Approved: July 11, 2012.

C.J. Spain,

Acting Deputy Assistant Judge Advocate, General (Admiralty and Maritime Law).

Dated: July 13, 2012.

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[FR Doc. 2012–17874 Filed 7–20–12; 8:45 am]

BILLING CODE 3810–FF–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 721

[EPA–HQ–OPPT–2010–1075; FRL–9354–2]

RIN 2070–AB27

Significant New Use Rules on Certain Chemical Substances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is finalizing significant new use rules (SNURs) under the Toxic Substances Control Act (TSCA) for the chemical substances rutile, tin zinc, calcium-doped (CAS No. 389623–01–2) and rutile, tin zinc, sodium-doped (CAS No. 389623–07–8) which were the subject of premanufacture notices (PMNs P–06–36 and P–06–37) and a TSCA consent order issued by EPA. This action requires persons who intend to manufacture, import, or process either of the 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. EPA believes that this action is necessary because new uses of the chemical substances 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 the activity before it occurs.

DATES: This final rule is effective August 22, 2012.

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPPT–2010–1075. All documents in the docket are listed in the docket index available at *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov,* or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave. NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

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

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

SUPPLEMENTARY INFORMATION:

I. Does this action apply to me?

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

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

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

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Chemical importers are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements promulgated at 19 CFR 12.118 through 12.127; see also 19 CFR 127.28. 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 provisions of TSCA section 12(b) (15 U.S.C. 2611(b)) (see § 721.20), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

II. Background

A. What action is the agency taking?

EPA is finalizing SNURs under TSCA section 5(a)(2) for two chemical substances which were the subject of PMNs and a TSCA section 5(e) consent order. The two chemical substances are identified as rutile, tin zinc, calcium-doped (PMN P–06–36; CAS No. 389623–01–2) and rutile, tin zinc, sodium-doped (PMN P–06–37; CAS No. 389623–07–8). The final SNURs on these substances are based on and consistent with the provisions in the underlying consent order. The final SNURs designate as a significant new use manufacture (including import) or processing in the absence of the protective measures required in the corresponding consent order. This action requires persons who intend to manufacture, import, or process either of these two chemical substances for an activity that is designated as a significant new use by this final rule to notify EPA at least 90 days before commencing that activity.

Previously, in the **Federal Register** issue of October 5, 2011 (76 FR 61566) (FRL–8880–2), EPA issued direct final SNURs on these two chemical substances (see §§ 721.10230 and 721.10231). However, EPA received notices of intent to submit adverse comments on these SNURs. Therefore,

as required by § 721.160(c)(3)(ii), in the **Federal Register** issue of December 5, 2011 (76 FR 75794) (FRL–9329–5), EPA withdrew the direct final SNURs on these two chemical substances and subsequently proposed SNURs using notice and comment procedures in the **Federal Register** issue of December 28, 2011 (76 FR 81441) (FRL–9329–4). More information on the specific chemical substances subject to this final rule can be found in the **Federal Register** documents announcing the direct final SNURs or the proposed SNURs. The record for the SNURs on these two chemical substances was established in the docket under docket ID number EPA–HQ–OPPT–2010–1075. That docket includes information considered by the Agency in developing the direct final rule and this final rule including comments on those rules.

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

1. Revises the protection in the workplace and hazard communication provisions.

2. Retains the industrial, commercial, and consumer activities provisions.

In response to the comments, EPA is including in the regulatory text the following modifications:

- Revision to the protection in the workplace provision in paragraph (a)(2)(i)(*1*) to reflect a New Chemical Exposure Limit (NCEL) of 2.4 mg/m^3.
- Revision to the hazard communication provision in paragraph (a)(2)(ii) to reflect an NCEL of 2.4 mg/m^3.

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 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 § 721.1(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.

III. Rationale and Objectives of the Final Rule

A. Rationale

During review of the PMNs submitted for these two chemical substances, EPA concluded that 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 order. For additional discussion of the rationale for the SNURs on these chemicals, see Units II. and V. of this document.

B. Objectives

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

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

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

EPA received comments from numerous submitters on the proposed rules for rutile, tin zinc, calcium-doped (PMN P–06–36; CAS No. 389623–01–2) and rutile, tin zinc, sodium-doped (PMN P–06–37; CAS No. 389623–07–8). A summary and discussion of the comments received and the Agency's responses follow.

Comment 1: In the proposed SNUR, EPA clarified that it considers nanomaterials to include substances with a particle size less than 100 nanometers (nm) where d10 particle size presents the particle size as determined by laser light scattering at which 10 percent by weight of the substance measured is smaller. The commenter supports this approach based on the need for a threshold since solid particulate material will contain a distribution of particle sizes. The 10 percent threshold strikes a reasonable balance between being adequately protective of human health and recognizing practical limitations associated with analytical methods available for quantifying materials at or below such a threshold. The commenter supports using the weight-based threshold, as methods and instrumentation for performing weight-based particle size measurements are more widely available than techniques for performing measurements based on particle number. There are other important elements that should be included in any definition of a nanomaterial including recognizing that aggregates and agglomerates are not the same as the primary particles of which they are comprised and that many agglomerates may not disagglomerate readily in any medium.

EPA Response: In the proposed rule, EPA did not attempt to clarify what it considers to be a definition of a nanomaterial, although particle size of less than 100 nm is often used to describe such chemical substances. Based on information contained in the PMNs, EPA believes that the PMN submitter is not manufacturing or processing the PMN substances with a d10 particle size less than 100 nm. EPA also believes it is possible that these chemical substances could be manufactured or processed with a d10 particle size less than 100 nm. EPA proposed a new use in the SNURs for these two PMN substances to require notification if those chemical substances were manufactured or processed with a d10 particle size less than 100 nm. Upon notification of this new use, EPA would review the properties and assess any potential risks that were different from the chemical substances as reported in the PMNs. While EPA believes that the threshold and method used to measure particle size for these PMN substances is appropriate and protective of human health, EPA will consider different thresholds and methods in other TSCA actions, depending on the chemical substances being measured and available scientific knowledge and technology.

Comment 2: The PMN substances are not nanoscale substances and any concerns or regulatory requirements derived from concerns related to nanoscale materials are not pertinent to the PMN substances.

EPA Response: As described in the consent order, the basis for EPA's concerns for the PMNs is not whether the substances constitute nanoscale materials but rather the fact that they qualify under the new chemicals category for respirable, poorly soluble particulates, under the subcategory of titanium dioxide (see *http://www.epa.gov/oppt/newchems/pubs/chemcat.htm*). The category document identifies that there is potential for respirability if workers handle material containing any particles less than or equal to 10 microns in diameter. Based on information in the PMNs, workers are likely to be exposed to particles less than or equal to 10 microns in diameter. In addition, based on information contained in the PMNs, EPA believes that manufacturers and processors could use these chemical substances at particle sizes less than 100 nm. Accordingly, EPA has proposed new uses that would enable EPA to review any manufacture or processing of the PMN substance without the use of appropriate respiratory protective equipment or engineering controls, or at particle sizes less than 100 nm. The purpose of these notifications (i.e., SNUNs) is to allow EPA to review any new properties and assess any potential risks presented by the new use.

Comment 3: EPA's risk assessment stated there is no exposure expected to the PMN substances, according to the human health effects summary in the consent order. EPA determined that there can be no risk warranting regulation under the proposed rule, because of the statement that no absorption of the PMNs is expected via any route of exposure if the PMN substances are produced via the calcination method. The PMN substances can only be manufactured using the calcining process and there is no known alternative industrial process for making chemical substances such as the PMN substances. Based on review of EPA's risk assessment in the 5(e) consent order and the extensive experience of the Color Pigment Manufacturers Association (CPMA) members with similar products, there is no substantiation of potential risk in the record for the proposed rule or the necessity for any regulation of the PMN substances.

EPA Response: The human health effects summary, contained in Unit IV. (''EPA's Assessment of the Risk'') of the consent order does not address potential exposures to the PMN substances; workplace inhalation exposures are addressed in a separate exposure summary of the same Unit IV. The health effects summary does state, however, that if the PMN substances are calcined then EPA does not expect the PMN substances to be absorbed by any route of exposure. In addition, the health effects summary identifies concerns for potential lung effects from exposure to the PMN substances, according to the chemical category for respirable, poorly soluble particulates under the subcategory of titanium dioxide (see *http://www.epa.gov/oppt/newchems/pubs/chemcat.htm*). There is concern for the potential lung effects when workers handle material containing particles less than or equal to 10 microns in diameter. Based on information in the PMNs, workers are likely to be exposed to particles less than or equal to 10 microns in diameter. The concern for lung effects is not mitigated by calcination; the concern is independent of potential for absorption. In fact, because these insoluble particles are not absorbed, they remain in the lung longer than other particles, causing further inflammation and lung effects. As mentioned earlier in this response, the exposure summary in the consent order identifies potential inhalation to workers. Based on the potential hazard and exposure to workers, EPA concluded that the PMN substances may present an unreasonable risk of lung effects to exposed workers. The commenter did not provide any specific information regarding CPMA's extensive experience with similar products to refute EPA's risk finding for the PMN substances.

Comment 4: EPA should clarify that the PMN substances are not salts. It is incorrect for EPA to characterize these chemical substances as salts. EPA's health risk analysis based on structural analogs does not demonstrate a risk warranting regulation because the regulated substances do not exhibit the properties of the constituent metals and do not represent an unregulated dust exposure. Titanium dioxide is not an analog surrogate for the PMN

substances. EPA's assessment should evaluate the risk of the finished crystal form of the PMN substances.

EPA Response: EPA is not characterizing the PMN substances as salts or as the constituent metals, and the structural analogy in the consent order was not based on analogy to salts or constituent metals. EPA's structural activity relationship (SAR) analysis was based on the category of respirable, poorly soluble particulates that cause lung effects as a result of inhaling particles (see *http://www.epa.gov/oppt/newchems/pubs/chemcat.htm).* Titanium dioxide was chosen as the subcategory based on its physical characteristics as a poorly soluble particulate, and not any chemically-mediated toxicological properties. The risk assessment, as described in the response to comment 3, is consistent with the Agency's concerns that potential exposure to particles of the finished crystal form of the PMN substances may cause an unreasonable risk of lung effects.

Comment 5: EPA relied on a recommended exposure level (REL) from the draft National Institute for Occupational Safety and Health (NIOSH) Current Intelligence Bulletin: Occupational Exposure to Titanium Dioxide as the source of the proposed NCEL of 1.5 mg/m^3. Since the final NIOSH intelligence bulletin set a higher REL of 2.4 mg/m^3, EPA should revise its risk assessment to incorporate this new information.

EPA Response: EPA agrees that using the REL of 2.4 mg/m^3 for titanium dioxide, from the final NIOSH bulletin, would be more appropriate. This document is located in the docket under docket ID number EPA–HQ–OPPT–2010–1075. In fact, paragraph (b)(2) of the NCEL of the consent order for the PMN substances contains an automatic sunset clause stating that the NCEL in the consent order would automatically and immediately be changed to the final REL for titanium dioxide issued by NIOSH. Accordingly, EPA will issue the final SNURs with a NCEL of 2.4 mg/m^3, based on the final NIOSH REL for titanium dioxide. However, because EPA estimates that there are potential exposures greater than 2.4 mg/m^3, EPA continues to find a potential risk of concern for the PMN substances.

Comment 6: These chemical substances are subject to existing Occupational Safety and Health Administration (OSHA) Permissible Exposure Levels (PELs) for inorganic tin compounds. Given the existing applicable OSHA PELs, the proposed SNURs are duplicative and unnecessary regulation. The NCELs provisions in the section 5(e) order states that the NCEL and respirator requirements are automatically nullified if OSHA promulgates a PEL for the same substance. There is a separate OSHA standard, applicable to all inert dust particles, of 5 mg/m^3. There is no need for EPA to require the development of additional and different regulatory monitoring techniques for the PMN substances because there are already analytical monitoring techniques developed for inorganic tin compounds and inert dust particles.

EPA Response: While the OSHA PEL for inorganic tin compounds would be applicable to the inorganic tin contained in the PMN substances, it does not apply to the PMN substances themselves. Based on information submitted in the PMNs, EPA considers the substances to be mixed metal oxide compounds. Previous comments made the argument that the constituent metals are not bioavailable and there should not be concern for exposure to bioavailable metals from the PMN substances. EPA agreed that it is not characterizing the PMN substances as metals and the basis of its risk assessment is not the constituent metals contained in the PMN substances. See EPA's response to comment 4. Therefore, the OSHA PEL for inorganic tin does not adequately address potential risks from the PMN substances. While there is an OSHA inert dust standard of 5 mg/m^3, EPA finds there is still a potential risk for lung effects from exposures less than 5 mg/m^3 for the PMN substances. Paragraph (b)(2) of the NCEL of the consent order for the PMN substances does state, that if OSHA promulgates a PEL specifically applicable to the PMN substances then the respirator requirements and NCEL become null and void. This paragraph (b)(2) also states that the requirements of the consent order are not negated by any pre-existing OSHA PEL, such as the PEL for inorganic tin compounds cited by the commenters. Because OSHA has not promulgated a PEL specifically applicable to the PMN substances, the respirator requirements and NCEL requirements in the consent order for the PMN substances remain in effect. Neither the PMN submitter nor commenters have supplied any information on whether existing monitoring techniques used for inorganic tin compounds would be appropriate for use with the PMN substances. EPA has issued the consent order and will issue the final SNURs with the NCEL provisions to allow for review of any monitoring techniques for the PMN substances that would be used to demonstrate compliance with the exposure limits.

Comment 7: The costs and economic impacts of the rule are underestimated significantly. Customers may not use the PMN substances because of compliance costs. Manufacturers of the PMN substances will incur costs as a result of complying with the SNUR requirements, and costs associated with submitting a SNUN, including submitting toxicological testing prior to manufacture or import of the PMN substances for a significant new use.

EPA Response: The economic assessment developed by EPA for this rule estimates and discusses the potential costs identified by the commenter. The commenter did not supply any additional information disputing EPA's specific cost estimates or conclusions. Therefore, EPA will not change any of its cost estimates or conclusions. Contrary to the commenter's assertions, the SNURs do not require testing, and submission of a SNUN does not require submission of toxicological testing. The preamble to the proposed SNURs did recommend testing that could address potential risks EPA has identified for the PMN substances, and states that SNUN submitters can submit any other data to address potential risks. Anyone submitting a SNUN is strongly encouraged to submit information addressing potential risks, but specific testing is not required.

Comment 8: EPA's economic assumptions pursuant to the Regulatory Flexibility Act do not reflect the current market. Nearly identical structural analogs of the PMN substances already on the TSCA Inventory are produced by companies in the United States and abroad. The PMN substances are produced abroad and imported in finished articles.

EPA Response: The commenter did not supply any information on present or future significant new uses by small or large entities of the substances subject to the SNURs. Therefore, the basis for EPA's finding under the Regulatory Flexibility Act, that the promulgation of the SNURs will not have a significant adverse economic impact on a substantial number of small entities, will remain unchanged in the final rule.

Comment 9: The rule would prevent U.S. manufacturers from manufacturing and using the PMN substances in finished products while the rule would not prevent the use of the PMN substances outside the United States. Foreign manufacturers of finished products containing the PMN

substances will be able to use the PMN substances and import them as part of articles exempt from TSCA reporting.

EPA Response: TSCA primarily addresses risks within the United States. The consent order and the SNURs do not prevent United States manufacturers from manufacturing and using the PMN substances in finished products. In fact, the consent order negotiated with the PMN submitter allows manufacture, subject to certain restrictions. Those restrictions are reflected in the SNURs. The SNURs exempt all manufacturers and processors from significant new use reporting once the PMN substances have been incorporated into a polymer, glass, dispersion, cementitious matrix, or a similar incorporation. This includes articles imported into the United States. For these uses, no significant exposures are expected. The consent order and the SNURs would only be applicable in the United States to manufacturers or processors of the PMN substances in particulate form. EPA issued the consent order and is issuing the SNURs to address potential worker exposures associated with manufacture and processing of the PMN substances that could result in a risk of lung effects.

Comment 10: There are economic and environmental benefits identified in the PMN submissions for these chemical substances. Specifically, the PMN substances are intended to replace pigments containing heavy metals such as lead and cadmium, which are associated with risks to human health and the environment.

EPA Response: While EPA agrees that it would be beneficial to replace pigments that contain lead and cadmium, EPA found that the potential unreasonable risks associated with the PMN substances warranted issuing a consent order and SNUR.

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 rule 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 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 specific chemical substances for any of the significant new uses designated in the proposed rule after the date of publication of the proposed rule must stop that activity before the effective date of this final rule. Persons who ceased those activities will have to meet all applicable SNUR notice requirements and wait until the notice review period, including any extensions, before engaging in any activities designated as significant new uses.

EPA has promulgated provisions to allow persons to comply with these SNURs before the effective date. If a person were to meet the conditions of advance compliance under § 721.45(h), the person would be considered to have met the requirements of this 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. 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 and test reporting.

EPA has determined that a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) in rats would help characterize the human health effects of the PMN substances. To access this guideline, please to go *http://www.epa.gov/ocspp* and select ''Test Methods and Guidelines.'' This test may not be the only means of addressing the potential risks of the chemical substances. However, submitting a SNUN without any test data may increase the likelihood that EPA will take action under TSCA section 5(e), particularly if satisfactory test results have not been obtained from a prior PMN or SNUN submitter. EPA recommends that potential SNUN submitters contact EPA early enough so that they will be able to conduct the appropriate tests.

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

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

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 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, importers, 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–2010–1075.

X. Statutory and Executive Order Reviews

A. Executive Order 12866

This final rule establishes SNURs for two new chemical substances that were the subject of PMNs and 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 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

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 $8,300.

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

This rule is within the scope of the February 18, 2012 certification. Based on the economic analysis discussed in Unit 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 $8,300. Therefore, the promulgation of the SNUR would not have a significant economic impact on a substantial number of small entities.

D. Unfunded Mandates Reform Act

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 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 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: July 16, 2012.

Maria J. Doa,

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

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

PART 9—[AMENDED]

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

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

■ 2. 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	
* * * * *	
721.10230	2070–0012
721.10231	2070–0012
* * * * *	

* * * * *

PART 721—[AMENDED]

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

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

■ 4. Add § 721.10230 to subpart E to read as follows:

§ 721.10230 Rutile, tin zinc, calcium doped.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as rutile, tin zinc, calcium-doped (PMN P–06–36; CAS No. 389623–01–2) 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 that have been incorporated into a polymer, glass, dispersion, cementitious matrix, or a similar incorporation.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(4), (a)(6)(i), (b) (concentration set at 1.0 percent), and (c). The following National Institute for Occupational Safety and Health (NIOSH)-certified respirators with an assigned protection factor (APF) of 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 loose- fitting hood or helmet and high efficiency particulate air (HEPA) filters;

(D) NIOSH-certified powered air-purifying respirator equipped with a tight-fitting face-piece (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 face-piece (either half-face or full-face).

(*1*) As an alternative to the respiratory requirements listed in paragraph (a)(2)(i), a manufacturer, importer, 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 2.4 mg/m^3 as an 8-hour time-weighted-average for this substance (PMN P–06–36; CAS No. 389623–01–2) and the substance referred to in 40 CFR 721.10231 (PMN P–06–37; CAS No. 389623–07–8) combined. 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.

(*2*) [Reserved]

(ii) *Hazard communication program.* Requirements as specified in § 721.72(a), (b), (c), (d), (e) (concentration set at 1.0 percent), (f), (g)(1)(ii), (g)(2)(ii), (g)(2)(iv) (use respiratory protection or maintain workplace airborne concentrations at or below an 8-hour time-weighted average of 2.4 mg/m^3), and (g)(5).

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k) (manufacture of the substance with a particle size less than 100 nanometers, where d10 particle size presents the particle size, as determined by laser light scattering, at which 10 percent by weight of the substance measured is smaller).

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

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

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

■ 5. Add § 721.10231 to subpart E to read as follows:

§ 721.10231 Rutile, tin zinc, sodium-doped.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as rutile, tin zinc, sodium-doped (PMN P–06–37; CAS No. 389623–07–8) 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 that have been incorporated into a polymer, glass, dispersion, cementitious matrix, or a similar incorporation.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(4), (a)(6)(i), (b) (concentration set at 1.0 percent), and (c). The following National Institute for Occupational Safety and Health (NIOSH)-certified respirators with an assigned protection factor (APF) of 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 loose-fitting hood or helmet and high efficiency particulate air (HEPA) filters;

(D) NIOSH-certified powered air-purifying respirator equipped with a

tight-fitting face-piece (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 face-piece (either half-face or full-face).

(*1*) As an alternative to the respiratory requirements listed in paragraph (a)(2)(i), a manufacturer, importer, 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 2.4 mg/m^3 as an 8-hour time-weighted-average for this substance (PMN P–06–37; CAS No. 389623–07–8) and the substance referred to in 40 CFR 721.10230 (PMN P–06–36; CAS No. 389623–01–2) combined. 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.

(*2*) [Reserved]

(ii) *Hazard communication program.* Requirements as specified in § 721.72(a), (b), (c), (d), (e) (concentration set at 1.0 percent), (f), (g)(1)(ii), (g)(2)(ii), (g)(2)(iv) (use respiratory protection or maintain workplace airborne concentrations at or below an 8-hour time-weighted average of 2.4 mg/m^3), and (g)(5).

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k) (manufacture of the substance with a particle size less than 100 nanometers, where d10 particle size presents the particle size, as determined by laser light scattering, at which 10 percent by weight of the substance measured is smaller).

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

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

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

[FR Doc. 2012–17895 Filed 7–20–12; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2011–0353; FRL–9699–5]

Approval and Promulgation of Implementation Plans; Tennessee; 110(a)(1) and (2) Infrastructure Requirements for the 1997 8-Hour Ozone National Ambient Air Quality Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is taking final action to approve in part, and conditionally approve in part, the State Implementation Plan (SIP) submission, submitted by the State of Tennessee, through the Tennessee Department of Environment and Conservation (TDEC), to demonstrate that the State meets the requirements of sections 110(a)(1) and (2) of the Clean Air Act (CAA or Act) for the 1997 8-hour ozone national ambient air quality standards (NAAQS). Section 110(a) of the CAA requires that each state adopt and submit a SIP for the implementation, maintenance, and enforcement of each NAAQS promulgated by EPA, which is commonly referred to as an ''infrastructure'' SIP. TDEC certified that the Tennessee SIP contains provisions that ensure the 1997 8-hour ozone NAAQS are implemented, enforced, and maintained in Tennessee (hereafter referred to as ''infrastructure submission''). With the exception of sub-element 110(a)(2)(E)(ii), which pertains to the requirements of section 128(a)(1) of the CAA, Tennessee's infrastructure submission, provided to EPA on December 14, 2007, addresses all the required infrastructure elements for the 1997 8-hour ozone NAAQS.

DATES: *Effective Date:* This rule will be effective August 22, 2012.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA–R04–OAR–2011–0353. All documents in the docket are listed on the *www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, i.e., Confidential Business Information 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 either electronically through *www.regulations.gov* or in hard copy at the Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. EPA requests that if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 to 4:30 excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Nacosta C. Ward, Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. The telephone number is (404) 562–9140. Ms. Ward can be reached via electronic mail at *ward.nacosta@epa.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background

Upon promulgation of a new or revised NAAQS, sections 110(a)(1) and (2) of the CAA require states to address basic SIP requirements, including emissions inventories, monitoring, and modeling to assure attainment and maintenance for that new NAAQS.

Section 110(a) of the CAA requires states to submit SIPs to provide for the implementation, maintenance, and enforcement of a new or revised NAAQS within three years following the promulgation of such NAAQS, or within such shorter period as EPA may prescribe. Section 110(a) imposes the obligation upon states to make a SIP submission to EPA for a new or revised NAAQS, but the contents of that submission may vary depending upon the facts and circumstances. In particular, the data and analytical tools available at the time the state develops and submits the SIP for a new or revised NAAQS affects the content of the submission. The contents of such SIP submissions may also vary depending upon what provisions the state's existing SIP already contains. In the case of the 1997 8-hour ozone NAAQS, states typically have met the basic program elements required in section 110(a)(2) through earlier SIP submissions in connection with previous ozone NAAQS.

More specifically, section 110(a)(1) provides the procedural and timing