

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 721

[EPA-HQ-OPPT-2009-0686; FRL-8865-4]

RIN 2070-AB27

Multi-walled Carbon Nanotubes; Significant New Use Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is issuing a significant new use rule (SNUR) under section 5(a)(2) of the Toxic Substances Control Act (TSCA) for the chemical substance identified generically as multi-walled carbon nanotubes (MWCNT) which was the subject of premanufacture notice (PMN) P-08-199. This action requires persons who intend to manufacture, import, or process the chemical substance 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 the chemical substance may be hazardous to human health. 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 *[insert date 30 days after date of publication in the Federal Register]*.

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPPT-2009-0686. 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:*

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

You may be potentially affected by this action if you manufacture, import, process, or use the chemical substance which is the subject of this final rule. Potentially affected entities may include, but are not limited to:

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

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

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

II. Background

A. What Action is the Agency Taking?

EPA is finalizing a SNUR under TSCA section 5(a)(2) for the chemical substance identified generically (due to confidentiality claims) as multi-walled carbon nanotubes (PMN P-08-199). This action requires persons who intend to manufacture, import, or process the subject chemical substance 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 February 3, 2010 (75 FR 5546) (FRL-8796-7), EPA issued a proposed SNUR on the chemical substance. On July 28, 2010 (75 FR 44198) (FRL-8828-3), in order to address public comment and add information to the docket, EPA reopened the comment period for 30 days. In response to comments on the basis for the SNUR, EPA developed a revised summary document entitled “Summary of EPA’s Current Assessments of Health and Environmental Effects of Carbon Nanotubes,” that specifies EPA’s current hazard concerns as supported by available information and data. The docket for the proposed SNUR on this chemical substance is found under docket ID number EPA-HQ-OPPT-2009-0686. That docket includes information considered by the Agency in developing this final rule, including comments on the rule and the aforementioned summary document. More information on the chemical substance subject to this final rule can be found in the proposed SNUR.

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. Taking into consideration these comments, EPA is issuing a final rule on this chemical substance that:

1. Retains the proposed workplace protection and specific use provisions as significant new uses.
2. Adds exclusions from applicability of the SNUR uses identified as ongoing.
3. Identifies those forms of the subject PMN substance which are exempt from the provisions of the SNUR. These exemptions apply to quantities of the PMN substance:

- 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.

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. Chemical importers must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA. For importers of a chemical substance subject to a final SNUR those requirements include the SNUR. 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 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

As discussed in the proposed rule, EPA identified concerns for lung effects, immunotoxicity, and mutagenicity from exposure to the PMN substance during its review of the chemical substance, which was the subject of P-08-199. These concerns were based on test data on analogous respirable, poorly soluble particulates and on other carbon nanotubes (CNTs). EPA determined that the PMN substance met the decisional criteria at § 721.170.

B. Objectives

EPA is issuing this final SNUR for a specific chemical substance that has 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 manufacture, import, or processing 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.

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-line 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 authorizes EPA to consider any other relevant factors.

To determine what would constitute a significant new use for the MWCNT subject to this final SNUR, EPA considered relevant information--included in the docket and discussed further in Unit V. of this document--about the toxicity of the chemical substance, likely human exposures and environmental releases associated with possible

uses, taking into consideration the four bulleted TSCA section 5(a)(2) factors listed in this unit, and the regulations at § 721.170 for issuing a SNUR after receipt of a PMN.

For the MWCNT described in P-08-199, EPA believes that certain changes from the use scenario described in the PMN could result in increased exposures. EPA has determined that activities being designated as a “significant new use” in this rule satisfy 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.

V. Response to Comments on Proposed SNUR on Multi-walled Carbon Nanotubes

EPA received public comments on the proposed SNUR for the MWCNT which was the subject of PMN P-08-199. A discussion of the comments received and the Agency’s responses follows.

Comment 1: One commenter requested that should EPA require testing, it should consider high-throughput methods that have been specifically designed for nanomaterials in order to reduce reliance on animal based testing, and so that testing does not become an unreasonable or unattainable burden for manufacturers as not to violate section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The commenter also requested that, in addition to relying on early characterization of nanomaterials using *in vitro* methods as outlined in EPA’s *Nanomaterial Testing Strategy*, EPA apply integrated testing strategies (ITS) to assess the toxicological risk of nanomaterials.

Response: EPA identified recommended testing in the preamble of the proposed SNUR. Any manufacturers, importers, or processors who intend to conduct testing or submit a SNUN are encouraged to contact EPA to avoid duplicative testing, to identify alternative testing, and to discuss protocols for any testing to be conducted. EPA recognizes the value of high-throughput methods for nanomaterials. When contacted by a manufacturer, importer, or processor who intends to conduct testing or requiring testing by a SNUN submitter, EPA will consider this and other alternatives identified by the commenter.

Comment 2: One commenter asked EPA to include language in the SNUR that clarifies the exempt status of its laboratory in particular and research laboratories in general to SNUR requirements.

Response: The general SNUR requirements of 40 CFR part 721, subpart A, apply to this SNUR. The requirements in § 721.45(b) exempts a person from the notification requirements of this SNUR when they manufacture, import, or process small quantities of the substance subject to the SNUR solely for research and development in accordance with the conditions in § 721.47.

Comment 3: One commenter supported the use of respiratory equipment to prevent exposures and another commenter supported timely issuance of the SNUR.

Response: EPA is issuing the final rule to include respiratory protection when workers are reasonably likely to be exposed.

Comment 4: One commenter noted that the proposed SNUR for the MWCNT, which was the subject of P-08-199, did not contain a no-release-to-water restriction and that other consent orders and SNURs for carbon nanotubes do contain a no-release-to-

water restriction. The commenter stated that this difference was inappropriate and that it should not be allowed to persist.

Response: The PMN submitter identified a release to water in the PMN for this substance and EPA did not act to restrict the activity under TSCA section 5(e). Because the release to water is an ongoing use, EPA is unable to issue a SNUR that includes a no release to water provision.

Comment 5: The PMN submitter commented that significant new uses must not be ongoing and should be consistent with the existing uses identified in its comments. The PMN submitter also outlined its understanding of how the rule would apply in practice to particular existing uses and requested that the Agency clarify that understanding.

Response: After reviewing the PMN and the PMN submitter's outline of how the SNUR would apply in practice to its existing uses, EPA confirms that the significant new uses in this rule are not ongoing and that the commenter's outline of how the rule would apply to existing uses is correct. However, in its March 5, 2010, comments on the proposed SNUR, the PMN submitter identified specific use(s) other than as an additive/filler for polymer composites and support media for industrial catalysts. The company claimed these specific uses as CBI. As described in the proposed SNUR, persons who begin, after the date of the proposed rule, commercial manufacture, import, or processing of the MWCNT that was the subject of P-08-199 for a use preliminarily designated as a "significant new use" in the proposed rule must cease any such activity before the effective date of the rule if and when finalized. After the final SNUR is effective, any person intending to manufacture, import, or process the substance for a use

other than as an additive/filler for polymer composites and support media for industrial catalysts must submit a SNUN (in accordance with the requirements of 40 CFR part 721, subpart A) at least 90 days before commencing such use.

Comment 6: The PMN submitter asked EPA to clarify the meaning of uses as described in the PMN. The uses described in the PMN were additive/filler for polymer composites and support media for industrial catalysts. The PMN submitter asked whether notification would be required for each specific polymer composite or for different equipment used to manufacture or process the PMN substance.

Response: If a manufacturer or processor is using the PMN substance as either an additive/filler for polymer composites, or support media for industrial catalysts, they may change processes to include new equipment or new polymer composites. If there is any question as to whether a specific use or application is not the use described in the PMN, a manufacturer or processor may contact EPA or submit a SNUN.

Comment 7: The PMN submitter commented that there should be an exemption for bound forms of the PMN substance when the SNUR would not apply, for example, when the PMN substance is embedded or incorporated into plastic resin pellets.

Response: EPA agrees that, consistent with other SNURs and consent orders for CNTs, (e.g., the MWCNT which was the subject of PMN P-08-177), and the existing uses of the PMN substance, there should be an exemption from the final SNUR requirements once the PMN substance has been fixed to a substrate or encapsulated within a plastic or other polymer matrix. The Agency has included language in the final SNUR to exempt from SNUR requirements persons that manufacture, import, or process the PMN substance when the substance has 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.

Comment 8: The PMN submitter asked EPA to specify the identity of the PMN substance specifically in relation to other MWCNTs, explaining how EPA is describing the PMN substance as a unique chemical type.

Response: Because of a lack of established nomenclature for CNTs, EPA has allowed PMN submitters to represent their CNTs using a generic name such as carbon nanotube (CNT), multi-walled carbon nanotube (MWCNT), or single-walled carbon nanotube (SWCNT) while submitting a detailed description of the CNT using specific structural characteristics. All submitters of new chemical notices for CNTs, including the submitter for the MWCNT described in P-08-199, 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 this MWCNT. Manufacturers may submit a *bona fide* intent to manufacture or import under § 720.25 to determine whether a specific CNT is on the TSCA Inventory.

Comment 9: The PMN submitter commented on the document entitled, “Material Characterization of Carbon Nanotubes for Molecular Identity (MI) Determination & Nomenclature” (docket ID number EPA-HQ-OPPT-2009-0686-0015), that identifies a list of chemical structural features, chemical particle properties, and manufacturing methods that may be important for making carbon nanotube molecular identity

determinations and naming them for TSCA purposes. The PMN submitter stated it was difficult to comment on the document, as the record does not identify either its particular provenance, or how the Agency is using, or plans to use it. The commenter also noted that many of the features may be impractical to observe, measure, or characterize with any consistency or statistical certainty, and others may be altered simply by the act of measuring. The commenter stated that several of the criteria refer only to properties of a CNT material (i.e., a collection of molecules rather than a single molecule), then asserted that these characteristics may be relevant to management considerations, but they are not relevant to defining molecular identity for TSCA purposes.

Response: EPA does not agree that these characteristics are not relevant to defining the molecular identity of a CNT. As noted in the response to “Comment 8,” because of a lack of established nomenclature for CNTs, EPA is currently representing CNTs using a generic chemical name along with the PMN number to identify them as distinct chemical substances. EPA included this list of physical features that may be important to demonstrate that it is considering additional characteristics when reviewing and identifying CNTs. EPA has used a wide variety of characteristics to identify chemical substances of unknown or variable composition, complex reaction products, and biological materials (UVCB) for TSCA purposes. As noted by the commenter, some of these characteristics may not be suitable for unambiguously determining molecular identity. As EPA learns more about the structures of CNTs, it will develop a set of characteristics to systematically identify CNTs.

Comment 10: A commenter noted that recent signed and draft consent orders for other CNTs contain additional updated hazard assessment information for both health and

environmental concerns. The commenter suggested this language should be referenced in the final SNUR so that all of EPA's concerns are described in a similar manner for all SNURs pertaining to CNTs. The PMN submitter stated that while EPA did place data in the public docket supporting the finding at § 721.170(b)(3)(ii) from inhalation exposure, there is no data in the public docket supporting the finding from dermal exposures.

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 cite additional data which was not referenced in the proposed SNUR for this PMN substance. EPA placed in the public docket a document entitled, "Summary of EPA's Current Assessment of Health and Environmental Effects of Carbon Nanotubes" (docket ID number EPA-HQ-OPPT-2009-0686-0016), in support of the health effects findings and significant new use designations made in the proposed rule. This document identifies those references available at the time of assessment of the chemical substance in this final rule. EPA also reopened the comment period on July 28, 2010 (75 FR 44198), to allow interested parties to comment on the additional information that was the basis for the SNUR.

Comment 11: EPA missed the 270-day deadline so it should use the procedure and analysis otherwise required by 5(a)(2) of TSCA.

Response: A schedule for issuing SNURs with various types of rulemaking, including proposed rules, interim rules, and direct final rules is included at § 721.170(e)(1). The schedule states that EPA will issue the SNUR within 270 days of receipt of the notice of commencement under § 720.102 for any substance for which the

notice of commencement was received on or after October 10, 1989. The schedule is not mandatory, and rulemaking is not contingent on meeting this schedule. Although EPA did not issue the rule within the time period set out in the schedule, the Agency remains able to do so by any rulemaking procedure compatible with the Administrative Procedure Act (APA). EPA believes the procedures followed in developing this rule are consistent with the requirements in TSCA section 5(a)(2) and the APA.

Comment 12: The PMN submitter expressed concerns with respect to the cited inhalation (or simulated inhalation) studies. The commenter questioned the validity of the studies as several of the cited studies exist only as abstracts of unpublished presentations. The commenter stated there is no assessment of the doses involved in these studies, or the studies underlying the poorly soluble particles chemical categories report. The commenter also noted a Bayer Material Science study for carbon nanotubes and detailed results of the inhalation studies that have been recently published in the peer-reviewed journals, *Inhalation Toxicology*, *Toxicological Sciences* and *Toxicology* that EPA should take into account in connection with the rulemaking. Finally, the commenter states that EPA does not explain how these studies satisfy the regulatory concern criteria on which EPA relies.

Response: EPA has found that the substance meets the decisional criteria in § 721.170(b)(3)(ii). The decisional criteria state that: The substance may cause serious chronic effects, serious acute effects, or developmentally toxic effects under reasonably anticipated conditions of exposure because the substance is closely analogous, based on toxicologically relevant similarities in molecular structure and physical properties, to another chemical substance that has been shown by valid test data to cause serious

chronic effects, serious acute effects, or developmentally toxic effects in humans or in at least one species of laboratory animal at dose levels that could be of concern under reasonably anticipated conditions of exposure. EPA is not required to conduct a quantitative risk assessment or establish safe dose levels. EPA must only establish that effects could occur under reasonably anticipated conditions of exposure. The papers referenced in the docket, the Bayer Material Science study and other data cited by the PMN submitter, and data that is the basis for the poorly soluble respirable particulates category, demonstrate the potential chronic pulmonary and cardiovascular effects (including pulmonary toxicity, fibrosis, carcinogenicity, mutagenicity, and immunotoxicity, and cardiovascular toxicity) of carbon nanotubes, including the PMN substance, at various dose levels. EPA considered this information in the review of the MWCNT described in PMN P-08-199, and concluded that the specified significant new uses of the PMN substance could result in inhalation exposures at levels where health effects were observed in the papers referenced in the docket. All of the papers referenced in the docket are publicly available peer reviewed scientific journals and publications.

Comment 13: The PMN submitter stated that the company supports minimizing dermal and inhalation exposures to the extent reasonably practicable on a voluntary basis, and that controls should be used where warranted, but they should not be required to prevent particular exposures for which the Agency has no reasoned basis to believe may cause significant effects. The commenter asserted that the materials in the public docket only address the potential direct and indirect effects of inhalation exposures. Further, in summary, the commenter stated that the proposal appears to lack any reasoned basis for the particular dermal controls proposed in the SNUR and does not appear to meet the

decisional criteria in § 721.170(b)(3)(ii) as the basis for establishing controls. The commenter stated that one cannot assess the basis and extent for the Agency's concern, making it impossible to comment on whether the suggested controls are reasonably tailored to those concerns.

Response: EPA believes it has demonstrated that the subject substance meets the decisional criteria in § 721.170(b)(3)(ii), including the significant new use of manufacturing, importing, or processing of the PMN substance without dermal protection where workers are reasonably likely to be exposed. As noted in the response to “Comment 12,” EPA has established that CNTs, including the PMN substance, may cause pulmonary toxicity, fibrosis, carcinogenicity, mutagenicity, and immunotoxicity, and cardiovascular toxicity. The “Summary of EPA’s Current Assessment of Health and Environmental Effects of Carbon Nanotubes” (docket ID number EPA–HQ–OPPT–2009–0686–0016) states that “absorption is expected to be poor for all routes” which includes dermal exposure. This suggests that some dermal absorption could occur. EPA considered this information in the review of the MWCNT described in PMN P–08–199, and concluded that the specified significant new uses of the PMN substance could also result in dermal exposures at levels where health effects were observed in the papers referenced in the docket.

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

As discussed in the **Federal Register** of April 24, 1990 (55 FR 17376), EPA has decided that the intent of TSCA section 5(a)(1)(B) is best served by designating a use as a significant new use as of the date of publication of 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 before the effective date of the final rule.

Any person who began commercial manufacture, import, or processing of the MWCNT described in PMN P-08-199 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 the chemical substance 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 § 720.50). However, upon review of PMNs and SNUNs, the Agency has the authority to require appropriate testing. In this case, EPA recommends persons, before performing any testing, to consult with the Agency pertaining to protocol selection.

The recommended testing specified in Unit IV. of the proposed rule 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 prior to submitting a SNUN.

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 substance.
- Potential benefits of the chemical substance.
- Information on risks posed by the chemical substance compared to risks posed by potential substitutes.

VIII. SNUN Submissions

According to § 721.1(c), persons submitting a SNUN must comply with the same notice requirements and EPA regulatory procedures as persons submitting a PMN,

including submission of test data on health and environmental effects as described in § 720.50. SNUNs must be on EPA Form No. 7710–25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in §§ 721.25 and 720.40. E-PMN software is available electronically at <http://www.epa.gov/opptintr/newchems>.

IX. Economic Analysis

EPA evaluated the potential costs of establishing SNUN requirements for potential manufacturers, importers, and processors of the chemical substance subject to this final rule. The Agency’s complete Economic Analysis is available in the docket under docket ID number EPA–HQ–OPPT–2009–0686.

X. Statutory and Executive Order Reviews

A. Executive Order 12866

This final rule establishes a SNUR for a chemical substance that was the subject of a PMN. 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 this SNUR 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 VIII.) is minimal regardless of the size of the firm. Therefore, EPA believes that the potential economic impacts of complying with this SNUR are not expected to be significant or adversely impact a substantial number of small entities. In a SNUR that published in the **Federal Register** of June 2, 1997 (62 FR 29684) (FRL–5597–1), the Agency presented its general determination that final SNURs are not expected to have a significant economic impact

on a substantial number of small entities, which was provided to the Chief Counsel for Advocacy of the Small Business Administration.

D. Unfunded Mandates Reform Act

Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reasons to believe that any State, local, or Tribal government will be impacted by this 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 final 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 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).

XI. 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: April 29, 2011.

Wendy C. Hamnett,

Director, Office of Pollution Prevention and Toxics.

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

PART 9--[AMENDED]

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

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

2. The table in § 9.1 is amended by adding the following section 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	
* * * * *	* * * * *
721.10183	2070–0012
* * * * *	* * * * *

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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 § 721.10183 to subpart E to read as follows:

§ 721.10183 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-08-199) 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)(4), (a)(5) (National Institute for Occupational Safety and Health (NIOSH)-approved full-face respirators with N100 cartridges), (a)(6)(i), and (c).

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(j) (additive/filler for polymer composites and support media for industrial catalysts).

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

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

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

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