



## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 721

[EPA-HQ-OPPT-2008-0918; FRL-9387-7]

RIN 2070-AB27

### Proposed Modification of Significant New Uses of 1-Propene, 2,3,3,3-tetrafluoro-

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** Under section 5(a)(2) of the Toxic Substances Control Act (TSCA), EPA is proposing to amend the significant new use rule (SNUR) for the chemical substance identified as 1-Propene, 2,3,3,3-tetrafluoro-, which was the subject of premanufacture notice (PMN) P-07-601. This action would amend the SNUR to allow the manufacture and processing for certain uses without requiring a significant new use notice (SNUN). EPA is proposing this amendment based on review of newly submitted exposure and toxicity data.

**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-2008-0918, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments.

- *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:* OPPT Document Control Office (DCO), EPA East Bldg., Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. ATTN: Docket ID Number EPA-HQ-OPPT-2008-0918. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564-8930. Such deliveries are only accepted during the DCO's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

*Instructions:* Direct your comments to docket ID number EPA-HQ-OPPT-2008-918. EPA's policy is that all comments received will be included in the docket without change and may be made available online at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through [regulations.gov](http://www.regulations.gov) or email. The [regulations.gov](http://www.regulations.gov) website is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through [regulations.gov](http://www.regulations.gov), your email address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

*Docket:* All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically at <http://www.regulations.gov>, or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

**FOR FURTHER INFORMATION CONTACT:** *For technical information contact:* Jim Alwood, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-8974; email address: [alwood.jim@epa.gov](mailto:alwood.jim@epa.gov).

*For general information contact:* The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: [TSCA-Hotline@epa.gov](mailto: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, import, process, or use the chemical substance identified as 1-Propene, 2,3,3,3-tetrafluoro- (PMN P-07-601). Potentially affected entities may include, but are not limited to:

- Manufacturers, importers, or processors of the subject chemical substance (NAICS codes 325 and 324110), e.g., chemical manufacturers and petroleum refineries.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in § 721.5. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

*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 submitting comments, remember to:

- i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).
- ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- iv. Describe any assumptions and provide any technical information and/or data that you used.
- v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- vi. Provide specific examples to illustrate your concerns and suggest alternatives.
- vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- viii. Make sure to submit your comments by the comment period deadline identified.

## II. Background

### *A. What Action is the Agency Taking?*

In the **Federal Register** of October 27, 2010 (75 FR 65987) (FRL-8846-8), EPA published a final SNUR (codified at § 721.10182) for the chemical substance identified as 1-Propene, 2,3,3,3-tetrafluoro-, (PMN P-07-601; CAS No. 754-12-1; which is also identified by the trade name HFO-1234yf), in accordance with the procedures at § 721.170. A SNUR requires persons who intend to manufacture, import, or process the chemical substance for an activity designated as a significant new use to notify EPA at least 90 days before commencing that activity.

EPA is proposing to amend the scope of the SNUR as detailed in this unit. In addition, EPA is proposing to clarify the language in the regulatory text to more clearly communicate that the manufacture and processing for use as a refrigerant in motor vehicle air conditioning systems in new passenger cars and vehicles as reported in the original PMN is not subject to the notification requirement. The docket includes information considered by the Agency in developing the final rule and the new information considered when proposing the modification to this rule.

#### **PMN Number P-07-601**

*Chemical name:* 1-Propene, 2,3,3,3-tetrafluoro-

*CAS number:* 754-12-1

**Federal Register** *publication date and reference:* October 27, 2010 (75 FR 65987).

*Basis for modification of the SNUR:* In the final SNUR, EPA explained that it sought additional information to review use by consumers attempting to recharge air conditioning systems in vehicles originally charged with the refrigerant. Specifically, EPA sought an acute rabbit inhalation toxicity study to better characterize health effects

from a single exposure and sought additional information on techniques or equipment to minimize exposure to consumers and data that quantifies exposures for durations shorter than the 30-minute time-weighted average (TWA) presented in the exposure study conducted by the PMN submitter. In response, the PMN submitter conducted an acute inhalation toxicity study with rabbits on the PMN substance. The submitted results demonstrated no toxicity in the one-hour exposure of rabbits to 0, 50,000, and 100,000 parts per million (ppm) of the PMN substance. The human equivalent concentration of the 100,000 ppm exposure in rabbits is 190,000 ppm and was utilized for a risk assessment. In addition, potential after-market manufacturers and the PMN submitter also provided additional information on the previously submitted exposure study that was conducted quantifying the exposures for durations shorter than 30 minutes and data on exposures from use of certain specified fittings. The test conditions demonstrated a highest 30-minute TWA exposure of 1,789 ppm. Based on the newly submitted data, EPA calculated the ratio of the level of exposure in rabbits that did not cause any effects with the highest measured TWA exposure. The calculated ratio is 106, which EPA considers protective of human health. The detailed risk assessment is contained in the public docket. Based on this new assessment, EPA proposes to find that use of the PMN substance by consumers to recharge air conditioning systems in vehicles originally charged with the refrigerant by the motor vehicle original equipment manufacturer (OEM) no longer meets the concern criteria at § 721.170(b). Based on this proposed finding, EPA is proposing to modify the SNUR by eliminating the requirement to submit a notice prior to the manufacture and processing for the specified consumer use of the PMN substance.

In addition, EPA is proposing to clarify the language in the regulatory text to more clearly communicate that manufacture and processing for use as a refrigerant in motor vehicle air conditioning systems in new passenger cars and vehicles as reported in the original PMN is not a significant new use. The current regulatory text identifies the significant new use by reference to 40 CFR 721.80(j), which refers to any “use other than” a use described in the premanufacture notice and then uses a parenthetical to more specifically identify the significant new use, beginning with “use other than.” However, using the language “use other than” when referring to a regulatory provision which begins with “use other than” can be confusing. As a result, EPA is proposing to clarify the regulatory text by simply identifying the significant new use as use other than as a refrigerant in motor vehicle air conditioning systems in new passenger cars and vehicles (i.e., as defined in 40 CFR 82.32 (c) and (d)). The docket established for this proposed amendment to the SNUR is available under docket ID number EPA–HQ–OPPT–2008–0918.

*CFR citation:* 40 CFR 721.10182.

*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 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, TSCA section 5(a)(1)(B) and 40 CFR part 721 requires persons to submit a significant new use notice (SNUN) to EPA at least 90

days before they manufacture (including import) or process the chemical substance for that use. Persons who must report are described in § 721.5.

EPA may respond to SNUNs by, among other things, issuing or modifying a TSCA section 5(e) consent 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.

### **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 to 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 authorizes EPA to consider any other relevant factors.

To determine that consumer use in the recharge of motor vehicle air conditioning systems originally charged with the PMN substance by the motor vehicle OEM is not a significant new use of the chemical substance identified as 1-Propene, 2,3,3,3-tetrafluoro- (PMN P-07-601), EPA considered relevant information about the toxicity of the chemical substance, likely human exposures and environmental releases associated with this chemical use, taking into consideration the four bulleted TSCA section 5(a)(2) factors listed in this unit.

#### **IV. Rationale for the Proposed Rule**

During review of PMN P-07-601, the chemical substance identified as 1-Propene, 2,3,3,3-tetrafluoro-, EPA determined that one or more of the criteria of concern established at § 721.170 were met and regulation under section 5(a)(2) of TSCA was warranted. The basis for such findings is outlined in Unit II. of this document and in the **Federal Register** document of June 26, 1990 (55 FR 26102). Based on these findings, a SNUR was promulgated pursuant to § 721.170.

After the review of new test data and information subsequent to issuance of the SNUR (see Unit II.), and consideration of the factors included in TSCA section 5(a)(2) (see Unit III.), EPA proposes to find that the concern criteria in § 721.170(b), are no longer met for the consumer use in the recharge of motor vehicle air conditioning systems originally charged with the PMN substance by the motor vehicle OEM.

#### **V. Economic Analysis**

EPA evaluated the potential costs of establishing SNUN requirements for potential manufacturers, importers, and processors of the chemical substances during the development of the direct final rule. The Agency's complete Economic Analysis is

available in the docket under docket ID number EPA–HQ–OPPT–2008-0918. This proposal will not add to the costs identified in that analysis as it would, if finalized, relieve an existing notification requirement for certain manufacturers and processors.

## **VI. Statutory and Executive Order Reviews**

### *A. Executive Order 12866*

This proposed rule would modify a SNUR for a chemical substance that is the subject of a PMN. 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*

According to the Paperwork Reduction Act (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 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, if applicable. 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 proposed rule would, if finalized, relieve an existing notification requirement for certain manufacturers and processors. 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 would not impose any

burden requiring additional OMB approval. If an entity were to submit a SNUN to the Agency under the existing SNUR, 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*

On February 18, 2012, EPA certified pursuant to section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), that promulgation of a SNUR does not have a significant economic impact on a substantial number of small entities where the following are true:

1. A significant number of SNUNs would not be submitted by small entities in response to the SNUR.
2. The SNUN submitted by any small entity would not cost significantly more than \$8,300.

A copy of that certification is available in the docket for this rule.

This rule is within the scope of the February 18, 2012 certification. Based on the Economic Analysis discussed in Unit V. 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 amendment.

- Submission of the SNUN would not cost any small entity significantly more than \$8,300. Therefore, the promulgation of the SNUR amendment would not have a significant economic impact on a substantial number of small entities.

#### *D. Unfunded Mandates Reform Act*

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 reason 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 sections 202, 203, 204, or 205 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

#### *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 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 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 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 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*

In addition, since this action does not involve any technical standards, section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, 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 FR7629, February 16, 1994).

**List of Subjects in 40 CFR Part 721**

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

Dated: May 22, 2013.

Maria J. Doa,

*Director, Chemical Control Division, 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. In § 721.10182, revise paragraphs (a)(1) and (a)(2)(i) to read as follows:

**§ 721.10182 1-Propene, 2,3,3,3-tetrafluoro-**

(a) \* \* \* (1) The chemical substance identified as 1-propene, 2,3,3,3-tetrafluoro- (PMN P- 07-601; CAS No. 754-12-1) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) \* \* \*

(i) *Industrial, commercial, and consumer activities.* A significant new use is use other than as a refrigerant in motor vehicle air conditioning systems in new passenger cars and vehicles (i.e., as defined in 40 CFR 82.32 (c) and (d)); § 721.80(m) (commercial use other than in passenger cars and vehicles in which the charging of motor vehicle air conditioning systems with the PMN substance was done by the motor vehicle original equipment manufacturer (OEM)); § 721.80(o) (use in consumer products other than products used to recharge the motor vehicle air conditioning systems in passenger cars and vehicles in which the charging of motor vehicle air conditioning systems with the PMN substance was done by the motor vehicle OEM).

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