

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

#### Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023-01 and Commandant Instruction M16475.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321-4370f), and have concluded this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded, under figure 2-1, paragraph (34)(g), of the Instruction. This rule involves establishing, disestablishing, or changing Regulated Navigation Areas and security or safety zones. An environmental analysis checklist and a categorical exclusion determination are available in the docket where indicated under **ADDRESSES**.

#### List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, and Waterways.

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

#### PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

**Authority:** 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701; 50 U.S.C. 191, 195; 33 CFR 1.05-1(g), 6.04-1, 6.04-6, and 160.5; Pub. L. 107-295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add temporary § 165.T11-367 to read as follows:

#### § 165.T11-367 Safety zone; Epic Roasthouse Private Party, San Francisco, CA.

(a) *Location.* This temporary safety zone is established for the waters of San Francisco Bay 1,000 yards off Epic Roasthouse Restaurant, San Francisco, CA. The fireworks launch site will be located in position 37° 46'35.30" N, 122° 23'13.33" W (NAD 83).

From 10:45 a.m. until 8:45 p.m. on November 5, 2010, the temporary safety zone applies to the navigable waters around the fireworks site within a radius of 100 feet. From 8:45 p.m. until 9:30 p.m. on November 5, 2010, the area to which the temporary safety zone applies will increase in size to

encompass the navigable waters around the fireworks site within a radius of 1,000 feet.

(b) *Definitions.* As used in this section, "designated representative" means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer on a Coast Guard vessel or a Federal, State, or local officer designated by or assisting the Captain of the Port San Francisco (COTP) in the enforcement of the safety zone.

#### (c) Regulations.

(1) Under the general regulations in § 165.23 of this title, entry into, transiting, or anchoring within this safety zone is prohibited unless authorized by the COTP or the COTP's designated representative.

(2) The safety zone is closed to all vessel traffic, except as may be permitted by the COTP or a designated representative.

(3) Vessel operators desiring to enter or operate within the safety zone must contact the COTP or a designated representative to obtain permission to do so. Vessel operators given permission to enter or operate in the safety zone must comply with all directions given to them by the COTP or the designated representative. Persons and vessels may request permission to enter the safety zone on VHF-16 or through the 24-hour Command Center at telephone 415-399-3547.

(d) *Effective period.* This section is effective from 10:45 a.m. through 9:30 p.m. on November 5, 2010.

Dated: October 15, 2010.

**C.L. Stowe,**

*Captain, U.S. Coast Guard, Captain of the Port San Francisco.*

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#### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Parts 9 and 721

[EPA-HQ-OPPT-2008-0918; FRL-8846-8]

RIN 2070-AB27

#### 1-Propene, 2,3,3,3-tetrafluoro-; Significant New Use Rule

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

**ACTION:** Final rule.

**SUMMARY:** EPA is issuing a significant new use rule (SNUR) under section 5(a)(2) of the Toxic Substances Control Act (TSCA) for the chemical substance identified as 1-Propene, 2,3,3,3-tetrafluoro- (CAS No. 754-12-1) which

was the subject of premanufacture notice (PMN) P-07-601. This action requires persons who intend to manufacture, import, or process the chemical substance for a use that is designated as a significant new use by this final rule to notify EPA at least 90 days before commencing that activity. EPA believes that this action is necessary because the chemical substance may be hazardous to human health. The required notification would provide EPA with the opportunity to evaluate the intended use and, if necessary, to prohibit or limit that activity before it occurs.

**DATES:** This final rule is effective November 26, 2010.

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPPT-2008-0918. 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., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket 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: 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; e-mail address: [moss.kenneth@epa.gov](mailto: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; e-mail address: [TSCA-Hotline@epa.gov](mailto:TSCA-Hotline@epa.gov).

#### SUPPLEMENTARY INFORMATION:

### I. Does this action apply to me?

You may be potentially affected by this action if you manufacture, import, process, or use the chemical substance contained in this final rule: 1-Propene, 2,3,3,3-tetrafluoro- (PMN P-07-601; CAS No. 754-12-1). 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 manufacturing 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**.

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; see also 19 CFR 127.28. Chemical importers must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA. For importers of the chemical substance subject to this SNUR those requirements include the SNUR. 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 this final rule on or after November 26, 2010 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.

### II. Background

#### A. What action is the agency taking?

EPA is finalizing a SNUR under TSCA section 5(a)(2) for the chemical substance identified as 1-Propene, 2,3,3,3-tetrafluoro- (PMN P-07-601; CAS No. 754-12-1; aka HFO-1234yf). This action requires persons who intend to manufacture, import, or process the chemical substance for an activity that is designated as a significant new use by this final rule to notify EPA at least 90 days before commencing that activity.

Previously, in the **Federal Register** of February 1, 2010 (75 FR 4983) (FRL-8438-4), EPA issued a direct final SNUR for the chemical substance. However, EPA received notices of intent to submit adverse comments on this SNUR. Therefore, as required by § 721.170(d)(4)(i), in the **Federal Register** of April 2, 2010 (75 FR 16670) (FRL-8816-9), EPA withdrew the direct final SNUR on this chemical substance and subsequently proposed a SNUR using notice and comment procedures in the **Federal Register** of April 2, 2010 (75 FR 16706) (FRL-8818-2). More information on the chemical substance subject to this final rule can be found in the direct final or proposed SNUR. The record for the direct final and proposed SNUR on this chemical substance was established in the docket under docket ID number EPA-HQ-OPPT-2008-0918. That docket includes information considered by the Agency in developing the direct final rule and this final rule, including comments on the proposed rule. The chemical substance addressed under this final SNUR is also being reviewed under the Clean Air Act (CAA) to determine whether it may be listed as an acceptable substitute for CFC-12 in motor vehicle air conditioning systems. See "Protection of Stratospheric Ozone: New Substitute in the Motor Vehicle Air Conditioning Sector under the Significant New Alternatives Policy (SNAP) Program" (74 FR 53445, October 19, 2009) (FRL-8969-7).

EPA received six comments on the proposed SNUR and two comments on the original direct final SNUR. A full discussion of EPA's response to these comments is included in Unit V. of this document. After consideration of these comments, EPA is issuing a modified final rule on the chemical substance that:

1. Clarifies the significant new use provisions by organizing them under the following paragraphs of § 721.80:
  - Section 721.80(j) (use other than as a refrigerant in motor vehicle air conditioning systems in new passenger cars and vehicles).

- Section 721.80(m) (commercial use other than in new 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)).

- Section 721.80(o) (distribution in commerce of products intended for use by a consumer for the purpose of servicing, maintenance, and disposal involving the PMN substance).

2. Removes the following significant new use provisions:

- All servicing, maintenance, and disposal involving the PMN substance will be done only by CAA section 609 certified technicians using CAA section 609 certified refrigerant handling equipment.

- Uses in which the chemical substance will be sold or distributed in other than 20-pound (net weight) containers or larger (this significant new use is now encompassed by § 721.80(o)).

Furthermore, EPA has provided in the docket to this rule additional human health information to supplement EPA's findings under § 721.170(d)(3)(i) and EPA's findings in the proposed rule. See Unit IV. of the proposed rule in the **Federal Register** of April 2, 2010 (75 FR 16706) for a discussion of EPA's findings.

#### 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). 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, import, or process the chemical substance for that use. Persons who must report are described in § 721.5.

#### C. Applicability of General Provisions

General provisions for SNURs appear in 40 CFR part 721, subpart A. These provisions describe persons subject to the rule, recordkeeping requirements, exemptions to reporting requirements, 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 this SNUR 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 may take regulatory action under TSCA section 5(e), 5(f), 6, or 7 to control the activities for which it has received the SNUN. If EPA does not take action, EPA is required under TSCA section 5(g) to explain in the **Federal Register** its reasons for not taking action.

Chemical importers are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements promulgated in Customs and Border Patrol regulations at 19 CFR 12.118 through 12.127; see also 19 CFR 127.28. Chemical importers must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA. For importers of the chemical substance subject to this final SNUR those requirements include the SNUR. 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 identified in this final SNUR 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.

### III. Rationale and Objectives of the Rule

#### A. Rationale

During the review of the chemical substance PMN P-07-601—as discussed in the proposed rule—based on test data on the PMN substance, EPA identified health concerns for developmental toxicity and lethality to workers and consumers if they were exposed to a significant amount of the PMN substance via inhalation. EPA determined that one or more of the criteria of concern established at § 721.170 were met. EPA did not find that the use scenarios described in the PMN triggered the determination set forth under section 5(e) of TSCA. EPA did, however, determine that certain changes from the use scenario described in the PMN could result in increased exposures, thereby constituting a “significant new use.” EPA has determined that activities proposed as a “significant new use” satisfy the two requirements stipulated in § 721.170(c)(2), i.e., these significant new use activities: “(i) Are different from those described in the premanufacture notice for the substance, including any amendments,

deletions, and additions of activities to the premanufacture notice, and (ii) may be accompanied by changes in exposure or release levels that are significant in relation to the health or environmental concerns identified” for the PMN substance.

#### B. Objectives

EPA is issuing this final SNUR for a chemical substance that has undergone premanufacture 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 a listed 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 a listed chemical substance for the described significant new use.
- EPA will be able to regulate prospective manufacturers, importers, or processors of a listed chemical substance before the described significant new use of that chemical substance occurs, provided that regulation is warranted pursuant to TSCA sections 5(e), 5(f), 6, or 7.

Issuance of a SNUR for a chemical substance does not signify that the chemical substance is listed on the TSCA Inventory. Guidance on how to determine if a chemical substance is on the TSCA Inventory is available on the Internet at <http://www.epa.gov/opptintr/newchems/pubs/invntory.htm>.

#### 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.

In addition to these factors enumerated in TSCA section 5(a)(2), the statute authorizes EPA to consider any other relevant factors.

To determine what would constitute a significant new use for HFO-1234yf, EPA considered relevant information—in the docket and discussed further in Unit V. of this document—about the toxicity of the chemical substance, likely human exposures and environmental releases associated with possible uses, taking into consideration the four bulleted TSCA section 5(a)(2) factors listed in this unit, and the regulations at § 721.170 for issuing a SNUR after receipt of a PMN.

### V. Response to Comments on Proposed SNUR on 1-Propene, 2,3,3,3-tetrafluoro-

EPA received comments from a number of submitters on the proposed rule for the chemical substance identified as 1-Propene, 2,3,3,3-tetrafluoro- (PMN P-07-601; CAS No. 754-12-1; aka HFO-1234yf). These comments, many of which covered similar issues, have been grouped under general headings. Many of the comments stated that EPA’s risk assessment for the PMN substance overstates both the potential hazards of the chemical substance and the potential exposures for “do-it-yourself” (DIY) consumer use, and uses a health effects endpoint from a toxicity study that is inappropriate given the duration of exposure that could result from DIY consumer use. These commenters evaluated EPA’s risk assessment and conducted their own quantitative risk assessments for single, short-term exposure scenarios, using where possible the same information and approach used in EPA’s Risk Assessment for the PMN Substance (Ref. 4). A discussion of the comments received and the Agency’s responses follows.

#### A. Risk Assessment: Toxicity

Commenters stated that adverse health impacts from use of HFO-1234yf under the conditions specified would not be expected for car occupants, servicing personnel, or DIY consumers. The comments relate to the choice of the point of departure (POD) for the Agency’s risk assessment of single-exposure (DIY consumers) use scenarios and to the Agency’s use of a Margin of Exposure (MOE), as opposed to Hazard Index (HI), approach to evaluate the chemical substance.

*Comment:* Why didn’t the Agency use the 200,000 parts per million (ppm) effect level from a 4-hour rat study on HFO-1234yf to select the POD for the risk assessment?

*Response:* This acute 4-hour exposure study in rats showed some lung effects at approximately 200,000 ppm, the lowest exposure level in the study.

Thus, EPA considers 200,000 ppm to be a LOAEL (low observed adverse effect level). If a LOAEL were used in the risk assessment instead of a NOAEL (no observed adverse effect level), EPA would use an uncertainty factor to estimate a NOAEL, which would result in a lower POD than what was used. Instead, EPA used the NOAEL for a subacute 14-day study on the chemical substance as the endpoint, because the LOAEL from the acute 4-hour study is an effect endpoint which is inappropriate for developing safe exposure levels for humans. Some of the animals in the 4-hour acute study had grey, discolored lungs at both exposure levels in the study, and EPA considered this an adverse effect. Therefore, EPA could not determine a NOAEL from the acute 4-hour study. It is Agency policy to use the NOAEL where available, because of greater assurance of a "safe" level. Where only the LOAEL is available, that will be used along with any necessary additional uncertainty factors. For example, if EPA had started with the LOAEL of 200,000 ppm, it would have required an additional MOE of 10 to estimate a NOAEL from a LOAEL, for a total MOE of 300 instead of 30. This would have resulted in a more conservative risk assessment than using the NOAEL from the 14-day subacute study.

*Comment:* Why didn't the Agency use the cardiac sensitization study in dogs as the POD?

*Response:* Cardiac sensitization studies are for very short durations—on the order of 10 minutes—and they only address cardiac sensitization. The PMN chemical does not induce cardiac sensitization. EPA selected the acute POD from a multiple-exposure, two-week rat inhalation study on the PMN substance, reasoning that if no effects were seen in the duration of the study, then no effects would be seen from a single exposure.

*Comment:* Why did EPA use the MOE rather than HI approach for risk assessment of HFO-1234yf?

*Response:* Where available, it is EPA policy to use a NOAEL for the POD. This is the highest exposure level that did not cause an adverse health effect in a study. In this case, EPA selected the POD from an animal (rat 2-week inhalation) study. Because animals may respond to different exposure levels than humans, there is some uncertainty when extrapolating from animals to humans. For this reason, an Uncertainty Factor (UF) is applied when extrapolating from animals to humans—typically a factor of 10 is used but, in this case, since there was a reasonable estimate of the pharmacokinetic

component of the uncertainty, this UF was reduced to 3. An additional UF is applied to account for variation in the human population response to a chemical exposure—in this case, a UF of 10 was used. The two UFs give a resultant UF of 30 to yield an acceptable level of health risk. EPA's policy for review of new chemicals under TSCA is to divide the POD by the exposure level to obtain the MOE. For this PMN substance, the "acceptable level of health risk" would be an MOE of 30 or greater.

One commenter proposed dividing the estimated exposure to the PMN chemical by the POD levels to obtain a HI. If the exposure is less than the POD, the HI is <1 and this would be considered an "acceptable level of health risk." This HI approach, however, does not factor in uncertainties about extrapolating from animal to human responses, nor does it address variability within the human population with regard to thresholds of response to chemical exposures. EPA has consistently applied the MOE approach to PMN evaluations (and for other risk assessments) in order to account for these uncertainties. This is the rationale for EPA continuing to use the MOE approach for this chemical substance.

Perhaps most important to EPA's position on this final SNUR is that EPA has uncertainties about using available single-exposure studies on HFO-1234yf to determine the MOEs for different exposure scenarios. As a result of concerns with these studies, EPA calculated single exposure MOEs from the NOAEL in the 2-week inhalation toxicity study of the PMN chemical in rats. There are some additional uncertainties in the single exposure (acute) assessments because of the observation of lethality in rabbit dams after multiple exposures in a developmental study to the PMN substance. For these reasons, as mentioned in Unit IV. of the proposed SNUR, EPA recommends a rabbit acute inhalation toxicity study to address the question of whether pregnant rabbits would die from a single exposure. Rabbits should be exposed for one hour, using the Organisation for Economic Co-operation and Development (OECD) 403 test guideline. Pregnant rabbits should be exposed on gestational day 12 (this is within the time-frame that pregnant rabbits started dieing in the developmental study).

#### B. Risk Assessment: Exposure

*Comment:* Commenter stated that EPA's assessment, using the Gradient Report (Ref. 6), overstates the potential exposures from consumer DIY use of

HFO-1234yf to refill MVAC systems. The commenter asserted that EPA's methodology to estimate the exposure levels associated with the DIY use greatly exaggerates the exposure that could be experienced in actual use conditions. The specific exposure parameters that the commenters questioned were assumptions regarding:

- Garage volume.
- Time the user spent under the hood during recharging operations.
- The size of the space where any leaking gas would disperse.
- The air exchange rate in a service area that should be well-ventilated when the engine is running.
- Use of the refrigerant in a closed garage with no ventilation.
- The amount of refrigerant used during recharge operations.

During the comment period for the proposed SNUR, the PMN submitter conducted a simulated vehicle service leak testing, using HFC-134a as a surrogate, indicating that exposures from use of a 12-oz can during consumer DIY use are below the Agency's level of concern for HFO-1234yf (Ref. 7).

*Response:* After reviewing the submitted consumer DIY use exposure study, EPA responded with a list of clarifying questions (Ref. 5), to which the PMN submitter subsequently responded (Ref. 8). Although the PMN submitter's responses were helpful, EPA still has concerns about potential exposures to consumers during DIY use and the inherent toxicity of HFO-1234yf. Therefore, the Agency has decided to retain requirements in the final rule for notification to the Agency prior to distribution in commerce of products intended for use by DIY consumers, while waiting for data from the acute inhalation toxicity study in rabbits described in Unit V.A. With regards to exposure, the peak concentration values from the submitted study are as high as 3% by volume, equivalent to 30,000 ppm. These peaks appeared to occur in the first one or two minutes of each emission. Accordingly, EPA would need exposure data presented and averaged out over shorter Time Weighted Averages (TWAs) than the 30 minutes currently in the study, because it would appear that a number of these early exposure peaks could result in TWA values that would result in MOEs less than the acceptable Agency level of 30 (see Unit V.A.). This is important because the data on HFO-1234yf are insufficient to differentiate whether the toxicity is due to blood level alone from an acute exposure, is due to accumulated exposure over time (area under the curve), or is due to some

combination of both. Since blood equilibrium levels are reached within minutes, a high level of exposure in a short duration could result in blood levels exceeding a threshold if the mode of action is due to blood levels. Additional TWAs of 3, 5, and 10 minutes are recommended.

The Agency's chief concern during its analysis of the submitted exposure study, and generally when estimating potential consumer exposure to HFO-1234yf, is that even if there is a low likelihood of the types of exposure scenarios assessed in this study occurring, there are estimates of 11 million DIY consumer recharging events per year in the United States (Ref. 1) (this is not necessarily 11 million people as some individuals recharge more than once). The Clodic survey commissioned by the California Air Resources Board (Ref. 3) indicated that 10% of DIY consumers released 100 g or more of refrigerant during servicing, including 2% releasing more than 500 g, and another 15% of DIY consumers released 50 to 100 g during servicing, due to faulty recharging equipment and poor technique. Both these percentages and the overall number of DIY consumer recharging events indicate that a substantial number of events could have significant leaks. The Agency recognizes that commenters have suggested, as an alternative to the container size limitation contained in the proposed SNUR, that the reductions in emissions and exposures can be accomplished by restricting sales and use of all refrigerants to qualified technicians, or by using DIY consumer containers and charging equipment that minimize the potential for releases (e.g., having a resealable/leak control device on all containers and using charging connection equipment that has a quick coupler with a moving rod to open the low pressure refrigerant valve on the vehicle). For example, CARB's "Certification Procedures for Small Containers of Automotive Refrigerant," effective March 10, 2010 (Ref. 2), mandates a self-sealing valve with leakage rate in storage of  $\leq 3.0$  g/yr, container labeling requirements, and education materials requirements. However, commenters provided insufficient information on these approaches for EPA to assess whether, for HFO-1234yf, they would reduce exposures during DIY consumer use and thus eliminate the potential toxicity risk. Consequently, the Agency has removed the specific container size limitation proposed as a significant new use, and replaced it with a description that directly addresses the issue of

potential exposure to DIY consumers by clarifying that significant new use, found at 40 CFR 721.80(o) ("use in a consumer product"), as "distribution in commerce of products intended for use by a consumer for the purpose of servicing, maintenance, and disposal involving the PMN substance."

Information on such techniques or equipment to minimize potential exposures to DIY consumers should accompany any SNUN submitted in response to this final SNUR that requests use of HFO-1234yf in DIY consumer products. Other information submitted with such a SNUN should include data that quantifies exposures for durations shorter than the 30-minute TWA presented in the exposure study submitted by the PMN submitter, in particular, TWAs for 3 minutes, 5 minutes, and 10 minutes, in addition to 30 minutes.

### C. CAA Section 609 Certification

*Comment:* One commenter stated that the training and equipment requirements currently in CAA section 609 relative to other refrigerants would not be necessary for environmentally safe usage of HFO-1234yf during initial charging in an automobile assembly plant. The commenter stated that a CAA section 609 certification is not currently required for automobile assembly plants workers or equipment; manufacturers perform their own training programs; and Occupational Safety and Health Administration (OSHA) requirements for handling flammable substances already fully address the flammability-related HFO-1234yf worker safety issues in automobile assembly facilities.

*Response:* EPA recognizes that the requirements for certification contained in CAA section 609 are reserved only for the MVAC servicing sector, i.e., "service for consideration," which includes paid technicians or mechanics being paid either with cash, credit, goods, or services when they perform a service in a vehicle involving a refrigerant in an air conditioning system (40 CFR 82.32 (g)).

The following scenarios are not covered under CAA section 609:

- Initial charge of an MVAC by OEMs.
- The action of disposing or disassembling an MVAC in a disposal facility in accordance with 40 CFR 82.152 and 40 CFR 82.156 (f). The action of extracting or recovering refrigerant from an MVAC at a disposal facility does not require CAA section 608 or 609 certification (40 CFR 82.34 (d)); however, such processing does require the use of an approved refrigerant handling equipment meeting

the requirements of 40 CFR 82.36 (i.e., CAA section 609 equipment).

- Servicing on gratitude (service done for free). For example, a DIY individual if not being paid with cash, credits, goods, or service would not be covered under CAA section 609 requirements.

Furthermore, intentionally venting any refrigerant is prohibited under section 608 of the CAA and under 40 CFR 82.154 (a)(1).

EPA expects, in accordance with 40 CFR 82.34, that all servicing and maintenance of the MVAC involving the PMN substance will be done only by CAA section 609-certified technicians using CAA section 609-certified refrigerant handling equipment, and that extraction or recovery of the PMN substance from MVAC bound for disposal and located at a motor vehicle disposal facility will be done with CAA section 609-approved refrigerant recovery equipment. In 2011, EPA expects to propose regulations under CAA section 609 that specifically address requirements for servicing using HFO-1234yf (e.g., certification of refrigerant handling equipment). EPA also expects that during initial charging by OEM, general industry requirements under OSHA 29 CFR 1910 for personal protective equipment, training and other measures for working with chemicals that may pose risks to their health and safety, are already applicable and any further restrictions under this final SNUR would be redundant and unnecessary.

Therefore, EPA agrees with the commenter and has modified the relevant language in the regulatory text of the proposed rule to remove specific references to the CAA section 609 certification.

### D. Use of HFO-1234yf as a Delivery Agent

*Comment:* One commenter expressed concern that HFC-134a refrigerant has been used to deliver chemicals into MVAC systems for the advertised purpose of increasing system-cooling performance and/or injecting oil, trace dyes, sealants to stop refrigerant system leakage, etc. The commenter requests that EPA not allow use of HFO-1234yf as transfer/delivery agent for such purposes. Another commenter requested that HFO-1234yf not be allowed for this use due to health concerns.

*Response:* Prior to marketing HFO-1234yf as a delivery agent, a person would need to submit notices to EPA under both the CAA SNAP program and under TSCA. If a person plans to market HFO-1234yf as a "delivery agent" in cans, rather than as a refrigerant for MVAC, then they must submit a SNAP

information notice to EPA for use of HFO-1234yf as an aerosol propellant. Under the SNAP program, the person would be allowed to market HFO-1234yf as an aerosol propellant 90 days after submission of a complete notice. Similarly, under the SNUR, that person would also need to submit a SNUN 90 days before engaging in a use other than as a refrigerant in MVAC, such as a delivery agent. In many cases, EPA responds to a SNUN by amending the SNUR to allow companies other than the SNUN submitter (such as the submitter's processor customers) to engage in the newly approved use(s).

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

As discussed in the **Federal Register** of April 24, 1990 (55 FR 17376), EPA has decided that the intent of TSCA section 5(a)(1)(B) is best served by designating a use as a significant new use as of the date of publication of the proposed SNUR rather than as of the effective date of the final rule. If uses begun after publication were considered ongoing, rather than new, it would be difficult for EPA to establish SNUR notice requirements because a person could defeat the SNUR by initiating the proposed significant new use before the rule became effective, and then argue that the use was ongoing as of the effective date of the final rule.

Any person who began commercial manufacture, import, or processing of 1-Propene, 2,3,3,3-tetrafluoro- (PMN P-07-601; CAS No. 754-12-1; aka HFO-1234yf) for any of the significant new uses designated in the proposed SNUR after the date of publication of the proposed SNUR must stop that activity before the effective date of this final rule. Persons who ceased those activities will have to meet all SNUR notice requirements and wait until the end of the notification review period, including all extensions, before engaging in any activities designated as significant new uses. If, however, persons who began manufacture, import, or processing of the chemical substance between the date of publication of the proposed SNUR and the effective date of this final SNUR meet the conditions of advance compliance as codified at § 721.45(h), those persons would be considered to have met the final SNUR requirements for those activities.

#### VII. Test Data and Other Information

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

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 section 4 test rule or a section 5(b)(4) listing covering the chemical substance, persons are required only to submit test data in their possession or control and to describe any other data known to or reasonably ascertainable by them (see 40 CFR 720.50). However, upon review of PMNs and SNUNs, the Agency has the authority to require appropriate testing. In this case, EPA recommends a rabbit acute inhalation toxicity study to address human health concerns. EPA strongly encourages persons, before performing any testing, to consult with the Agency pertaining to protocol selection. The OECD test guidelines are available from the OECD Bookshop at <http://www.oecdbookshop.org> or SourceOECD at <http://www.sourceoecd.org>.

The recommended tests may not be the only means of addressing the potential risks of the chemical substance. However, SNUNs submitted without any test data may increase the likelihood that EPA will respond by taking action under TSCA section 5(e), particularly if satisfactory test results have not been obtained from a prior PMN or SNUN submitter. EPA recommends that potential SNUN submitters contact EPA early enough so that they will be able to conduct the appropriate tests.

SNUN submitters should be aware that EPA will be better able to evaluate SNUNs which provide detailed information on the following:

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

#### VIII. SNUN Submissions

As stated in Unit II.C. of this document, according to § 721.1(c), persons submitting a SNUN must comply with the same notice requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in 40 CFR 720.50. SNUNs must be submitted to EPA on EPA Form

No. 7710-25 in accordance with the procedures set forth in § 721.25 and § 720.40. This form is available from the Environmental Assistance Division (7408M), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. Forms and information are also available online at <http://www.epa.gov/opptintr/newchems>.

#### IX. Economic Analysis

EPA evaluated the potential costs of establishing SNUN requirements for potential manufacturers, importers, and processors of the chemical substance 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.

#### X. References

The following is a listing of those documents used to prepare the preamble to this final rule. Additional information for this final rule can be located under docket ID number EPA-HQ-OPPT-2008-0918, which is available for inspection as specified under **ADDRESSES**.

1. CARB 2008. Technical Support Document Staff Analysis on Emissions and Economic Impact of Proposed Regulation for Small Containers of Automotive Refrigerant. Appendix G to CARB, 2010 (Ref. 2).

2. CARB 2010. Certification Procedures for Small Containers of Automotive Refrigerant. *California Air Resources Board*, effective March 10, 2010. Document incorporated by reference in California Code of Regulations (CCR), title 17, sections 95360 through 9537. Available on-line at <http://www.arb.ca.gov/regact/2009/hfc09/hfc09.htm>.

3. Clodic *et al.* 2008. Clodic, D., Tremoulet, A, Riachi, Y, et al. Evaluation of the Potential Impact of Emissions of HFC-134a from Non Professional Servicing of Motor Vehicle Air Conditioning Systems. *Prepared under CARB Agreement No. 06-341*. December 2008.

4. EPA 2009. Risk Assessment: PMN 07-0601; Reflecting Deliberations and Decisions From the 03/04/09 RAD Dispo. Docket ID number: EPA-HQ-OPPT-2008-0918-0034.

5. EPA 2010. EPA Questions to Honeywell on Submitted Exposure Study. Docket ID number: EPA-HQ-OPPT-2008-0918.

6. Gradient 2009. Risk Assessment for Alternative Refrigerant HFO-1234yf. Gradient Corporation, Seattle, Washington. April 3, 2009. Prepared for SAE International, Cooperative Research Program 1234.

7. Honeywell 2010a. Comment on EPA Proposed Rule. *Simulated Vehicle Service Leak Testing and Exposure Study*. Docket ID number: EPA-HQ-OPPT-2008-0918-0088.

8. Honeywell 2010b. Honeywell Response to EPA Questions on Submitted Exposure Study. Docket ID number: EPA-HQ-OPPT-2008-0918.

## XI. Statutory and Executive Order Reviews

### A. Executive Order 12866

This final rule establishes a SNUR for a chemical substance that was 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. EPA is amending the table in 40 CFR part 9 to list the OMB approval number for the information collection requirements contained in this final rule. This listing of the OMB control numbers and their subsequent codification in the CFR satisfies the display requirements of PRA and OMB's implementing regulations at 5 CFR part 1320. This Information Collection Request (ICR) was previously subject to public notice and comment prior to OMB approval, and given the technical nature of the table, EPA finds that further notice and comment to amend it is unnecessary. As a result, EPA finds that there is "good cause" under section 553(b)(3)(B) of the Administrative Procedure Act, 5 U.S.C. 553(b)(3)(B), to amend this table without further notice and comment.

The information collection requirements related to this action have already been approved by OMB pursuant to PRA under OMB control number 2070-0012 (EPA ICR No. 574). This action does not impose any burden requiring additional OMB approval. If an entity were to submit a SNUN to the Agency, the annual burden is estimated to average between 30 and 170 hours

per response. This burden estimate includes the time needed to review instructions, search existing data sources, gather and maintain the data needed, and complete, review, and submit the required SNUN.

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

### C. Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency hereby certifies that promulgation of this SNUR will not have a significant adverse economic impact on a substantial number of small entities. The rationale supporting this conclusion is discussed in this unit. 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 over 1,400 SNURs, the Agency receives on average only 5 notices per year. Of those SNUNs submitted from 2006-2008, only one appears to be from a small entity. In addition, the estimated reporting cost for submission of a SNUN (see Unit IX.) is minimal regardless of the size of the firm. Therefore, EPA believes that the potential economic impacts of complying with these SNURs 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.

### 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 reasons to believe that any State, local, or Tribal government will be impacted by this final rule. As such, EPA has determined that this rule does 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) (Pub. L. 104-4).

### E. Executive Order 13132

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, entitled *Federalism* (64 FR 43255, August 10, 1999).

### F. Executive Order 13175

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

### G. Executive Order 13045

This action is not subject to Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997), because this is not an economically significant regulatory action as defined by Executive Order 12866, and this action does not address environmental health or safety risks disproportionately affecting children.

### H. Executive Order 13211

This action is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply,

distribution, or use and because this action is not a significant regulatory action under Executive Order 12866.

*I. National Technology Transfer and Advancement Act*

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 FR 7629, February 16, 1994).

**XII. Congressional Review Act**

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a "major rule" as defined by 5 U.S.C. 804(2).

**List of Subjects**

*40 CFR Part 9*

Environmental protection, Reporting and recordkeeping requirements.

*40 CFR Part 721*

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

Dated: October 14, 2010.

**Wendy C. Hamnett,**

*Director, Office of Pollution Prevention and Toxics.*

Therefore, 40 CFR parts 9 and 721 are amended as follows:

**PART 9—[AMENDED]**

1. The authority citation for part 9 continues to read as follows:

**Authority:** 7 U.S.C. 135 *et seq.*, 136-136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601-2671; 21 U.S.C. 331j, 346a, 348; 31 U.S.C. 9701; 33 U.S.C. 1251 *et seq.*, 1311, 1313d, 1314, 1318, 1321, 1326, 1330, 1342, 1344, 1345 (d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971-1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g-1, 300g-2, 300g-3, 300g-4, 300g-5, 300g-6, 300j-1, 300j-2, 300j-3, 300j-4, 300j-9, 1857 *et seq.*, 6901-6992k, 7401-7671q, 7542, 9601-9657, 11023, 11048.

2. The table in § 9.1 is amended by adding the following section in numerical order under the undesignated center heading "Significant New Uses of Chemical Substances" to read as follows:

**§ 9.1 OMB approvals under the Paperwork Reduction Act.**

40 CFR Citation	OMB Control No.
*	*
<b>Significant New Uses of Chemical Substances</b>	
*	*
721.10182 .....	2070-0012
*	*
*	*

**PART 721—[AMENDED]**

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

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

4. Add § 721.10182 to subpart E to read as follows:

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

(a) *Chemical substance and significant new uses subject to reporting.*

(1) The chemical substance identified as 1-propene, 2,3,3,3-tetrafluoro- (PMN P-07-601; CAS No. 754-12-1; also known as HFO-1234yf) 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) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(j) (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 new 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)); and § 721.80(o) (distribution in commerce of products intended for use by a consumer for the purpose of servicing, maintenance, and disposal involving the PMN substance).

(ii) [Reserved]

(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), and (i) are applicable to manufacturers, importers, and processors of this chemical substance.

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