rats (40 CFR 798.2650) would help characterize the health effects of the PMN substance.
CFR citation: 40 CFR 721.8673.

PMN Number P–95–512

Chemical name: (generic) Aminofluoran derivative.
CAS number: Not available.
Basis for action: The PMN substance will be used as a color former for carbonless copy paper. Based on analogy to neutral organic chemicals, EPA is concerned that toxicity to aquatic organisms may occur at concentrations as low as 1 ppb of the PMN substance in surface waters. EPA determined that use of the substance did not present an unreasonable risk because significant environmental exposure would not occur since the substance was not manufactured domestically. EPA has determined that domestic manufacture of the substance may result in significant environmental exposure. Based on this information the PMN substance meets the concern criteria at § 721.170(b)(4)(ii).
Recommended testing: EPA has determined that a chronic 60-day fish early life stage toxicity test in rainbow trout (40 CFR 797.1600) and a 21-day chronic daphnid toxicity test (40 CFR 797.1330) would help characterize the environmental effects of the PMN substance.
CFR citation: 40 CFR 721.646.

PMN Number P–95–513

Chemical name: (generic) *N*-[2-[(substituted dinitrophenyl)azo]diallylamino-4-substituted phenyl] acetamide.
CAS number: Not available.
Basis for action: The PMN substance will be used a colorant. Based on analogy to similar substances, EPA is concerned that liver toxicity, blood toxicity, oncogenicity, neurotoxicity, and developmental toxicity will occur in exposed workers. EPA determined that use of the substance did not present an unreasonable risk because significant worker exposure would not occur because the substance was not manufactured domestically. EPA has determined that domestic manufacture of the substance may result in significant worker exposure. Based on this information the PMN substance meets the concern criteria at § 721.170 (b)(1)(i)(C), (b)(3)(ii), and (b)(3)(iii).
Recommended testing: EPA has determined that a 2-year two-species oral bioassay (40 CFR 798.3300), a developmental toxicity test (40 CFR 798.4900) and a 90-day subchronic oral study in rats (40 CFR 798.2650) would help characterize the health effects of the PMN substance.
CFR citation: 40 CFR 721.267.

PMN Number P–95–514

Chemical name: (generic) Substituted diphenylazo dye.
CAS number: Not available.
Basis for action: The PMN substances will be used as a dye. Based on analogy to similar substances, EPA is concerned that liver toxicity, blood toxicity, oncogenicity, neurotoxicity, and developmental toxicity will occur in exposed workers. EPA determined that use of the substances did not present an unreasonable risk because significant worker exposure would not occur because the substances were not manufactured domestically. EPA has determined that domestic manufacture of the substances may result in significant worker exposure. Based on this information the PMN substance meets the concern criteria at § 721.170 (b)(1)(i)(C), (b)(3)(ii), and (b)(3)(iii).
Recommended testing: EPA has determined that a 2-year two-species oral bioassay (40 CFR 798.3300), a developmental toxicity test (40 CFR 798.4900) and a 90-day subchronic oral study in rats (40 CFR 798.2650) would help characterize the health effects of the PMN substance.
CFR citation: 40 CFR 721.2527.

PMN Number P–95–529

Chemical name: (generic) Alkaline titania silica gel.
CAS number: Not available.
Basis for action: The PMN substance will be used as an intermediate. Based

on potential silicosis, EPA is concerned that lung effects will in workers exposed via inhalation. EPA determined that use of the substance as described in the PMN does not present an unreasonable risk; significant worker inhalation exposure is not expected because the substance will not be manufactured, processed, or used as a powder. EPA has determined that manufacture, processing, and use of the substance as a powder may result in significant worker inhalation exposure. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(3)(ii).
Recommended testing: EPA has determined that a 90-day subchronic inhalation study (40 CFR 798.2650) with a 60-day holding period would help characterize the human health effects of the PMN substance.
CFR citation: 40 CFR 721.9680.

PMN Number P–95–538

Chemical name: 2-Naphthalenol, heptyl-1-[[(4-phenylazo)phenyl] azo]-, *ar*',*ar*''-Me derivs.
CAS number: Not available.
Basis for action: The PMN substance will be used as a colorant in high sulfur diesel fuel. Based on data on the potential diaminoazo reduction product and by analogy to similar chemicals, EPA is concerned that reproductive effects and cancer will occur in workers exposed via inhalation. EPA determined that use of the substance as described in the PMN does not present an unreasonable risk; significant worker inhalation exposure is not expected because the substance will not be manufactured, processed, or used as a powder. EPA has determined that manufacture, processing, and use of the substance as a powder may result in significant worker inhalation exposure. Based on this information the PMN substance meets the concern criteria at § 721.170 (b)(1)(i)(C) and (b)(3)(ii).
Recommended testing: EPA has determined that a 2-year two-species oral bioassay (40 CFR 798.3300) and a two-generation reproductive toxicity study (40 CFR 798.4700) would help characterize the human health effects of the PMN substance.
CFR citation: 40 CFR 721.5276.

PMN Numbers P–95–655, P–95–782, and P–95–871

Chemical name: (generic) Substituted phenyl azo substituted phenyl esters.
CAS number: Not available.
Basis for action: The PMN substances will be used as textile dyes. Based on analogy to similar substances and submitted toxicity data, EPA is concerned that liver toxicity, blood toxicity, oncogenicity, kidney toxicity, and sensitization will occur in exposed workers. EPA determined that use of the substances did not present an unreasonable risk because the substances would not be manufactured as a powder and significant worker exposure would not occur. EPA has determined that manufacture of the substances as a powder may result in significant worker exposure. Based on this information the PMN substances meet the concern criteria at § 721.170 (b)(1)(i)(C), (b)(3)(ii), and (b)(3)(iii).
Recommended testing: EPA has determined that a 2-year two-species oral bioassay (40 CFR 798.3300) and a 90-day subchronic oral study in rats (40 CFR 798.2650) would help characterize the health effects of the PMN substance.
CFR citation: 40 CFR 721.3063.

PMN Numbers P–95–979/980/981

Chemical name: Fluorinated carboxylic acid alkali metal salts.
CAS number: Not available.
Basis for action: The PMN substances will be used as intermediates. Based on analogy of the PMN substances to anionic surfactants and perfluorinated fatty acids, EPA expects toxicity to aquatic organisms at surface water concentrations as low as 100 ppb for P–95–979, 30 ppb for P–95–980, and 3 ppb for P–95–981. EPA expects liver toxicity based on analogy to a structurally similar substance, developmental toxicity based on branched carboxylic acids, and lung toxicity due to surfactancy. EPA determined that use of the substances as described in the PMN did not present an unreasonable risk because there were no significant inhalation exposures or environmental releases. EPA has determined that other uses of the substances may result in significant inhalation or environmental exposures. 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 a 90-day subchronic inhalation assay (40 CFR 798.2450) would help characterize the health effects of the PMN substances and a fish acute toxicity study (40 CFR 797.1400), a daphnid acute toxicity study (40 CFR 797.1300) and an algal acute toxicity study (40 CFR 797.1050) would help characterize the environmental effects of the PMN substances.
CFR citation: 40 CFR 721.4663.

PMN Number P–95–1022

Chemical name: (generic) Polyester silane.
CAS number: Not available.
Basis for action: The PMN substance will be used as described in the PMN. Based on analogy of the PMN substance to alkoxysilanes EPA expects irritation to mucous membranes and lung toxicity. EPA determined that use of the substance as described in the PMN did not present an unreasonable risk because there were no significant inhalation exposures. EPA has determined that industrial uses of the substance may result in significant inhalation exposures. Based on this information the PMN substance meets the concern criteria at § 721.170(b)(3)(ii).
Recommended testing: EPA has determined that a 90-day subchronic inhalation assay (40 CFR 798.2450) would help characterize the health effects of the PMN substance.
CFR citation: 40 CFR 721.9507.

PMN Numbers P–95–1024/1040

Chemical name: (generic) Acrylosilane resins.
CAS number: Not available.
Basis for action: The PMN substances will be used as described in the PMN. Based on analogy of the PMN substances to alkoxysilanes, EPA expects irritation to mucous membranes and lung toxicity. EPA determined that use of the substances as described in the PMN did not present an unreasonable risk because there were no significant inhalation exposures. EPA has determined that nonindustrial uses of the substances may result in significant inhalation exposures. Based on this information the PMN substances meet the concern criteria at § 721.170(b)(3)(ii).
Recommended testing: EPA has determined that a 90-day subchronic inhalation assay (40 CFR 798.2450) would help characterize the health effects of the PMN substances.
CFR citation: 40 CFR 721.9495.

PMN Number P–95–1030

Chemical name: (generic) *o*-Xylene compound.
CAS number: Not available.
Basis for action: The PMN substance will be used as described in the PMN. Based on toxicity data submitted with the PMN, EPA identified health concerns for liver, kidney, thyroid, and developmental toxicity and chronic toxicity to aquatic organisms. EPA determined that use of the substance as described in the PMN did not present an unreasonable risk because significant human or environmental exposure would not occur. EPA has determined that use of the substance other than as described in the PMN may result in significant human or environmental

exposure. Based on this information the PMN substance meets the concern criteria at § 721.170 (b)(3)(i) and (b)(4)(i).
Recommended testing: EPA has determined that a 28-day contaminated sediment test with chironomids and natural sediments would help characterize the environmental effects of the PMN substance.
CFR citation: 40 CFR 721.9970.

PMN Number P–95–1208

Chemical name: (generic) Fluorinated acrylic copolymer.
CAS number: Not available.
Basis for action: The PMN substance will be used as a soil repellant. Based on the molecular weight and physical properties of the substance, EPA is concerned that a significant risk of lung toxicity would occur. EPA determined that use of the substance did not present an unreasonable risk because the substance would not be manufactured, processed, or used as a powder or an aerosol and significant worker inhalation exposure would not occur. EPA has determined that manufacture, processing, or use of the substance as a powder or an aerosol may result in significant worker inhalation exposure. Based on this information the PMN substance meets the concern criteria at § 721.170(b)(3)(ii).
Recommended testing: EPA has determined that a 90-day subchronic inhalation study in rats (40 CFR 798.2450) would help characterize the health effects of the PMN substance.
CFR citation: 40 CFR 721.484.

PMN Number P–95–1242

Chemical name: (generic) Chromate(3-), bis 2-[[substituted-3-[(5sulfo-1-naphthalenyl) azo]phenyl]azo]substituted monocycle, trisodium.
CAS number: Not available.
Basis for action: The PMN substance will be used as a leather dye. Based on potential azo reduction products, EPA is concerned that blood toxicity, oncogenicity, mutagenicity, neurotoxicity, and developmental toxicity will occur in exposed workers. EPA determined that use of the substance did not present an unreasonable risk because significant worker exposure would not occur because the substance was not manufactured domestically or in the form of a powder. EPA has determined that domestic manufacture of the substance or any use of the substance as a powder may result in significant worker exposure. Based on this information the PMN substance meets the concern criteria at § 721.170 (b)(1)(i)(D) and (b)(3)(iii).
Recommended testing: EPA has determined that a 2-year two-species oral bioassay (40 CFR 798.3300), a developmental toxicity study (40 CFR 798.4900), and a 90-day subchronic oral study in rats (40 CFR 798.2650) would help characterize the health effects of the PMN substance.
CFR citation: 40 CFR 721.2095.

PMN Number P–96–175

Chemical name: Lithium Manganese Oxide (LiMn204)
CAS number: Not applicable.
Effective date of section 5(e) consent order: April 17, 1996.
Basis for section 5(e) consent order: The order was issued under section 5 (e)(1)(A)(i), (e)(1)(A)(ii)(I), and (e)(1)(A)(ii)(II), of TSCA based on findings that this substance is expected to be produced in substantial quantities and there may be significant or substantial human exposure to the substances.
Recommended testing: EPA has determined that a sediment and soil adsorption isotherm test (40 CFR 796.2750) and a 90-day subchronic study via the inhalation route with a 60-day holding period (40 CFR 798.2450). The PMN submitter has agreed not to exceed the production volume limit without performing these tests.
CFR citation: 40 CFR 721.4587.

IV. Objectives and Rationale of the Rule

During review of the PMNs submitted for the chemical substances that are subject to this SNUR, EPA concluded that for 19 of the 45 substances regulation was warranted under section 5(e) of TSCA, pending the development of information sufficient to make reasoned evaluations of the health or environmental effects of the substances. The basis for such findings is outlined in Unit III of this preamble. Based on these findings, section 5(e) consent orders requiring the use of appropriate controls were negotiated with the PMN submitters; the SNUR provisions for these substances designated herein are consistent with the provisions of the section 5(e) orders.

In the other 26 cases for which the proposed uses are not regulated under a section 5(e) order, EPA determined that one or more of the criteria of concern established at 40 CFR 721.170 were met.

EPA is issuing this SNUR for specific chemical substances which have undergone premanufacture review to ensure that:

(1) EPA will receive notice of any company's intent to manufacture, import, or process a listed chemical substance for a significant new use before that activity begins.

(2) EPA will have an opportunity to review and evaluate data submitted in a SNUR notice before the notice submitter begins manufacturing, importing, or processing a listed chemical substance for a significant new use.

(3) When necessary to prevent unreasonable risks EPA will be able to regulate prospective manufacturers, importers, or processors of a listed chemical substance before a significant new use of that substance occurs.

(4) All manufacturers, importers, and processors of the same chemical substance which is subject to a section 5(e) order are subject to similar requirements.

Issuance of a SNUR for a chemical substance does not signify that the substance is listed on the TSCA Inventory. Manufacturers, importers, and processors are responsible for ensuring that a new chemical substance subject to a final SNUR is listed on the TSCA Inventory.

V. Direct Final Procedures

EPA is issuing these SNURs as direct final rules, as described in 40 CFR 721.160(c)(3) and 721.170(d)(4). In accordance with 40 CFR 721.160(c)(3)(ii), this rule will be effective January 31, 1997, unless EPA receives a written notice by January 2, 1997 that someone wishes to make adverse or critical comments on EPA's action. If EPA receives such a notice, EPA will publish a notice to withdraw the direct final SNUR for the specific substance to which the adverse or critical comments apply. EPA will then propose a SNUR for the specific substance providing a 30-day comment period.

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

VI. Test Data and Other Information

EPA recognizes that section 5 of TSCA does not require developing any particular test data before submission of a SNUN. Persons are required only to submit test data in their possession or control and to describe any other data known to or reasonably ascertainable by them. In cases where a section 5(e) order requires or recommends certain testing, Unit III of this preamble lists those recommended tests.

However, EPA has established production limits in the section 5(e)

orders for several of the substances regulated under this rule, 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 substances. These production limits cannot be exceeded unless the PMN submitter first submits the results of toxicity tests that would permit a reasoned evaluation of the potential risks posed by these substances. Under recent consent orders, each PMN submitter is required to submit each study at least 14 weeks (earlier orders required submissions at least 12 weeks) before reaching the specified production limit. Listings of the tests specified in the section 5(e) orders are included in Unit III of this preamble. The SNURs contain the same production volume limits as the consent orders. Exceeding these production limits is defined as a significant new use.

The recommended studies may not be the only means of addressing the potential risks of the substance. However, SNUNs submitted for significant new uses without any test data may increase the likelihood that EPA will take action under section 5(e), particularly if satisfactory test results have not been obtained from a prior submitter. EPA recommends that potential SNUN submitters contact EPA early enough so that they will be able to conduct the appropriate tests.

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

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

(2) Potential benefits of the substances.

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

VII. Procedural Determinations

EPA is establishing through this rule some significant new uses which have been claimed as CBI. EPA is required to keep this information confidential to protect the CBI of the original PMN submitter. EPA promulgated a procedure to deal with the situation where a specific significant new use is CBI. This procedure appears in 40 CFR 721.1725(b)(1) and is similar to that in § 721.11 for situations where the chemical identity of the substance subject to a SNUR is CBI. This procedure is cross-referenced in each of these SNURs.

A manufacturer or importer may request EPA to determine whether a proposed use would be a significant new use under this rule. Under the procedure incorporated from § 721.1725(b)(1), a manufacturer or importer must show that it has a bona fide intent to manufacture or import the substance and must identify the specific use for which it intends to manufacture or import the substance. If EPA concludes that the person has shown a bona fide intent to manufacture or import the 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 substances subject to these SNURs are also CBI, manufacturers and processors can combine the bona fide submission under the procedure in § 721.1725(b)(1) with that under § 721.11 into a single step.

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

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

To establish a significant ''new'' use, EPA must determine that the use is not ongoing. The chemical substances subject to this rule have recently undergone premanufacture review. Section 5(e) orders have been issued for 19 substances and notice submitters are prohibited by the section 5(e) 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 substance has not been added to the Inventory, no other person may commence such activities without first submitting a PMN. For substances for which an NOC has not been submitted at this time, EPA has concluded that the uses are not ongoing. However, EPA recognizes in cases when chemical substances identified in this SNUR are added to the Inventory prior to the effective date of the rule, the substances may be manufactured, imported, or processed by other persons for a significant new use as defined in this rule before the effective date of the rule. However, 39 of the 45 substances contained in this rule have CBI chemical identities, and since EPA has received a limited number of post-PMN bona fide submissions, the Agency believes that it is highly unlikely that any of the significant new uses described in the following regulatory text are ongoing.

As discussed in the Federal Register of April 24, 1990 (55 FR 17376) (FRL–3658–5), EPA has decided that the intent of section 5(a)(1)(B) is best served by designating a use as a significant new use as of the date of publication rather than as of the effective date of the rule. Thus, persons who begin commercial manufacture, import, or processing of the substances regulated through this SNUR will have to cease any such activity before the effective date of this rule. To resume their activities, these persons would have to comply with all applicable SNUR notice requirements and wait until the notice review period, including all extensions, expires.

EPA has promulgated provisions to allow persons to comply with this SNUR before the effective date. If a person were to meet the conditions of advance compliance under § 721.45(h), the person would be considered to have met the requirements of the final SNUR for those activities. If persons who begin commercial manufacture, import, or processing of the substance between publication and the effective date of the SNUR do not meet the conditions of advance compliance, they must cease that activity before the effective date of the 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.

IX. Economic Analysis

EPA has evaluated the potential costs of establishing significant new use notice requirements for potential manufacturers, importers, and processors of the chemical substance subject to this rule. EPA's complete economic analysis is available in the

public record for this rule (OPPTS–50623).

X. Rulemaking Record

A record has been established for this rulemaking under docket number OPPTS–50623 (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI is available for inspection from 12 noon to 4 p.m., Monday through Friday, except legal holidays. The public record is located in the TSCA Nonconfidential Information Center Rm. NE–B607, 401 M St., SW., Washington, DC 20460.

Electronic comments can be sent directly to EPA at:
oppt.ncic@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer all comments received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the address in ''ADDRESSES'' at the beginning of this document.

XI. Regulatory Assessment Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' subject to review by the Office of Management and Budget (OMB). In addition, this action does not require prior consultation with State officials as specified by Executive Order 12875 (58 FR 58093, October 28, 1993), nor does it involve special considerations of environmental justice related issues as required by Executive Order 12898 (59 FR 7629, February 16, 1994).

This action will not result in the annual expenditure of $100 million or more for State, local, and tribal governments, in the aggregate, or to the private sector, and is not a Federal mandate, as defined by the Unfunded Mandates Reform Act of 1995 (UMRA)(Pub. L. 104–4), nor does it uniquely affect small govbernments in any way. As such, the requirements of sections 202, 203, and 205 of Title II of the UMRA do not apply to this action.

EPA has determined that this action does not impose any adverse economic impacts on a substantial number of small entities. Pursuant section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The Agency has certified that this action will not impose a significant economic impact on a substantial number of small entities. Information relating to this determination is included in the docket for this rulemaking. Any comments regarding the economic impacts that this action imposes on small entities should be submitted to the Agency at the address listed above.

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, an agency may not conduct or sponsor, and a person is not required to respond to, an information collection request unless it displays a currently valid control number assigned by OMB. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR chapter 15. The information collection requirements related to this action have already been approved by OMB under OMB control number 2070–0012 (EPA ICR No. 574). This action does not impose any burdens requiring additional OMB approval. The public reporting burden for this collection of information is estimated to average 100 hours per response. The burden estimate includes the time needed for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

XII. Submission to Congress and the General Accounting Office

This action is not a ''major rule'' as defined by 5 U.S.C. 804(2) of the Administrative Procedure Act. Pursuant to 5 U.S.C. 801(a)(1)(A), EPA submitted this action to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the General Accounting Office prior to its publication in today's Federal Register.

List of Subjects in 40 CFR Part 721

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

Dated: November 21, 1996.

Charles M. Auer,

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

Therefore, 40 CFR part 721 is amended as follows:

PART 721—[AMENDED]

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

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

2. By adding new § 721.267 to subpart E to read as follows:

§ 721.267 N-[2-[(substituted dinitrophenyl)azo]diallylamino-4-substituted phenyl] acetamide (generic name).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as *N*-[2-[(substituted dinitrophenyl)azo]diallylamino-4-substituted phenyl] acetamide (PMN P–95–513) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

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

(ii) [Reserved]

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

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

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

3. By adding new § 721.336 to subpart E to read as follows:

§ 721.336 Perfluoroalkylethyl acrylate copolymer (generic name).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as a perfluoroalkylethyl acrylate copolymer (PMN P–94–241) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

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

(ii) [Reserved]

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

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

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

4. By adding new § 721.484 to subpart E to read as follows:

§ 721.484 Fluorinated acrylic copolymer (generic name).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as a fluorinated acrylic copolymer (PMN P–95–1208) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

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

(ii) [Reserved]

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

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

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

5. By adding new § 721.646 to subpart E to read as follows:

§ 721.646 Aminofluoran derivative (generic name).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as aminofluoran derivative (PMN P–95–512) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

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

(ii) [Reserved]

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

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

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

6. By adding new § 721.785 to subpart E to read as follows:

§ 721.785 Halogenated alkane aromatic compound (generic name).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as a halogenated alkane aromatic compound (PMN P–94–1747) 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)(3), (a)(4), (a)(5)(iv), (a)(5)(v), (6)(i), (b) (concentration set at 0.1 percent), and (c).

(ii) *Hazard communication program.* Requirements as specified in § 721.72 (a), (b), (c), (d), (e) (concentration set at 0.1 percent), (g)(1)(vii), (g)(2)(iv), (g)(2)(v), (g)(3)(ii), (g)(4)(iii), and (g)(5).

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

(iv) *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), (f), (g), (h), (i), and (k) are applicable to manufacturers, importers, and processors of this substance.

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

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

7. By adding new § 721.979 to subpart E to read as follows:

§ 721.979 l-Aspartic acid, homopolymer and ammonium and potassium salts.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substances l-Aspartic acid, homopolymer and ammonium and potassium salts (P–91–1299 and P–95–1667, P–91–1298, and P–91–1297) (CAS Nos. 25608–40–6 and 64723–18–8) are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Hazard communication program.* A significant new use of these substance is any manner or method of manufacture, import, or processing associated with any use of these substances without providing risk notification as follows:

(A) If as a result of the test data required under the section 5(e) consent order for these substances, the employer becomes aware that these substances may present a risk of injury to human health or the environment the employer must incorporate this new information, and any information on methods for protecting against such risk, into a Material Safety Data Sheet (MSDS) as described in § 721.72(c) within 90 days from the time the employer becomes aware of the new information. If these substances are not being manufactured, imported, processed, or used in the employer's workplace, the employer must add the new information to an MSDS before the substances are reintroduced into the workplace.

(B) The employer must ensure that persons who will receive, or who have received their substances from the employer within 5 years from the date the employer becomes aware of the new information described in paragraph (a)(2)(i)(A) of this section, are provided an MSDS as described in § 721.72(c) containing the information required under paragraph (a)(2)(i)(A) of this section within 90 days from the time the employer becomes aware of the new information.

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

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

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (h), and (i) are applicable to manufacturers, importers, and processors of these substances.

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

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

8. By adding new § 721.1737 to subpart E to read as follows:

§ 721.1737 Benzotriazole derivative.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as a benzotriazole derivative (PMN P–94–2061) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(4), and (b)(concentration set at 5.0 percent) and (c). The following paragraphs apply during manufacturing and processing: (a)(5)(ii), (a)(5)(iv), and (a)(5)(v). The following paragraphs apply during use: (a)(5)(iii), (a)(5)(viii), (a)(5)(ix), (a)(5)(x), (a)(5)(xi), and (a)(6)(ii).

(ii) *Hazard communication program.* Requirements as specified in § 721.72 (a), (b), (c), (d), (e)(concentration set at 5.0 percent), (f), (g)(1)(vi), (g)(2)(ii),

(g)(2)(iii), and (g)(2)(iv). The following additional statements shall appear on each label and MSDS required by this paragraph: This substance may cause kidney effects. This substance may cause liver effects. This substance may cause neurotoxicity effects. This substance may cause blood effects.

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

(iv) *Release to water.* Requirements as specified in § 721.90 (a)(1) and (b)(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), (f), (g), (h), (i), (j) and (k) are applicable to manufacturers, importers, and processors of this substance.

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

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

9. By adding new § 721.1738 to subpart E to read as follows:

§ 721.1738 Substituted benzotriazole (generic name).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as a substituted benzotriazole (PMN P–94–1744) 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)(3), (a)(4), (a)(5)(ii), (a)(5)(iv), (a)(6)(i), (b) (concentration set at 1.0%), and (c).

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

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

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

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

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

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

10. By adding new § 721.2095 to subpart E to read as follows:

§ 721.2095 Chromate(3-), bis 2-[[substituted-3-[(5-sulfo-1-naphthalenyl)azo]phenyl]azo]substituted monocycle, trisodium (generic name).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as chromate(3-), bis 2-[[substituted-3-[(5-sulfo-1-naphthalenyl) azo]phenyl]azo]substituted monocycle, trisodium (PMN P–95–1242) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

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

(ii) [Reserved]

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

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

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

11. By adding new § 721.2097 to subpart E to read as follows:

§ 721.2097 Azo chromium complex dyestuff preparation (generic name).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as an azo chromium complex dyestuff preparation (PMN P–95–240) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial and consumer activities.* Requirements as specified in § 721.80 (v)(1), (v)(2), (w)(1), (w)(2), (x)(1), and (x)(2).

(ii) [Reserved]

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

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

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

12. By adding new § 721.2527 to subpart E to read as follows:

§ 721.2527 Substituted diphenylazo dye (generic name).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as a substituted diphenylazo dye (PMN P–95–514) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

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

(ii) [Reserved]

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

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

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

13. By adding new § 721.3063 to subpart E to read as follows:

§ 721.3063 Substituted phenyl azo substituted phenyl esters (generic name).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substances identified generically as substituted phenyl azo substituted phenyl esters (PMNs P–95–655, P–95–782 and P–95–871) 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(w)(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) 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 significant new use rule.

14. By adding new § 721.3628 to subpart E to read as follows:

§ 721.3628 Fatty acids, C(14-18)-unsaturated, branched and linear, methyl and butyl esters.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substances fatty acids, C(14-18) unsaturated, branched and linear, methyl and butyl esters (P–94–1634/35/36/37/38/39) are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Hazard communication program.* A significant new use of this substance is any manner or method of manufacture, import, or processing associated with any use of this substance without providing risk notification as follows:

(A) If as a result of the test data required under the section 5(e) consent order for this substance, the employer becomes aware that this substance may present a risk of injury to human health or the environment the employer must incorporate this new information, and any information on methods for protecting against such risk, into a Material Safety Data Sheet (MSDS) as described in § 721.72(c) within 90 days from the time the employer becomes aware of the new information. If this substance is not being manufactured, imported, processed, or used in the employer's workplace, the employer must add the new information to an MSDS before the substance is reintroduced into the workplace.

(B) The employer must ensure that persons who will receive, or who have received this substance from the employer within 5 years from the date the employer becomes aware of the new information described in paragraph (a)(2)(i)(A) of this section, are provided an MSDS as described in § 721.72(c) containing the information required under paragraph (a)(2)(i)(A) of this section within 90 days from the time the employer becomes aware of the new information.

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

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

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

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

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

15. By adding new § 721.4484 to subpart E to read as follows:

§ 721.4484 Halogenated indane (generic name).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as a halogenated indane (PMN P–94–351) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to P–94–351 after incorporation into a plastic, resin matrix, or pelletized so humans are not reasonally likely to be exposed.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements during manufacture as specified in § 721.72 (a)(5)(iii), (a)(5)(iv), (a)(5)(v), (a)(5)(vi), (a)(5(vii), (a)(6)(i), (b) (concentration set at 0.1 percent), and (c).

(ii) *Hazard communication program.* Requirements during manufacture as specified in § 721.63 (a), (b), (c), (d), (e), (f), (g)(1)(vii), (g)(2)(ii), (g)(2)(iii), (g)(2)(iv), and (g)(5).

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

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

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

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

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

16. By adding new § 721.4494 to subpart E to read as follows:

§ 721.4494 Polycyclic isocyanate.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as a polycyclic isocyanate (PMN P–94–437) 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)(3), (a)(4), (a)(5)(i), (a)(6)(i), (a)(6)(ii), (a)(6)(iii), (a)(6)(iv), (a)(6)(v), (a)(6)(vi), (b) (concentration set at 1.0%), and (c).

(ii) *Hazard communication program.* Requirements as specified in § 721.72 (a), (b), (c), (d), (e) (concentration set at 1.0 percent), (f), (g)(1)(i), (g)(1)(ii), (g)(2)(i), (g)(2)(ii), (g)(2)(iii), (g)(2)(iv), (g)(2)(v), (g)(3)(i), (g)(3)(ii), (g)(4)(i), and (g)(5). In addition the following human health and environmental hazard and precautionary statements shall appear on each label as specified in paragraph (b) of this section and the MSDS as specified in paragraph (c) of this section: This substance may cause skin sensitization. This substance may cause pulmonary sensitization.

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

(iv) *Release to water.* Requirements as specified in § 721.90 (a)(3), (b)(3), and (c)(3).

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

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

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

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

17. By adding new § 721.4497 to subpart E to read as follows:

§ 721.4497 Aliphatic polyisocyanates (generic name).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substances identified generically as aliphatic polyisocyanates (P–91–1210 and P–92–714) are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. Non-spray uses are exempt from the provisions of this rule.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(1), (a)(2)(i), (a)(2)(iii), (a)(3), (a)(4), (a)(5)(i), (a)(5)(ii), (a)(5)(iii), (a)(5)(viii), (a)(5)(ix), (a)(5)(x), (a)(5)(xi), (a)(6)(i), (a)(6)(ii), (a)(6)(iv), (b) (concentration set at 1.0 percent), and (c).

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

implement the product stewardship provisions of the section 5(e) consent order for these substances are exempt from the requirements of §§ 721.63 and 721.72.

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

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a) through (h) are applicable to manufacturers, importers, and processors of this substance. Manufacturers, importers, and processors who implement the product stewardship provisions or keep records as required by the section 5(e) consent order for these substances are exempt from the requirements of § 721.125.

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

(3) *Applicability of § 721.5.* The provisions of § 721.5 do not apply to manufacturers, importers, and processors, implementing the product stewardship provisions in the section 5(e) consent order for these substances.

18. By adding new § 721.4525 to subpart E to read as follows:

§ 721.4525 Isothiazolinone derivatives (generic name).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substances identified generically as isothiazolinone derivatives (PMNs P–95–116/117) 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).

(ii) *Release to water.* Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) (where n = 10).

(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.

19. By adding new § 721.4587 to subpart E to read as follows:

§ 721.4587 Lithium Manganese Oxide (LiMn204) (generic name).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as lithium manganese oxide (LiMn204) (P–96–175) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Hazard communication program.* A significant new use of this substance is any manner or method of manufacture, import, or processing associated with any use of these substances without providing risk notification as follows:

(A) If as a result of the test data required under the section 5(e) consent order for these substances, the employer becomes aware that these substances may present a risk of injury to human health or the environment the employer must incorporate this new information, and any information on methods for protecting against such risk, into a Material Safety Data Sheet (MSDS) as described in § 721.72(c) within 90 days from the time the employer becomes aware of the new information. If these substances are not being manufactured, imported, processed, or used in the employer's workplace, the employer must add the new information to an MSDS before the substances are reintroduced into the workplace.

(B) The employer must ensure that persons who will receive, or who have received their substances from the employer within 5 years from the date the employer becomes aware of the new information described in paragraph (a)(2)(i)(A) of this section, are provided an MSDS as described in § 721.72(c) containing the information required under paragraph (a)(2)(i)(A) of this section within 90 days from the time the employer becomes aware of the new information.

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

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

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (h), and (i) are applicable to manufacturers, importers, and processors of these substances.

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

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

20. By adding new § 721.4663 to subpart E to read as follows:

§ 721.4663 Fluorinated carboxylic acid alkali metal salts.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substances identified as fluorinated carboxylic acid alkali metal salts (PMNs P–95–979/980/981) 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 (v)(2), (w)(2), and (x)(2).

(ii) *Release to water.* Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4), (N = 100 ppb for P–95–979), (N = 30 ppb for P–95–980), and (N = 3 ppb for P–95–981).

(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.

21. By adding new § 721.4668 to subpart E to read as follows:

§ 721.4668 Hydrated alkaline earth metal salts of metalloid oxyanions.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as hydrated alkaline earth metal salts of metalloid oxyanions (PMN P–94–1557) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(4), (a)(5)(iii), (a)(5)(iv), (a)(5)(v), (a)(5)(vi), (a)(5)(vii), (a)(5)(viii), (a)(6)(i), (b), and (c).

(ii) *Hazard communication program.* Requirements as specified in § 721.72 (a), (b), (c), (d), (e), (f), (g)(1)(vi), (g)(1)(ix), (g)(2)(ii), (g)(2)(iii), (g)(2)(iv), and (g)(5).

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

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

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

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

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

22. By adding new § 721.4685 to subpart E to read as follows:

§ 721.4685 Substituted purine metal salt (generic name).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as a substituted purine metal salt (PMN P–95–175) 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) (where N = 8)

(ii) [Reserved]

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

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

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

23. By adding new § 721.5276 to subpart E to read as follows:

§ 721.5276 2-Naphthalenol, heptyl-1-[[(4-phenylazo)phenyl]azo]-, *ar*',*ar*''-Me derivs.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 2-naphthalenol, heptyl-1-[[(4-phenylazo)phenyl] azo]-, *ar*',*ar*''-Me derivs (PMN P–95–538) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

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

(ii) [Reserved]

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

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

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

24. By adding new § 721.5545 to subpart E to read as follows:

§ 721.5545 3-(Dichloroacetyl)-5-(2-furanyl)-2,2-dimethyl-oxazolidine.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 3-(dichloroacetyl)-5-(2-furanyl)-2,2-dimethyloxazolidine (PMN P–93–1694) (CAS no. 121776–57–6) 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)(3), (a)(4), (a)(5)(i), (a)(6)(i), (b) (concentration set at 0.1%), and (c).

(ii) *Hazard communication program.* Requirements as specified in § 721.72 (a), (b), (c), (d), (e) (concentration set at 0.1%), (f), (g)(1)(iv), (g)(1)(vii), (g)(1)(ix), (g)(2)(iii), (g)(2)(iv), (g)(2)(v), (g)(3)(i), (g)(3)(ii), and (g)(5).

(iii) *Industrial, commercial, and consumer activites.* Requirements as specified in § 721.80 (b), (c), (k) (as a seed safener), and (o).

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

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

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

25. By adding new § 721.5930 to subpart E to read as follows:

§ 721.5930 Phenylenebis[imino (chlorotriazinyl)imino(substituted naphthyl)azo(substituted phenyl)azo, sodium salt (generic name).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as phenylenebis[imino (chlorotriazinyl)imino(substituted naphthyl)azo (substituted phenyl) azo, sodium salt (PMN P–95–274) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

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

(ii) [Reserved]

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

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

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

26. By adding new § 721.6097 to subpart E to read as follows:

§ 721.6097 Phosphoric acid derivative (generic name).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as a phosphoric acid derivative (PMN P–95–284) 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.

27. By adding new § 721.8673 to subpart E to read as follows:

§ 721.8673 [(Disubstituted phenyl)]azo dihydro hydroxy alkyl oxo alkyl-substituted-pyridines (generic name).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substances identified generically as [(disubstituted phenyl)]azo dihydro hydroxy alkyl oxo alkyl-substituted-pyridines (PMN P–95–510/511) 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).

(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 significant new use rule.

28. By adding new § 721.9495 to subpart E to read as follows:

§ 721.9495 Acrylosilane resins.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substances identified as acrylosilane resins (PMNs P–95–1024/1040) 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(l).

(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.

29. By adding new § 721.9507 to subpart E to read as follows:

§ 721.9507 Polyester silane.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as a polyester silane (P–95–1022) 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(l).

(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.

30. By adding new § 721.9680 to subpart E to read as follows:

§ 721.9680 Alkaline titania silica gel (generic name).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as an alkaline titania silica gel (PMN P–95–529) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

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

(ii) [Reserved]

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

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

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this significant new use rule.

31. By adding new § 721.9970 to subpart E to read as follows:

§ 721.9970 o-Xylene compound (generic name).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as an *o*-xylene compound (PMN P–95–1030) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

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

(ii) [Reserved]

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

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

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 401, 403, 405, 411, 413, 447, and 493

[BPO–118–FC]

RIN 0938–AC99

Medicare Program; Changes Concerning Suspension of Medicare Payments, and Determinations of Allowable Interest Expenses

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule with comment period.

SUMMARY: We are revising the Medicare regulations concerning suspension of Medicare payments and determination of allowable interest expenses. These changes are being made to conform the regulations with law and established policy, to provide necessary clarification, and to protect the Government's interests.

DATES: *Effective date:* These regulations are effective January 2, 1997.

Comment Date: We are providing a comment period on the issues described in section V of this preamble. Written comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on January 31, 1997.

ADDRESSES: Mail written comments (an original and three copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: BPO–118–FC, P.O. Box 26688, Baltimore, MD 21207.

If you prefer, you may deliver your written comments (an original and three copies) to one of the following addresses:

Room 309–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201, or

Room C5–09–26, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Because of staffing and resource limitations, we cannot accept comments by facsimile (Fax) transmission. In commenting, please refer to file code BPO–118–FC. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 309–G of the Department's offices at 200 Independence Ave., SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690–7890).