

Prepublication Copy Notice:

The Director of the Office of Pollution Prevention and Toxics signed the following Federal Register document on January 24, 2018:

Title: **Modification of Significant New Use of a Certain Chemical Substance**

Action: Proposed Rule

RIN: 2070-AB27

FRL: 9973-02

Docket No.: **EPA-HQ-OPPT-2011-0941**

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For further information about the docket and, if applicable, instructions for commenting, please consult the ADDRESSES section in the front of the Federal Register document.

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[EPA-HQ-OPPT-2011-0941; FRL-9973-02]

RIN 2070-AB27

Modification of Significant New Use of a Certain Chemical Substance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to amend the significant new use rule (SNUR) under section 5(a)(2) of the Toxic Substances Control Act (TSCA) for Oxazolidine, 3,3'-methylenebis[5-methyl-, which was the subject of a premanufacture notice (PMN) and a significant new use notice (SNUN). This action would amend the SNUR to (1) allow certain new uses reported in the SNUN without requiring additional SNUNs and (2) make the lack of certain worker protections a new use. EPA is proposing this amendment based on review of new and existing data as described for the chemical substance. A SNUR requires persons who intend to manufacture (including import) or process this chemical substance 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 initiates EPA's evaluation of the intended use within the applicable review period. Manufacture and processing for the significant new use would be unable to commence until EPA conducted a review of the notice, made an appropriate

determination on the notice, and took such actions as are required with that determination.

DATES: Comments must be received on or before [*insert date 15 days after date of publication in the Federal Register*].

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2011-0941, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *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:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Kenneth Moss, 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: *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, process, or use the chemical substance 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 the chemical substance (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 § 721.20), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

Because TSCA now requires EPA to make determinations for all SNUNs and the Lautenberg Act includes other changes applying to section 5 submissions, the appropriateness of the advance compliance provision in § 721.45(h) is questionable. Therefore, the Agency would suspend the applicability of the provision for these significant new uses, and will pursue a resolution of the issue.

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 preparing and submitting your comments, see the commenting tips at <http://www.epa.gov/dockets/comments.html>.

II. Background

A. What Action is the Agency Taking?

EPA is proposing amendments to the SNUR for the chemical substance in 40 CFR 721.10461. This proposed action would require persons who intend to manufacture or process this chemical substance for an activity that is designated as a significant new use by this amended rule to notify EPA at least 90 days before commencing that activity. The required notification would initiate EPA's evaluation of the intended use within the applicable review period. Manufacture and processing for the significant new use would be unable to commence until EPA conducted a review of the notice, made an appropriate determination on the notice, and took such actions as are required with that determination.

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. of this document. Once EPA determines that a use of a chemical substance is a significant new use and promulgates a SNUR, 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, (but see discussion in Unit II.A. of advance compliance under 40 CFR 721.45(h)), 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 must make a determination under TSCA section 5(a)(3). If EPA determines that the new use, under the conditions of use, is not likely to present unreasonable risk of injury to health or the environment, the submitter of the SNUN may immediately commence manufacture or processing for the new use. Otherwise, EPA must take regulatory action under TSCA section 5(e) or 5(f) to control the activities for which it has received the SNUN.

D. Effective Date of Final Rule

EPA proposes to make the final rule effective 15 days after publication. There is good cause for a 15-day effective period, because the rule largely relieves a restriction, and because the SNUR modification pertains only to new uses, there are no persons who need time to adjust existing operations.

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 authorized EPA to consider any other relevant factors.

In EPA's determination of the appropriate modification of the scope of the existing significant new use for the chemical substance that is the subject of this SNUR, EPA considered relevant information about the toxicity of the chemical substance, 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. Substance Subject to a Proposed Significant New Use Rule Amendment

EPA is proposing to amend the significant new use and recordkeeping requirements for one chemical substance in 40 CFR part 721 Subpart E. In this unit, EPA provides the following information for the chemical substance:

- PMN number and SNUN number.
- Chemical name (generic name, if the specific name is claimed as CBI).
- Chemical Abstracts Service (CAS) number (if assigned for non-confidential chemical identities).
- **Federal Register** publication date and reference for the final SNUR previously issued.
- Basis for the Proposed Amendment.
- 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 rule.

PMN Number P-03-325 and SNUN Number S-17-4

Chemical name: Oxazolidine, 3,3'-methylenebis[5-methyl-

CAS number: 66204-44-2.

Federal Register *publication date and reference:* September 21, 2012 (77 FR 58666) (FRL-9357-2).

Basis for the modified significant new use rule: The PMN stated that the use of the chemical substance is as a metalworking fluid. The original SNUR was issued based on meeting the concern criteria at § 721.170(b)(3)(i), (b)(4)(i), and (b)(ii). EPA identified

concerns for toxicity to aquatic organisms at concentrations exceeding 40 and 100 parts per billion (ppb) in surface waters, salt and fresh, respectively. EPA also identified concerns for systemic toxicity and severe skin and eye irritation. The original SNUR required notification if the chemical substance was used other than as a metalworking fluid and involving environmental releases during manufacture, processing or use that would result in surface water concentrations exceeding a concentration of 40 ppb in surface saltwater or 100 ppb in freshwater.

On April 12, 2017 EPA received a SNUN, S-17-4 for the chemical substance for the significant new use as an anti-corrosive agent in oilfield operations and hydraulic fluids. The 90-day review period for the SNUN expired on October 30, 2017. Based on the activities described in the SNUN, a consent order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a determination that the substance may present an unreasonable risk of injury to human health and the environment.

EPA identified concerns, based on test data on the substance and on new data regarding the expected release of formaldehyde from the substance, for skin and eye irritation, neurotoxicity, mutagenicity, oncogenicity, allergic responses, and developmental toxicity. In addition to the existing water release notification requirements under the SNUR, the Consent Order for S-17-4 requires the SNUN submitter to provide personal protective equipment and respirators to workers to prevent dermal and inhalation exposure, refrain from unloading, processing, or using the substance without using enclosed equipment or systems, label containers and provide worker training, and use the substance only as an anti-corrosive agent in oilfield operations and hydraulic fluids and as a metalworking

fluid. The modified SNUR proposes to designate as a “significant new use” the absence of these protective measures.

Recommended testing: The results of a formaldehyde release assay (ASTM D5197 or ISO 16000-3) would help characterize the health effects of the chemical substance.

CFR citation: 40 CFR 721.10461.

V. Rationale for the Proposed Rule

During review of the PMN and SNUN submitted for the chemical substance that is the subject of this proposed SNUR, EPA identified concerns, as discussed in Unit IV, associated with reasonably foreseen changes from the conditions of use identified in the PMN and the requirements of the consent order for the SNUN. EPA determined that those changes could result in changes in the type or form of exposure to the chemical substance and/or increased exposures to the chemical substance and/or changes in the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of the chemical substance.

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. EPA solicits comments on whether any of the uses proposed as significant new uses are ongoing. EPA designates [*insert date of publication in the Federal Register*] (the date of public release/web posting of this rule) as the cutoff date for determining whether the new use is ongoing. 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 public release

of the proposed SNUR rather than as of the effective date of the final rule. If uses begun after public release 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 substance that are not currently a significant new use under the current rule but which would be regulated as a “significant new use” if this proposed 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.

VII. 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. There is an exception: TSCA section 5(b)(1) requires development of test data where the chemical substance subject to the SNUR is also subject to a rule, order or consent agreement under TSCA section 4 (15 U.S.C. 2603).

In the absence of a rule, order, or consent agreement under TSCA section 4 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. Unit IV. lists recommended testing for the subject proposed listed SNUR. 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. 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>.

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) or 5(f), 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.
- Information on risks posed by the chemical substances compared to risks posed by potential substitutes.

VIII. 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 40 CFR 721.25 and 40 CFR 720.40. E-PMN software is available electronically at <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca>.

IX. Economic Analysis

EPA evaluated the potential costs of SNUN requirements for potential manufacturers and processors of the chemical substances in the proposed rule. The Agency's complete Economic Analysis is available in the docket under docket ID number EPA-HQ-OPPT-2011-0941.

X. Statutory and Executive Order Reviews

A. Executive Order 12866

This proposed action would modify a SNUR for a chemical substance that was the subject of a PMN and a SNUN. 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 proposed 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 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 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 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 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 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).

List of Subjects in 40 CFR Part 721

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

Dated: January 24, 2018.

Jeffery T. Morris,

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. Amend § 721.10461 as follows:

a. Revise paragraph (a)(1).

b. Revise paragraph (a)(2).

c. Revise paragraph (b)(1).

d. Add new paragraph (b)(3).

The additions and revisions read as follows:

§ 721.10461 Oxazolidine, 3,3'-methylenebis[5-methyl-

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as oxazolidine, 3,3'-methylenebis[5-methyl- (PMN P-03-325 and SNUN S-17-4; CAS No. 66204-44-2) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in §721.63(a)(1), (2)(i), (3), (4) (use of the respirator only applies to inhalation exposures to the substance when manufactured in the United States), when determining which persons are reasonably

likely to be exposed as required for §721.63 (a)(1) and (4) engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (a)(5) (respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 1,000), (a)(6)(v), (vi), (b) (concentration set at 0.1 percent), and (c). It is a significant new use for the substance to be unloaded, processed and used other than with fully enclosed equipment.

(ii) *Hazard communication program.* Requirements as specified in §721.72(a), (b) (concentration set at 0.1 percent), (c), (d), (f), (g)(1)(allergic or sensitization response), (ii), (iii), (v), (vi), (ix), (2)(i), (ii), (iii), (v), (iv), (3)(i), (ii), (4) (do not release to water such that concentrations exceed 40 or 100 ppb in saltwater or freshwater, respectively), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System (GHS) and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80. A significant new use is use other than as a metalworking fluid and an anti-corrosive agent in oilfield operations and hydraulic fluids.

(iv) *Release to water:* Requirements as specified in §721.90(a)(4), (b)(4), and (c)(4) (N = 40 (saltwater) and N = 100 (freshwater)).

(b) * * *

(1) *Recordkeeping.* Recordkeeping requirements as specified in §721.125(a) through (i) and (k) are applicable to manufacturers and processors of this substance.

* * *

(3) *Advance compliance.* The provisions of § 721.45(h) do not apply to significant new uses to which this section applies.

* * * * *