



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 721

[EPA-HQ-OPPT-2014-0277; FRL-9911-05]

RIN 2070-AB27

Significant New Use Rules on Certain Chemical Substances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is promulgating significant new use rules (SNURs) under the Toxic Substances Control Act (TSCA) for 13 chemical substances which were the subject of premanufacture notices (PMNs). Three of these chemical substances are subject to TSCA section 5(e) consent orders issued by EPA. This action requires persons who intend to manufacture or process any of these 13 chemical substances for an activity that is designated as a significant new use by this rule to notify EPA at least 90 days before commencing that activity. The required notification will provide EPA with the opportunity to evaluate the intended use and, if necessary, to prohibit or limit that activity before it occurs.

DATES: This rule is effective on *[insert date 60 days after date of publication in the Federal Register]*. For purposes of judicial review, this rule shall be promulgated at 1 p.m. (e.s.t.) on *[insert date 14 days after date of publication in the Federal Register]*.

Written adverse or critical comments, or notice of intent to submit adverse or critical comments, on one or more of these SNURs must be received on or before *[insert*

*date 30 days after date of publication in the **Federal Register***] (see Unit VI. of the **SUPPLEMENTARY INFORMATION**). If EPA receives written adverse or critical comments, or notice of intent to submit adverse or critical comments, on one or more of these SNURs before [*insert date 30 days after date of publication in the **Federal Register***], EPA will withdraw the relevant sections of this direct final rule before its effective date.

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

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2014-0277, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:*

Kenneth Moss, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-9232; email address: *moss.kenneth@epa.gov*.

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

SUPPLEMENTARY INFORMATION:**I. General Information***A. Does this Action Apply to Me?*

You may be potentially affected by this action if you manufacture, process, or use the chemical substances contained in this rule. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

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

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Chemical importers are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements promulgated at 19 CFR 12.118 through 12.127 and 19 CFR 127.28. Chemical importers must certify that the shipment of the chemical substance complies with all applicable rules and orders

under TSCA. Importers of chemicals subject to these SNURs must certify their compliance with the SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export a chemical substance that is the subject of a proposed or final rule are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)) (see § 721.20), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

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

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

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

- i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).
- ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

- iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- iv. Describe any assumptions and provide any technical information and/or data that you used.
- v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- vi. Provide specific examples to illustrate your concerns and suggest alternatives.
- vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- viii. Make sure to submit your comments by the comment period deadline identified.

II. Background

A. What Action is the Agency Taking?

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

B. What is the Agency's Authority for Taking this Action?

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a “significant new use.” EPA must make this determination by rule after considering all relevant factors, including the four bulleted TSCA section 5(a)(2) factors listed in Unit III. Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1)(B) requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture or process the chemical substance for that use. Persons who must report are described in § 721.5.

C. Applicability of General Provisions

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

III. Significant New Use Determination

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

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

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

To determine what would constitute a significant new use for the 13 chemical substances that are the subject of these SNURs, EPA considered relevant information about the toxicity of the chemical substances, likely human exposures and environmental releases associated with possible uses, and the four bulleted TSCA section 5(a)(2) factors listed in this unit.

IV. Substances Subject to this Rule

EPA is establishing significant new use and recordkeeping requirements for 13 chemical substances in 40 CFR part 721, subpart E. In this unit, EPA provides the following information for each chemical substance:

- PMN number.

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

This rule includes two PMN substances, P-10-5 and P-11-339, whose reported chemical names include the term “carbon nanotube” or “CNT”. Because of a lack of established nomenclature for carbon nanotubes, the TSCA Inventory names for carbon nanotubes are currently in generic form, e.g., carbon nanotube (CNT), multi-walled carbon nanotube (MWCNT), double-walled carbon nanotube (DWCNT), or single-walled carbon nanotube (SWCNT). EPA uses the specific structural characteristics provided by the PMN submitter to more specifically characterize the Inventory listing for an individual CNT. All submitters of new chemical notices for CNTs in this SNUR have claimed those specific structural characteristics as CBI. EPA is publishing the generic chemical name along with the PMN number to identify that a distinct chemical substance was the subject of the PMN without revealing the confidential chemical identity of the PMN substance. Confidentiality claims preclude a more detailed description of the identity of these CNTs. If an intended manufacturer or processor of CNTs is unsure of whether its CNTs are subject to this SNUR or any other SNUR, the company can either contact EPA or obtain a written determination from EPA pursuant to the bona fide procedures at § 721.11. EPA

is using the specific structural characteristics, for all CNTs submitted as new chemical substances under TSCA, to help develop standard nomenclature for placing these chemical substances on the TSCA Inventory. EPA has compiled a generic list of those structural characteristics entitled “Material Characterization of Carbon Nanotubes for Molecular Identity (MI) Determination & Nomenclature.” A copy of this list is available in the docket for these SNURs under docket ID number EPA-HQ-OPPT-2014-0277. If EPA develops a more specific generic chemical name for these materials, that name will be made publicly available.

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

This rule includes 3 PMN substances (P-10-5, P-11-339 and P-12-125) that are subject to “risk-based” consent orders under TSCA section 5(e)(1)(A)(ii)(I) where EPA determined that activities associated with the PMN substances may present unreasonable risk to human health or the environment. Those consent orders require protective measures to limit exposures or otherwise mitigate the potential unreasonable risk. The so-called “TSCA section 5(e) SNURs” on these PMN substances are promulgated pursuant to § 721.160, and are based on and consistent with the provisions in the underlying consent orders. The TSCA section 5(e) SNURs designate as a “significant new use” the absence of the protective measures required in the corresponding consent orders.

This rule also includes SNURs on 10 PMN substances that are not subject to

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

PMN Number P-10-5

Chemical name: Single-walled carbon nanotubes (generic).

CAS number: Claimed confidential.

Effective date of TSCA section 5(e) consent order: November 30, 2010.

Basis for TSCA section 5(e) consent order: The PMN states that the uses of the substance will be as a component for a conductive coating using the PMN substance in a dispersion or ink, and as an additive in resins/thermoplastics/elastomers for mechanical reinforcement. Based on structure-activity relationship (SAR) analysis of test data on analogous respirable, poorly soluble particulates and other carbon nanotubes (CNTs), EPA identified concerns for pulmonary toxicity, fibrosis, carcinogenicity, mutagenicity,

and immunotoxicity. Further, available data suggests that pulmonary deposition of some nanoparticles, including CNT may induce cardiovascular toxicity if inhaled. Based on the uncertainty of the characterization and exposure of nanoscale materials in general, there may be additional potential for translocation across the dermis and effects on target organs via the oral route of exposure. Finally, EPA expects that some fraction of the CNTs, if released into the environment, will eventually be suspended in water. Based on findings of sublethal effects observed for CNTs in rainbow trout at levels as low as 100 parts per billion (ppb) and that toxicity of CNTs may be further altered by the presence of natural organic matter that may be associated with nanomaterials when released into the natural environment, EPA identified concerns for toxicity to aquatic organisms. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) based on a finding that this substance may present an unreasonable risk of injury to human health and the environment. To protect against this risk, the Order requires:

1. Use of personal protective equipment including gloves and protective clothing impervious to the substance when there is potential dermal exposure and use of a National Institute of Occupational Safety and Health (NIOSH)-certified air-purifying, tight-fitting full-face respirator equipped with N-100 cartridges when there is potential inhalation exposure.
2. Use of the substance only as a component for a conductive coating using the PMN substance in a dispersion or ink or as an additive in resins/thermoplastics/elastomers for mechanical reinforcement.

3. Manufacture of the substance at a volume not to exceed a confidential volume specified in the consent order unless the company has submitted the results of certain health studies and physical/chemical properties data.

4. No surface water releases of the PMN substance, except for limited water releases resulting in no more than 1 ppb waste water effluent concentration determined by monitoring. The Company shall analyze the concentration of the PMN substance in waste water discharged to the city sewer from the facility every year and adhere to the monitoring procedure referenced in the consent order.

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

Recommended testing: EPA has determined that the results of a 90-day inhalation toxicity study in rats (OPPTS Test Guideline 870.3465 or Organisation for Economic Co-operation and Development (OECD) Test Guideline 413) with a post-exposure observation period of up to 3 months, including bronchoalveolar lavage fluid (BALF) analysis, a determination of cardiovascular toxicity (clinically-based blood/plasma protein analyses), and histopathology of the heart; and certain physical/chemical properties, would help characterize possible effects of the substance. The PMN submitter has agreed not to exceed the confidential production volume stated in the consent order without performing the inhalation toxicity study. In addition, in the consent order, the PMN submitter agreed to provide physical/chemical properties data within a specified time limit.

CFR citation: 40 CFR 721.10755.

PMN Number P-11-339

Chemical name: Multi-walled carbon nanotubes (generic).

CAS number: Claimed confidential.

Effective date of TSCA section 5(e) consent order: August 25, 2011.

Basis for TSCA section 5(e) consent order: The PMN states that the use of the substance will be as an additive in resins, thermoplastics, and elastomers for mechanical reinforcement and enhanced electrical performance, as a coating on metallic foils for battery applications, or in the manufacture of fabric composites. Based on SAR analysis of test data on analogous respirable, poorly soluble particulates and other CNTs, EPA identified concerns for pulmonary toxicity, fibrosis, carcinogenicity, mutagenicity, and immunotoxicity. Further, available data suggests that pulmonary deposition of some nanoparticles, including CNT may induce cardiovascular toxicity if inhaled. Finally, EPA expects that some fraction of the CNTs, if released into the environment, will eventually be suspended in water. Based on findings of sublethal effects observed for CNTs in rainbow trout at levels as low as 100 ppb and that toxicity of CNTs may be further altered by the presence of natural organic matter that may be associated with nanomaterials when released into the natural environment, EPA identified concerns for toxicity to aquatic organisms. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) based on a finding that this substance may present an unreasonable risk of injury to human health and the environment. To protect against this risk, the Order requires:

1. Use of personal protective equipment including gloves and protective clothing impervious to the substance when there is potential dermal exposure and a NIOSH-

certified air-purifying, tight-fitting full-face respirator equipped with N-100, R-100, or P-100 cartridges when there is potential for inhalation exposure.

2. Use of the substance only as an additive in resins, thermoplastics, and elastomers for mechanical reinforcement and enhanced electrical performance, as a coating on metallic foils for battery applications, or in the manufacture of fabric composites.

3. Manufacture of the substance at a volume not to exceed a confidential volume specified in the consent order unless the company has submitted the results of certain health studies and physical/chemical properties data.

4. No surface water releases of the PMN substance, except for limited water releases resulting in no more than 1 ppb waste water effluent concentration determined by monitoring. The Company shall analyze the concentration of the PMN substance in waste water discharged to the city sewer from the facility every year and adhere to the monitoring procedure referenced in the consent order.

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

Recommended testing: EPA has determined that the results of a 90-day inhalation toxicity study in rats (OPPTS Test Guideline 870.3465 or OECD Test Guideline 413) with a post exposure observation period of up to 3 months, including BALF analysis, a determination of cardiovascular toxicity (clinically-based blood/plasma protein analyses), and histopathology of the heart; and certain physical/chemical properties, would help characterize possible effects of the substance. The PMN submitter has agreed not to exceed the confidential production volume stated in the consent order without performing

the inhalation toxicity study. In the consent order, the PMN submitter agreed to provide physical/chemical properties data within a specified time limit.

CFR citation: 40 CFR 721.10756.

PMN Numbers P-12-100 and P-12-150

Chemical names: Fatty acids, diesters with dihydroxy bicyclic diether (generic).

CAS numbers: Claimed confidential.

Basis for action: The PMNs state that the uses of the substances will be as a polymer modifier and a seal swell additive for industrial applications. Based on test data on the PMN substances, as well as SAR analysis of test data on analogous esters, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PMN substances in surface waters for greater than 20 days per year. This 20-day criterion is derived from partial life cycle tests (daphnid chronic and fish early life stage tests) that typically range from 21 to 28 days in duration. EPA predicts toxicity to aquatic organisms may occur if releases of the substances to surface water, from uses other than as described in the PMNs, exceed releases from the uses described in the PMNs. For the uses described in the PMNs, environmental releases did not exceed 1 ppb for more than 20 days per year. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substances may present an unreasonable risk. EPA has determined, however, that any use of the substances other than as polymer modifiers and seal swell additives for industrial applications may cause significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(i) and (b)(4)(ii).

Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400) and a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300) would help characterize the environmental effects of the PMN substances.

CFR citation: 40 CFR 721.10757.

PMN Number P-12-125

Chemical name: Thermolized wasted plastic (generic).

CAS number: Claimed confidential.

Effective date of TSCA section 5(e) consent order: October 2, 2013.

Basis for TSCA section 5(e) consent order: The PMN states that the generic (non-confidential) use of the substance will be as a petroleum feedstock. Based on SAR analysis of test data on analogous styrenes and benzenes, EPA identified concerns for solvent irritation and solvent neurotoxicity; hydrocarbon pneumonia; liver, kidney, blood, developmental and reproductive toxicities; immunotoxicity, mutagenicity, and oncogenicity. Further, polychlorinated dibenzo-p-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs) impurities in the PMN substance are known to be highly persistent, bioaccumulative, and toxic (PBT) chemicals that cause developmental toxicity, inhalation effects, carcinogenicity and are highly toxic to aquatic life. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) based on a finding that the substance may present an unreasonable risk of injury to human health and the environment. To protect against this risk, the consent order requires:

1. Establishment and use of a hazard communication program.

2. Manufacture of the PMN substance: (a) According to the chemical composition section of the consent order, including analyzing and reporting PCDD and PCDF levels in the PMN substance to EPA; (b) without exceeding the maximum established limit of 110 picogram/gram (pg/g) of PCDD/PCDF toxic equivalents (using the World Health Organization 2005 Toxic Equivalency Factors as detailed in the consent order; and (c) while monitoring the pH of the aqueous effluent stream from the manufacturing process as outlined in the consent order.

3. Use of the substance only as described in the consent order.

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

Recommended testing: EPA has determined, at this time, that there is no testing that would help further characterize the environmental/human health effects of the PMN substance. In the consent order, the PMN submitter agreed to analyze for PCDD and PCDF impurities every quarter during manufacture of the PMN substance, using EPA Test Method 8290A.

CFR citation: 40 CFR 721.10758.

PMN Number P-13-369

Chemical name: Polyphosphoric acids, esters with substituted amines, compounds with alkyl pyridines (generic).

CAS number: Claimed confidential.

Basis for action: The PMN states that the use of the substance is as a solids conglomeration additive for down-hole treatment of oil and gas wells to prevent the undesirable production of solids. Based on test data on the PMN substance, EPA predicts

chronic toxicity to aquatic organisms may occur at concentrations that exceed 8 ppb of the PMN substance in surface waters. As described in the PMN, releases of the substance are not expected to result in surface water concentrations that exceed 8 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 8 ppb or use other than as described in the PMN, or if disposed of during manufacturing by means other than incineration may result in significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(i).

Recommended testing: EPA has determined that the results of a mysid chronic toxicity test (OCSPP Test Guideline 850.1350); an algal toxicity test (OCSPP Test Guideline 850.4500); and a modified algal toxicity test (OCSPP Test Guideline 850.4500) where the PMN substance is substituted for the phosphate nutrient in the algal growth medium would help characterize the environmental effects of the PMN substance:

CFR citation: 40 CFR 721.10759.

PMN Number P-13-854

Chemical name: Zinc carboxylate salt (generic).

CAS number: Claimed confidential.

Basis for action: The PMN states that the use of the substance is as a petroleum production chemical. Based on SAR analysis of test data on analogous organozinc compounds, EPA predicts chronic toxicity to aquatic organisms may occur at concentrations that exceed 3 ppb of the PMN substance in surface waters. As described in the PMN, releases of the substance are not expected to result in surface water

concentrations that exceed 3 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk.

EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 3 ppb may result in significant adverse environmental effects.

Based on this information, the PMN substance meets the concern criteria at

§ 721.170(b)(4)(ii).

Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substance.

CFR citation: 40 CFR 721.10760.

PMN Numbers P-14-12, P-14-13, P-14-15, and P-14-16

Chemical names: Fatty acid amide (generic).

CAS numbers: Claimed confidential.

Basis for action: The PMNs state that the substances will be used as emulsifiers for use in asphalt applications. Based on SAR analysis of test data on analogous aliphatic amines, EPA predicts chronic toxicity to aquatic organisms may occur at concentrations that exceed the following values of the PMN substances in surface waters.

PMN Number	Concentration
P-14-12	110 ppb
P-14-13	240 ppb
P-14-15	53 ppb

P-14-16	110 ppb
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For the use described in the PMNs, releases of the substances are not expected to result in surface water concentrations exceeding these values. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substances other than as emulsifiers for use in asphalt applications may cause significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(ii).

Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substances. The Agency recommends that testing be conducted on P-14-15 as EPA predicts this substance to be the most acutely toxic to aquatic organisms of these four PMN substances.

CFR citation: 40 CFR 721.10761.

PMN Number P-14-60

Chemical name: 1,1'-methylenabis[isocyanatobenzene], polymer with polycarboxylic acids in alkane polyols (generic).

CAS number: Claimed confidential.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as a coating component. Based on SAR analysis of test data on analogous

diisocyanates, EPA identified concerns for dermal and respiratory sensitization to persons exposed to the PMN substance. As described in the PMN, worker exposure will be minimal due to the use of adequate personal protective equipment, and EPA does not expect significant consumer exposure as the substance is not used in a consumer product. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance without a NIOSH-certified respirator with an assigned protection factor (APF) of at least 10, where there is potential inhalation exposure; or any use of the substance in consumer products may cause serious health effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(3)(ii).

Recommended testing: EPA has determined that the results of a skin sensitization test (OPPTS Test Guideline 870.2600) and a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) would help characterize the human health effects of the PMN substance.

CFR citation: 40 CFR 721.10762.

PMN Number P-14-143

Chemical name: Alkanaminium, [substituted carbomonocycle [(alkylamino)carbomonocycle]alkylene]-substituted carbomonocycle, carboxylate salt (generic).

CAS number: Claimed confidential.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as an ingredient used in pigment synthesis. Based on SAR analysis of test data on analogous delocalized cationic dyes, EPA predicts toxicity to aquatic organisms may

occur at concentrations that exceed 1 ppb of the PMN substance in surface waters. As described in the PMN, environmental releases are not expected to result in surface water concentrations that exceed 1 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 1 ppb may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(ii).

Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); a fish acute toxicity mitigated by humic acid test (OPPTS Test Guideline 850.1085); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substance.

CFR citation: 40 CFR 721.10763.

V. Rationale and Objectives of the Rule

A. Rationale

During review of the PMNs submitted for the chemical substances that are subject to these SNURs, EPA concluded that for 3 of the 13 chemical substances, regulation was warranted under TSCA section 5(e), pending the development of information sufficient to make reasoned evaluations of the health or environmental effects of the chemical substances. The basis for such findings is outlined in Unit IV. Based on these findings, TSCA section 5(e) consent orders requiring the use of appropriate exposure controls were

negotiated with the PMN submitters. The SNUR provisions for these chemical substances are consistent with the provisions of the TSCA section 5(e) consent orders. These SNURs are promulgated pursuant to § 721.160 (see Unit VI.).

In the other 10 cases, where the uses are not regulated under a TSCA section 5(e) consent order, EPA determined that one or more of the criteria of concern established at § 721.170 were met, as discussed in Unit IV.

B. Objectives

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

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

Issuance of a SNUR for a chemical substance does not signify that the chemical substance is listed on the TSCA Chemical Substance Inventory (TSCA Inventory).

Guidance on how to determine if a chemical substance is on the TSCA Inventory is available on the Internet at

<http://www.epa.gov/opptintr/existingchemicals/pubs/tscainventory/index.html>.

VI. Direct Final Procedures

EPA is issuing these SNURs as a direct final rule, as described in § 721.160(c)(3) and § 721.170(d)(4). In accordance with § 721.160(c)(3)(ii) and § 721.170(d)(4)(i)(B), the effective date of this rule is [*insert date 60 days after date of publication in the **Federal Register***] without further notice, unless EPA receives written adverse or critical comments, or notice of intent to submit adverse or critical comments before [*insert date 30 days after date of publication in the **Federal Register***].

If EPA receives written adverse or critical comments, or notice of intent to submit adverse or critical comments, on one or more of these SNURs before [*insert date 30 days after date of publication in the **Federal Register***], EPA will withdraw the relevant sections of this direct final rule before its effective date. EPA will then issue a proposed SNUR for the chemical substance(s) on which adverse or critical comments were received, providing a 30-day period for public comment.

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

VII. Applicability of the Significant New Use Designation

To establish a significant new use, EPA must determine that the use is not ongoing. The chemical substances subject to this rule have undergone premanufacture review. In cases where EPA has not received a notice of commencement (NOC) and the chemical substance has not been added to the TSCA Inventory, no person may commence such activities without first submitting a PMN. Therefore, for chemical substances for which an NOC has not been submitted, EPA concludes that the designated significant new uses are not ongoing.

When chemical substances identified in this rule are added to the TSCA Inventory, EPA recognizes that, before the rule is effective, other persons might engage in a use that has been identified as a significant new use. However, TSCA section 5(e) consent orders have been issued for 3 of the 13 chemical substances, and the PMN submitters are prohibited by the TSCA section 5(e) consent orders from undertaking activities which would be designated as significant new uses. The identities of all 13 of the chemical substances subject to this rule have been claimed as confidential and EPA has received no post-PMN *bona fide* submissions (per §§ 720.25 and 721.11). Based on this, the Agency believes that it is highly unlikely that any of the significant new uses described in the regulatory text of this rule are ongoing.

Therefore, EPA designates [*insert date of publication in the Federal Register*] as the cutoff date for determining whether the new use is ongoing. Persons who begin commercial manufacture or processing of the chemical substances for a significant new use identified as of that date would have to cease any such activity upon the effective date of the final rule. To resume their activities, these persons would have to first comply with all applicable SNUR notification requirements and wait until the notice review period,

including any extensions, expires. If such a person met the conditions of advance compliance under § 721.45(h), the person would be considered exempt from the requirements of the SNUR. Consult the **Federal Register** document of April 24, 1990 for a more detailed discussion of the cutoff date for ongoing uses.

VIII. Test Data and Other Information

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

1. Development of test data is required where the chemical substance subject to the SNUR is also subject to a test rule under TSCA section 4 (see TSCA section 5(b)(1)).
2. Development of test data may be necessary where the chemical substance has been listed under TSCA section 5(b)(4) (see TSCA section 5(b)(2)).

In the absence of a TSCA section 4 test rule or a TSCA section 5(b)(4) listing covering the chemical substance, persons are required only to submit test data in their possession or control and to describe any other data known to or reasonably ascertainable by them (see 40 CFR 720.50). However, upon review of PMNs and SNUNs, the Agency has the authority to require appropriate testing. In cases where EPA issued a TSCA section 5(e) consent order that requires or recommends certain testing, Unit IV. lists those tests. Unit IV. also lists recommended testing for non-TSCA section 5(e) SNURs. Descriptions of tests are provided for informational purposes. EPA strongly encourages persons, before performing any testing, to consult with the Agency pertaining to protocol selection. To access the OCSPP test guidelines referenced in this document electronically, please go to <http://www.epa.gov/ocspp> and select “Test Methods and Guidelines.” The Organisation for Economic Co-operation and Development (OECD)

test guidelines are available from the OECD Bookshop at <http://www.oecdbookshop.org> or SourceOECD at <http://www.sourceoecd.org>.

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

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

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

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

IX. Procedural Determinations

By this rule, EPA is establishing certain significant new uses which have been claimed as CBI subject to Agency confidentiality regulations at 40 CFR part 2 and 40 CFR part 720, subpart E. Absent a final determination or other disposition of the confidentiality claim under 40 CFR part 2 procedures, EPA is required to keep this information confidential. EPA promulgated a procedure to deal with the situation where a specific significant new use is CBI, at 40 CFR 721.1725(b)(1).

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

bona fide submission under the procedure in § 721.1725(b)(1) with that under § 721.11 into a single step.

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

X. SNUN Submissions

According to § 721.1(c), persons submitting a SNUN must comply with the same notification requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in 40 CFR 720.50. SNUNs must be submitted on EPA Form No. 7710-25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in 40 CFR 720.40 and § 721.25. E-PMN software is available electronically at <http://www.epa.gov/opptintr/newchems>.

XI. Economic Analysis

EPA has evaluated the potential costs of establishing SNUN requirements for potential manufacturers and processors of the chemical substances subject to this rule.

EPA's complete economic analysis is available in the docket under docket ID number EPA-HQ-OPPT-2014-0277.

XII. Statutory and Executive Order Reviews

A. Executive Order 12866

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

B. Paperwork Reduction Act (PRA)

According to PRA (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable. EPA is amending the table in 40 CFR part 9 to list the OMB approval number for the information collection requirements contained in this rule. This listing of the OMB control numbers and their subsequent codification in the CFR satisfies the display requirements of PRA and OMB's implementing regulations at 5 CFR part 1320. This Information Collection Request (ICR) was previously subject to public notice and comment prior to OMB approval, and given the technical nature of the table, EPA finds that further notice and comment to amend it is unnecessary. As a result, EPA finds that there is “good cause” under section 553(b)(3)(B)

of the Administrative Procedure Act (5 U.S.C. 553(b)(3)(B)) to amend this table without further notice and comment.

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

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

C. Regulatory Flexibility Act (RFA)

On February 18, 2012, EPA certified pursuant to RFA section 605(b) (5 U.S.C. 601 *et seq.*), that promulgation of a SNUR does not have a significant economic impact on a substantial number of small entities where the following are true:

1. A significant number of SNUNs would not be submitted by small entities in response to the SNUR.

2. The SNUR submitted by any small entity would not cost significantly more than \$8,300.

A copy of that certification is available in the docket for this rule.

This rule is within the scope of the February 18, 2012 certification. Based on the Economic Analysis discussed in Unit XI. and EPA's experience promulgating SNURs (discussed in the certification), EPA believes that the following are true:

- A significant number of SNUNs would not be submitted by small entities in response to the SNUR.

- Submission of the SNUN would not cost any small entity significantly more than \$8,300.

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

D. Unfunded Mandates Reform Act (UMRA)

Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reasons to believe that any State, local, or Tribal government will be impacted by this rule. As such, EPA has determined that this rule does not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the requirements of UMRA sections 202, 203, 204, or 205 (2 U.S.C. 1501 *et seq.*).

E. Executive Order 13132

This action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and

responsibilities among the various levels of government, as specified in Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999).

F. Executive Order 13175

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

G. Executive Order 13045

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

H. Executive Order 13211

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

I. National Technology Transfer and Advancement Act (NTTAA)

In addition, since this action does not involve any technical standards, NTTAA section 12(d) (15 U.S.C. 272 note), does not apply to this action.

J. Executive Order 12898

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

XIII. Congressional Review Act

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

List of Subjects

40 CFR Part 9

Environmental protection, Reporting and recordkeeping requirements.

40 CFR Part 721

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

Dated: June 27, 2014.

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

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

PART 9--[AMENDED]

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

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

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

§ 9.1 OMB approvals under the Paperwork Reduction Act.

* * * * *

40 CFR citation	OMB control No.
* * *	* *
Significant New Uses of Chemical Substances	
* * *	* *
721.10755	2070-0012
721.10756	2070-0012
721.10757	2070-0012
721.10758	2070-0012
721.10759	2070-0012
721.10760	2070-0012

721.10761	2070-0012
721.10762	2070-0012
721.10763	2070-0012
*	* * *

* * *

PART 721--AMENDED

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

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

4. Add § 721.10755 to subpart E to read as follows:

§ 721.10755 Single-walled carbon nanotubes (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as single-walled carbon nanotubes (PMN P-10-5) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this rule do not apply to quantities of the PMN substance after it has been completely reacted (cured); embedded or incorporated into a polymer matrix that has been reacted (cured); or embedded in a permanent solid polymer form that is not intended to undergo further processing except for mechanical processing.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in §721.63(a)(1), (a)(2)(i), (a)(2)(ii) (clothing that covers other exposed areas of the arms, legs, and torso), (a)(3), (a)(4) (National Institute for Occupational Safety and Health (NIOSH)-certified air-purifying, tight-fitting full-face respirator equipped with N100 cartridges), (a)(6)(i),

and (c). When determining which persons are reasonably likely to be exposed as required for §721.63(a)(1) and (a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible.

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k) (a significant new use is any use other than as a component for a conductive coating using the PMN substance in a dispersion or ink, and additive in resins/thermoplastics/elastomers for mechanical reinforcement.) and (q).

(iii) *Release to water.* Requirements as specified in § 721.90(a)(1), (b)(1), and (c)(1), except for water releases determined by monitoring the concentration of the PMN substance in waste water effluent according to a monitoring procedure approved for such purpose by EPA and when the concentration of the PMN substance does not exceed 1 part per billion (ppb). EPA will review and act on written requests to approve monitoring procedures within 90 days after such requests are received. EPA will inform submitters of the disposition of such requests in writing, and will explain the reasons therefore when they are denied.

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

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a), (b), (c), (d), (e), (i), and (k) are applicable to manufacturers 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 paragraphs (a)(2)(ii) and (a)(2)(iii) of this section.

5. Add § 721.10756 to subpart E to read as follows:

§ 721.10756 Multi-walled carbon nanotubes (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as multi-walled carbon nanotubes (PMN P-11-339) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this rule do not apply to quantities of the PMN substance after it has been completely reacted (cured); embedded or incorporated into a polymer matrix that has been reacted (cured); or embedded in a permanent solid polymer form that is not intended to undergo further processing except for mechanical processing.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in §721.63(a)(1), (a)(2)(i), (a)(2)(ii) (clothing that covers other exposed areas of the arms, legs, and torso), (a)(3), (a)(4) (National Institute for Occupational Safety and Health (NIOSH)-certified air-purifying, tight-fitting full-face respirator equipped with N100, P100, or R100 cartridges), (a)(6)(i), and (c). When determining which persons are reasonably likely to be exposed as required for §721.63(a)(1) and (a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible.

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k) (a significant new use is any use other than as an additive in resins, thermoplastics, and elastomers for mechanical reinforcement and enhanced electrical performance, as a coating on metallic foils for battery applications, or in the manufacture of fabric composites.) and (q).

(iii) *Release to water.* Requirements as specified in § 721.90(a)(1), (b)(1), and (c)(1), except for water releases determined by monitoring the concentration of the PMN substance in waste water effluent according to a monitoring procedure approved for such purpose by EPA and when the concentration of the PMN substance does not exceed 1 part per billion (ppb). EPA will review and act on written requests to approve monitoring procedures within 90 days after such requests are received. EPA will inform submitters of the disposition of such requests in writing, and will explain the reasons therefore when they are denied.

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

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a), (b), (c), (d), (e), (i), and (k) are applicable to manufacturers 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 paragraphs (a)(2)(ii) and (a)(2)(iii) of this section.

6. Add § 721.10757 to subpart E to read as follows:

§ 721.10757 Fatty acids, diesters with dihydroxy bicyclic diether (generic).

(a) *Chemical substances and significant new uses subject to reporting.* (1) The chemical substances identified generically as fatty acids, diesters with dihydroxy bicyclic diether (PMNs P-12-100 and P-12-150) 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. A significant new use is any use other than as a polymer modifier or a seal swell additive for industrial applications.

(ii) [Reserved]

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

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

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

7. Add § 721.10758 to subpart E to read as follows:

§ 721.10758 Thermolized wasted plastic (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as thermolized wasted plastic (PMN P-12-125) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this rule do not apply to quantities of the PMN substance after it has been completely fractionated, distilled, or chemically

reacted resulting in the manufacture of one or more new chemical substances subject to PMN review or other chemical substances listed on the TSCA Inventory.

(2) The significant new uses are:

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

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k)(a significant new use is any use other than as allowed by the TSCA section 5(e) consent order which includes analysis and reporting and limitations of maximum levels of polychlorinated dibenzo-*p*-dioxin and polychlorinated dibenzofuran impurities and monitoring the pH of the aqueous effluent stream from the manufacturing process as outlined in the Consent Order.)

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

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

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(ii) of this section.

8. Add § 721.10759 to subpart E to read as follows:

§ 721.10759 Polyphosphoric acids, esters with substituted amines, compounds with alkyl pyridines (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as polyphosphoric acids, esters with substituted amines, compounds with alkyl pyridines (PMN P-13-369) 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. A significant new use is any use of the PMN substance other than as a solids conglomeration additive for down-hole treatment of oil and gas wells to prevent the undesirable production of solids.

(ii) *Disposal.* Requirements as specified in § 721.85(a)(1).

(iii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) (N=8) (for marine discharges, a dilution factor of 65 should be applied).

(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), (j), and (k) are applicable to manufacturers and processors of this substance.

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

9. Add § 721.10760 to subpart E to read as follows:

§ 721.10760 Zinc carboxylate salt (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as zinc carboxylate salt (PMN P-13-854) is

subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Release to water.* Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) (N=3).

(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 and processors of this substance.

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

10. Add § 721.10761 to subpart E to read as follows:

§ 721.10761 Fatty acid amide (generic).

(a) *Chemical substances and significant new uses subject to reporting.* (1) The chemical substances identified generically as fatty acid amide (PMNs P-14-12, P-14-13, P-14-15, P-14-16) 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. A significant new use is any use of the PMN substance other than as an emulsifier for use in asphalt applications.

(ii) [Reserved]

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

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

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

11. Add § 721.10762 to subpart E to read as follows:

§ 721.10762 1,1'-methylenebis[isocyanatobenzene], polymer with polycarboxylic acids in alkane polyols (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as 1,1'-methylenebis[isocyanatobenzene], polymer with polycarboxylic acids in alkane polyols (PMN P-14-60) 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)(6)(i) through (a)(6)(iv), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. The following National Institute for Occupational Safety and Health (NIOSH)-certified respirators with an assigned protection factor (APF) of at least 10 meet the requirements of § 721.63(a)(4):

(A) NIOSH-certified power air-purifying respirator with a hood or helmet and with appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridges in combination with HEPA filters;

(B) NIOSH-certified continuous flow supplied-air respirator equipped with a loose fitting facepiece, hood, or helmet; and

(C) NIOSH-certified negative pressure (demand) supplied-air respirator with a full facepiece.

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(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), and (i) are applicable to manufacturers and processors of this substance.

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

12. Add § 721.10763 to subpart E to read as follows:

§ 721.10763 Alkanaminium, [substituted carbomonocycle [(alkylamino)carbomonocycle]alkylene]-substituted carbomonocycle, carboxylate salt (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as alkanaminium, [substituted carbomonocycle [(alkylamino)carbomonocycle]alkylene]-substituted carbomonocycle, carboxylate salt

(PMN P-14-143) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

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

(ii) [Reserved]

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

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

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