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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[EPA-HQ-OPPT-2011-0941; FRL-9995-09]

RIN 2070-AB27

Modification of Significant New Uses for Oxazolidine, 3,3'-Methylenebis[5-methyl-,

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is amending a 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 premanufacture notice (PMN) P-03-325 and significant new use notice (SNUN) S-17-4. The chemical substance is also subject to an Order issued by EPA pursuant to TSCA section 5(e). This action amends the SNUR to the uses allowable without further SNUN reporting requirement to include use as an anti-corrosive agent in oilfield operations and hydraulic fluids and makes the lack of certain worker protections a significant new use. The SNUR requires persons who intend to manufacture (defined by statute to include import) or process this chemical substance 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 initiates EPA's evaluation of the use, under the conditions of use for the chemical substance, within the applicable review period. Persons may not commence manufacture or processing for the significant new use until EPA has conducted a review of the notice, made an appropriate determination on the notice, and has taken such actions as are required with that determination.

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-2011-0941, 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 substance identified as oxazolidine, 3,3′-methylenebis[5-methyl- (PMN P-03-325 and SNUN S-17-4. 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, but are not

limited to: Manufacturers (including importers) or processors of the subject 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 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 proposed or final SNUR 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?

EPA is finalizing amendments to the SNUR for the chemical substance in 40 CFR 721.10461. Previously, in the **Federal Register** of February 8, 2018 (83 FR 5599) (FRL-9973-02), EPA proposed an amendment to the SNUR for the chemical substance in 40 CFR 721.10461. EPA received public comments for that proposed amendment, including that additional information should be added to the public docket and stakeholders should be allowed additional time to comment on the proposed amendment. EPA added additional information to the public docket that it considered in developing the proposed amendment. In the **Federal Register** of July 23, 2018 (83 FR 34819) (FRL-9979-23), EPA published notification that

additional data was available in the docket and provided an additional 30-day comment period for the proposed amendment. EPA received one additional comment to the proposed amendment. EPA will address public comments to the proposed SNUR amendment in this Unit. Because EPA did not receive any comments that led to changes to the proposed SNUR amendment, EPA is issuing the final SNUR amendment as proposed. The record for the SNUR was established in the docket under docket ID number EPA-HQ-OPPT-2011-0941. That docket includes information considered by the Agency in developing the proposed and final rules.

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

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a "significant new use." EPA must make this determination by rule after considering all relevant factors, including those listed in TSCA section 5(a)(2). EPA may respond to SNUNs by, among other things, issuing or modifying a TSCA section 5(e) Order and/or amending the SNUR promulgated under TSCA section 5(a)(2). Amendment of the SNUR will often be necessary to allow persons other than the SNUN submitter to engage in the newly authorized use(s), because even after a person submits a SNUN and the review period expires, other persons still must submit a SNUN before engaging in the significant new use. Procedures and criteria for modifying or revoking SNUR requirements appear at § 721.185.

C. Applicability of General Provisions

General provisions for SNURs appear in 40 CFR part 721, subpart A. These provisions describe persons subject to the final rule, recordkeeping requirements, exemptions to reporting requirements, and applicability of the rule to uses occurring before the effective date of the final rule. Provisions relating to user fees appear at 40 CFR part 700. According to § 721.1(c), persons subject to these SNURs must comply with the same notice requirements and EPA regulatory

procedures as submitters of PMNs under TSCA section 5(a)(1)(A). In particular, these requirements include the information submission requirements of TSCA section 5(b) and 5(d)(1), the exemptions authorized by TSCA section 5(h)(1), (h)(2), (h)(3), and (h)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUN, EPA must either determine that the significant new use, under the conditions of use for the chemical, is not likely to present an unreasonable risk of injury or take such regulatory action as is associated with an alternative determination before the manufacture or processing for the significant new use can commence. If EPA determines that the significant new use, under the conditions of use for the chemical, is not likely to present an unreasonable risk, EPA is required under TSCA section 5(g) to make public, and submit for publication in the **Federal Register**, a statement of EPA's findings.

Response to Comments:

Comment 1: The commenter stated that EPA has failed to consider all reasonably available information and to consider relevant aspects of the problem when proposing the SNUR amendment. The commenter specifically noted that EPA failed to consider the data submitted under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and EPA Office of Pesticide Programs (OPP) reviews of the same chemical substance, including FIFRA restrictions for its pesticide use and its microbiocidal properties.

Response: EPA did consider all reasonably available information when reviewing the SNUN and proposing the SNUR amendment, including the available data from the OPP review of the chemical substance. As noted in the SNUN risk assessment, OPP assessed inhalation risk using an inhalation NOAEC of 0.12 mg/m^3 (0.015 mg/kg-bw) from a study that reported nasal and respiratory effects in workers occupationally exposed to formaldehyde via inhalation. EPA used the same effect level to assess the SNUN. When assessing worker exposure levels from use

of the SNUN substance, EPA made the same assumptions as the OPP review, concerning inhalation exposure from the closed system that is used to produce, load, sample or dispense the SNUN substance from containers. For the SNUN review, EPA quantified the worker exposure to the SNUN substance during use and concluded no unreasonable risk from inhalation exposures to the SNUN substance including the same level of potential exposure to formaldehyde. The SNUN submitter did not notify EPA that they intended to exceed the water release limits in the SNUR of 40 ppb in saltwater and 100 ppb in freshwater. As described in the assessments for the original PMN P-03-325 and SNUN S-17-4, EPA concludes that there are no unreasonable risks if surface water concentrations do not exceed these levels. The SNUR continues to require notification before exceeding these limits. Regarding FIFRA restrictions for pesticide use of the SNUN substance, EPA used all the available data to assess hazards and risks. When determining the requirements for the Order and SNUR under TSCA, EPA based those decisions on exposures and risks for TSCA uses. FIFRA restrictions are based on exposures and risks for FIFRA uses, which includes use as a microbiocide.

Comment 2: A commenter stated that EPA should enhance the SNUR's incorporation of the industrial hygiene hierarchy of controls, under which engineering, work practice, and administrative controls are to be the primary means used to reduce employee exposure to occupational hazards. Because the SNUR would require that the hierarchy of controls "be considered and implemented to prevent exposure, *where feasible*", EPA should clarify that its references to "feasible" have the same meaning as does that term under the Occupational Safety and Health Act. The commenter also asserted that use of the term "where feasible" allows a manufacturer or processor to decide on their own that use of the chemical without engineering or administrative controls would not constitute a significant new use requiring filing of a SNUN, in

which case EPA would not have the opportunity to review such use and that associated claim of infeasibility. The commenter observed that the Supreme Court has defined this ability in the context of worker protection and urges EPA to confirm in its final rule that the requirement to consider and implement the hierarchy of controls where "feasible" applies wherever it is "capable of being done," regardless of cost.

Response: EPA's approach to the hierarchy of controls is the same for this SNUR as all other Orders and SNURs since June 2013 (see 78 FR 38210, June 26, 2013). EPA developed an approach that incorporates OSHA requirements that the hierarchy of controls should be considered before using personal protective equipment for workers. EPA retained worker personal protection equipment requirements to prevent unreasonable risks for those situations where engineering and other controls have yet to be validated or proven effective in reducing exposures sufficiently or would not prevent exposures**.** In this regard, EPA's approach is that the TSCA requirement is the same as the OSHA requirement. Feasibility is a commonly used term that is not the same as discretion. It is a concept, like other concepts in the rule, that requires an objective analysis. That the Supreme Court has defined a specific term provides no legal or policy rationale for EPA including its own definition.

Comment 3: A commenter stated that personal protective clothing, testing and use requirements in the SNUR are not as protective as those in the Consent Order. The commenter specifically noted that the Order requires permeation testing to be conducted according to the American Society for Testing and Materials (ASTM) F739 "Standard Test Method for Permeation of Liquids and Gases through Protective Clothing Materials under Conditions of Continuous Contact" and that this language should be included in the SNUR.

Response: The comment references language in the Order requiring this ASTM method.

The commenter also notes that, as an alternative, the Order and SNUR allow evaluation of manufacturers' specifications to demonstrate imperviousness. The Order unfortunately contains incorrect language that the ASTM method is the only test method a company can conduct to demonstrate imperviousness of dermal protective equipment. In most Orders issued by the Agency, there is no requirement for a specific method and this ASTM method is cited as one example of a test acceptable to EPA. EPA will consult with the SNUN submitter and determine if the Order should be amended.

Comment 4: A commenter stated that respirators need to be required for processing and other downstream uses as well as in manufacturing settings.

Response: The Order and the SNUR require respiratory protection during manufacture but require fully enclosed equipment to be used during unloading, processing, and use. Because of this enclosed equipment requirement, there is only limited inhalation exposure during unloading, processing and use that does not present an unreasonable risk (see the response to Comment 1). Therefore, respiratory protection is not required during unloading, processing, and use.

Comment 5: The commenter noted numerous areas where it appears that EPA did not properly document the basis for its worker exposure estimates including the number of sites, number of workers, and dermal and inhalation exposure to workers. Because of this the commenter stated the public has no ability to know whether these numbers reflect real-world worker exposures and cannot judge whether the proposed amendments to the SNUR are sufficient. The commenter added that EPA appears to have been working with entirely insufficient information from the SNUN submitter bearing on worker exposure to the SNUN substance and it appears the Agency has relied on models, uncited or insufficiently cited sources,

or in some cases what seem to be complete guesses. The commenter assumed that the Organization for Economic Co-operation and Development (OECD) Emission Scenario Document on Chemicals Used in Oil Well Production was used to make numerous exposure estimates. The commenter noted that the OECD document referenced the 2002 U.S. Census for arriving at an estimate of 8 workers per site. The commenter stated this means that this estimate value is 16 years old and given the explosion in domestic oil production and hydraulic fracturing activities since 2002, there is no reason to believe that value reflects current occupational exposures in this sector. EPA needs to account for this factor and adjust its estimates accordingly.

Response: The SNUN contained available information from the SNUN submitter regarding how the chemical is used. EPA properly documented the basis for its worker exposure estimates in the EPA Engineering Report for the use of the SNUN substance. The engineering report gives the basis for each exposure estimate made in the report, including when no information is available from the submitter. In many cases, including this one, this means EPA estimates reasonable worst-case exposures based on models and professional judgment. When using these tools EPA can only state that in most cases they are reasonable worst-case estimates. The commenter is correct that one of the generic scenarios used for the SNUN was the OECD Emission Scenario Document on Chemicals Used in Oil Well Production. The OECD document contains the 2002 data cited by the commenter. The OECD document was finalized in 2012 using the best available information. EPA also used the PMN submission P-03-325 as the best source of identifying the number of use sites for the SNUN. EPA's general approach to estimating exposure with limited data is available at *https://www.epa.gov/tsca-screening-tools/using-predictive-methods-assess-exposure-and-fate-under-tsca#fate*. EPA uses all

available information to make reasonable worst-case estimates. When newer information is available, EPA would adjust its estimates accordingly. Growth in an industry is not the only factor to affect worst-case estimates of number of sites, number of workers per site, and dermal and inhalation exposure to workers.

Comment 6: A commenter stated that EPA must codify its exposure assumptions as notification triggers in the amended SNUR. The commenter noted that given that EPA has chosen to rely on a number of exposure assumptions in its review of the SNUN that serve as the basis for its proposed amendments to the SNUR and presuming these assumptions can be adequately justified and documented, the Agency must incorporate these assumptions as notification triggers in the amended SNUR itself in order to make those assumptions enforceable.

Response: Codifying EPA's exposure assumptions as notification requirements for SNURs would not add meaningful protective measures beyond those significant new uses now included in the SNUR, which were proposed after a consideration of all relevant factors, including those listed in Unit IV. The significant new uses identified in the SNUR (based on requirements in the Order) already consider potential exposures and address those activities that could lead to changes in exposures and therefore potential risks.

Comment 7: One commenter noted that EPA should exercise its authority to require submission of records required to be kept under the amended SNUR. Given the critical role that the exposure assumptions EPA has made in determining the level of risk that will be allowed under the SNUR without triggering notification, it is essential that EPA determine what the actual conditions are. It should use its existing authorities to require submission of records from companies using the SNUN substance for the uses to be allowed under the amended SNUR, and from the company under the Order.

Response: EPA already requires records to be retained by the company demonstrating compliance with the SNUR, identifying how much of the chemical substance it manufactures or processes, and how much and where it distributes the chemical substance. These records are available for EPA to review when a company is inspected. Requiring companies manufacturing and processing the substance to submit records to EPA would be an additional administrative burden for both EPA and the companies, without any increase in enforcement capability or compliance with the rule. Therefore, EPA is not requiring submission of records required to be retained under the rule.

Comment 8: A commenter stated that EPA needs to explain and justify why a NIOSH-certified respirator with an assigned protection factor (APF) of at least a 1,000 is sufficient to ensure protection against exposure via inhalation.

Response: Based on data supplied by the S-17-4 SNUN submitter and reviewed by EPA regarding formaldehyde exposure to workers when manufacturing the S-17-4 SNUN substance outside the United States, a respirator with an APF of 1000 would limit exposure with an adequate margin of safety based on the NOAEC of 0.12 mg/m^3 level.

Comment 9: A commenter stated that key health and safety studies are missing from the docket, preventing the public from understanding and independently assessing the consequences of the Agency's proposed amendments to the SNUR. The missing information includes: 1) an acute inhalation study conducted according to OECD guideline 436, and 2) monitoring studies of formaldehyde release in specific industrial settings.

Response: EPA added these additional health and safety information studies to the docket. EPA also added additional information to the docket as described in the response to Comment 13.

Comment 10: One commenter asserted that EPA has impermissibly redacted portions of the health and safety studies provided in violation of TSCA section 14. Without this information, it is difficult to adequately or sufficiently characterize potential risks to workers. The commenter also stated that for all of the documents in the docket, EPA should immediately review the redactions and disclose the information that does not qualify for confidentiality under TSCA section 14. Health and safety information never qualifies for confidentiality unless it meets one of the two narrow exceptions of TSCA section 14(b)(2). With respect to all other information, information only qualifies for nondisclosure if it meets all of the substantive and procedural requirements of TSCA section 14.

Response: The SNUN submitter redacted any confidential business information for submissions contained in the SNUN. All health and safety studies and information relevant to EPA's risk assessment have been disclosed. For example, all toxicity study results which includes the level of toxicity used to assess the SNUN substance is available in the docket. For the monitoring studies of formaldehyde during manufacture, the average ambient concentration of formaldehyde in air of 0.068 mg/m^3 and the maximum concentration of 0.094 mg/m^3 is available in the docket. The information in the public docket identifies the inhalation NOAEC of 0.12 mg/m^3 (0.015 mg/kg-bw) used for risk assessment and the potential inhalation exposures during manufacture (0.068 mg/m^3 of formaldehyde) and use (0.052 mg/m^3 of the PMN substance). It is this information that is the basis for EPA's conclusion. Thus, the information in the public docket allows stakeholders to understand and comment on the basis for EPA's risk assessment.

Comment 11: A commenter stated that the precautionary statements EPA has required under the Consent Order, and that would be incorporated in the amended SNUR, are inadequate

and should be rectified by the Agency. Specifically, EPA should add "severe skin and eye irritant" and "cancer" as EPA has identified these as known health hazards of the SNUN substance.

Response: EPA expects there is compliance with federal and state laws, such as worker protection standards, unless case-specific facts indicate otherwise, and therefore existing OSHA regulations for worker protection and hazard communication will result in use of appropriate PPE consistent with the applicable SDSs in a manner adequate to protect workers. In this case, warnings for severe skin and eye burns are already contained in the submitter's SDS for the SNUN substance. Additionally, given the severely irritating and corrosive nature of the chemical, EPA expects limited exposures. Because of the limited exposure, EPA determined that the hazard warnings for "severe skin and eye irritant" and "cancer" were not necessary to include in the Consent Order. For the same reasons, EPA is not incorporating the warnings in this final SNUR.

Comment 12: A commenter stated that EPA has not taken into account other sources of formaldehyde exposures to workers using the SNUN substance. EPA's exclusion from consideration of these other sources of formaldehyde means that the Agency has likely significantly underestimated the risks associated with SNUN substance. EPA needs to explain whether and if so, how, it took these additional potential exposures into account in establishing conditions to limit exposure included in the proposed amended SNUR.

Response: As described in the response to Comment 1, EPA estimated inhalation exposures to the SNUN substance during use, which would result in potential exposure to formaldehyde during use. The Order and SNUR contain provisions to prevent risks from these potential exposures. Based on the use limitation in the SNUR as a metal working fluid and the

submission of a SNUN for use as an anti-corrosive agent in oilfield operations and hydraulic fluids, EPA did not identify and does not expect any other sources of exposures to the SNUN substance during its use. The other sources of formaldehyde cited by the commenter do not identify the specific sources of the formaldehyde and also identify several other hazardous chemicals contained in the air at oil and gas production sites. Assessment and findings of risks from a new chemical substance under TSCA do not include sources of chemical exposure unrelated to the new chemical substance.

Comment 13: A commenter stated that EPA has failed to complete the docket with critical health and safety information. EPA has provided an inadequate amount of time for the public to comment based on a full record.

Response: In response to comments received on the initial proposed SNUR modification in the **Federal Register** of February 8, 2018 (83 FR 5598) (FRL-9973-02), EPA posted additional risk assessment documents and health and safety studies to the docket that were used in the risk assessment of the SNUN substance. EPA included the FIFRA documents that were used in the risk assessment of the SNUN substance but did not repost the entire FIFRA docket as it is publicly available (see Docket ID EPA-HQ-OPP-2009-0997). In the **Federal Register of** July 23, 2018 (83 FR 34819) (FRL-9979-23), EPA published notification that additional data was available in the docket and that there would be an additional 30-day comment period for the proposed amendment.

Comment 14: One commenter supplied a public SDS for a product containing the chemical substance as evidence that the chemical substance was used for a significant new use before submission of a SNUN. The commenter noted that EPA should have been able to find and use this information in its review.

Response: Because this is evidence that someone may have engaged in a significant new use before submission of a SNUN, EPA has referred this information to its Office of Enforcement and Compliance Assurance for investigation. The information contained in that document, however, does not contribute pertinent information that would affect EPA's assessment or findings for the Order and SNUR. The SDS only contains information on basic chemical properties, hazard warnings, and handling procedures. This information was already available to EPA from the PMN and SNUN submissions. The SDS does not contain the detailed toxicity and exposure data submitted with the PMN and SNUN submissions that EPA used in the SNUN risk assessment.

III. Rationale and Objectives for the Final Rule

A. Rationale

During review of the SNUN submitted for this chemical substance, EPA concluded that regulation was warranted under TSCA section 5(e)(1)(A)(ii)(I), pending the development of information sufficient to make reasoned evaluations of the human health effects of the chemical substance. Based on these findings, a TSCA section 5(e) Order requiring the use of appropriate exposure controls was negotiated with the SNUN submitters. EPA is amending the SNUR provisions for this chemical substance to be consistent with the provisions of the TSCA section 5(e) Orders. See the docket under docket ID number EPA–HQ–OPPT–2011–0491 for the corresponding Orders. For additional discussion of the rationale for the SNUR on this chemical, see Units II. and V. of the proposed rule.

B. Objectives

EPA is issuing this final SNUR for a chemical substance that has undergone premanufacture and significant new use notice review because the Agency wants to achieve the

following objectives with regard to the significant new uses designated in this final rule:

• EPA will receive notice of any person's intent to manufacture, import, or process the chemical substance for the described significant new use before that activity begins.

• EPA will have an opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing, importing, or processing the chemical substance for the described significant new use.

• EPA will be able to regulate prospective manufacturers, importers, or processors of the chemical substance before the described significant new use of the chemical substance occurs, provided that regulation is warranted pursuant to TSCA sections 5(e), 5(f), 6, or 7.

• EPA will ensure that all manufacturers, importers, and processors of the same chemical substance that is subject to a TSCA section 5(e) Order are subject to similar requirements.

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.

To determine what would constitute a 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 TSCA section 5(a)(2) factors listed in this unit.

V. Applicability of 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 solicited comments in the proposed rule on whether any of the uses proposed as significant new uses were ongoing. EPA designated February 8, 2018 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. EPA received no comments that any of the uses were ongoing. 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 the proposed rule is finalized, must cease any such activity as of the effective date of the rule if and when finalized. Before resuming their activities, these persons would have to first comply with all applicable SNUR notice requirements and receive an affirmative determination on the notice from EPA.

VI. Test Data and Other Information

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

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

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

In the absence of a TSCA section 4 test rule or a TSCA section 5(b)(4) listing covering the chemical substance, persons are required only to submit test data in their possession or control and to describe any other data known to or reasonably ascertainable by them (see § 720.50). However, upon review of PMNs and SNUNs, the Agency has the authority to require appropriate testing.

In the TSCA section 5(e) Order for the chemical substance regulated under this rule, EPA has established restrictions in view of the lack of data on the potential health and environmental risks that may be posed by the significant new uses or increased exposure to the chemical substance. These restrictions will not be removed until EPA determines that the unrestricted use is not likely to present an unreasonable risk of injury.

Unit IV. of the proposed rule lists information identified in the section 5(e) Order underlying the proposed SNUR modification. 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.

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 substance.

VII. 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 § 720.50. SNUNs must be submitted on EPA Form No. 7710-25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in §§ 721.25 and 720.40. E-PMN software is available electronically at https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/how-submit-e-pmn.

IX. Economic Analysis

EPA has evaluated the potential costs of establishing SNUN requirements for potential manufacturers, importers, and processors of the chemical substances during the development of the proposed rule. EPA's complete Economic Analysis is available in the docket under docket ID number EPA–HQ–OPPT–2011–0941.

X. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *http://www2.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This final rule modifies a SNUR for a chemical substance that was subject of a PMN, SNUNs, and a TSCA section 5(e) Order. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011).

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

This action is not subject to Executive Order 13771 (82 FR 9339, February 3, 2017),

because this action is not a significant regulatory action under Executive Order 12866.

C. Paperwork Reduction Act (PRA)

This action does not impose any new information collection burden under the PRA, 44 U.S.C. 3501 *et seq*. Burden is defined in 5 CFR 1320.3(b). The information collection activities associated with new chemical SNURs have already been approved under OMB control number 2070-0012 (EPA ICR No. 0574). 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.

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 the 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, as applicable.

D. Regulatory Flexibility Act (RFA)

Pursuant to RFA section 605(b), 5 U.S.C. 601 *et seq*., the Agency hereby certifies that promulgation of this SNUR does not have a significant adverse economic impact on a substantial number of small entities. The requirement to submit a SNUN applies to any person (including small or large entities) who intends to engage in any activity described in the final rule as a ''significant new use.'' Because these uses are ''new,'' based on all information currently available to EPA, it appears that no small or large entities presently engage in such activities. A

SNUR requires that any person who intends to engage in such activity in the future must first notify EPA by submitting a SNUN. Although some small entities may decide to pursue a significant new use in the future, EPA cannot presently determine how many, if any, there may be. However, EPA's experience to date is that, in response to the promulgation of SNURs covering over 1,000 chemicals, the Agency receives only a small number of notices per year. For example, the number of SNUNs received was seven in Federal fiscal year (FY) 2013, 13 in FY2014, six in FY2015, 10 in FY2016, and 14 in FY2017, and only a fraction of these were from small businesses. In addition, the Agency currently offers relief to qualifying small businesses by reducing the SNUN submission fee from $16,000 to $2,800. This lower fee reduces the total reporting and recordkeeping of cost of submitting a SNUN to about $10,116 for qualifying small firms. Therefore, the potential economic impacts of complying with this SNUR are not expected to be significant or adversely impact a substantial number of small entities. In a SNUR that published in the **Federal Register** of June 2, 1997 (62 FR 29684) (FRL-5597-1), the Agency presented its general determination that final SNURs are not expected to have a significant economic impact on a substantial number of small entities, which was provided to the Chief Counsel for Advocacy of the Small Business Administration.

E. 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, the requirements of UMRA sections 202, 203, 204, and 205, 2 U.S.C. 1531-1538, do not apply to this action.

F. Executive Order 13132: Federalism

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 (64 FR 43255, August 10, 1999).

G. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

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 (65 FR 67249, November 9, 2000), do not apply to this final rule.

H. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because this action does not address environmental health or safety risks, and EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that EPA has reason to believe may disproportionately affect children, per the definition of "covered regulatory action" in section 2-202 of the Executive Order.

I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not a "significant energy action" as defined in Executive Order 13211 (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply, distribution, or use.

J. National Technology Transfer and Advancement Act (NTTAA)

This action does not involve any technical standards and is therefore not subject to considerations under section 12(d) of NTTAA, 15 U.S.C. 272 note.

K. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

This action will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations as specified in Executive Order 12898 (59 FR 7629, February 16, 1994). This action does not affect the level of protection provided to human health or the environment.

L. Congressional Review Act (CRA)

This action is subject to the CRA, 5 U.S.C. 801–808, and EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. 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: July 8, 2019.

Tala Henry,

Deputy Director, 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 § 721.10461 by revising paragraphs (a) and (b)(1) to 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), (a)(2)(i), (a)(3), (a)(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) and (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), (g)(1)(ii),

(iii), (v), (vi), and (ix), (g)(2)(i), (ii), (iii), (v), and (iv), (g)(3)(i) and (ii), (g)(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 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.

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