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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[EPA-HQ-OPPT-2014-0649; FRL-9935-43]

RIN 2070-AB27

Modification of Significant New Uses of Certain Chemical Substances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is amending the significant new use rules (SNURs) under section 5(a)(2) of the Toxic Substances Control Act (TSCA) for five chemical substances which were the subject of premanufacture notices (PMNs). This action amends the SNURs to allow certain uses without requiring a significant new use notice (SNUN), and extends SNUN requirements to certain additional uses. EPA is amending these SNURs based on review of new data for each chemical substance. This action requires persons who intend to manufacture (including import) or process any of these chemical substances for an activity that is designated as a significant new use by this rule to notify EPA at least 90 days before commencing that activity. The required notification would provide EPA with the opportunity to evaluate the intended use and, if necessary, to prohibit or limit that activity before it occurs.

DATES: This final rule is effective *[insert date 60 days after date of publication in the Federal Register]*.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2014-0649, 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), West William Jefferson Clinton 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:* Jim Alwood, Chemical Control Division, 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, process, or use the chemical substances contained in this 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 a modified 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 the chemical substance that is the subject of a final rule are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)) (see 40 CFR 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?

In the **Federal Register** of April 9, 2015 (80 FR 19307) (FRL-9924-10), EPA proposed amendments to the SNURs for 24 chemical substances in 40 CFR part 721 subpart E. This action would require persons who intend to manufacture or process these chemical substances for an activity that is designated as a significant new use by these amended rules to notify EPA at least 90 days before commencing that activity. Receipt of such notices allows EPA to assess risks that

may be presented by the intended uses and, if appropriate, to regulate the proposed use before it occurs. The proposed rule included 23 chemical substances where EPA determined, based on new information, there is no need to require additional notice from persons who propose to engage in identical or similar activities, or a rational basis no longer exists for the findings that activities involving the substance may present an unreasonable risk of injury to human health or the environment required under section 5(e)(1)(A) of the Act. The proposed rule also included a chemical substance, P-01-781, where EPA is modifying the chemical identity information. In the **Federal Register** of June 30, 2015 (80 FR 37161) (FRL-9928-93), EPA issued amendments to the SNURs for 19 of those chemical substances in 40 CFR part 721 subpart E. EPA is now issuing a final SNUR amendment for the other five chemical substances. EPA received public comments for the proposed SNUR amendments for the remaining five chemical substances of the 24 included in the proposed rule subject to SNURs at 40 CFR 721.5575, 721.9675, and 721.10515. As described in Unit III., EPA is finalizing the SNURs as proposed for the SNURs at 40 CFR 721.9675, and 721.10515 and is finalizing the SNUR at 40 CFR 721.5575 with one change. EPA is now amending the SNURs of these five chemical substances pursuant to 40 CFR 721.185.

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

Upon conclusion of the review of the five chemical substances in this SNUR amendment, EPA designated certain activities as significant new uses. Under § 721.185, EPA may at any time amend a SNUR for a chemical substance which has been added to subpart E of 40 CFR part 721 if EPA makes one of the determinations set forth in § 721.185. Amendments may occur on EPA's initiative or in response to a written request. Under § 721.185(b)(3), if EPA concludes that a SNUR should be amended, the Agency will propose the changes in the **Federal Register**, briefly describe the grounds for the action, and provide interested parties an opportunity to comment.

Pursuant to § 721.185 and as described in Unit IV. of the proposed rule for the five chemical substances, EPA determined, based on new information, that there is no need to require additional notice from persons who propose to engage in identical or similar activities, or a rational basis no longer exists for the findings that activities involving the substance may present an unreasonable risk of injury to human health or the environment required under section 5(e)(1)(A) of the Act.

III. Response to Comments on Proposed SNURs

Comment 1: One commenter stated that for the chemical substance subject to 40 CFR 721.5575 SNUR requirements should be excluded when the substance is incorporated or encapsulated in plastic as there would no longer be exposure.

Response: EPA reviewed uses of the chemical substance during PMN/SNUN reviews where it was incorporated or encapsulated into plastic. EPA estimated limited human and environmental exposures that were not expected to cause an unreasonable risk. Therefore, the final SNUR will remove from the scope of the SNUR any use where the chemical substance is incorporated or encapsulated into plastic.

Comment 2 : One commenter stated that, for the chemical substance subject to 40 CFR 721.9675, one of the SNUN submitters cited in the proposed rule was actually manufacturing a different chemical substance, which was instead the subject of P-06-0149 and a SNUR at 40 CFR 721.10553.

Response: Each of the SNUNs cited in the proposed SNUR modification were submitted to EPA pertained to the chemical substance titanate [Ti₆O₁₃ (2-)], dipotassium, which is the chemical substance subject to 40 CFR 721.9675. But regardless of whether any of the SNUN submitters are manufacturing or processing a different chemical substance, any manufacturer and

processor who is manufacturing potassium titanium oxide (which was the chemical substance submitted for P-06-149 and subject to the SNUR at 40 CFR 721.10553) is subject to the requirements of the SNUR at 40 CFR 721.10553.

Comment 3: EPA proposed to modify the SNUR at 40 CFR 721.10515 to include P-10-184, because P-10-184 pertains to the same chemical substance as P-10-60, which is already the subject of 40 CFR 721.10515. A commenter asked EPA to clarify if the SNUR would require the PMN submitter of P-10-184 to conduct the same triggered testing required in the consent order for P-10-60.

Response: The consent order for P-10-60 requires certain fate and physical property testing to be conducted at five different aggregate production volume limits. The consent order for P-10-184 does not require any testing to be conducted by production volume limits. The SNUR, however, requires *notification* before exceeding the manufacture of the five aggregate production volume limits. While the SNUR does not require the submitter of P-10-184, or any other manufacturer, to conduct testing, the SNUR does require that a SNUN be submitted before exceeding the aggregate production volume limit. If EPA receives a SNUN from the submitter of P-10-184, or any other manufacturer, EPA will then determine what testing, if any, would be required. This could be the testing required in the consent order for P-10-60 or other appropriate testing. This is the same procedure EPA uses for SNURs of consent orders with testing requirements at certain production volume or time limits.

IV. Applicability of the 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. As discussed in the **Federal Register** issue of April 24, 1990 (55 FR 17376) (FRL-3658-5), EPA has decided that the intent of TSCA section 5(a)(1)(B) is best served by designating a use as a

significant new use as of the date of publication of the proposed SNUR rather than as of the effective date of the final rule. If uses begun after publication were considered ongoing rather than new, it would be difficult for EPA to establish SNUR notice requirements, because a person could defeat the SNUR by initiating the proposed significant new use before the rule became effective, and then argue that the use was ongoing as of the effective date of the final rule.

Thus, any persons who begin commercial manufacture or processing activities with the chemical substances that are not currently a significant new use under the current rule but which would be regulated as a “significant new use” when this rule is finalized, must cease any such activity as of 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 SNUR 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 the final SNUR for those activities.

V. Test Data and Other Information

EPA recognizes that TSCA section 5 does not require the development of any particular test data before submission of a SNUN. 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, the Agency has the authority to require appropriate testing. In this case, EPA recommends persons, before performing any testing, to consult with the Agency pertaining to protocol selection. 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 Organisation for Economic Co-operation and Development (OECD) test guidelines are available from the OECD Bookshop at <http://www.oecdbookshop.org> or SourceOECD at <http://www.sourceoecd.org>. ASTM International standards are available at <http://www.astm.org/Standard/index.shtml>.

The recommended testing specified in Unit IV. of the proposed rule may not be the only means of addressing the potential risks of the chemical substance. However, SNUNs submitted without any test data may increase the likelihood that EPA will 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.

VI. SNUN Submissions

According to 40 CFR 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 40 CFR 720.50. SNUNs must be on EPA Form No. 7710-25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in §§ 721.25 and 720.40. E-PMN software is available electronically at <http://www.epa.gov/opptintr/newchems>.

VII. Economic Analysis

EPA evaluated the potential costs of SNUN requirements for potential manufacturers and processors of the chemical substances in the rule. The Agency's complete Economic Analysis is available in the docket under docket ID number EPA-HQ-OPPT-2014-0649.

VIII. Statutory and Executive Order Reviews

A. Executive Order 12866

This action will modify SNURs for five 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 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 rule.

This rule is within the scope of the February 18, 2012 certification. Based on the Economic Analysis discussed in Unit VI 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 rule would 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 UMRA sections 202, 203, 204, or 205 (2 U.S.C. 1501 *et seq.*).

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 rule would not have Tribal implications because it is not expected to have substantial direct effects on Indian Tribes. This rule would 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 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).

IX. 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 in 40 CFR Part 721

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

Dated: November 2, 2015.

Maria J. Doa,

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

Therefore, 40 CFR chapter I is 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. Amend § 721.5575 by revising paragraphs (a)(1) and (a)(2)(iii) to read as follows:

§721.5575 Oxirane, 2,2'-(1,6-hexanediylbis (oxymethylene)) bis-

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as oxirane, 2,2'-(1,6-hexanediylbis(oxymethylene))bis- (PMN P-88-2179; PMN P-89-539; and SNUN S-08-3; CAS No. 16096-31-4) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The reporting requirements of this rule do not apply once the chemical substance has been incorporated or encapsulated into plastic.

(2) * * *

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in §721.80(q). A significant new use of the chemical substance is any commercial use other than the commercial use described in S-08-3.

* * * * *

3. Amend § 721.9675 by revising paragraphs (a)(1) and (a)(2)(i), remove and reserve paragraph (a)(2)(ii), and revise paragraph (b)(1).

The revisions read as follows:

§721.9675 Titanate [Ti₆O₁₃ (2-)], dipotassium.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as titanate [Ti₆O₁₃ (2-)], dipotassium (PMN P-90-226; SNUNs P-96-1408, S-08-6, S-09-4, and S-13-49; CAS No. 12056-51-8) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) * * *

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in §721.80 (f) and (l). In addition, a significant new use of the substance is importation of the chemical substance if:

(A) Manufactured by other than the method described in premanufacture notice P-90-226 and significant new use notices P-96-1408, S-08-6, S-09-4, and S-13-49.

(B) Manufactured producing respirable, acicular fibers with an average aspect ratio of greater than 5. The average aspect ratio is defined as the ratio of average length to average diameter.

* * * * *

(b) * * *

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

* * * * *

4. Amend § 721.10515 by revising paragraphs (a)(1) and (a)(2)(i) to read as follows:

§ 721.10515 Partially fluorinated alcohol substituted glycols (generic).

(a) * * *

(1) The chemical substances identified generically as partially fluorinated alcohol substituted glycols (PMNs P-10-58, P-10-59, P-10-60, and P-10-184) are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) * * *

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k) (manufacture of the PMN substances according to the chemical synthesis and composition section of the TSCA section 5(e) consent order, including analysis, reporting, and limitations of maximum impurity levels of certain fluorinated impurities; manufacture and import of P-10-60 and P-10-184 other than when the mean number of moles of the ethoxy group is between 3 and 11 or the average number molecular weight is between 496 and 848 daltons based on the amounts of raw materials charged to the reactor; manufacture and import of P-10-58 and P-10-59 only as intermediates for the manufacture of P-10-60), and (q).

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