

§ 36.4408 Submission of proof to the Secretary.

The Secretary may, at any time, require submission of such proof of costs and other matters as the Secretary deems necessary.

(Authority: 38 U.S.C. 501, 2101(d))

(The Office of Management and Budget has approved the information collection provisions in this section under control numbers 2900-0031 and 2900-0300.)

§ 36.4409 Delegations of authority.

(a) Each employee of the Department of Veterans Affairs appointed to or lawfully filling any of the following positions is hereby delegated authority, within the limitations and conditions prescribed by law, to exercise the powers and functions of the Secretary with respect to assisting eligible individuals in acquiring specially adapted housing:

- (1) Under Secretary for Benefits.
 - (2) Director, Loan Guaranty Service.
 - (3) Deputy Director, Loan Guaranty Service.
 - (4) Assistant Director, Loan Policy and Valuation.
 - (5) Chief, Specially Adapted Housing, Loan Guaranty Service.
 - (6) Director, VA Medical Center.
 - (7) Director, VA Regional Office.
 - (8) Loan Guaranty Officer.
 - (9) Assistant Loan Guaranty Officer.
- (b) Nothing in this section will be construed to authorize the determination of basic eligibility or medical feasibility under § 36.4404(a), (b)(1)(i), or (b)(1)(ii) by any employee designated in this section, except as otherwise authorized.

(Authority: 38 U.S.C. 501, 512, ch. 21)

§ 36.4410 Supplementary administrative action.

Subject to statutory limitations and conditions prescribed in title 38, U.S.C., the Secretary may take such action as may be necessary or appropriate to relieve undue prejudice to an eligible individual or a third party contracting or dealing with such eligible individual which might otherwise result.

(Authority: 38 U.S.C. 501, 2101(d))

§ 36.4411 Annual adjustments to the aggregate amount of assistance available.

(a) On October 1 of each year, the Secretary will increase the aggregate amounts of assistance available for grants authorized under 38 U.S.C. 2101(a) and 2101(b). Such increase will be equal to the percentage by which the Turner Building Cost Index for the most recent calendar year exceeds that of the next preceding calendar year.

(b) Notwithstanding paragraph (a) of this section, if the Turner Building Cost Index for the most recent full calendar year is equal to or less than the next preceding calendar year, the percentage increase will be zero.

(c) No later than September 30 of each year, the Secretary will publish in the **Federal Register** the aggregate amounts of assistance available for the upcoming fiscal year.

(Authority: 38 U.S.C. 2102(e))

[FR Doc. 2010-23277 Filed 9-16-10; 8:45 am]

BILLING CODE 8320-01-P

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Parts 9 and 721**

[EPA-HQ-OPPT-2008-0252; FRL-8835-5]

RIN 2070-AB27

Multi-Walled Carbon Nanotubes and Single-Walled Carbon Nanotubes; Significant New Use Rules

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is issuing significant new use rules (SNURs) under section 5(a)(2) of the Toxic Substances Control Act (TSCA) for two chemical substances which were the subject of Premanufacture Notices (PMNs). The two chemical substances are identified generically as multi-walled carbon nanotubes (MWCNT) (PMN P-08-177) and single-walled carbon nanotubes (SWCNT) (PMN P-08-328). This action requires persons who intend to manufacture, import, or process either of these two chemical substances for a use that is designated as a significant new use by this final rule to notify EPA at least 90 days before commencing that activity. EPA believes that this action is necessary because these chemical substances may be hazardous to human health and the environment. The required notification would provide EPA with the opportunity to evaluate the intended use and, if necessary, to prohibit or limit that activity before it occurs.

DATES: This final rule is effective October 18, 2010.

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPPT-2008-0252. All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available,

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

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Jim Alwood, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-8974; e-mail address: alwood.jim@epa.gov.

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

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

You may be potentially affected by this action if you manufacture, import, process, or use either of the chemical substances contained in this final rule: Multi-walled carbon nanotubes (MWCNT) (PMN P-08-177) and single-walled carbon nanotubes (SWCNT) (PMN P-08-328). Potentially affected entities may include, but are not limited to:

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

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

entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in § 721.5. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Chemical importers are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements promulgated at 19 CFR 12.118 through 12.127; see also 19 CFR 127.28 (the corresponding EPA policy appears at 40 CFR part 707, subpart B). Chemical importers must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA. Importers of chemicals subject to these SNURs must certify their compliance with the SNUR requirements. In addition, any persons who export or intend to export a chemical substance that is the subject of this final rule on or after October 18, 2010 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.

II. Background

A. What Action is the Agency Taking?

EPA is finalizing SNURs under TSCA section 5(a)(2) for two chemical substances which were the subject of PMNs. The two chemical substances are identified generically (due to confidentiality claims) as multi-walled carbon nanotubes (MWCNT) (PMN P-08-177) and single-walled carbon nanotubes (SWCNT) (PMN P-08-328). This action requires persons who intend to manufacture, import, or process either of these two chemical substances for an activity that is designated as a significant new use by this final rule to notify EPA at least 90 days before commencing that activity.

Previously, in the **Federal Register** issue of June 24, 2009 (74 FR 29982) (FRL-8417-6), EPA issued direct final SNURs on these two chemical substances (see §§ 721.10155 and 721.10156). However, EPA received notices of intent to submit adverse comments on these SNURs. Therefore,

as required by § 721.160(c)(3)(ii), in the **Federal Register** issue of August 21, 2009 (74 FR 42177) (FRL-8433-9), EPA withdrew the direct final SNURs on these two chemical substances and subsequently proposed SNURs using notice and comment procedures in the **Federal Register** issue of November 6, 2009 (74 FR 57430) (FRL-8436-8). More information on the specific chemical substances subject to this final rule can be found in the direct final or proposed SNURs. The record for the direct final and proposed SNURs on these two chemical substances was established in the docket under docket ID number EPA-HQ-OPPT-2008-0252. That docket includes information considered by the Agency in developing the direct final rule and this final rule including comments on those rules.

EPA received several comments on the proposed rule. A full discussion of EPA's response to these comments is included in Unit V. of this document. Based on these comments, EPA is issuing a modified final rule on these chemical substances that:

1. Retains the proposed workplace protection, specific use, aggregate manufacturing and importation volume limitations, and release to water provisions.
2. Provides clarification on the exemptions from applicability of the SNUR.
3. Provides additional human health and environmental summary information to support EPA's findings under § 721.170(b)(4)(ii) and EPA's findings in the proposed rule. See the proposed rule for a discussion of EPA's findings and recommended testing.

In response to comments on the applicability of the SNURs, EPA included in the regulatory text clarifying language for those forms of the subject PMN substances which are exempt from the provisions of the SNURs. These exemptions apply to quantities of the PMN substances:

- After they have been completely reacted (cured);
- Incorporated or embedded into a polymer matrix that itself has been reacted (cured); or
- Embedded in a permanent solid polymer form that is not intended to undergo further processing except for mechanical processing.

In response to comments on the basis for the SNURs, EPA developed revised Human Health Effects and Environmental Effects Summaries for carbon nanotubes (CNTs). See Unit V. of this document. These summaries specify EPA's current hazard concerns as supported by available information

and data. See Unit X. of this document for a list of those sources.

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

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a "significant new use." EPA must make this determination by rule after considering all relevant factors, including those listed in TSCA section 5(a)(2). Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1)(B) requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture, import, or process the chemical substance for that use. 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 final rule. Provisions relating to user fees appear at 40 CFR part 700. According to § 721.1(c), persons subject to these SNURs must comply with the same notice requirements and EPA regulatory procedures as submitters of PMNs under TSCA section 5(a)(1)(A). In particular, these requirements include the information submission requirements of TSCA section 5(b) and 5(d)(1), the exemptions authorized by TSCA section 5(h)(1), (h)(2), (h)(3), and (h)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUN, EPA may take regulatory action under TSCA section 5(e), 5(f), 6, or 7 to control the activities for which it has received the SNUN. If EPA does not take action, EPA is required under TSCA section 5(g) to explain in the **Federal Register** its reasons for not taking action.

Chemical importers are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements promulgated in Customs and Border Patrol regulations at 19 CFR 12.118 through 12.127; see also 19 CFR 127.28 (the corresponding EPA policy appears at 40 CFR part 707, subpart B). Chemical importers must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA. For importers of chemical substances subject to a final SNUR those requirements include the SNUR. In addition, any persons who export or intend to export a chemical substance identified in a final SNUR are subject to the export notification provisions of

TSCA section 12(b) (15 U.S.C. 2611 (b)) (see § 721.20), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

III. Rationale and Objectives of the Rule

A. Rationale

During review of the PMNs submitted for these two chemical substances, EPA concluded that regulation was warranted under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I), pending the development of information sufficient to make reasoned evaluations of the human health effects of the chemical substances. 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 including the recent modifications to the consent orders. These final SNURs are issued pursuant to § 721.160. EPA also finds that, based on the environmental effects data, the PMN substances meet the concern criteria at § 721.170(b)(4)(ii). See the docket under docket ID number EPA-HQ-OPPT-2008-0252 for the corresponding consent orders. For additional discussion of the rationale for the SNURs on multi-walled carbon nanotubes (MWCNT) (PMN P-08-177) and single-walled carbon nanotubes (SWCNT) (PMN P-08-328) see Units II and V. of this document.

B. Objectives

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

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

processors of the same chemical substance that is subject to a TSCA section 5(e) consent order are subject to similar requirements.

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

IV. 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 two chemical substances that are the subject of these final 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.

V. Response to Comments on Proposed SNURs on Multi-Walled Carbon Nanotubes and Single-Walled Carbon Nanotubes

EPA received comments from numerous submitters on the proposed rules for MWCNTs that are the subject of PMN P-08-177 and SWCNTs that are the subject of PMN P-08-328. A discussion of the comments received and the Agency's responses follows.

Comment 1: The SNURs did not properly identify the chemical identity of the substances and the submitter of the PMNs did not claim the chemical name of the substances as CBI; therefore there is no basis for the use of bona fide procedures under 40 CFR part 721. Further, EPA did not give any objective identifying information to identify

specific substances subject to the SNURs. It was requested that EPA clarify the particular chemical identity of the substances covered by these SNURs and how users can tell the difference.

Response: The SNURs for MWCNTs and SWCNTs did properly present the chemical identity of the PMN substances. The SNURs contain the same objective identifying information as hundreds of previously published SNURs where the chemical identity was claimed as CBI. EPA published the generic 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. Because of a lack of established nomenclature for CNTs, EPA has allowed PMN submitters to represent their CNTs using a name such as CNT, MWCNT, or SWCNT while submitting a detailed description of the CNTs using specific structural characteristics. In these instances, the PMN submitters claimed those specific structural characteristics as CBI. If an intended manufacturer, importer, or processor of CNTs is unsure of whether its CNTs are subject to this 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 chemicals substances under TSCA, to 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 this SNUR. If EPA develops a more specific generic name for these materials, that name will be made publicly available.

Comment 2: Reviewing the proposed SNUR gives the impression that EPA considered that MWCNTs and SWCNTs were categories of new substances that may present unreasonable risks to human health. EPA informally noted that the SNURs apply only to the specific CNTs in the PMNs. It appears that EPA has taken the position that some CNTs made by different manufacturers are different chemical substances for purposes of reporting new chemicals under TSCA. EPA should clarify "whether the SNURs are intended to apply to the PMN substances made by other manufacturers."

Response: The SNURs and the findings in the SNURs apply only to the specific CNTs that were the subject of PMNs P-08-177 and P-08-328. As noted in the public comments to this SNUR, EPA has also received and reviewed numerous other new chemical notices for CNTs. EPA acknowledges that CNTs made by different manufacturers and processes may be considered different chemical substances for purposes of reporting new chemical substances under TSCA. EPA will make this determination on a case-by-case basis. The Agency will assess and manage the risks of CNTs in a similar manner when that assessment is based on similar data. EPA may assess and manage CNTs differently as new data becomes available, especially in cases where there are new environmental health and safety data for specific CNTs.

Comment 3: Specify how EPA defines CNT chemical identities so that downstream users can determine when processing of CNTs sufficiently change them so that a new substance is formed that requires new chemical notification under TSCA?

Response: Processing activities that causes a chemical reaction, where new chemical bonds are formed, could result in new chemical substances reportable under TSCA. However, processing activities that change the physical state or physical properties would not result in a new chemical substance reportable under TSCA. Companies with specific questions for specific materials should contact the Agency for a Prenotice Consultation. See <http://www.epa.gov/oppt/newchems/pubs/roster.htm> for Agency contact information.

Comment 4: In some instances companies may not be able to make the certifications required to make a bona fide submission and obtain an identity determination under § 721.11 for carbon nanotubes.

Response: Companies that manufacture, import, or process CNTs can identify the specific structural characteristics referenced in the response to "Comment 1" in order to file a bona fide submission. EPA recommends that companies that have any questions regarding the information required or the need for a bona fide submission for CNTs contact the Agency. See <http://www.epa.gov/oppt/newchems/pubs/roster.htm> for Agency contact information.

Comment 5: The SNURs did not include one of the terms included in the consent order which exempts from the Order's requirements quantities of the PMN substances that have been completely reacted (cured). EPA should

clarify (1) whether quantities of the PMN substances that have been completely reacted (cured) are subject to the disposal restrictions in the SNURs; (2) what other terms of the SNURs are applicable once the PMN substances have been fixed to a substrate or encapsulated within plastic; and (3) applicability of the entire SNURs once the PMN substances have been incorporated into an article.

Response: EPA agrees that all terms of the consent orders should be included in the SNURs and has now amended the regulatory text to include an exemption from SNUR requirements once the PMN substance has been completely reacted or cured. EPA has also developed new, more specific language that addresses applicability of the consent orders once the PMN substances have been fixed to a substrate or encapsulated within a plastic or other matrix. The Agency has included this new language in the regulatory text of the SNURs to exempt from SNUR requirements PMN substances that have been incorporated or embedded into a polymer matrix that itself has been reacted (cured) or embedded in a permanent solid polymer form that is not intended to undergo further processing except for mechanical processing. As stated in § 721.45(f), once a chemical substance has been incorporated into an article the notification requirements of the SNUR do not apply. The term "article" is defined in 40 CFR 720.3(c).

Comment 6: The proposed rules do not reference highly controlled circumstances of use where exposure criteria are met.

Response: The rules do not reference exposure criteria or exposure-based criteria. The rules establish significant new uses that may result in changes of the types, forms, magnitude, and duration of exposures. A SNUR requires notification before any persons manufacture or process for a significant new use so that EPA can evaluate any potential exposures and assess potential risks.

Comment 7: The rules require manufacturers and importers to provide testing at a specified production volume.

Response: The SNURs require notification when a manufacturer or importer exceeds a maximum aggregate manufacturing and importation volume limit. The 90-day inhalation toxicity study (Harmonized Test Guideline 870.3465) is EPA's recommended testing in the proposed SNURs preamble. This is the same study required in the TSCA section 5(e) consent orders for the PMN substances before the PMN submitter exceeds the

specified aggregate maximum manufacturing and importation volume. Other manufacturers or importers who intend to conduct testing or send a SNUN if they believe that they will exceed that limit, are encouraged to contact EPA to avoid duplicative testing, to identify alternative testing, and to discuss protocols for any testing to be conducted.

Comment 8: Differences in legislation could result in different market situations for companies in the United States and the European Union. Emphasis was placed on the utility of taking into account the volumes of manufacture or importation of a substance, the potential hazard and/or exposures when proposing requirements for generation of information on substances. EPA was encouraged to ensure convergence of requirements, minimize the economic burden on industry, and the number of tests on vertebrate animals through development of tools, especially testing approaches and subsequent guidance, under the OECD Working Party on Manufactured Nanomaterials.

Response: EPA agrees with these comments. When considering testing requirements, EPA takes into account all of the factors suggested by the commenter. However, differences in legislation do result in different regulatory situations in each jurisdiction. EPA is committed to addressing all of the issues identified by the commenter under the Organization for Economic Cooperation and Development (OECD) Working Party on Manufactured Nanomaterials. EPA participates in or chairs each project in the OECD Working Party.

Comment 9: EPA should further clarify the meaning of predictable or purposeful releases to water. For example, a regulated entity may seek to comply with this standard by using a well-designed filtration system. Manufacturers and engineers cannot warrant 100% removal. Because there is no evidence to believe that trace losses in water may cause significant environmental harm, the proposed standard should allow for small but arguably predictable losses associated with well designed filtration systems without triggering notice obligations. Carbon nanotubes occur naturally and are produced from many anthropogenic sources, making the proposed rule impractical and unenforceable (i.e., one cannot necessarily distinguish between incidental carbon nanotubes found in nature and these PMN Substances). Adopting a 100% restriction on any arguably predictable loss of the PMN Substances under such circumstances

would impose significant and unnecessary costs on the nation's burgeoning nanotechnology industry.

Response: Purposeful or predictable releases to water include any intentional or reasonably foreseeable releases to water from a waste stream you identify as part of a manufacturing process or other industrial process. For example, when filling out a PMN (EPA Form 7710-25), submitters are asked to identify environmental releases of the PMN substance from their manufacturing process and other known industrial processes. Section 5(d) of TSCA, which specifies the required content of the PMNs, refers to TSCA section 8(a)(2) which specifies a standard of requiring information that is "known to or reasonably ascertainable by" the PMN submitter. Any water releases of the PMN substance identified in the PMN would qualify as purposeful or predictable releases. The commenter example, a waste stream subject to water filtration before release to water, qualifies as a purposeful or predictable release to water.

Purposeful or predictable releases to water would not include accidents or spills. This significant new use designation was not intended to prevent every single molecule of a subject chemical substance from being released to surface waters. For the uses identified in PMNs P-08-177 and P-08-328, EPA did not identify any purposeful or predictable releases to water. To prevent any potential unreasonable risks, EPA prohibited predictable or purposeful releases to water as a restriction in the consent orders and also designated such water releases as significant new uses in the SNURs. EPA is willing to consider alternatives that establish an acceptable level of release to water in these SNURs and future CNT submissions when information on the toxicity, exposure, and fate for that specific CNT is available. EPA has included a significant new use designation of no purposeful or predictable releases to water in SNURs for hundreds of PMN substances. EPA will continue this approach on a case-by-case basis depending on the findings in the SNUR and the environmental exposures identified in the PMN.

Comment 10: EPA should clarify that the term predictable or purposeful releases to waters of the United States does not prevent disposal of the PMN substance as a solid waste.

Response: General SNUR provisions at § 721.3 define the term "Waters of the United States" as having the meaning set forth in 40 CFR 122.2 which describes surface waters of the United States. This does not prevent disposal of the PMN

substances as a solid waste in landfills or by incineration. In addition, as stated in the response to "Comment 5," the terms of the SNUR do not apply once the PMN substance is completely reacted or cured, incorporated or embedded into a polymer matrix that itself has been reacted (cured) or embedded in a permanent solid polymer form that is not intended to undergo further processing except for mechanical processing.

Comment 11: EPA should clarify what constitutes a dust including if the term dust applies only to dry forms and what types of exposure to dusts are included.

Response: The term dust applies to any dry solid particle with a size ranging from submicroscopic to macroscopic. It does not apply to wet forms. As stated in the terms of the consent orders and SNURs, the standard for using the required personal protective equipment is to protect anyone who is reasonably likely to be exposed dermally or by inhalation to the PMN substance in the form of a dust. It does not matter how the dust is generated.

Comment 12: The Agency did not give an adequate basis for the no-release-to-water provision. Request the Agency to consider establishing a safe level of exposure in water utilizing SNUR provisions in § 721.90 (b)(2), (b)(3), and (b)(4). Another commenter stated that EPA should not issue a SNUR before there is evidence that the PMN substance may present an "unreasonable risk."

Response: EPA is not required to make a "may present unreasonable risk" finding in order to issue a SNUR. As discussed in Unit IV. of this document, TSCA section 5(a)(2) describes the factors EPA must consider when issuing a SNUR. EPA may issue a SNUR for a new chemical substance subject to a TSCA section 5(e) consent order as described at § 721.160, or for a new chemical substance that has completed PMN review as described at § 721.170, when, respectively, activities other than those described in the TSCA section 5(e) consent order or the PMN may result in significant changes in human exposure or environmental release levels and/or that concern exists about the chemical substance's health or environmental effects. See § 721.170(a).

The TSCA section 5(e) consent orders for these PMN substances, which are the bases for these SNURs, do include a finding that the PMN substances may present an unreasonable risk to human health. In addition to referencing potential risks to workers exposed by inhalation and dermal routes, the consent orders also reference potential

risks to the general population from exposures via releases to water, landfill, or incineration. While the TSCA New Chemicals Program's Poorly Soluble Respirable Particles chemical category (see "Human Health Effects Summary for CNTs," in the response to "Comment 13") does not specifically reference these routes of exposure, EPA identified a potential unreasonable risk from these exposures based on a lack of environmental fate and exposure data for CNTs to make a reasoned evaluation.

EPA's review of the PMNs did not identify any predictable or purposeful releases to water. To prevent any potential unreasonable risks, EPA prohibited predictable or purposeful releases to water as a restriction in the consent orders and also designated such water releases as significant new uses in the SNURs. EPA is willing to consider alternatives that establish an acceptable level of release to water in a modification to these SNURs and future CNT submissions when information on the toxicity, exposure, and fate for that specific CNT is available. The response to "Comment 13" also contains information supporting EPA's environmental effects findings and terms in the consent orders and SNURs.

Comment 13: It was noted that more recent signed and draft consent orders contain additional updated hazard assessment information for both health and environmental concerns. It was suggested this language should be referenced in the final SNURs so that all of EPA's concerns are described in a similar manner for all SNURs pertaining to CNTs.

Response: EPA is continually refining and adding to its risk assessment and risk management approaches especially for new chemical substances such as CNTs that have limited available hazard, exposure, and fate data. Recent consent orders for CNTs do cite additional data which was not part of the basis for the consent orders or SNURs for these PMN substances, P-08-177 and P-08-328. EPA is incorporating this most current language in the next two paragraphs as part of this preamble to the final rules. This language does repeat some of the information found in the consent order for the PMN substances. EPA has also placed, in the reference section of this document (Unit X. of this document), and in the docket references to publicly available data on the health and environmental effects of CNTs. These data support the findings and significant new use designations already made in the rule. The environmental effects summary is also being used in CNT consent orders to support a finding of

potential unreasonable risk. EPA also finds that, based on the environmental effects data, the PMN substances meet the concern criteria at § 721.170(b)(4)(ii).

“Human Health Effects Summary for CNTs”: Absorption is expected to be poor via all routes for CNTs based on test data for chemicals with similar molecular structures and chemicals with similar physical/chemical properties. Data on other analogous substances indicate the potential for generation of increased amounts of respirable or absorbable particles during processing and use of nanoscale materials. Further evaluation is needed to determine the toxicity of nanoscale materials for all routes of exposure. In addition, there are concerns for lung effects, based on EPA’s Poorly Soluble Respirable Particulates chemical category. See www.epa.gov/oppt/newchems/pubs/cat02.htm#Respirable. Based on test data for analogous chemicals, including other CNTs, there are concerns for pulmonary toxicity, fibrosis, carcinogenicity, mutagenicity, and immunotoxicity. There are also data suggesting that pulmonary deposition of some nanoscale materials, including CNTs in the agglomerated form, may induce cardiovascular toxicity when these nanoscale materials are inhaled. The major health concerns are for potential pulmonary toxicity, fibrosis, and cancer to workers exposed via inhalation. 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.

“Environmental Effects Summary for CNTs”: Toxicity from exposure to CNTs has been reported in many aquatic species at concentrations that exceed estimated solubility limits. Although CNTs are not appreciably water soluble as manufactured, aqueous suspensions can be easily formed by reaction with strong acids, ozone, or dispersing agents. Recent laboratory research shows that CNTs may be combined with dissolved organic matter to form stable aqueous suspensions. To date, there is a lack of available studies on CNTs which investigate a broad range of production methods, sources, purification, functionalization, etc. EPA expects that some fraction of the CNTs, if released into the environment, will eventually become suspended in water. Sublethal effects, including respiratory stress, ventilation rate, gill mucus secretion, gill damage, and aggressive behaviors, have been noted for SWCNTs in fish at levels as low as 100 parts per billion (ppb). Liver cell injuries were

readily apparent at these exposure levels, suggesting the possibility of liver tumor formation over longer exposure periods. These injuries are notable as the effects were seen in cells closest to blood vessels, suggesting transport of respired or ingested SWCNTs via the blood stream. Some effects in the gut lumen were also observed at these exposure levels. Further studies need to be conducted before EPA can establish a concentration of concern. Such studies must measure actual concentrations of CNTs and control for the effects of contaminants, solvents, and physical factors such as blockage of gills or intestines. Before such testing is conducted, advanced fate testing may be needed to determine the environmental behavior. EPA also finds that, based on the environmental effects data, the PMN substances meet the concern criteria at § 721.170(b)(4)(ii).

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

As discussed in the **Federal Register** issue of April 24, 1990 (55 FR 17376), EPA has decided that the intent of TSCA section 5(a)(1)(B) is best served by designating a use as a significant new use as of the date of publication of the proposed SNUR rather than as of the effective date of the final rule. If uses begun after publication were considered ongoing, rather than new, it would be difficult for EPA to establish SNUR notice requirements because a person could defeat the SNUR by initiating the proposed significant new use before the rule became effective, and then argue that the use was ongoing as of the effective date of the final rule.

Any person who began commercial manufacture, import, or processing of multi-walled carbon nanotubes (PMN P-08-177) or single-walled carbon nanotubes (PMN P-08-328) for any of the significant new uses designated in the proposed SNUR after the date of publication of the proposed SNUR must stop that activity before the effective date of this final rule. Persons who ceased those activities will have to meet all SNUR notice requirements and wait until the end of the notification review period, including all extensions, before engaging in any activities designated as significant new uses. If, however, persons who began manufacture, import, or processing of either of these chemical substances between the date of publication of the proposed SNUR and the effective date of this final SNUR meet the conditions of advance compliance as codified at § 721.45(h), those persons would be considered to

have met the final SNUR requirements for those activities.

VII. Test Data and Other Information

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

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, see Unit II. of the proposed rule which lists those tests, descriptions of tests are provided for informational purposes. EPA strongly encourages persons, before performing any testing, to consult with the Agency pertaining to protocol selection. To access the Harmonized Test Guidelines referenced in this document electronically, please go to <http://www.epa.gov/ocspp> and select “Test Methods and Guidelines.” The Organisation for Economic Co-operation and Development (OECD) test guidelines are available from the OECD Bookshop at <http://www.oecdbookshop.org> or SourceOECD at <http://www.sourceoecd.org>.

In the TSCA section 5(e) consent orders for the two chemical substances regulated under this final rule, EPA has established an aggregate maximum manufacturing and importation volume limits in view of the lack of data on the potential health and environmental risks that may be posed by the significant new uses or increased exposure to the chemical substances. These limits cannot be exceeded unless the PMN submitter first submits the results of toxicity tests that would permit a reasoned evaluation of the potential risks posed by these chemical substances. Under recent TSCA section 5(e) consent orders, each PMN submitter is required to submit each study at least 14 weeks (earlier TSCA section 5(e) consent orders required submissions at least 12 weeks) before reaching the specified production limit. Listings of

the tests specified in the TSCA section 5(e) consent orders are included in the proposed rule for these chemical substances. The SNURs contain the same 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 this limit must notify the Agency by submitting a SNUN at least 90 days in advance of commencement of non-exempt commercial manufacture, import, or processing.

The recommended tests may not be the only means of addressing the potential risks of the chemical substance. However, SNUNs submitted without any test data may increase the likelihood that EPA will respond by taking 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.

VIII. SNUN Submissions

As stated in Unit II.C. of this document, according to § 721.1(c), persons submitting a SNUN must comply with the same notice requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in 40 CFR 720.50. SNUNs must be submitted to EPA on EPA Form No. 7710–25 in accordance with the procedures set forth in § 721.25 and 40 CFR 720.40. This form is available from the Environmental Assistance Division (7408M), 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. Forms and information are also available online at <http://www.epa.gov/opptintr/newchems>.

IX. Economic Analysis

EPA evaluated the potential costs of establishing SNUN requirements for potential manufacturers, importers, and processors of the chemical substances during the development of the direct final rule. The Agency's complete

Economic Analysis is available in the docket under docket ID number EPA–HQ–OPPT–2008–0252.

X. References

The following is a listing of those documents used to prepare the preamble to this final rule. A copy of this list is available in the docket for this final rule under docket ID number EPA–HQ–OPPT–2008–0252, which is available for inspection as specified under ADDRESSES.

1. Baun A, Hartmann NB, Grieger K, and Kusk KO. (2008) Ecotoxicity of Engineered Nanoparticles to Aquatic Invertebrates: A Brief Review and Recommendations for Future Toxicity Testing. *Ecotoxicology*. 17:387–395.
2. Blaise C, Gagne F, Ferard JF, and Eullaffroy P. (2008) Ecotoxicity of Selected Nano-Materials to Aquatic Organisms. *Environmental Toxicology*. 23:591–598.
3. Bonner JC, et al. (2009) Inhaled multi-walled carbon nanotubes stimulate a pleural inflammatory response in the lung of mice. *Society of Toxicology*. Abstract No. 2205.
4. Cheng J, Flahaut E, and Cheng SH. (2007) Effect of Carbon Nanotubes on Developing Zebrafish (*Danio rerio*) Embryos. *Environmental Toxicology and Chemistry*. 26:708–716.
5. EPA. (2010) Material Characterization of Carbon Nanotubes for Molecular Identity (MI) Determination & Nomenclature. Available in the docket under docket ID number EPA–HQ–OPPT–2008–0252.
6. Farre M, Gajda-Schrantz K, Kantiani L, and Barcelo D. (2009) Ecotoxicity and Analysis of Nanomaterials in the Aquatic Environment. *Analytical and Bioanalytical Chemistry*. 393:81–95.
7. Hubbs A, Mercer RR, Coad JE, and Batelli LA. (2009) Persistent pulmonary inflammation, airway mucous metaplasia and migration of multi-walled carbon nanotubes from the lung after subchronic exposure. *The Toxicologist*. 108:A2193.
8. Hyung H, Fortner JD, Hughes JB, and Kim JH. (2007) Natural Organic Matter Stabilizes Carbon Nanotubes in the Aqueous Phase. *Environmental Science & Technology*. 41:179–184.
9. Klaine SJ, Alvarez PJJ, Batley GE, Fernandes TF, Handy RD, Lyon DY, Mahendra S, McLaughlin MJ, and Lead JR. (2008) Nanomaterials in the Environment: Behavior, Fate, Bioavailability, and Effects. *Environmental Toxicology and Chemistry*. 27:1825–1851.
10. Lam CW, James JT, McClusky R, and Hunter R. (2004) Pulmonary Toxicity of Single-Walled Carbon Nanotubes in Mice 7 and 90 Days after Intratracheal Instillation. *Toxicological Sciences*. 77:126–134.
11. Landsiedel, et al. (2009) Carbon nanotubes tested in 5- and 90-day inhalation studies in rats. *Society of Toxicology*. Abstract No. 2194.
12. Ma-Hock L, Treumann S, Strauss V, Brill S, Luizi F, Mertler M, Wiench K, Gamer AO, van Ravenzwaay B, and Landsiedel R. (2009) Inhalation toxicity of multiwall carbon nanotubes in rats exposed for 3 months. *Toxicological Sciences*. 112:468–481.
13. Mitchell LA, Gao J, Wal RV, Gigliotti A, Burchiel SW, and McDonald JD. (2007) Pulmonary and systemic immune response to inhaled multiwalled carbon nanotubes. *Toxicological Sciences*. 100:203–214.
14. Mouchet F, Landois P, Sarremejean E, Bernard G, Puech P, Pinelli E, Flahaut E, and Gauthier L. (2008) Characterisation and in vivo ecotoxicity evaluation of double-wall carbon nanotubes in larvae of the amphibian *Xenopus laevis*. *Aquatic Toxicology*. 87:127–137.
15. Muller J, Huaux F, Moreau N, Misson P, Heilier J, Delos M, Arras M, Fonseca A, Nagy JB, and Lison D. (2005) Respiratory toxicity of multi-wall carbon nanotubes. *Toxicology and Applied Pharmacology*. 207: 221–231.
16. Nurkiewicz TR, Porter DW, Hubbs AF, Cumpston JL, Chen BT, Frazer DG, and Castranova V. (2008) Nanoparticle inhalation augments particle-dependent systemic microvascular dysfunction. *Particle and Fibre Toxicology*. 5:1. Available at <http://www.particleandfibretoxicology.com/content/5/1/1>.
17. Petersen EJ, Huang Q, and Weber Jr WJ. (2008) Ecological Uptake and Depuration of Carbon Nanotubes by *Lumbricus variegatus*. *Environmental Health Perspectives*. 116:496–500.
18. Poland CA, Duffin R, Kinloch I, Maynard A, Wallace WAH, Seaton A, Stone V, Brown S, MacNee W, and Donaldson K. (2008) Carbon nanotubes introduced into the abdominal cavity of mice show asbestos-like pathogenicity in a pilot study. *Nature Nanotechnology*. 3:423–428.
19. Roberts AP, Mount AS, Seda B, Souther J, Qiao R, Lin S, Ke PC, Rao AM, and Klaine SJ. (2007) In vivo Biomodification of Lipid-Coated Carbon Nanotubes by *Daphnia magna*. *Environmental Science & Technology*. 41:3025–3029.
20. Schladweiler, et al. (2009) Single-walled carbon nanotubes induced pulmonary and vascular response following intratracheal instillation. *Society of Toxicology*. Abstract No. 2203.

21. Shvedova AA, Kisin ER, Mercer AR, Murray AR, Johnson VJ, Potapovich AI, Tyurina YY, Gorelik O, Arepalli S, Schwegler-Berry D, Hubbs AF, Antonini J, Evans DE, Ku BK, Ramsey D, Maynard A, Kagan VE, Castranova V, and Baron P. (2005) Unusual Inflammatory and Fibrogenic Pulmonary Responses to Single Walled Carbon Nanotubes in Mice. *American Journal Physiology Lung Cellular and Molecular Physiology*. 10:1152–1184.

22. Shvedova AA, Fabisiak JP, Kisin E, Murray AR, Roberts JR, Tyurina YY, Antonini JM, Feng WH, Kommineni C, Reynolds J, Barchowsky A, Castranova V, and Kagan VE. (2008) Sequential exposure to carbon nanotubes and bacteria enhances pulmonary inflammation and infectivity. *American Journal of Respiratory Cell and Molecular Biology*. 38:579–590.

23. Smith CJ, Shaw BJ, and Handy RD. (2007) Toxicity of Single Walled Carbon Nanotubes to Rainbow Trout, (*Oncorhynchus mykiss*): Respiratory Toxicity, Organ Pathologies, and other Physiological Effects. *Aquatic Toxicology*. 82:94–109.

24. Templeton RC, Ferguson PL, Washburn KM, Scrivens WA, and Chandler GT. (2006) Life-Cycle Effects of Single-Walled Carbon Nanotubes (SWNTs) on an Estuarine Meiobenthic Copepod. *Environmental Science & Technology*. 40:7387–7393.

25. Warheit DB, Laurence BR, Reed KL, Roach DH, Reynolds GAM, and Webb TR. (2004) Comparative Pulmonary Toxicity Assessment of Single-wall Carbon Nanotubes in Rats. *Toxicological Sciences*. 77:117–125.

26. Wolfarth, MG, et al. (2009) Pulmonary toxicity of multi-walled carbon nanotubes. *Society of Toxicology*. Abstract No. 2196.

27. Zhu X, Zhu L, Chen Y, and Tian S. (2009) Acute Toxicities of Six Manufactured Nanomaterial Suspensions to *Daphnia magna*. *Journal of Nanoparticle Research*. 11:67–75.

XI. Statutory and Executive Order Reviews

A. Executive Order 12866

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

B. Paperwork Reduction Act

According to the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et*

seq., an Agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under 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 final rule. This listing of the OMB control numbers and their subsequent codification in the CFR satisfies the display requirements of PRA and OMB's implementing regulations at 5 CFR part 1320. This Information Collection Request (ICR) was previously subject to public notice and comment prior to OMB approval, and given the technical nature of the table, EPA finds that further notice and comment to amend it is unnecessary. As a result, EPA finds that there is "good cause" under section 553(b)(3)(B) of the Administrative Procedure Act, 5 U.S.C. 553(b)(3)(B), to amend this table without further notice and comment.

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

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

C. Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency hereby certifies that promulgation of these

SNURs will not have a significant adverse economic impact on a substantial number of small entities. The rationale supporting this conclusion is discussed in this unit. The requirement to submit a SNUN applies to any person (including small or large entities) who intends to engage in any activity described in the final rule as a "significant new use." Because these uses are "new," based on all information currently available to EPA, it appears that no small or large entities presently engage in such activities. A SNUR requires that any person who intends to engage in such activity in the future must first notify EPA by submitting a SNUN. Although some small entities may decide to pursue a significant new use in the future, EPA cannot presently determine how many, if any, there may be. However, EPA's experience to date is that, in response to the promulgation of over 1,400 SNURs, the Agency receives on average only 5 notices per year. Of those SNUNs submitted from 2006–2008, only one appears to be from a small entity. In addition, the estimated reporting cost for submission of a SNUN (see Unit XI. of this document) is minimal regardless of the size of the firm. Therefore, EPA believes that the potential economic impacts of complying with these SNURs are not expected to be significant or adversely impact a substantial number of small entities. In a SNUR that published in the **Federal Register** issue of June 2, 1997 (62 FR 29684) (FRL–5597–1), the Agency presented its general determination that final SNURs are not expected to have a significant economic impact on a substantial number of small entities, which was provided to the Chief Counsel for Advocacy of the Small Business Administration.

D. Unfunded Mandates Reform Act

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

E. Executive Order 13132

This action will not have a substantial direct effect on States, on the relationship between the national

government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999).

F. Executive Order 13175

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

G. Executive Order 13045

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

H. Executive Order 13211

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

I. National Technology Transfer and Advancement Act

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

J. Executive Order 12898

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

XII. Congressional Review Act

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

List of Subjects

40 CFR Part 9

Environmental protection, Reporting and recordkeeping requirements.

40 CFR Part 721

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

Dated: September 10, 2010.

Wendy Cleland-Hamnett,

Director, Office of Pollution Prevention and Toxics.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 9—[AMENDED]

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

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

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

§ 9.1 OMB approvals under the Paperwork Reduction Act.

40 CFR citation	OMB control No.
* * * * *	* * *
Significant New Uses of Chemical Substances	
* * * * *	* * *
721.10155	2070–0012
721.10156	2070–0012

40 CFR citation	OMB control No.
* * * * *	* * *
* * * * *	* * *

* * * * *

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 § 721.10155 to subpart E to read as follows:

§ 721.10155 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–08–177) 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 chemical substance after it has been completely reacted (cured); incorporated or embedded into a polymer matrix that itself 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), (a)(3), (a)(4), (a)(5) (National Institute for Occupational Safety and Health (NIOSH)-approved air-purifying, tightfitting full-face respirator equipped with N100 filters), (a)(6)(i), and (c).
 (ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k) and (q).
 (iii) *Release to water.* Requirements as specified in § 721.90(a)(1), (b)(1), and (c)(1).

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

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

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

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

■ 5. Add § 721.10156 to subpart E to read as follows:

§ 721.10156 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-08-328) 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 chemical substance after it has been completely reacted (cured); incorporated or embedded into a polymer matrix that itself 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), (a)(3), (a)(4), (a)(5) (National Institute for Occupational Safety and Health (NIOSH)-approved air-purifying, tightfitting full-face respirator equipped with N100 filters), (a)(6)(i), and (c).

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

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

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

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

[FR Doc. 2010-23321 Filed 9-16-10; 8:45 am]

BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R09-OAR-2010-0569; FRL-9200-6]

Revisions to the California State Implementation Plan, San Diego County Air Pollution Control District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action to approve revisions to the San Diego County Air Pollution Control District (SDCAPCD) portion of the California State Implementation Plan (SIP). This revision concerns the definition of volatile organic compound (VOC). We are approving a local rule that regulates these emission sources under the Clean Air Act as amended in 1990 (CAA or the Act).

DATES: This rule is effective on November 16, 2010 without further notice, unless EPA receives adverse comments by October 18, 2010. If we receive such comments, we will publish a timely withdrawal in the **Federal Register** to notify the public that this direct final rule will not take effect.

ADDRESSES: Submit comments, identified by docket number [EPA-R09-OAR-2010-0569], by one of the following methods:

1. *Federal eRulemaking Portal:* www.regulations.gov. Follow the on-line instructions.

2. E-mail: steckel.andrew@epa.gov.

3. *Mail or deliver:* Andrew Steckel (Air-4), U.S. Environmental Protection Agency Region IX, 75 Hawthorne Street, San Francisco, CA 94105-3901.

Instructions: All comments will be included in the public docket without change and may be made available online at www.regulations.gov, including any personal information provided, unless the comment includes Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Information that you consider CBI or otherwise protected should be clearly identified as such and should not be submitted through www.vregulations.gov or e-mail. www.vregulations.gov

www.regulations.gov is an “anonymous access” system, and EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send e-mail directly to EPA, your e-mail address will be automatically captured and included as part of the public comment. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: The index to the docket for this action is available electronically at www.regulations.gov and in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California. While all documents in the docket are listed in the index, some information may be publicly available only at the hard copy location (e.g., copyrighted material), and some may not be publicly available in either location (e.g., CBI). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Cynthia Allen, EPA Region IX, (415) 947-4120, allen.cynthia@epa.gov.

SUPPLEMENTARY INFORMATION: Throughout this document, “we,” “us,” and “our” refer to EPA.

Table of Contents

- I. The State’s Submittal
 - A. What rule did the State submit?
 - B. Are there other versions of this rule?
 - C. What is the purpose of the submitted rule revisions?
- II. EPA’s Evaluation and Action
 - A. How is EPA evaluating this rule?
 - B. Does this rule meet the evaluation criteria?
 - C. Public Comment and Final Action
- III. Statutory and Executive Order Reviews

I. The State’s Submittal

A. What rule did the State submit?

Table 1 lists the rule we are approving with the date that it was adopted by the local air agency and submitted by the California Air Resources Board (CARB).

TABLE 1—SUBMITTED RULES

Local agency	Rule No.	Rule title	Adopted	Submitted
SDCAPCD	2	Definitions	06/30/99	05/17/10