

Prepublication Copy Notice:

The Director of the Chemical Control Division in the Office of Pollution Prevention and Toxics signed the following *Federal Register* document on August 15, 2016:

Title: **Significant New Use Rule on Certain Chemical Substances**

ACTION: Proposed Rule

RIN: 2070-AB27

FRL: 9951-06

Docket No.: **EPA-HQ-OPPT-2016-0491**

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Once the official version of the document publishes in the *Federal Register*, the prepublication version of the document posted on the agency's internet will be replaced with a link to the document that appears in the *Federal Register* publication. At that time, you will also be able to access the on-line docket for this *Federal Register* document at <http://www.regulations.gov>.

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-2016-0491; FRL-9951-06]

RIN 2070-AB27

Significant New Use Rule on Certain Chemical Substances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing significant new use rules (SNURs) under the Toxic Substances Control Act (TSCA) for two chemical substances which were the subject of premanufacture notices (PMNs). This action would require persons who intend to manufacture (defined by statute to include import) or process any of the chemical substances for an activity that is designated as a significant new use by this proposed rule to notify EPA at least 90 days before commencing that activity. The required notification initiates EPA's evaluation of the intended use within the applicable review period. Manufacture and processing for the significant new use is unable to commence until EPA has conducted a review of the notice, made an appropriate determination on the notice, and taken such actions as are required in association with that determination.

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

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2016-0491, 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 (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-9232; email address: moss.kenneth@epa.gov.

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

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you manufacture, process, or use the chemical substances contained in this proposed 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 (including importers) or processors of one or more subject chemical substances (NAICS codes 325 and 324110), *e.g.*, chemical manufacturing and petroleum refineries.

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Chemical importers are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements promulgated at 19 CFR 12.118 through 12.127 and 19 CFR 127.28. Chemical importers must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA. Importers of chemicals subject to these SNURs must certify their compliance with the SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export a chemical substance that is the subject of this proposed rule on or after [*insert date 30 days after date of publication in the **Federal Register***] are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)) (see § 721.20), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

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

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific

information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket.

Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. Tips for preparing your comments. When 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 these SNURs under TSCA section 5(a)(2) for two chemical substances which were the subject of PMNs P-14-321 and P-14-323. These SNURs would require persons who intend to manufacture or process any of these chemical substances for an activity that is designated as a significant new use to notify EPA at least 90 days before commencing that activity.

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

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a “significant new use.” EPA must make this determination by rule after considering all relevant factors, including the four bulleted TSCA section 5(a)(2) factors listed in Unit III. Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1)(B) requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture or process the chemical substance for that use (15 U.S.C. 2604(a)(1)(B)(i)). TSCA furthermore prohibits such manufacturing or processing from commencing until EPA has conducted a review of the

notice, made an appropriate determination on the notice, and taken such actions as are required in association with that determination (15 U.S.C. 2604(a)(1)(B)(ii)). As described in Unit V., the general SNUR provisions are found at 40 CFR 721, subpart A.

C. Applicability of General Provisions

General provisions for SNURs appear in 40 CFR part 721, subpart A. These provisions describe persons subject to the rule, recordkeeping requirements, exemptions to reporting requirements, and applicability of the rule to uses occurring before the effective date of the 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 SNUN requirements and EPA regulatory procedures as submitters of PMNs under TSCA section 5(a)(1)(A). In particular, these requirements include the information submission requirements of TSCA section 5(b) and 5(d)(1), the exemptions authorized by TSCA section 5(h)(1), (h)(2), (h)(3), and (h)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUN, EPA must either determine that the significant new use 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 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..

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.

To determine what would constitute a significant new use for the chemical substances that are the subject of these SNURs, EPA considered relevant information about the toxicity of the chemical substances, likely human exposures and environmental releases associated with possible uses, and the four bulleted TSCA section 5(a)(2) factors listed in this unit.

IV. Substances Subject to This Proposed Rule

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

- PMN number.
- Chemical name (generic name, if the specific name is claimed as CBI).
- Chemical Abstracts Service (CAS) Registry number (assigned for non-confidential chemical identities).
- Tests recommended by EPA to provide sufficient information to evaluate the chemical substance (see Unit VII. for more information).

- CFR citation assigned in the regulatory text section of this proposed rule.

The regulatory text section of this proposed rule specifies the activities designated as significant new uses. Certain new uses, including production volume limits (*i.e.*, limits on manufacture volume) and other uses designated in this proposed rule, may be claimed as CBI.

PMN Number P-14-321 and P-14-323

Chemical name: Hydrochlorofluoropropane and Hydrochlorofluoropropene (generic).

CAS number: Claimed confidential.

Effective date of TSCA section 5(e) consent order: August 12, 2016.

Basis for TSCA section 5(e) consent order: The PMN states that the generic (non-confidential) use of the substances will be as site-limited, isolated and recycled intermediates. Based on test data on the PMN substances, EPA identified concerns for acute toxicity including lethality to animals. The Order was issued under TSCA section 5(a)(3)(B)(ii)(I) based on a finding that the substance may present an unreasonable risk of injury to human health. To protect against these risks, the consent order requires:

1. Submission of certain toxicity testing on the PMN substances prior to exceeding the time trigger specified in the consent order of the PMN substances.
2. Use of impervious gloves and protective clothing where dermal exposure is reasonably likely for workers.
3. Use of respirators with an APF of 1000, in conjunction with a minimum set of engineering controls to prevent inhalation exposure for workers, or, as an alternative to using respirators, maintain workplace airborne concentrations of the PMN substances at or below a specified New Chemical Exposure Limit (NCEL) of 130 parts per million (ppm) for P-14-

321 and 33 parts per billion (ppb) for P-14-323 as an 8-hour time-weighted average, where inhalation exposure is reasonably likely for workers.

4. Use of engineering controls to limit worker exposure and air release of the PMN substances to the environment.

5. Label containers of the PMN substances and provide Safety Data Sheets and worker training.

6. Manufacture, process and use the PMN substances only in an enclosed process.

7. Use of the PMN substances only as chemical intermediates.

8. No predictable or purposeful release of the PMN substances from manufacturing, processing or use into the waters of the United States that result in surface water concentrations exceeding 8 ppb.

9. Prohibition on the distribution of the PMN substances.

The SNUR designates as a “significant new use” the absence of these protective measures.

Recommended testing: EPA has determined that the results of a subacute inhalation toxicity: 28-day study (OECD Test Guideline 412) in three species: mouse, rat, and rabbit (6 studies total) and a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (OECD Test Guideline 422) would help characterize the human health effects of the PMN substances. The submitter has agreed to complete this testing by the production limits identified in the consent order.

V. Rationale and Objectives of the Proposed Rule

A. Rationale

During review of the PMNs submitted for the chemical substances that are subject to

these SNURs, EPA concluded that regulation was warranted under TSCA section 5(e), pending the development of information sufficient to make reasoned evaluations of the health or environmental effects of the chemical substances. The basis for such findings is outlined in Unit IV. Based on these findings, TSCA section 5(e) consent orders requiring the use of appropriate exposure controls were negotiated with the PMN submitters. The SNUR provisions for these chemical substances are consistent with the provisions of the TSCA section 5(e) consent orders. These SNURs are promulgated pursuant to § 721.160 (see Unit VI.).

B. Objectives

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

- EPA would receive notice of any person's intent to manufacture or process a listed chemical substance for the described significant new use before that activity begins.
- EPA would have an opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing or processing a listed chemical substance for the described significant new use.
- EPA would be able to either determine that the prospective manufacture or processing is not likely to present an unreasonable risk, or to take necessary regulatory action associated with any other determination, before the described significant new use of the chemical substance occurs.

Issuance of a SNUR for a chemical substance does not signify that the chemical substance is listed on the TSCA Chemical Substance Inventory (TSCA Inventory). Guidance

on how to determine if a chemical substance is on the TSCA Inventory is available on the Internet at <https://www.epa.gov/tsca-inventory>.

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

To establish a significant new use, EPA must determine that the use is not ongoing. The chemical substances subject to this proposed rule have undergone premanufacture review. In cases where EPA has not received a notice of commencement (NOC) and the chemical substance has not been added to the TSCA Inventory, no person may commence such activities without first submitting a PMN. Therefore, for chemical substances for which an NOC has not been submitted EPA concludes that the designated significant new uses are not ongoing.

When chemical substances identified in this proposed rule are added to the TSCA Inventory, EPA recognizes that, before the rule is effective, other persons might engage in a use that has been identified as a significant new use. The identities of the two chemical substances subject to this proposed rule have been claimed as confidential and EPA has received no post-PMN *bona fide* submissions (per §§ 720.25 and 721.11). Based on this, the Agency believes that it is highly unlikely that any of the significant new uses described in the regulatory text of this proposed rule are ongoing.

Therefore, EPA designates August 15, 2016 (the date of public release / web posting of this proposal) as the cutoff date for determining whether the new use is ongoing. This designation varies slightly from EPA's past practice of designating the date of **Federal Register** publication as the date for making this determination. The objective of EPA's approach has been to ensure that a person could not defeat a SNUR by initiating a significant

new use before the effective date of the final rule. In developing this proposal, EPA has recognized that, given EPA's practice of now posting proposed rules on its website a week or more in advance of **Federal Register** publication, this objective could be thwarted even before that publication. Thus, EPA has slightly modified its approach in this rulemaking and plans to follow this modified approach in future significant new use rulemakings.

Persons who begin commercial manufacture or processing of the chemical substances for a significant new use identified as of August 15, 2016 would have to cease any such activity upon the effective date of the final rule. To resume their activities, these persons would have to first comply with all applicable SNUR notification requirements and wait until all TSCA prerequisites for the commencement of manufacture or processing have been satisfied. If such a person met the conditions of advance compliance under § 721.45(h), the person would be considered exempt from the requirements of the SNUR. Consult the **Federal Register** document of April 24, 1990 (55 FR 17376) for a more detailed discussion of the cutoff date for ongoing uses.

VII. Test Data and Other Information

EPA recognizes that TSCA section 5 does not require developing new information (e.g., generating test data) before submission of a SNUN. There is an exception:

1. Development of test data is required where the chemical substance subject to the SNUR is also subject to a test rule, order, or consent agreement 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 test rule, order, or consent agreement under TSCA section 4

covering the chemical substance, persons are required only to submit information in their possession or control and to describe any other information 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. 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 Guidelines for Pesticides and Toxic Substances.”

The recommended tests specified in Unit IV. may not be the only means of addressing the potential risks of the chemical substance. However, submitting a SNUN that does not itself include information sufficient to permit a reasoned evaluation may increase the likelihood that EPA will either respond with a determination that the information available to the Agency is insufficient to permit a reasoned evaluation of the health and environmental effects of the significant new use or, alternatively, that in the absence of sufficient information, the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance may present an unreasonable risk of injury.

SNUN submitters should be aware that EPA will be better able to evaluate SNUNs and define the terms of any potentially necessary controls if the submitter provides detailed information on:

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

potential substitutes.

VIII. SNUN Submissions

EPA recommends that submitters consult with the Agency prior to submitting a SNUN to discuss what information may be useful in evaluating a significant new use. Discussions with the Agency prior to submission can afford ample time to conduct any tests that might be helpful in evaluating risks posed by the substance. According to § 721.1(c), persons submitting a SNUN must comply with the same notification requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in 40 CFR 720.50. SNUNs must be submitted on EPA Form No. 7710-25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in 40 CFR 720.40 and 721.25. 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. Scientific Standards, Evidence, and Available Information

EPA has used scientific information, technical procedures, measures, methods, protocols, methodologies, and models consistent with the risk assessment documents included in the public docket.

The clarity and completeness of the data, assumptions, methods, quality assurance, and analyses employed in EPA's decision are documented, as applicable and to the extent necessary for purposes of this proposed significant new use rule, in Unit II and in the documents noted above. EPA recognizes, based on the available information, that there is variability and uncertainty in whether any particular significant new use would actually present an unreasonable risk. For precisely this reason, it is appropriate to secure a future

notice and review process for these uses, at such time as they are known more definitely. The extent to which the various information, procedures, measures, methods, protocols, methodologies or models used in EPA's decision have been subject to independent verification or peer review is adequate to justify their use, collectively, in the record for a significant new use rule.

X. Economic Analysis

EPA has evaluated the potential costs of establishing SNUN requirements for potential manufacturers and processors of the chemical substances subject to this proposed rule, during the development of the direct final rule. EPA's complete economic analysis is available in the docket under docket ID number EPA-HQ-OPPT-2016-0491.

XI. Statutory and Executive Order Reviews

A. Executive Order 12866

This proposed rule would establish SNURs for two chemical substances that were the subject of PMNs. 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.

The information collection requirements related to this proposed rule have already been approved by OMB pursuant to PRA under OMB control number 2070-0012 (EPA ICR No. 574). This proposed rule would not impose any burden requiring additional OMB approval. If an entity were to submit a SNUN to the Agency, the annual burden is estimated to average between 30 and 170 hours per response. This burden estimate includes the time needed to review instructions, search existing data sources, gather and maintain the data needed, and complete, review, and submit the required SNUN.

Send any comments about the accuracy of the burden estimate, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques, to the Director, Collection Strategies Division, Office of Environmental Information (2822T), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001. Please remember to include the OMB control number in any correspondence, but do not submit any completed forms to this address.

C. Regulatory Flexibility Act (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 SNUR 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 proposed 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 would be impacted by this proposed rule. As such, EPA has determined that this proposed rule would not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the requirements of UMRA sections 202, 203, 204, or 205 (2 U.S.C. 1501 *et seq.*).

E. Executive Order 13132

This proposed rule would not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999).

F. Executive Order 13175

This proposed rule would not have Tribal implications because it is not expected to

have substantial direct effects on Indian Tribes. This proposed rule would not significantly nor uniquely affect the communities of Indian Tribal governments, nor would it involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000), do not apply to this proposed rule.

G. Executive Order 13045

This proposed rule 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 proposed rule does not address environmental health or safety risks disproportionately affecting children.

H. Executive Order 13211

This proposed rule is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001), because this proposed rule is not expected to affect energy supply, distribution, or use and because this proposed rule is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

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

J. Executive Order 12898

This proposed rule 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: August 15, 2016.

Maria J. Doa,

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

Therefore, it is proposed that 40 CFR chapter I be amended as follows:

PART 721--[AMENDED]

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

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

2. Add § 721.10926 to subpart E to read as follows:

§ 721.10926 Hydrochlorofluoropropane and Hydrochlorofluoropropene (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substances identified generically as hydrochlorofluoropropane and hydrochlorofluoropropene (generic) (PMNs P-14-321 and P-14-323) are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(1), (a)(2)(i), (a)(3), (a)(4), (a)(6)(v), (a)(6)(vi), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(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. The following National Institute for Occupational Safety and Health (NIOSH)-certified respirators with an Assigned Protection Factor (APF) of at least 1000 meet the requirements of § 721.63(a)(4):

(A) Any NIOSH-certified powered air purifying full facepiece respirator equipped with appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridges.

(B) Any NIOSH-certified powered air-purifying respirator equipped with a hood or helmet and appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridges

with evidence demonstrating protection level of 1,000 or greater. (Note: OSHA has assigned APFs of 1000 for certain types of hoods and helmets with powered air purifying respirators (PAPRs) or supplied air respirators (SARs) where the manufacturer can demonstrate adequate air flows to maintain positive pressure inside the hood or helmet in normal working conditions. However, the employer must have evidence provided by the respirator manufacturer that the testing of these respirators demonstrates performance at a level of protection of 1,000 or greater to receive an APF of 1,000. This level of performance can best be demonstrated by performing a Workplace Protection Factor (WPF) or Simulated Workplace Protection Factor (SWPF) study or equivalent testing. Without testing data that demonstrates a level of protection of 1,000 or greater, all PAPRs and SARs with helmets/hoods are to be treated as loose-fitting facepiece respirators, and receive an APF of 25.)

(C) Any NIOSH-certified continuous flow supplied-air respirator equipped with a full facepiece.

(D) Any NIOSH-certified continuous flow supplied-air respirator equipped with a hood or helmet with evidence demonstrating protection level of 1,000 or greater. (See Note under (II), above)

(E) Any NIOSH-certified pressure-demand or other positive pressure mode supplied-air respirator equipped with a full facepiece.

(1) As an alternative to the respiratory requirements listed here, a manufacturer or processor may choose to follow the New Chemical Exposure Limit (NCEL) provisions listed in the TSCA section 5(e) consent order for this substance. The NCEL is 130 parts per million for P-14-321 and 33 parts per billion for P-14-323 as an 8-hour time weighted average

(TWA) verified by actual monitoring data.

(ii) *Hazard communication program.* Requirements as specified in § 721.72 (a), (b), (c), (d), (f), (g)(1)(i), (g)(1)(fatal if inhaled), (g)(2)(ii), (g)(2)(iv), (g)(2)(v), and (g)(2)(do not release to water).

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80 (a) and (g). It is a significant new use to manufacture, process, or use the PMN substances without the engineering controls described in the consent order to prevent worker and environmental exposures. It is a significant new use to manufacture the PMN substances for more than one year.

(iii) *Release to water.* Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) (N=8).

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

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d), (e), (f), (g), (h), (i), and (k) are applicable to manufacturers and processors of this substance.

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