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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 721

[EPA-HQ-OPPT-2011-0941; FRL-9922-30]

RIN 2070-AB27

Significant New Use Rule for Pentane, 1,1,1,2,3,3-hexafluoro-4-(1,1,2,3,3,3-hexafluoropropoxy)-.

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is finalizing a significant new use rule (SNUR) under the Toxic Substances Control Act (TSCA) for the chemical substance Pentane, 1,1,1,2,3,3-hexafluoro-4-(1,1,2,3,3,3-hexafluoropropoxy)- that was the subject of premanufacture notice (PMN) P-07-204. This action requires persons who intend to manufacture (including import) this 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. The required notification will 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 [*insert date 30 days after date of publication in the Federal Register*].

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2011-0941, is available at <http://www.regulations.gov> or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Please review the visitor instructions and additional information about the docket, available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Kenneth Moss, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-9232; email address: moss.kenneth@epa.gov.

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

SUPPLEMENTARY INFORMATION:

I. Does this Action Apply to Me?

You may be potentially affected by this action if you manufacture, process, or use the chemical substance Pentane, 1,1,1,2,3,3-hexafluoro-4-(1,1,2,3,3,3-hexafluoropropoxy)- (PMN P-

07-204; CAS No. 870778-34-0) contained in this final rule. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

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

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Chemical importers are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements promulgated at 19 CFR 12.118 through 12.127 and 19 CFR 127.28. Chemical importers must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA. Importers of chemicals subject to 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 final rule are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)) (see § 721.20), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

II. Background

A. What Action is the Agency Taking?

EPA is finalizing a SNUR, under TSCA section 5(a)(2), for the chemical substance Pentane, 1,1,1,2,3,3-hexafluoro-4-(1,1,2,3,3,3-hexafluoropropoxy)- (PMN P-07-204; CAS No. 870778-34-0) codified at 40 CFR 721.10509. This final rule requires persons who intend to

manufacture 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.

In the **Federal Register** of September 21, 2012 (77 FR 58666)(FRL-9357-2), EPA issued a direct final SNUR for the chemical substance. EPA received notice of intent to submit adverse comments for the direct final SNUR. In response to that notification a rule was proposed in the **Federal Register** issue of January 23, 2013 (78 FR 4806) (FRL-6369-9). In response to the proposed rule, EPA received one public comment from the submitter of PMN P-07-204.

The comment noted that in the time period between filing of a Notice of Commencement of Manufacture or Import in March 2008, and the time of publication of the direct final SNUR in September 2012, the company had entered into an industrial solvent use that did not specifically fall within the scope of the 40 CFR 721.80(j) (the confidential uses identified in the amended premanufacture notice) significant new use reporting requirement contained in the rule. Therefore, the use was considered an ongoing use at the time of the direct final SNUR.

Further, the commenter mentioned the intent to submit several health and safety studies on the PMN substance that were completed after the expiration of the PMN review period. The following table identifies the studies that were subsequently submitted to the Agency for review and the results of EPA's review of those studies:

Study	EPA Findings from Study
5-day Inhalation toxicity test in rats	Uncertain increase in liver weights at highest dose
Acute dermal toxicity test in rats	No Observed Adverse Effect Level (NOAEL) of 2,000 milligram/kilogram/day (mg/kg/day)
Acute eye irritation/corrosion test in	Not an eye irritant

rabbits	
Assessment of contact hypersensitivity in the mouse	Not a skin sensitizer
Color microarray analysis of liver RNA	Indications of ability to activate the xenobiotic nuclear receptor CAR (constitutive androstane receptor), but of uncertain significance relative to ability to affect clinical chemistry endpoints
Primary skin irritation/corrosion test in rabbits	Not a skin irritant
Sub-acute (29-day) inhalation toxicity test in rats	Lowest Observed Adverse Effect Level (LOAEL) of 495 parts per million (ppm) based on liver effects
Analysis of the effect on primary cell cultures (low potency peroxisome proliferator-activated receptor (PPAR) agonist)	Uncertain significance

Agency review of the 29-day inhalation toxicity study, which demonstrated liver effects, along with the perfluorochemical analog data cited in the proposed SNUR, demonstrate the concern cited in the proposed SNUR for neurotoxicity and liver effects as a result of unprotected occupational exposures via the dermal route. Therefore, the Agency is issuing a final SNUR as proposed that designates as a significant new use manufacture or processing of the substance without impervious gloves, where there is a potential for dermal exposure, and simplifies the wording in the significant new use designation under 40 CFR 721.80 to encompass the ongoing use as follows: “A significant new use is any use of the substance other than for the specific confidential industrial solvent uses identified in the amended premanufacture notice (PMN).”

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 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 final 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), (2), (3), and (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.

III. Rationale and Objectives of the Final Rule

A. Rationale

During review of the PMN for the chemical substance Pentane, 1,1,1,2,3,3-hexafluoro-4-(1,1,2,3,3,3-hexafluoropropoxy)- (PMN P-07-204; CAS No. 870778-34-0), EPA determined that one or more of the criteria of concern established at § 721.170 were met. For additional discussion of the rationale for the SNUR on this chemical, see Units II., IV., and V. of the proposed rule.

B. Objectives

EPA is issuing this final SNUR for the chemical substance Pentane, 1,1,1,2,3,3-hexafluoro-4-(1,1,2,3,3,3-hexafluoropropoxy)- (PMN P-07-204; CAS N. 870778-34-0) 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 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 or processing a listed chemical substance for the described significant new use.
- EPA will be able to regulate prospective manufacturers 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 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 <http://www.epa.gov/opptintr/existingchemicals/pubs/tscainventory/index.html>.

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 authorized EPA to consider any other relevant factors.

To determine what would constitute a significant new use for the chemical substance pentane, 1,1,1,2,3,3-hexafluoro-4-(1,1,2,3,3,3-hexafluoropropoxy)- (PMN P-07-204; CAS No. 870778-34-0), 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.

V. Applicability of the Significant New Use Designation

If uses begun after the proposed rule was published were considered ongoing rather than new, any person could defeat the SNUR by initiating the significant new use before the

final rule was issued. Therefore EPA has designated the date of publication of the proposed rule as the cutoff date for determining whether the new use is ongoing. Consult the **Federal Register** Notice of April 24, 1990 (55 FR 17376, FRL 3658-5) for a more detailed discussion of the cutoff date for ongoing uses.

Any person who began commercial manufacture or processing of the chemical substance identified as pentane, 1,1,1,2,3,3-hexafluoro-4-(1,1,2,3,3,3-hexafluoropropoxy)- (PMN P-07-204; CAS No. 870778-34-0) 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 the final rule. Persons who ceased those activities will have to first comply with all applicable SNUR notification requirements and wait until the notice review period, including any extensions, expires, before engaging in any activities designated as significant new uses. If a person were to meet the conditions of advance compliance under 40 CFR § 721.45(h), the person would be considered to have met the requirements of the final SNUR for those activities.

VI. Test Data and Other Information

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

1. Development of test data is required where the chemical substance subject to the SNUR is also subject to a test rule under TSCA section 4 (see TSCA section 5(b)(1)).
2. Development of test data may be necessary where the chemical substance has been listed under TSCA section 5(b)(4) (see TSCA section 5(b)(2)).

In the absence of a TSCA section 4 test rule or a TSCA section 5(b)(4) listing covering the chemical substance, persons are required only to submit test data in their possession or control and to describe any other data known to or reasonably ascertainable by them (see 40 CFR 720.50). However, upon review of PMNs and SNUNs, the Agency has the authority to require appropriate testing.

Recommended testing that would address the criteria of concern of § 721.170 can be found in Unit IV. of the proposed rule. Descriptions of tests are provided only for informational purposes. EPA strongly encourages persons, before performing any testing, to consult with the Agency pertaining to protocol selection.

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

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

VII. SNUN Submissions

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 <http://www.epa.gov/opptintr/newchems>.

VIII. Economic Analysis

EPA has evaluated the potential costs of establishing SNUN requirements for potential manufacturers and processors of the chemical substance 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-2011-0941.

IX. 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 (PRA)

According to PRA (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable. EPA is amending the table in 40 CFR part 9 to list the OMB approval number for the information collection requirements contained in this 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 (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 final rule.

This final rule is within the scope of the February 18, 2012 certification. Based on the Economic Analysis discussed in Unit VIII. and EPA's experience promulgating SNURs (discussed in the certification), EPA believes that the following are true:

- A significant number of SNUNs would not be submitted by small entities in response to the SNUR.

- Submission of the SNUN would not cost any small entity significantly more than \$8,300.

Therefore, the promulgation of the SNUR would not have a significant economic impact on a substantial number of small entities.

D. Unfunded Mandates Reform Act (UMRA)

Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reasons to believe that any State, local, or Tribal government will be impacted by this final rule. As such, EPA has determined that this action does 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 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 action does not have Tribal implications because it is not expected to have substantial direct effects on Indian Tribes. This final rule does not significantly nor uniquely affect the communities of Indian Tribal governments, nor does it involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of Executive Order 13175, 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 (NTTAA)

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

J. Executive Order 12898

This action does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

X. Congressional Review Act (CRA)

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this final 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 final rule in the **Federal Register**. This action 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: February 23, 2015.

Maria J. Doa,

Director, Chemical Control Division, 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. In § 9.1, add 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.
* * * * *	* * *
Significant New Uses of Chemical Substances	
* * * * *	* * *
721.10509	2070-0012
* * * * *	* * *

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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 § 721.10509 to subpart E to read as follows:

§ 721.10509 Pentane, 1,1,1,2,3,3-hexafluoro-4-(1,1,2,3,3,3-hexafluoropropoxy)-.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as pentane, 1,1,1,2,3,3-hexafluoro-4-(1,1,2,3,3,3-hexafluoropropoxy)- (PMN P-07-204; CAS No. 870778-34-0) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i), (a)(3), (b)(concentration set at 1.0 percent), and (c).

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80. A significant new use is any use of the substance other than for the specific confidential industrial solvent uses identified in the amended premanufacture notice (PMN).

(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) through (e), and (i) 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.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(ii) of this section.

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