

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[EPA-HQ-OPPT-2010-1075; FRL-9329-4]

RIN 2070-AB27

Proposed Significant New Use Rules on Certain Chemical Substances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing significant new use rules (SNURs) under section 5(a)(2) of 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 TSCA section 5(e) consent orders issued by EPA. The proposed SNURs on these substances, which are based on and consistent with the provisions of the underlying consent orders, would designate as a significant new use the absence of the protective measures required in the consent orders. This action would require 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 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 the activity before it occurs.

DATES: Comments must be received on or before [*insert date 30 days after date of publication in the Federal Register*].

ADDRESSES: Submit your comments, identified by docket identification (ID) number

EPA-HQ-OPPT-2010-1075, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments.

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

- *Hand Delivery*: OPPT Document Control Office (DCO), EPA East Bldg., Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. Attention: Docket ID Number EPA-HQ-OPPT-2010-1075. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564-8930. Such deliveries are only accepted during the DCO's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to docket ID number EPA-HQ-OPPT-2010-1075. EPA's policy is that all comments received will be included in the docket without change and may be made available online at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through [regulations.gov](http://www.regulations.gov) or email. The [regulations.gov](http://www.regulations.gov) website is an “anonymous access” system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through [regulations.gov](http://www.regulations.gov), your email address will be automatically captured and included as part of the comment that is placed in the

docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: 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., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically 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:*

Kenneth Moss, Chemical Control Division (7405M), Office of Pollution Prevention and

Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-9232; email address:

moss.kenneth@epa.gov.

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

TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

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

INFORMATION CONTACT.

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

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

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

2. *Tips for preparing your comments.* When submitting comments, remember to:
- i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).
 - ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
 - iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
 - iv. Describe any assumptions and provide any technical information and/or data that you used.
 - v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
 - vi. Provide specific examples to illustrate your concerns and suggest alternatives.
 - vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
 - viii. Make sure to submit your comments by the comment period deadline identified.

II. Background

A. What Action is the Agency Taking?

EPA is proposing significant new use rules (SNURs) under section 5(a)(2) of TSCA for two chemical substances which were the subject of PMNs and TSCA section 5(e) consent orders. 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 proposed SNUR on these substances are based on and consistent with the provisions in the underlying consent orders. The proposed SNURs designate as a significant new use the absence of the protective measures required in the corresponding consent orders. These SNURs would require persons who intend to manufacture, import, or process either of these chemical substances for an activity that is designated as a significant new use to notify EPA at least 90 days before commencing that activity.

In the **Federal Register** of October 5, 2011 (76 FR 61566) (FRL-8880-2), EPA issued direct final SNURs on these two chemical substances in accordance with the procedures at § 721.160(c)(3)(i). EPA received notice of intent to submit adverse comments on these SNURs. Therefore, as required by § 721.160(c)(3)(ii), in the **Federal Register** of December 5, 2011 (76 FR 75794) (FRL-9329-5), EPA withdrew the direct final SNURs and is now issuing this proposed rule on the two chemical substances. The record for the direct final SNURs on these substances was established as docket EPA-HQ-OPPT-2010-1075. That record includes information considered by the Agency in developing the direct final rule and the notice of intent to submit adverse comments.

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

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

manufacture, import, or process the chemical substance for that use. Persons who must report are described in § 721.5.

C. Applicability of General Provisions

General provisions for SNURs appear in 40 CFR part 721, subpart A. These provisions describe persons subject to the rule, recordkeeping requirements, exemptions to reporting requirements, and applicability of the rule to uses occurring before the effective date of the 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. Significant New Use Determination

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

- The projected volume of manufacturing and processing of a chemical substance.
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.

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

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

To determine what would constitute a significant new use for the two chemical substances that are the subject of these proposed 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.

IV. Substances Subject to this Proposed Rule

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

- PMN number.
- Chemical name.
- Chemical Abstracts Service (CAS) number.
- Basis for the TSCA section 5(e) consent order.
- Toxicity concerns.
- Tests recommended by EPA to provide sufficient information to evaluate the chemical substance (see Unit VII. for more information).
- CFR citation assigned in the regulatory text section of this proposed rule.

This proposed rule concerns two PMN substances that are subject to “risk-based” consent orders under TSCA section 5(e)(1)(A)(ii)(I). Those consent orders require protective measures to limit exposures or otherwise mitigate the potential unreasonable risk. The so-called “5(e) SNURs” on these PMN substances are promulgated pursuant to § 721.160, and are based on and consistent with the provisions in the underlying consent orders. The 5(e) SNURs designate as a “significant new use” the absence of the protective measures required in the corresponding consent orders.

PMN Numbers P-06-36 and P-06-37

Chemical names: (P-06-36) Rutile, tin zinc, calcium-doped and (P-06-37) Rutile, tin zinc, sodium-doped.

CAS numbers: (P-06-36) 389623-01-2 and (P-06-37) 389623-07-8.

Effective date of TSCA section 5(e) consent order: February 17, 2009.

Basis for TSCA section 5(e) consent order: The PMN states that the substances will be used as colorants for polymers and industrial coatings. The order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) based on a finding that the substances may present an unreasonable risk of injury to human health. To protect against these risks, the consent order requires: Use of personal respiratory equipment, including a National Institute for Occupational Safety and Health (NIOSH)-certified respirator with an Assigned Protection Factor (APF) of at least 10, or compliance with a New Chemical Exposure Limit (NCEL) of 1.5 mg/m³ as an 8-hour time weighted average; establishment of a hazard communication program; and restricts the company from manufacturing the PMN substances with a d10 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; and corresponding recordkeeping. The SNUR designates as a “significant new use” the absence of these protective measures.

Toxicity concern: Based on structural activity relationship analysis derived from test data on structurally similar respirable, poorly soluble particulates, the PMN substances may cause lung overload and fibrosis in workers exposed to the PMN substances by the inhalation route.

Recommended testing: EPA has determined that the following test would help characterize the human health effects of the PMN substances: A 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) in rats. The testing should include a 60-day recovery period to assess the progression or regression of any lesions; and include special attention to histopathology (inflammation and cell proliferation) of the lung tissues and to various parameters of the bronchoalveolar lavage fluid (BALF), e.g., marker enzyme activities, total protein content, total cell count, cell differential, and cell viability. The order does not require submission of the aforementioned information at any specified time or production volume. However, the order’s restrictions on manufacturing, import, processing, distribution in commerce, use, and disposal of the PMN substances will remain in effect until the order is modified or revoked by EPA based on submission of that or other relevant information.

CFR citations: 40 CFR 721.10230 (P-06-36) and 40 CFR 721.10231 (P-06-37).

V. Rationale and Objectives of the Proposed 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), pending the

development of information sufficient to make reasoned evaluations of the human health effects of the chemical substances. The basis for such findings is outlined in Unit IV.

Based on these findings, TSCA section 5(e) consent orders requiring the use of appropriate exposure controls were negotiated with the PMN submitters. The proposed SNUR provisions for these chemical substances are consistent with the provisions of the TSCA section 5(e) consent orders. These proposed SNURs are issued pursuant to § 721.160.

B. Objectives

EPA is proposing these 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 proposed rule:

- EPA would 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 would 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 would 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 would 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>.

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

To establish a significant “new” use, EPA must determine that the use is not ongoing. The chemical substances subject to this proposed rule have undergone premanufacture review and are subject to TSCA section 5(e) consent orders. The PMN submitters are prohibited by these TSCA section 5(e) consent orders from undertaking activities which EPA is proposing as significant new uses. EPA solicits comments on whether any of the uses proposed as significant new uses are ongoing.

As discussed in the **Federal Register** issue of April 24, 1990 (55 FR 17376), EPA has decided that the intent of TSCA section 5(a)(1)(B) is best served by designating a use as a significant new use as of the date of publication of the proposed 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 final, and then argue that the use was ongoing before the effective date of the final rule. Thus, persons who begin commercial manufacture, import, or processing activities with the chemical substances regulated through this proposed SNUR must cease any such activity before the effective date of the rule, if and when

finalized. To resume their activities, these persons would have to comply with all applicable SNUR notice requirements and wait until the notice review period, including all extensions, expires.

EPA has promulgated provisions to allow persons to comply with this proposed SNUR before the effective date. If a person meets the conditions of advance compliance under § 721.45(h), the person is considered exempt from the requirements of the SNUR.

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 cases where EPA issued a TSCA section 5(e) consent order that requires or recommends certain testing, Unit IV. describes those tests. Descriptions of tests are provided for informational purposes. EPA strongly encourages persons, before performing any testing, to consult with the Agency pertaining to protocol selection and test reporting. To access the harmonized test guidelines referenced in this

document electronically, please go to <http://www.epa.gov/ocspp> and select “Test Methods and Guidelines.”

In the TSCA section 5(e) consent orders for the two chemical substances regulated under this proposed rule, EPA has established restrictions in view of the lack of data on the potential human health risks that may be posed by the significant new uses or increased exposure to the chemical substances. 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.

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

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

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

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

B. Paperwork Reduction Act

According to the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, an Agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under PRA, unless it has been

approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable. EPA would amend the table in 40 CFR part 9 to list the OMB approval number for the information collection requirements contained in this proposed 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 would not impose any burden requiring additional OMB approval. If an entity were to submit a SNUN to the Agency, the annual burden is estimated to average between 30 and 170 hours per response. This burden estimate includes the time needed to review instructions, search existing data sources, gather and maintain the data needed, and complete, review, and submit the required SNUN.

Send any comments about the accuracy of the burden estimate, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques, to the Director, Collection Strategies Division, Office of

Environmental Information (2822T), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. Please remember to include the OMB control number in any correspondence, but do not submit any completed forms to this address.

C. Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency hereby certifies that promulgation of this SNUR would not have a significant adverse economic impact on a substantial number of small entities. The requirement to submit a SNUN applies to any person (including small or large entities) who intends to engage in any activity described in the final rule as a “significant new use.” Because these uses are “new,” based on all information currently available to EPA, it appears that no small or large entities presently engage in such activities. A SNUR requires that any person who intends to engage in such activity in the future must first notify EPA by submitting a SNUN. Although some small entities may decide to pursue a significant new use in the future, EPA cannot presently determine how many, if any, there may be. However, EPA’s experience to date is that, in response to the promulgation of SNURs covering over 1,000 chemicals substances, the Agency receives only a handful of SNUNs per year. For example, the number of SNUNs was four in Federal fiscal year (FY) 2005, eight in FY 2006, six in FY 2007, eight in FY 2008, and seven in FY 2009. During this 5-year period, three small entities submitted a SNUN. In addition, the estimated reporting cost for submission of a SNUN (see Unit VIII.) is minimal regardless of the size of the firm. Therefore, EPA believes that the potential economic impacts of complying with those SNURs are not expected to be significant or adversely impact a

substantial number of small entities. In a SNUR that published in the **Federal Register** issue of June 2, 1997 (62 FR 29684) (FRL-5597-1), the Agency presented its general determination that final SNURs are not expected to have a significant economic impact on a substantial number of small entities, which was provided to the Chief Counsel for Advocacy of the Small Business Administration.

D. Unfunded Mandates Reform Act

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

E. Executive Order 13132

This action would 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 proposed rule would not have Tribal implications because it is not expected to have substantial direct effects on Indian Tribes. This proposed rule would not significantly nor uniquely affect the communities of Indian Tribal governments, nor

would 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 proposed 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 proposed rule 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).

List of Subjects in 40 CFR Part 721

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

Dated: December 16, 2011.

Wendy C. Hamnett,

Director, Office of Pollution Prevention and Toxics.

Therefore, it is proposed that 40 CFR part 721 be amended as follows:

PART 721--[AMENDED]

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

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

2. 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)(5), (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)(5):

(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 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).

(I) 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 these substances. The NCEL is 1.5 mg/m³ as an 8-hour time-weighted-average for both chemical substances 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 1.5 mg/m³), and (g)(5).

(iii) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(k) (manufacture of the substances 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.

3. 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)(5), (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)(5):

(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 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).

(I) 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 these substances. The NCEL is 1.5 mg/m^3 as an 8-hour time-weighted-average for both chemical substances 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 1.5 mg/m³), and (g)(5).

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k) (manufacture of the substances 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.