

requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.1712 to read as follows:

§ 165.1712 Safety Zone; Alaska Marine Highway System Port Valdez Ferry Terminal, Port Valdez; Valdez, AK.

(a) *Location.* The following area is a safety zone: all navigable waters of Port Valdez extending 200 yards in all directions from the edges of the Alaska Marine Highway System Terminal dock located in Port Valdez at 61°07'26" N and 146°21'50" W.

(b) *Enforcement period.* The rule will be enforced whenever there is an Alaska Marine Highway System Ferry vessel transiting within the area described in paragraph (a) of this section and there is a Commercial Salmon Fishery Opener that includes the navigable waters within the safety zone. Each enforcement period will be announced by a broadcast notice to mariners when the Commercial Salmon Fishery Opener is announced.

(c) *Definitions.* The following definitions apply to this section:

(1) The term “designated representative” means any Coast Guard commissioned, warrant or petty officer of the U. S. Coast Guard who has been designated by the Captain of the Port, Prince William Sound, to act on his or her behalf.

(2) The term “official patrol vessel” may consist of any Coast Guard, Coast Guard Auxiliary, state, or local law enforcement vessels assigned or approved by the COTP, Prince William Sound.

(3) The term ‘AMHS vessel’ means any vessel owned or operated by the Alaska Marine Highway System, including, but not limited to: M/V AURORA, M/V CHENEGA, M/V COLUMBIA, M/V FAIRWEATHER, M/V KENNICOTT, M/V LECONTE, M/V LITUYA, M/V MALASPINA, M/V MATANUSKA, M/V TAKU and M/V TUSTUMENA.

(d) *Regulations.* (1) The general regulations contained in 33 CFR 165.23, as well as the requirements in

paragraphs (d)(2) through (5) of this section, apply.

(2) No vessels, except for AMHS ferries and vessels owned or operated by AMHS will be allowed to transit the safety zone without the permission of the COTP Prince William Sound or the designated representative during periods of enforcement.

(3) All persons and vessels shall comply with the instructions of the COTP or the designated representative. Upon being hailed by a U.S. Coast Guard vessel or other official patrol vessel by siren, radio, flashing light or other means, the operator of the hailed vessel shall proceed as directed.

(4) Vessel operators desiring to enter or operate within the regulated area may contact the COTP or the designated representative via VHF channel 16 or 907–835–7205 (Prince William Sound Vessel Traffic Service) to request permission to do so.

(5) The COTP, Prince William Sound may be aided by other Federal, state, borough and local law enforcement officials in the enforcement of this regulation. In addition, members of the Coast Guard Auxiliary may be present to inform vessel operators of this regulation.

Dated: January 9, 2013.

Benjamin J. Hawkins,
Commander, U.S. Coast Guard, Captain of the Port, Prince William Sound.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 721

[EPA–HQ–OPPT–2012–0182; FRL–9399–1]

RIN 2070–AB27

Significant New Use Rule on Certain Chemical Substances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is finalizing a significant new use rule (SNUR) under the Toxic Substances Control Act (TSCA) for chemical substances identified generically as complex strontium aluminate, rare earth doped, which were the subject of several premanufacture notices (PMNs). This action requires persons who intend to manufacture (including import) or process any 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.

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 April 7, 2014.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPPT–2012–0182, is available at <http://www.regulations.gov> or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

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. Does this action apply to me?

You may be potentially affected by this action if you manufacture, process, or use the chemical substances contained in this final rule. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

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

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 and 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 these SNURs 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 a SNUR under TSCA section 5(a)(2) for five chemical substances which were the subject of PMNs. The five chemical substances are all identified generically as complex strontium aluminate, rare earth doped, which were the subject of PMNs P-12-22, P-12-23, P-12-24, P-12-25, and P-12-26. This SNUR requires persons who intend to manufacture or process any 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** issue of April 25, 2012 (77 FR 24613) (FRL-9345-4), EPA issued a direct final SNUR on these five chemical substances in accordance with the procedures at § 721.160(c)(3)(i). EPA received notice of intent to submit adverse comments on this SNUR. Therefore, as required by § 721.160(c)(3)(ii), in the **Federal Register** issue of June 22, 2012 (77 FR 37609) (FRL-9353-2), EPA withdrew the direct final SNUR in a separate document, and subsequently proposed a SNUR on the five chemical substances using notice and comment procedures in the **Federal Register** issue of June 22, 2012 (77 FR 37634) (FRL-9353-3). More information on the specific chemical substances subject to this final rule can be found in the **Federal Register** documents announcing the direct final SNUR or the proposed SNUR. The docket for the direct final SNUR on these chemical substances was established as docket ID number EPA-HQ-OPPT-2012-0182. 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. Based on these comments, this final rule:

1. Corrects the chemical identity of the PMN substances.
2. Simplifies the description of the significant new use.

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 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 SNUN 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 Rule

A. Rationale

During review of the PMNs submitted for these five chemical substances, EPA determined that one or more of the criteria of concern established at § 721.170 were met, as discussed in Unit II. and IV.

B. Objectives

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

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

- EPA can ensure that all manufacturers and processors of the same chemical substance that is subject to a TSCA section 5(e) consent order are subject to similar requirements.

Issuance of a SNUR for a chemical substance does not signify that the chemical substance is listed on the TSCA Chemical Substance Inventory (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 requires EPA to consider any other relevant factors.

To determine what would constitute a significant new use for the five chemical

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

V. Response to Comments on Proposed SNUR

A summary and discussion of the comments received on the proposed rule and the Agency's response follow.

Comment 1: The commenter noted that EPA incorrectly identified the chemical substances as "complex strontium aluminum, rare earth doped (generic)" in the proposed rule.

EPA Response: EPA acknowledges the error and has corrected the generic name to read: "complex strontium aluminate, rare earth doped (generic)".

Comment 2: The commenter stated the proposed significant new uses are ongoing with respect to chemical substances very similar to the PMN substances. Activated phosphors, including strontium aluminates similar to the PMN substances, have been manufactured, processed, and used in the United States for many years.

EPA Response: Regardless of whether chemical substances similar to the PMN substances are currently being used for purposes similar to the significant new use proposed, such use is irrelevant to determining ongoing use of the PMN substances for this rulemaking.

Comment 3: The health and safety data on the PMN substances do not justify a SNUR.

EPA Response: EPA believes that these chemicals will act in the respiratory tract similarly to other poorly soluble respirable particles causing adverse lung effects. The submitter provided no health and safety data information on the PMN substance or analogous chemical substances. The commenter submitted no data refuting EPA's concerns regarding poorly soluble respirable particles, as more than 5% of the PMN substances particles are less than 10 microns. The SNUR is therefore appropriate.

Comment 4: The commenter stated that EPA did not properly consider the four factors in TSCA section 5(a)(2) to determine that use of a chemical substance is a significant new use, and reasonable consideration of them shows that a SNUR is not justified for use of the PMN substances. The commenter also contended that because chemical substances similar to the PMN substances are widely manufactured (including imported) and processed in the United States, and because worker

safety and environmental laws already apply to the PMN substances, approval of the PMN substances without imposing a SNUR will not increase the magnitude or duration of exposure of human beings or the environment to the PMN substances because the scale of current use is significantly larger than any potential increase of use without the SNUR. The commenter also stated that strontium aluminates and titanium dioxide are regulated by the Occupational Safety and Health Administration (OSHA) as an inert or nuisance dust with a permissible exposure limit (PEL) of 5 milligrams/cubic meter (mg/m³) and that the level of exposure required for effects would not be a "reasonably anticipated condition of exposure."

EPA Response: Among the factors that must be considered under TSCA section 5(a)(2) is "(C) the extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance." This factor pertains to the potential changes in exposure to a specific chemical substance, not to other, possibly related, chemical substances which may have other exposure patterns. EPA identified concerns for potential lung overload to workers from inhalation exposure to the PMN substance based on analogous respirable, poorly soluble particulate chemical substances and predicts potential toxicity to workers from inhalation when more than 5% of the PMN substances particles are less than 10 microns. The fact that similar chemical substances are widely manufactured and processed in the United States and that worker safety and environmental laws apply to the PMN substance does not affect the potential for change in magnitude and duration of exposure to the PMN substances that are the subject of the SNUR. The commenter submitted no information to alleviate EPA's concern, based on analogy to exposure patterns of other respirable, poorly soluble particulates, that the significant new uses (manufacture, process or use of the chemical substances where more than 5% of the particles are less than 10 microns) could increase the magnitude and duration of exposure of human beings to respirable particles of the PMN substances when greater than 5% of the PMN substances particles are less than 10 microns. The OSHA PEL for nuisance dust is 5 milligrams/cubic meter (mg/m³) respirable fraction (OSHA, 29 CFR 1910.1000, Table Z-3). The change in particle size at the reasonably anticipated levels of

inhalation exposure to the PMN substances, which is the PEL of 5 mg/m³, could result in potential lung effects.

Comment 5: The commenter stated that activated phosphors, including strontium aluminates, have been subject to reporting under TSCA section 8(e) for many years, and is aware of no TSCA section 8(e) reports, and EPA references no such reports in the regulations.gov for this docket. The docket does not support that use of the strontium aluminate other than as described in the PMNs may cause serious health effects.

EPA Response: EPA acknowledges that it has not received TSCA section 8(e) information for these chemical substances. However, the fact that data has not been received does not demonstrate that hazards for activated phosphors containing respirable particles do not exist, just that none have been reported under TSCA section 8(e). Based on analogous respirable and poorly soluble chemical substances, any use of the chemical substances other than as described in the PMNs may cause serious health effects to workers from inhalation when more than 5% of the PMN substances particles are less than 10 microns.

Comment 6: The commenter stated that EPA identified concerns regarding potential lung overload to workers from inhalation exposure to the PMN substance based on data for titanium oxide, and that apparently based on these concerns, EPA found that changes in exposure or release levels for "any use of the substances other than as described in the PMNs may cause serious health effects." The commenter stated that the PMN substances are not closely analogous to titanium oxide, however, and the docket contains no support for the conclusion that their use other than as described in the PMNs would involve changes in exposure or release levels that are significant in relation to the health or environmental concerns in accordance with § 721.170(c)(2)(ii). The commenter also stated that the data on titanium oxide does not justify a SNUR for the PMN substances. Even if titanium oxide were closely analogous to the PMN substances, the toxicological data on titanium oxide are inconclusive.

EPA Response: The Agency's concern for the PMN substances is based on how these chemical substances will physically act in the respiratory tract, not on chemical composition or how they chemically interact with the respiratory tract. This concern is for the ability of the chemicals to enter the deep lung via inhalation of small particles. The PMN substances are

considered analogous in their physical properties to respirable, poorly soluble particulates (RPSP). See "TSCA New Chemicals Program Chemical Categories," at <http://www.epa.gov/oppt/newchemicals/pubs/npcchemicalcategories.pdf>, for a discussion of these concerns. The RPSP category identifies that there is potential for lung effects if workers are exposed by inhalation to particles less than or equal to 10 microns in diameter, based on five different types, or subcategories, of poorly soluble particulates.

Accordingly, the significant new use in this SNUR is based on an increased exposure to particles less than 10 microns which may cause lung effects. Each subcategory in the RPSP category lists a New Chemicals Exposure Limit based on available information for specific compounds. As is described in the RPSP category, EPA will also consider the specific toxicity of the metal compound that is a respirable poorly soluble particulate. However, no such data was provided for the PMN substances. As there is no toxicity data available on the PMN substances indicating potential for chemical toxicity, EPA is considering only its attributes as a respirable, poorly soluble particulate chemical substance. As a result, EPA believes the metal oxide titanium dioxide subcategory is the appropriate subcategory based on physical-chemical considerations. Adverse lung effects are associated with the inhalation of crystalline metal compound particulates. Crystalline particles more readily embed in lung alveolar sacs than amorphous particles, and are difficult to clear with mucous flow or coughing, leading to irritation and clogging of the sacs and hampering of carbon dioxide-oxygen exchange in the lungs. EPA considers the metal compound titanium dioxide to be a surrogate for most non-silica, crystalline poorly soluble respirable metal compound particulates, such as the PMN substances, that contain this type of crystalline structure. This physical analogy with the metallic poorly soluble respirable PMN substances is the primary driver in this case. There are several studies, cited in the EPA's RPSP category, that document lung effects from titanium dioxide exposure, and the RPSP category also states that available data are inconclusive for carcinogenicity effects from exposure to titanium dioxide. The National Institute for Occupational Safety and Health (NIOSH) Current Intelligence Bulletin 63: Occupational Exposure to Titanium Dioxide (<http://www.cdc.gov/niosh/docs/2011-160/pdfs/2011-160.pdf>) also

cites data demonstrating lung effects from exposure to titanium dioxide.

Comment 7: The definition of the significant new use is ambiguous and, as drafted, could be interpreted to impose the proposed SNUR on uses described in the PMN, referenced in § 721.10423(a)(2). The commenter would like EPA to change the language of the proposed rule to make clear that the particle size limitation does not apply to the uses of the strontium aluminates described in the PMN.

EPA Response: Although § 721.10423(a)(2) of the proposed rule is correct as written, EPA agrees that the wording in the regulatory text for § 721.80(j) can be confusing. Therefore, EPA has simplified the wording in the regulatory text to now read "A significant new use of the substance is a use other than manufacture, processing, or use where no more than 5 percent of particles are less than 10 microns." The SNUR would permit any use of the PMN substances as long as the particle size limits are being met.

VI. Applicability of the Significant New Use Designation

If uses begun after the proposed rule was published were considered ongoing rather than new, any person could defeat the SNUR by initiating the significant new use before the final rule was issued. Therefore, EPA has designated the date of publication of the proposed rule as the cutoff date for determining whether the new use is ongoing. See the **Federal Register** notice of April 24, 1990 (55 FR 17376) (FRL-3658-5) for a more detailed discussion of the cutoff date for ongoing uses. Any person who began commercial manufacture, import, or processing of the chemical substances identified generically as complex strontium aluminate, rare earth doped, which were the subject of PMNs P-12-22, P-12-23, P-12-24, P-12-25, and P-12-26 for any of the significant new uses, designated in the proposed SNUR after the date of publication of the proposed SNUR, must stop that activity before the effective date of the final rule. Persons who ceased those activities will have to first comply with all applicable SNUR notification requirements, and wait until the notice review period, including any extensions, expires, before engaging in any activities designated as significant new uses. If a person were to meet the conditions of advance compliance under § 721.45(h), the person would be considered to have met the requirements of the final SNUR for those activities.

VII. Test Data and Other Information

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

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

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

In the absence of a TSCA section 4 test rule, or a TSCA section 5(b)(4) listing covering the chemical substance, persons are required only to submit test data in their possession or control and to describe any other data known to or reasonably ascertainable by them (see 40 CFR 720.50). However, upon review of PMNs and SNUNs, EPA has the authority to require appropriate testing. Unit IV. of the proposed rule lists the testing recommended by EPA. Specifically, EPA has determined that a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) would help characterize the human health effects of the PMN substances. 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 selection. To access the OCSPP test guidelines referenced in this document electronically, please go to <http://www.epa.gov/ocspp> and select "Test Methods and Guidelines."

The recommended tests 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 notification requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in 40 CFR 720.50. SNUNs must be submitted 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 40 CFR 720.40. E-PMN software is available electronically at <http://www.epa.gov/opptintr/newchems>.

IX. Economic Analysis

EPA has evaluated the potential costs of establishing SNUN requirements for potential manufacturers and processors of the chemical substances subject to this final rule. EPA's complete economic analysis is available in the docket under docket ID number EPA–HQ–OPPT–2012–0182.

X. Statutory and Executive Order Reviews

A. Executive Order 12866

This final rule establishes a SNUR for 5 chemical substances that were the subject of PMNs. 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 (PRA)

According to 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 (RFA)

On February 18, 2012, EPA certified pursuant to RFA section 605(b) (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 final rule.

This final 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 (UMRA)

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 UMRA sections 202, 203, 204, or 205 (2 U.S.C. 1501 *et seq.*).

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 (NTTAA)

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

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 (CRA)

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), 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 action 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: January 20, 2014.

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. In § 9.1, add the following section in numerical order under the undesignated center heading “Significant New Uses of Chemical Substances” to read as follows:

§ 9.1 OMB approvals under the Paperwork Reduction Act.

*	*	*	*	*
40 CFR citation			OMB Control No.	
*	*	*	*	*
Significant New Uses of Chemical Substances				
*	*	*	*	*
721.10423			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 § 721.10423 to subpart E to read as follows:

§ 721.10423 Complex strontium aluminate, rare earth doped (generic).

(a) *Chemical substances and significant new uses subject to reporting.* (1) The chemical substances identified generically as complex strontium aluminate, rare earth doped (PMNs P–12–22, P–12–23, P–12–24, P–12–25, and P–12–26) are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* A significant new use of the substance is a use other than manufacture, processing, or use where no more than 5 percent of particles are less than 10 microns.

(ii) [Reserved]

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

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

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 424

[CMS–6046–N]

Medicare, Medicaid, and Children’s Health Insurance Programs: Announcement of New and Extended Temporary Moratoria on Enrollment of Ambulances and Home Health Agencies in Designated Geographic Locations

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Extension and establishment of temporary moratoria.

SUMMARY: This document announces the imposition of temporary moratoria on the enrollment of new ambulance suppliers and home health agencies in designated geographic locations to prevent and combat fraud, waste, and abuse.

DATES: Effective January 30, 2014.

FOR FURTHER INFORMATION CONTACT: August Nemec, (410) 786–0612. News media representatives must contact CMS’ Public Affairs Office at (202) 690–6145 or email them at press@cms.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

A. CMS’ Authority To Impose Temporary Enrollment Moratoria

Under the Patient Protection and Affordable Care Act (Pub. L. 111–148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (collectively known as the Affordable Care Act), the Congress provided the Secretary with new tools and resources to combat fraud, waste, and abuse in Medicare, Medicaid, and the Children’s Health Insurance Program (CHIP). Section 6401(a) of the Affordable Care Act added a new section 1866(j)(7) to the Social Security Act (the Act) to provide the Secretary with authority to impose a temporary moratorium on the enrollment of new Medicare, Medicaid or CHIP providers and suppliers, including categories of providers and suppliers, if the Secretary determines a moratorium is necessary to prevent or combat fraud, waste, or abuse under these programs. Section 6401(b) of the Affordable Care Act added specific moratorium language applicable to Medicaid at section 1902(kk)(4) of the Act, requiring States to comply with any