40 CFR Parts 9 and 721

SUMMARY: EPA is finalizing significant new use rules (SNURs) under section 5(a)(2) of the Toxic Substances Control Act (TSCA) for 17 chemical substances which were the subject of premanufacture notices (PMNs). Fifteen of these chemical substances are subject to TSCA section 5(e) consent orders issued by EPA. This action would require persons who intend to manufacture, or process any of these 17 chemical substances for an activity that is designated as a significant new use by this proposed rule to notify EPA at least 90 days before commencing that activity. 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 August 26, 2013.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPPT–2010–0279, is available at http://www.regulations.gov or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280. Please review the visitor instructions and additional information about the docket available at http://www.epa.gov/dockets.
I. Does this action apply to me?

You may be potentially affected by this action if you manufacture, process, or use any of the 17 chemical substances contained in this final rule. Potentially affected entities may include, but are not limited to:

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

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 requirements under TSCA. Chemical importers are subject to the TSCA section 15 (U.S.C. 2612) import certification requirements promulgated at 19 CFR 12.118 through 12.127; see also 19 CFR 127.28. Chemical importers must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA. Importers of chemicals subject to a final SNUR must certify their compliance with the SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export a chemical substance that is the subject of this final rule are subject to the export notification requirements 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 17 chemical substances which were the subject of PMNs. Fifteen of these chemical substances are subject to TSCA section 5(e) consent orders issued by EPA. The final SNURs for these substances are based on and consistent with the provisions in the underlying consent order. The final SNURs designate a significant new use manufacture (including import) or processing in the absence of the protective measures required in the corresponding consent order. The final SNURs for the 2 remaining substances are not subject to a consent order under TSCA section 5(e). In these two cases, EPA has determined in the final SNURs that 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. This action requires persons who intend to manufacture, or process these 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 December 28, 2011 (76 FR 81447) (FRL–9326–2), EPA proposed SNURs for these seventeen chemical substances. More information on the specific chemical substances subject to this final rule can be found in the Federal Register documents proposing the SNURs. The record for the SNURs for these seventeen chemical substances was established in the docket under docket ID number EPA–HQ–OPPT–2010–0279. That docket includes information considered by the Agency in developing the proposed and final rules, including comments on those rules.

EPA received numerous 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 modified final rules for these chemical substances as described in Unit V. of this document.

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, 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 final 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 §721.11(c), persons subject to these SNURs must comply with the same notice requirements and EPA regulatory procedures as submitters of PMNs under TSCA section 5(a)(1)(A). In particular, these requirements include the information submission requirements of TSCA section 5(b) and 5(d)(1), the exemptions authorized by TSCA section 5(h)(1), (h)(2), (h)(3), and (h)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUN, EPA may take regulatory action under TSCA section 5(e), 5(f), 6, or 7 to control the activities for which it has received the SNUN. If EPA does not take action, EPA is required under TSCA section 5(g) to explain in the Federal Register its reasons for not taking action.

III. Rationale and Objectives of the Final Rule

A. Rationale

During review of the PMNs submitted for these chemical substances, EPA concluded that for 15 of the 17 chemical substances, regulation was warranted under TSCA section 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, a TSCA section 5(e) consent order requiring the use of appropriate exposure controls was negotiated with
the PMN submitter. The SNUR provisions for these chemical substances are consistent with the provisions of the TSCA section 5(e) consent order. These final SNURs are issued pursuant to § 721.160. See the docket under docket ID number EPA–HQ–OPPT–2010–1075 for the corresponding consent orders.

In the other two cases, where the uses were not regulated under a TSCA section 5(e) consent order, EPA determined that one or more of the criteria of concern established at § 721.170 were met. For additional discussion of the rationale for the SNURs on these chemicals, see Units II. and V. of the proposed rule.

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

Issuance of a SNUR for a chemical substance does not signify that the chemical substance is listed on the TSCA Inventory. Guidance on how to determine if a chemical substance is on the TSCA Inventory is available on the Internet at http://www.epa.gov/opptintr/existingchemicals/pubs/tscainventory/index.html.

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 chemical substances that are the subject of these SNURs, EPA considered relevant information about the toxicity of the chemical substances, likely human exposures and environmental releases associated with possible uses, taking into consideration the four bulleted TSCA section 5(a)(2) factors listed in this unit.

V. Response to Comments on Proposed SNURs

Comment 1: One commenter stated that the practice of EPA negotiating consent orders with the PMN submitter first without public comment or input has limited the public’s ability to use the comment process to change requirements for SNURs based on consent orders and has contributed to SNURs requiring personal protective equipment rather than following the industrial hygiene hierarchy of controls where personal protective equipment is the last option selected to control exposures.

EPA Response: EPA issues orders under section 5(e) of TSCA in response to PMNs submitted under Section 5(a) of TSCA. EPA can only negotiate consent orders with persons who submitted the PMN. Because the consent order only restricts the activities of the PMN submitter, EPA issues a SNUR to extend the same requirements to all manufacturers, and processors. SNURs are issued either using notice and comment rulemaking or as direct final rules. Regardless of which procedure is used, the public is permitted an opportunity to comment. In accordance with the procedural rules for promulgating SNURs based on section 5(e) orders (see 40 CFR §721.160(b)), such SNURs are generally based on and consistent with the underlying section 5(e) consent order. However, EPA may also designate additional activities as significant new uses (SNUs). These additional SNUs may be in response to public comment. For an example, see the response to Comment 14.

Comment 2: A commenter objected to the requirement that domestic manufacture of certain PMN substances is not permitted. The commenter states that if it is unacceptable for Americans to be exposed to these substances, then it is unacceptable for other humans to be exposed. Conversely, the commenter stated that if these substances can be manufactured safely then Americans should also have that opportunity.

EPA Response: The SNUR does not prevent domestic manufacture from occurring, it only requires notification beforehand. Because domestic manufacture is not currently anticipated and may never occur, EPA does not review potential risks associated with domestic manufacture when a PMN is submitted with an indication that the substance will only be imported and not domestically manufactured. EPA did not review or address potential risks of manufacture outside the United States because the statutory authority of TSCA is not applicable to actions outside the United States. If and when a person decides to begin domestic manufacture of the substance, the SNUN review will then permit EPA to assess and address potential risks associated with the SNU before they occur.

Comment 3: For the SNUR for the chemical substance which was the subject of PMN P–04–244, one commenter stated that there was no need for a production volume limit for the SNUR, based on the limited use of the PMN substance as a herbicide intermediate, minimal toxicity effects, and the use of personal protective equipment to limit exposures. Another commenter, who is subject to the consent order, stated that they would petition the Agency to eliminate the testing requirement in the consent order. The second commenter recommended that EPA finalize the SNUR after the agency takes action on the petition.

EPA Response: The consent order requires testing at a specific production volume limit, which is the basis for the production volume limit of manufacture of the PMN substance contained in the SNUR at §721.80(q). After reviewing the petition to modify the consent order, EPA decided to retain the testing requirement in the consent order, because the petitioner did not submit alternative data that addressed the testing requirement in the consent order. EPA retained the testing requirement in the consent order at a
specific production volume limit to address EPA’s finding that the available information is insufficient to permit a reasoned evaluation of the health effects of the PMN substance at larger production volumes. Thus, the final rule will contain the same production volume limit for manufacture. If the person subject to the consent order submits the required testing before exceeding the production volume limit, that person is permitted to exceed the production volume limit without a significant new use notification. EPA will review the testing results and take appropriate action to continue to address any potential unreasonable risks. Processors of the PMN substance are not subject to the production volume limit.

Comment 4: EPA should make it clear to PMN submitters of carbon nanotubes and other nanomaterials that required test methods will be decided on a case-by-case basis and that preference will be given to in vitro nanomaterial-specific methods. There are several EPA and National Academy of Science testing strategies that support this approach. In addition to problems with extrapolating information from animal studies to humans for conventional chemicals, nanomaterials possess unique physical and toxicological properties that render animal testing even more problematic. It is critical to completely and accurately characterize nanomaterials and then apply in vitro and in silico methods within an integrated test strategy. In the event that additional data is requested, EPA should require manufacturers to use high-throughput methods that have been specifically designed for nanomaterials in order to reduce reliance on animal-based testing. EPA Response: EPA identified recommended testing in the preamble of the proposed SNUR. Any manufacturers, or processors who intend to conduct testing or submit a SNUR are encouraged to contact EPA prior to commencing testing to avoid duplicative testing, to identify alternative testing, and to discuss protocols and testing strategies for any testing to be conducted. EPA recognizes the potential value of high-throughput methods, in vitro nanomaterial specific methods, and integrated testing strategies for nanomaterials. EPA continues to evaluate proposed testing methods for carbon nanotubes and other nanomaterials. In assessing this on a case-by-case basis, EPA will continue to consider the alternatives identified by the commenter.

Comment 5: The chemical name for P–10–476 should include the word brominated.

EPA Response: EPA agrees that brominated is part of the chemical name and will include the corrected chemical name in the final SNUR.

Comment 6: All data regarding environmental and health effects of nanomaterials, especially adverse effects, should be made publicly available. EPA must challenge claims of confidential business information (CBI) by manufacturers. EPA could disclose CBI in connection with a public proceeding to determine whether a nano product causes unreasonable adverse effects on health or the environment. If EPA finds such disclosure is necessary in the public interest.

EPA Response: EPA is committed to ensuring that CBI claims do not limit the public availability of environmental and health effects data beyond the confidentiality protections provided in TSCA Section 14. EPA has well established provisions that provide, as appropriate, a mechanism to evaluate CBI claims to ensure such claims are consistent with the law. Regarding the chemical substances that are nanomaterials and intended to be subject to the proposed SNUR, each consent order and SNUR clearly articulates the basis for EPA’s findings and describes the data used to assess health and environmental effects and risks. Moreover there were no CBI claims for health and safety data in the health and safety studies for the substances subject to the proposed SNUR.

Comment 7: The proposed regulations fail to address a number of concerns including addressing the public’s and worker’s right to know by not providing for mandatory nano-specific ingredient and warning labeling requirements.

EPA Response: The SNURs and the consent orders which are the basis for the SNURs do not require labeling of nano-specific ingredients or nano-specific warnings because (1) the basis for the consent orders and SNURs is not that they are nanomaterials per se, but rather is based on their specific properties and potential risks, and (2) companies that manufacture, process, and use chemical substances that are carbon nanotubes and fullerenes already clearly identify those chemical substances as nanomaterials.

Comment 8: The requirements for the proposed SNURs for P–09–55 and P–09–54–57 are inconsistent with requirements in the consent order. Specifically, the proposed SNURs required § 721.63(a)(2)(ii), which is full body protective clothing, when the consent orders required clothing that covers any other exposed areas of the arms, legs, and torso. In addition, for P–09–55, the proposed SNUR includes language that respirators must be used “with an assigned protection factor (APF) of at least 50”. The consent order for P–09–55 does not contain language requiring a respirator with an APF of 50.

EPA Response: Because the use of clothing that covers any other exposed areas of the arms, legs, and torso, as required by the consent orders for the PMN substances, is an ongoing use, the proposed SNUR requirements have been changed in the final rule to be consistent with the ongoing use. In the final rule, EPA has changed the requirements in § 721.63 to require clothing that covers any other exposed areas of the arms, legs, and torso for these SNURs. Because the consent order for P–09–54–57 does not require that the PMN submitter demonstrate that the clothing is impervious, the SNUR has been revised accordingly to reflect the ongoing use. However, the consent order for P–09–142–144 does require that the PMN submitter demonstrate that the protective clothing is impervious. Therefore, EPA will retain the language in the final rules for P–09–142–144 that imperviousness must be demonstrated for the clothing. EPA incorrectly included in the proposed rule for P–09–55 in § 721.63 the language, “with an assigned protection factor (APF) of at least 50”. EPA removed that language for P–09–55 in the final rule.

Comment 9: NIOSH recommends a hierarchical approach to reduce worker exposure that relies on respiratory protection only after other approaches have been attempted. The proposed rules allow persons who would be subject to SNURs for CNT to submit data to EPA in support of a New Chemical Exposure Limit (NCEL) under 40 CFR 721.30. The following comments pertain primarily to the CNT chemical substances in the proposed SNUR. To ensure that the PMN substances that are CNT are handled in a safe manner, EPA may want to add a requirement that employers submit information about specific workplace exposure controls in addition to the supporting evidence of airborne exposure data. EPA should also consider providing guidance on methods to measure process emissions and worker exposures, and interpretation of those data in making risk management decisions. NIOSH has published guidance on general approaches as well as specific CNT information. The basis of any NCEL should be compatible with current United States government risk assessment policies and practices used to set occupational exposure limits. NIOSH recommends that EPA use the
NIOSH REL of 1 ug/m³ as an 8-hour-time-weighted average as identified in its final CNT bulletin. This would be an interim recommendation for controlling workplace exposures, until results of ongoing research can elucidate which physical and chemical characteristics of CNT affect their toxicity and until improved methods to measure airborne exposures are established.

EPA Response: EPA agrees that a hierarchy of controls should be applied and that personal protective equipment is the last resort to prevent exposures. See EPA’s response to comment 14 describing language it will add to the applicable SNURs in this action. EPA’s NCEL language in consent orders states that preventing exposures is the preferred method for protecting workers, see: http://www.epa.gov/oppt/newchems/pubs/consent-pdf/ riskhhncel.pdf. Most PMN and SNUN submissions describe engineering controls and other steps that will be taken to reduce worker exposures. However, in many cases these measures may not sufficiently reduce exposures or may not used by every manufacturer or processor. EPA requires personal protective equipment for workers who are reasonably likely to be exposed in order to prevent unreasonable risks. However, persons subject to the SNURs for carbon nanotubes may submit information under 40 CFR 721.30 on any alternative exposure controls, including a NCEL, to support a determination that those exposure controls are equivalent to the requirements in the SNUR. While EPA encourages submission of as much information as possible to support that determination, EPA does not require submission of specific workplace exposure controls in addition to airborne exposure data. EPA can provide information on the approach used to measure releases and exposures on a case-by-case basis to support a determination that those exposure controls are equivalent to the requirements in the SNUR. Such information would take into consideration the fact that new chemical substances do not have established methods of detection. When establishing a NCEL or other alternative exposure control, EPA will consider all available data including United States government policies and practices used to set occupational exposure limits. Because of the uncertainty surrounding the NIOSH REL of 1 ug/m³ (as NIOSH noted in its final CNT bulletin the REL is based on analytical limit of quantification and may not be preventative of all known health effects see: http://www.cdc.gov/niosh/docs/2013-145/pdfs/2013-145.pdf). EPA will not adopt the NIOSH REL as a NCEL at this time because EPA cannot determine that at the REL the potential exposures may not present an unreasonable risk. EPA will consider the final NIOSH REL or other alternative exposure controls for CNTs if a submission requesting such is made under 40 CFR 721.30. This would allow the submitter to send EPA data in support of a proposed exposure level and to demonstrate a technique to comply with that level. EPA would then evaluate the proposal and data as described in 40 CFR 721.30. See: http://www.epa.gov/oppt/newchems/pubs/consent-pdf/riskhhncel.pdf and http://www.epa.gov/oppt/newchems/pubs/ncelesp.pdf, which, respectively, are EPA’s boilerplate TSCA 5(e) consent order containing a NCEL and EPA’s Response to Comments on NCELS in TSCA 5(e) Orders. These two documents contain additional information on EPA’s approach to NCELS and developing techniques to comply with those requirements.

Comment 10: Each CNT SNUR includes a statement that this rule does not apply “. . . to quantities of the PMN substance after they have been completely reacted (cured); embedded or incorporated in a polymer matrix . . . that is not intended to undergo further processing, except for mechanical processing.” NIOSH agrees with this approach. The wording in § 721.10274 of the proposed rule (page 81460) differ from that in some other sections by stating “. . . or embedded in a permanent solid polymer form with a concentration of the PMN substance equal to or below 30 percent. The other sections did not include the “30 percent” requirement. Please clarify the basis for EPA’s determination for this particular PMN substance.

EPA Response: Based on confidential information in the PMN, EPA determined, that for this PMN substance, P=0.0—0.1%88, there may not be an unreasonable risk if the PMN substance was contained in a polymer form with a concentration of the PMN substance equal to or below 30 percent; however, EPA is concerned about potential risks above a 30 percent concentration. Consequently, the consent order does not apply when the concentration of the PMN substance is equal to or below 30 percent in a permanent solid polymer form.

Comment 11: The proposed rules for the carbon nanotube chemical substances include statements requiring PMN initial control levels be 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, and the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance. A change in these factors may not necessarily address potential risk to workers.

EPA Response: These comments pertain to the four factors identified in section 5(a)(2) of TSCA that EPA must consider when determining significant new uses of a chemical substance. EPA must also consider all other relevant factors. These factors are not requirements for information that must be included in PMNs or SNUNs. EPA agrees that a change in these factors does not necessarily result in a risk to human health or the environment.

Persons who intend to manufacture, or process chemical substances for an activity that is designated as a significant new use by this final rule must notify EPA at least 90 days before commencing that activity. This required significant new use notification would provide EPA with the opportunity to evaluate the intended new use and to prohibit or limit any activity associated with the new use. EPA would assess the potential risks from those new uses and take action to prevent any unreasonable risks to human health or the environment from activities described in the SNUN.

Comment 12: One commenter stated that the proposed SNURs for the carbon nanotubes restrict the uses of the PMN substances to those specified in the consent order and require certain dermal and respiratory personal protective equipment. Submission of a PMN or SNUN will allow EPA to review these chemical substances but would not address worker safety as the notices would not require reporting of information relevant to risk assessment. There are several uncertainties associated with risk assessment of nanomaterials including a lack of reliable studies, smaller particles may have more detrimental and more potent effects, and smaller particles may cause different or greater exposures to humans and the environment. Because of these uncertainties, risk assessment of nanomaterials will not be adequate.

EPA Response: Despite the uncertainties cited by the commenter, EPA believes that its assessment and risk management of nanomaterials, although sometimes hampered by a lack of submitted data, is adequate to
identify and prevent potential unreasonable risks to human health or the environment from manufacturing processing, and using nanomaterials including risks to workers. EPA has consistently limited exposures to and releases of nanomaterials that are new chemical substances to prevent unreasonable risks through the use of TSCA section 5(e) orders and SNURs.

Comment 13: The SNURs for the carbon nanotubes should require reporting of risk assessment methods and findings, including nanoparticle dimension and relevant information. Personal protective equipment should be required as the last step in risk management. The SNURs should also require some form of engineering and administrative controls on top of the required personal protective equipment with exhaust ventilation systems designed, tested, and maintained as per the recommendations of the American Conference of Governmental Industrial Hygienists and requiring ongoing risk monitoring.

EPA Response: If a manufacturer or processor wants to engage in one of the new uses, the submitter of the SNUN must report all test data that are in the possession or control of the submitter as well as all other data concerning health or environmental effects known or reasonably ascertainable by the submitter, as described in 40 CFR 720.45 and 40 CFR 721.25. Risk assessment methods and findings are not specifically required in these regulations to be submitted in a SNUN and EPA has not required them for other SNUNs because they are not statutorily required to be submitted for section 5 notices under TSCA Section 5(d)(1). However, pursuant to TSCA Section 5(d)(1)(B), available information relevant to potential hazards and risks must be included in a SNUN and could include any relevant risk assessment findings that have been developed by the SNUN submitter. For example, SNUN submitters should report any available particle size data for carbon nanotubes. The SNURs allow for specific engineering and administrative controls proposed by a submitter under 40 CFR 721.30, once EPA has evaluated those controls. See also the responses to comments 9 and 14 for further discussion of engineering and administrative controls.

Comment 14: EPA received a similar set of comments from 26 public submissions. Each of these comments generally stated that EPA’s approach to exclusively requiring personal protective equipment in SNURs to prevent worker exposure instead of requiring engineering controls is not following the best occupational health and safety practices. The commenters suggest approaches that EPA could adopt. Several commenters identified the “hierarchy of controls” approach for industrial hygiene and workplace safety and controls, where elimination, substitution, engineering controls, and workplace or administrative controls should be used before personal protective equipment. Several commenters stated that persons subject to the SNUR should follow the OSHA requirements that a hierarchy of controls is required before employers use personal protective equipment. Some commenters suggest that EPA should specifically incorporate OSHA requirements at 40 CFR 1910.134(a)(1) into each SNUR or modify requirements in the SNUR at §721.63 to require a hierarchy of controls. Several commenters also suggested that EPA incorporate into SNURs applicable to CNT the recommendations in NIOSH Current Intelligence Bulletin for CNT. Other commenters noted that a NIOSH Progress Toward Safe Nanotechnology publication, a 2006 Rand Report summarizing a 2005 workshop, EPA’s Nanotechnology White Paper, a NIEHS report on training workers, ANSI standards, and a Safe Work of Australia information sheet on use of carbon nanotubes either specifically recommend a hierarchy of controls or recommend an approach using engineering controls to prevent exposures before using personal protective equipment.

EPA Response: EPA agrees that a hierarchy of controls should be applied and that personal protective equipment should be the last option to prevent exposures. EPA’s NCELS language in consent orders states that preventing exposures is the preferred method for protecting workers. See: http://www.epa.gov/oppt/newchems/pubs/consent-pdf/riskنحن.pdf. Most PMN and SNUN submitters describe engineering controls and other steps that will be taken to reduce worker exposures. However, in many cases these measures may not sufficiently reduce exposures or it may not be feasible for every manufacturer or processor to use engineering controls. EPA requires personal protective equipment only for workers who are reasonably likely to be exposed in order to prevent unreasonable risks. It should be noted that OSHA regulations only recommend but do not require specific engineering controls for existing chemical substances when there are available methods for detecting those chemical substances and there are engineering controls known to prevent exposures. For new chemical substances, there is often no data on detection methods and limited data on which engineering controls prevent worker exposures in all situations. In addition, because new chemical substances have not previously been in commerce, there are no specific applicable exposure limits or protective equipment requirements under any other statute. In the case of nanomaterials, such as carbon nanotubes, there is currently even more uncertainty associated with detection methods and effectiveness of certain engineering controls.

EPA has added language to the SNURs in this final action to require engineering controls and administrative controls where feasible but will not change its approach at this time for new chemical substances for any of the other statutes. In the case of TSCA section 5(e) orders and SNURs, there is currently even more uncertainty associated with detection methods and effectiveness of certain engineering controls.

Comment 15: EPA also received one comment supporting the SNURs and another comment discussing efforts of the tire industry to incorporate nanomaterials into their products.

EPA response: Neither comment contained a substantive comment regarding the rule so EPA has no response.

VI. Applicability of the Significant New Use Designation

If uses begun after the proposed rule was published were considered ongoing rather than new, any person could defeat the SNUR by initiating the significant new use before the final rule was issued. Therefore EPA has designated the date of publication of the proposed rule as the cutoff date for determining whether the new use is ongoing. Consult the Federal Register notice of April 24, 1990 (55 FR 17376) (FRL–3658–5) for a more detailed discussion of the cutoff date for ongoing uses.

Any person, who began commercial manufacture, or processing of the chemical substances 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 the final rule. Persons who ceased those activities will have to first comply with all applicable SNUR notification requirements and wait until the notice review period, including any extensions, expires, before engaging in any activities designated as significant new uses. If a person were to meet the conditions of advanced compliance under 40 CFR 721.45(h), the person would be considered to have met the requirements of the final SNUR for those activities.

VII. Test Data and Other Information

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

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

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

In the absence of a TSCA section 4 test rule or a TSCA section 5(b)(4) listing covering the chemical substance, persons are required only to submit test data in their possession or control and to describe any other data known to or reasonably ascertainable by them (see §720.50). However, upon review of PMNs and SNUNs, the Agency has the authority to require appropriate testing.

In the TSCA section 5(e) consent orders for 15 of the chemical substances regulated under this rule, EPA has established restrictions in view of the lack of data on the potential health and environmental risks that may be posed by the significant new uses or increased environmental release. These restrictions will not be removed until EPA determines that the unrestricted use will not present an unreasonable risk of injury or result in significant or substantial exposure or environmental release. This determination is usually made based on the results of the required or recommended toxicity tests.

In cases where EPA issued a TSCA section 5(e) consent order that requires or recommends certain testing, Unit IV. of the proposed rule lists tests required or recommended in each of the section 5(e) consent orders underlying the proposed 5(e) SNURs, and lists tests recommended for the substances subject to the proposed non-5(e) SNURs. Descriptions of tests are provided for informational purposes. EPA strongly encourages persons, before performing any testing, to consult with the Agency pertaining to protocol selection.

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

According to §721.11(c), persons submitting a SNUN must comply with the same notice requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in §720.50. SNUNs must be submitted on EPA Form No. 7710–25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in §§721.25 and 720.40. E–PMN software is available electronically at http://www.epa.gov/opptintr/newchems.

IX. Economic Analysis

EPA has evaluated the potential costs of establishing SNUN requirements for potential manufacturers, and processors of the chemical substances during the development of the direct final rule. EPA's complete Economic Analysis is available in the docket under docket ID number EPA–HQ–OPPT–2010–0279.

X. Statutory and Executive Order Reviews

A. Executive Order 12866

This final rule establishes SNURs for several new chemical substances that were the subject of PMNs and, in some cases, a TSCA section 5(e) consent order. 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 ICR, 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

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

1. A significant number of SNUNs would not be submitted by small entities in response to the SNUR.
2. The SNUN submitted by any small entity would not cost significantly more than $8300.

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

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

- A significant number of SNUNs would not be submitted by small entities in response to the SNUR.
- Submission of the SNUN would not cost any small entity significantly more than $8300. Therefore, the promulgation of the SNUR would not have a significant economic impact on a substantial number of small entities.

D. Unfunded Mandates Reform Act

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 effect on small governments subject to the requirements of sections 202, 203, 204, or 205 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4).

E. Executive Order 13132

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

F. Executive Order 13175

This 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 20885, 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

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

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 final 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: June 14, 2013.

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

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

PART 9—[AMENDED]

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


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

* * * * *

721.10265 ........................................ 2070–0012

721.10266 ........................................ 2070–0012

721.10267 ........................................ 2070–0012

721.10268 ........................................ 2070–0012

721.10269 ........................................ 2070–0012

721.10270 ........................................ 2070–0012

721.10271 ........................................ 2070–0012

721.10272 ........................................ 2070–0012

721.10273 ........................................ 2070–0012

721.10274 ........................................ 2070–0012

721.10275 ........................................ 2070–0012

721.10276 ........................................ 2070–0012

721.10277 ........................................ 2070–0012

721.10278 ........................................ 2070–0012

721.10279 ........................................ 2070–0012

721.10280 ........................................ 2070–0012

* * * * *

PART 721—[AMENDED]

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


2. Add §721.10265 to subpart E to read as follows:
§ 721.10265 Ethane, 2-bromo-1,1-difluoro-

(a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as ethane, 2-bromo-1,1-difluoro- (PMN P–04–244; CAS No. 359–07–9) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this rule do not apply to quantities of the PMN substance after it has been completely reacted (cured).

(2) The significant new uses are:

(i) Protection in the workplace.

Requirements as specified in § 721.63(a)(1), (a)(2)(i), (a)(3), (a)(4), (a)(6)(vi), (a)(6)(vi)(b), (b) (concentration set at 0.1 percent), (c).

When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) and (a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. The following National Institute for Occupational Safety and Health (NIOSH)-certified respirator with an assigned protection factor (APF) of at least 1000 meets the minimum requirements for § 721.63(a)(4): NIOSH-certified supplied-air respirator operated in pressure demand or other positive pressure mode and equipped with a tight-fitting full facepiece.

(A) As an alternative to the respiratory requirements listed in paragraph (a)(2)(i), a manufacturer, or processor may choose to follow the new chemical exposure limit (NCEL) provisions listed in the TSCA section 5(e) consent order for this substance. The NCEL is 0.5 mg/m3 as an 8-hour time-weighted average. Persons who wish to pursue NCELs as an alternative to the § 721.63 respirator requirements may request to do so under § 721.30. Persons whose § 721.30 requests to use the NCELs approach are approved by EPA will receive NCELs provisions comparable to those contained in the corresponding section 5(e) consent order.

(B) [Reserved]

(ii) Hazard communication program.

Requirements as specified in § 721.72(a), (b), (c), (d), (e) (concentration set at 0.1 percent), (f), (g)(1)(iv), (g)(1)(vi), (g)(1)(vii), (g)(1)(ix), (g)(2)(ii), (g)(2)(iii), (g)(2)(iv)(a) use respiratory protection or maintain workplace airborne concentrations at or below an 8-hour time-weighted average of 0.5 mg/m3.

(iii) Industrial, commercial, and consumer activities. Requirements as specified in § 721.80(k)(chemical intermediate for a herbicide) and (q).

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

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

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

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

■ 3. Add § 721.10266 to subpart E to read as follows:


(a) Chemical substances and significant new uses subject to reporting. (1) The chemical substances identified generically as multi-wall carbon nanotubes (PMNs P–08–733 and P–08–734) are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this rule do not apply to quantities of the PMN substances after they have been completely reacted (cured); embedded or incorporated into a polymer matrix that has been reacted (cured); embedded, encapsulated or incorporated by the polymer binder into a permanent solid matrix (does not include slurries) that is not intended to undergo further processing, except for mechanical processing.

(ii) The significant new uses are:

(i) Protection in the workplace.

Requirements as specified in § 721.63(a)(1), (a)(2)(ii), (a)(2)(iii), (a)(3), (a)(4), (a)(6)(i), (a)(6)(ii), and (c).

When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) and (a)(4), engineering control measures (e.g., physical containment, exhaust control ventilation, or isolation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. The following National Institute for Occupational Safety and Health (NIOSH)—certified respirator with an assigned protection factor (APF) of at least 50 meets the minimum requirements for § 721.63(a)(4): NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N–100, P–100, or R–100 filter.

(ii) Industrial, commercial, and consumer activities. Requirements as specified in § 721.80 (f), (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, and processors of these substances.

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

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

■ 4. Add § 721.10267 to subpart E to read as follows:

§ 721.10267 [5,6]Fullerene-C60-Ih.

(a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as [5,6]Fullerene-C60-Ih (PMN P–09–54; CAS No. 99685–96–8) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this rule do not apply to quantities of the PMN substance after it has been completely reacted (cured); embedded or incorporated into a polymer matrix that itself has been reacted (cured); embedded in a permanent solid polymer form that is not intended to undergo further processing except for mechanical processing.

(ii) The significant new uses are:

(i) Protection in the workplace.

Requirements as specified in § 721.63(a)(1), (a)(2)(i), (a)(2)(iv), (a)(3), (a)(4), (a)(6)(i), (a)(6)(ii), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) and (a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. The following National Institute for Occupational Safety and Health (NIOSH)—certified respirator meets the minimum requirements for § 721.63(a)(4): NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N–100, P–100, or R–100 filter.
(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in §721.80(k) (an intermediate compound for use in producing downstream products that will in turn be used in organic electronic devices and an additive to improve mechanical properties or conductivity; a compound used to improve the mechanical properties of rubbers, plastics, and lubricants; or a compound for use as an additive to increase the conductivity of materials).

(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, and processors of this substance.

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

5. Add §721.10268 to subpart E to read as follows:


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

(1) The chemical substance identified as [5,6] Fullerene-C70–D5h(6) (PMN P–09–55; CAS No. 115383–22–7) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this rule do not apply to quantities of the PMN substance after it has been completely reacted (cured); embedded or incorporated into a polymer matrix that itself has been completely reacted (cured); embedded in a permanent solid polymer form; or a compound for use as an additive to improve the mechanical properties of rubbers, plastics, and lubricants; or a compound for use as an additive to increase the conductivity of materials.

(2) **Protection in the workplace.** Requirements as specified in §721.63(a)(1), (a)(2)(ii), (a)(2)(iv), (a)(3), (a)(4), (a)(6)(i), (a)(6)(ii), and (c). When determining which persons are reasonably likely to be exposed as required for §721.63(a)(1) and (a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. The following National Institute for Occupational Safety and Health (NIOSH)-certified respirator meets the minimum requirements for §721.63(a)(4); NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N–100, P–100, or R–100 filter.

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in §721.80(k) (an intermediate compound for use in producing downstream products that will in turn be used in organic electronic devices and an additive to improve mechanical properties or conductivity; a compound used to improve the mechanical properties of rubbers, plastics, and lubricants; or a compound for use as an additive to increase the conductivity of materials).

(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, and processors of this substance.

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

6. Add §721.10269 to subpart E to read as follows:


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

(1) The chemical substance identified as [5,6] Fullerene-C84–D2 (PMN P–09–56; CAS No. 145809–19–4) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this rule do not apply to quantities of the PMN substance after it has been completely reacted (cured); embedded or incorporated into a polymer matrix that itself has been completely reacted (cured); 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)(ii), (a)(2)(iv), (a)(3), (a)(4), (a)(6)(i), (a)(6)(ii), and (c). When determining which persons are reasonably likely to be exposed as required for §721.63(a)(1) and (a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. The following National Institute for Occupational Safety and Health (NIOSH)-certified respirator meets the minimum requirements for §721.63(a)(4); NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N–100, P–100, or R–100 filter.

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in §721.80(k) (an intermediate compound for use in producing downstream products that will in turn be used in organic electronic devices and an additive to improve mechanical properties or conductivity; a compound used to improve the mechanical properties of rubbers, plastics, and lubricants; or a compound for use as an additive to increase the conductivity of materials).

(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, and processors of this substance.

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

7. Add §721.10270 to subpart E to read as follows:

§721.10270 [5,6] Fullerene-C84–D2d.

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

(1) The chemical substance identified as [5,6] Fullerene-C84–D2d (PMN P–09–57; CAS No. 145809–20–7) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this rule do not apply to quantities of the PMN substance after it has been completely reacted (cured); embedded or incorporated into a polymer matrix that itself has been completely reacted (cured); 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)(ii), (a)(2)(iv), (a)(3), (a)(4), (a)(6)(i), (a)(6)(ii), and (c). When determining which persons are reasonably likely to be exposed as required for §721.63(a)(1) and (a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. The following National Institute for Occupational Safety and Health (NIOSH)-certified respirator meets the minimum requirements for §721.63(a)(4); NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N–100, P–100, or R–100 filter.
engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. The following National Institute for Occupational Safety and Health (NIOSH)-certified respirator meets the minimum requirements for § 721.63(a)(4): NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 cartridges.

(ii) Industrial, commercial, and consumer activities. Requirements as specified in § 721.80(k) (an intermediate compound for use in producing downstream products that will in turn be used in organic electronic devices and an additive to improve mechanical properties or conductivity; a compound used to improve the mechanical properties of rubbers, plastics, and lubricants; or a compound for use as an additive to increase the conductivity of materials).

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

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

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

§ 721.10271 3′H-Cyclopenta[1,9][5,6]fullerene-C60-th-3′-butanoic acid, 3′-phenyl-, methyl ester.

(a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as 3′H-Cyclopenta[1,9][5,6]fullerene-C60-th-3′-butanoic acid, 3′-phenyl-, methyl ester, (PMNs P–09–143 and Chemical B in P–09–416, CAS Number 609771–63–3) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this rule do not apply to quantities of the PMN substances after they have been completely reacted (cured); embedded or incorporated 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)(ii), (a)(2) (clothing which covers any other exposed areas of the arms, legs, and torso), (a)(3), (a)(4), (a)(6)(i), (a)(6)(ii), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) and (a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. The following National Institute for Occupational Safety and Health (NIOSH)-certified respirator meets the minimum requirements for § 721.63(a)(4): NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 cartridges.

(ii) Industrial, commercial, and consumer activities. Requirements as specified in § 721.80(k) (use as a compound used in fabrication and/or operation of electronic devices that enables or improves the conductivity, efficiency, voltage or other characteristics of the device, a compound that improves the mechanical properties of lubricants and plastics, or use as an acceptor molecule in a polymer coating in an encapsulated organic photovoltaic electronic device) 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), (j), (i), and (k) are applicable to manufacturers, and processors of this substance.

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

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

§ 721.10272 3′H-Cyclopenta[839][5,6]fullerene-C70–D5h(6)-3′-butanoic acid, 3′-phenyl-, methyl ester.

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

(1) The chemical substances identified as 3′H-Cyclopenta[839][5,6]fullerene-C70–D5h(6)-3′-butanoic acid, 3′-phenyl-, methyl ester (PMNs P–09–143 and Chemical B in P–09–416, CAS Number 609771–63–3) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this rule do not apply to quantities of the PMN substances after they have been completely reacted (cured); embedded or incorporated 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)(ii), (a)(2) (clothing which covers any other exposed areas of the arms, legs, and torso), (a)(3), (a)(4), (a)(6)(i), (a)(6)(ii), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) and (a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. The following National Institute for Occupational Safety and Health (NIOSH)-certified respirator meets the minimum requirements for § 721.63(a)(4): NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 cartridges.

(ii) Industrial, commercial, and consumer activities. Requirements as specified in § 721.80(k) (use as a compound used in fabrication and/or operation of electronic devices that enables or improves the conductivity, efficiency, voltage or other characteristics of the device, a compound that improves the mechanical properties of lubricants and plastics, or use as an acceptor molecule in a polymer coating in an encapsulated organic photovoltaic electronic device) 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), (j), (i), and (k) are applicable to manufacturers, and processors of this substance.

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

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

§ 721.10273 3′H-Cyclopenta[839][5,6]fullerene-C70–D5h(6)-3′-butanoic acid, 3′-phenyl-, methyl ester.

(a) Chemical substance and significant new uses subject to reporting.
are applicable to manufacturers, and processors of this substance.

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

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

■ 10. Add §721.10273 to subpart E to read as follows:

§721.10273 3′H-Cyclopropa[7,22][5,6]fullerene-C70–D5h(6)-3′-butanoic acid, 3′-phenyl, methyl ester.

(a) Chemical substance and significant new uses subject to reporting. (1) The chemical substances identified as 3′H-Cyclopropa[7,22][5,6]fullerene-C70–D5h(6)-3′-butanoic acid, 3′-phenyl, methyl ester (P–09–144 and Chemical C in P–09–416, CAS Number 1051371–21–1) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this rule do not apply to quantities of the PMN substances after they have been completely reacted (cured); embedded or incorporated 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)(2)(iii), (a)(4), (a)(6), (a)(6), and (c). When determining which persons are reasonably likely to be exposed as required for §721.63(a)(1) and (a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. The following National Institute for Occupational Safety and Health (NIOSH)-certified respirator meets the minimum requirements for §721.63(a)(4): NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 cartridges.

(ii) Industrial, commercial, and consumer activities. Requirements as specified in §721.80(k) (use of a compound used in fabrication and/or operation of electronic devices that enables the device to enhance the conductivity, efficiency, voltage or other characteristics of the device, a compound that improves the mechanical properties of lubricants and plastics, or use as an acceptor molecule in a polymer coating in an encapsulated organic photovoltaic electronic device) and (g).

(iii) Release to water. Requirements as specified in §721.90(a)(1), (a)(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, and processors of this substance.

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

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

■ 11. Add §721.10274 to subpart E to read as follows:

§721.10274 Multi-walled carbon nanotubes (generic) (P–09–188).

(a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as multi-walled carbon nanotubes (PMN P–09–188) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this rule do not apply to quantities of the PMN substances after it has been completely reacted (cured); embedded or incorporated into a polymer matrix that itself has been reacted (cured); or embedded in a permanent solid polymer form with a concentration of the PMN substance equal to or below 30 percent 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)(6), and (c). When determining which persons are reasonably likely to be exposed as required for §721.63(a)(1) and (a)(4), engineering control measures (e.g., physical containment, exhaust control ventilation, or isolation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. The following National Institute for Occupational Safety and Health (NIOSH)-certified respirator meets the minimum requirements for §721.63(a)(4): NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N–100, P–100, or R–100 filters.

(ii) Industrial, commercial, and consumer activities. Requirements as specified in §721.80(f), (k), (m), (o), 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, and processors of this substance.

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

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

■ 12. Add §721.10275 to subpart E to read as follows:

§721.10275 Multi-walled carbon nanotubes (generic) (P–09–0417).

(a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as multi-walled carbon nanotubes (PMN P–09–0417) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this rule do not apply to quantities of the PMN substance it has been completely reacted (cured); embedded or incorporated 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)(6), and (c). When determining which persons are reasonably likely to be exposed as required for §721.63(a)(1) and (a)(4), engineering control measures (e.g., physical containment, exhaust control ventilation, or isolation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. The following National Institute for Occupational Safety and Health (NIOSH)-certified respirator with an assigned protection factor (APF) of at
least 50 meets the minimum requirements for § 721.63(a)(4); NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N–100, P–100, or R–100 filter. (ii) Industrial, commercial, and consumer activities. Requirements as specified in § 721.80(f), (k) (plastics additive to improve electrical, thermal and/or mechanical properties), (m), and (o).

(iii) Release to Water. Requirements as specified in § 721.90(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, and processors of this substance.

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

13. Add § 721.10276 to subpart E to read as follows:


Chemical substance and significant new uses subject to reporting.

(1) The chemical substance identified generically as multi-walled carbon nanotubes (PMN P–10–39) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this rule do not apply to quantities of the PMN substance after it has been completely reacted (cured); embedded or incorporated into a polymer matrix that itself has been reacted (cured); embedded in a permanent solid polymer, metal, glass, or ceramic 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), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) and (a)(4), engineering control measures (e.g., physical containment, exhaust control ventilation, or isolation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. The following National Institute for Occupational Safety and Health (NIOSH)-certified respirators with an approved protection factor (APF) of at least 50 meets the minimum requirements for § 721.63(a)(4); NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N–100, P–100, or R–100 filter.

(ii) Industrial, commercial, and consumer activities. Requirements as specified in § 721.80(k), (m), (o), and (p)(120,000 kilograms of the aggregate of P–10–39 and P–10–40 the substance described in § 721.10277).

(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), (o), and (k) are applicable to manufacturers, and processors of these substances.

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

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

14. Add § 721.10277 to subpart E to read as follows:


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

(1) The chemical substance identified generically as single-walled and multi-walled carbon nanotubes (PMN P–10–40) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this rule do not apply to quantities of the PMN substance after it has been completely reacted (cured); embedded or incorporated into a polymer matrix that itself has been reacted (cured); embedded in a permanent solid polymer, metal, glass, or ceramic 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), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) and (a)(4), engineering control measures (e.g., physical containment, exhaust control ventilation, or isolation) or administrative control measures (e.g., physical containment, exhaust control ventilation, or isolation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. The following National Institute for Occupational Safety and Health (NIOSH)-certified respirators with an assigned protection factor (APF) of at least 50 meets the minimum requirements for § 721.63(a)(4); NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N–100, P–100, or R–100 filter.

(ii) Industrial, commercial, and consumer activities. Requirements as specified in § 721.80(k), (m), (o), and (p)(120,000 kilograms of the aggregate of P–10–40 and P–10–39 the substance described in § 721.10276).

(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, and processors of these substances.

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

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

15. Add § 721.10278 to subpart E to read as follows:

§ 721.10278 4,4′-Bipyridinium, 1-(phosphonoalkyl)-1′-substituted-, salt with anion (1:2) (generic).

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

(1) The chemical substance identified generically as 4,4′-Bipyridinium, 1-(phosphonoalkyl)-1′-substituted-, salt with anion (1:2) (PMN P–10–224) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) Protection in the workplace.

Requirements as specified in § 721.63(a)(1), (a)(2)(i), (a)(3)(applicable to gloves only), (a)(4), (a)(6), (b)(concentration set at 1.0 percent), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) and (a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. The following National Institute for Occupational Safety and Health (NIOSH)-certified respirators with an assigned protection factor (APF) of at
least 10 meet the minimum requirements for § 721.63(a)(4):
(A) NIOSH-certified air-purifying, tight-fitting half-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters;
(B) NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters;
(C) NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (either half-face or full-face) and HEPA filters; or
(E) NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (either half-face or full-face).
(ii) Industrial, commercial, and consumer activities. Requirements as specified in § 721.80(f), (j), (s)(1000 kilograms), (y)(1), and (y)(2).
(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), and (i) are applicable to manufacturers, and processors of this substance.
(2) Limitations or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.
(3) Determining whether a specific use is subject to this section. The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(ii) of this section.
The provisions of § 721.1725(b)(1) apply to this section.

(a) Chemical substance and significant new uses subject to reporting.
(1) The chemical substance identified generically as multi-walled carbon nanotubes (PMN P–10–246) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
(b) Specific requirements. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
(1) Recordkeeping. Recordkeeping requirements as specified in § 721.125(a), (b), (c), and (i) are applicable to manufacturers, and processors of this substance.
(2) Limitations or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.
(3) Determining whether a specific use is subject to this section. The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(ii) of this section.

§ 721.10280 Benzene ethenyl- polymer with 1,3-butadiene, brominated.
(a) Chemical substance and significant new uses subject to reporting.
(1) The chemical substance identified as benzene ethenyl- polymer with 1,3-butadiene, brominated (PMN P–10–476; CAS No. 1195978–93–8)) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
(2) The significant new uses are:
(i) Industrial, commercial, and consumer activities. Requirements as specified in § 721.80(j) (manufacture by the method where the average number molecular weight is in the range of 1000 to 10,000 daltons, or where less than 5 percent of the particles are in the respirable range of 10 microns or less and the average number molecular weight is greater than or equal to 10,000 daltons).