



BILLING CODE 6560-50-P

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 721**

**[EPA-HQ-OPPT-2013-0399; FRL-9991-17]**

**RIN 2070-AB27**

**Proposed Revocation of Significant New Use Rule for Fatty Acid Amide**

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

**ACTION:** Proposed rule.

**SUMMARY:** EPA is proposing to revoke the significant new use rule (SNUR) promulgated under the Toxic Substances Control Act (TSCA) for a chemical substance which was identified generically as fatty acid amide which was the subject of premanufacture notice (PMN) P-13-267. EPA issued a SNUR based on the PMN designating certain activities as significant new uses. EPA has received a significant new use notice (SNUN) and test data for the chemical substance and is proposing to revoke the SNUR based on the information in the submission.

**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-2013-0399, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail*: Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** *For technical information contact:* Jim Alwood, Chemical Control Division, 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 (including import), process, or use the chemical substance contained in this rule. Potentially affected entities may include, but are not limited to:

- Manufacturers or processors of the chemical substances (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 and 19 CFR 127.28. Chemical importers must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA. Importers of chemicals subject to a SNUR must certify their compliance with the SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. Importers of the chemical, the subject of this action, would no longer be required to certify compliance with the SNUR requirements if the revocation becomes effective. In addition, if this proposed SNUR revocation becomes effective, persons who export or intend to export the chemical that is the subject of this action would no longer be subject to the TSCA section 12(b)(15 U.S.C. 2611(b) export notification requirements at 40 CFR part 707, that are currently triggered by the SNUR.

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

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI

information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <http://www.epa.gov/dockets/comments.html>.

## **II. Background**

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

In the **Federal Register** of August 7, 2013 (78 FR 48051) (FRL-9393-4), EPA promulgated a SNUR at § 721.10691 for the chemical substance identified generically as fatty acid amide (PMN P-13-267). The SNUR designated release to water resulting in concentrations greater than 1 part per billion as a significant new use. EPA has received a SNUN that included human health and environmental toxicity testing for the chemical substance and, based on its review of these data, EPA now proposes to revoke the SNUR pursuant to § 721.185. In this unit, EPA provides a brief description of the chemical substance, including the PMN and SNUN numbers, generic chemical name, the **Federal Register** publication date and reference, the docket number, the basis for revoking the SNUR under § 721.185, and the CFR citation of the SNUR.

### **PMN Number P-13-267 and SNUN S-15-9**

*Chemical name:* Fatty acid amide (generic).

*CAS number:* Not available.

*Federal Register* publication date and reference: August 7, 2013 (78 FR 48051).

*Basis for revocation of SNUR:* EPA issued a SNUR for this substance that designated certain activities as significant new uses based on a finding that the substance may cause significant adverse environmental effects and met the concern criteria at § 721.170(b)(4)(ii). The SNUR required notification before any use of the substance resulting in surface water concentrations exceeding 1 part per billion (ppb). Subsequently, a manufacturer of the substance submitted a SNUN to allow surface water concentrations exceeding 1 ppb. Acute and chronic toxicity values measured for fish, aquatic invertebrates, and algae in the submitted data all demonstrated no effects at saturation in the aqueous environment. In addition, the chronic toxicity value measured for sediment-dwelling invertebrates is > 788 milligrams/kilogram (mg/kg) dry weight (Lowest Observed Effect Concentration). Test data on the chemical substance were negative for the following human health hazards: mutagenicity, irritation to the eyes and skin, and skin sensitization. A No-Observed Adverse Effect Level of 1,000 mg/kg-bodyweight (bw)/day was identified based on no treatment-related adverse effects at the highest dose tested in a 28-day oral repeated-dose toxicity study (OECD Test Guideline 407). Based on the results of the testing, EPA determined that the substance has inherently low toxicity. The studies are available in the public docket. As a result, EPA made a determination of not likely to present an unreasonable risk under TSCA section 5(a)(3)(C) for the SNUN. EPA concludes that the substance does not meet the criteria under § 721.170(b). Therefore, EPA proposes that the SNUR for these chemical substances be revoked pursuant to § 721.185(a)(4).

*CFR citation:* 40 CFR 721.10691.

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

Under § 721.185, EPA may at any time revoke a SNUR for a chemical substance which has been added to subpart E of § 721 if EPA makes one of the determinations set forth in § 721.185(a)(1) through (a)(6). Revocation may occur on EPA's initiative or in response to a written request. Under § 721.185(b)(3), if EPA concludes that a SNUR should be revoked, the Agency will propose the changes in the **Federal Register**, briefly describe the grounds for the action, and provide interested parties an opportunity to comment.

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

This proposed rule would revoke or eliminate an existing regulatory requirement and does not contain any new or amended requirements. As such, the Agency has determined that this proposed SNUR revocation would not have any adverse impacts, economic or otherwise.

The Office of Management and Budget (OMB) has exempted these types of regulatory actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This proposed rule does not contain any information collections subject to approval under the *Paperwork Reduction Act (PRA)*, (44 U.S.C.3501 *et seq.*). Since this proposed rule eliminates a reporting requirement, the Agency certifies pursuant to section 605(b) of the *Regulatory Flexibility Act (RFA)* (5 U.S.C.601 *et seq.*), that this SNUR revocation would not have a significant economic impact on a substantial number of small entities.

For the same reasons, this action does not require any action under Title II of the *Unfunded Mandates Reform Act of 1995 (UMRA)* (Pub. L.104-4). This proposed rule has neither Federalism implications, because it would not have substantial direct effects 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), nor Tribal implications, because it would

not have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes, as specified in Executive Order 13175 entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000).

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 under Executive Order 12866, and it does not address environmental health or safety risks disproportionately affecting children. This action is not subject to Executive Order 13111, 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. Because 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. This action does not involve special considerations of environmental justice related issues as required by Executive Order 12898 entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

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

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

Dated: July 11, 2019.

**Tala Henry,**

*Deputy Director, 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. Remove § 721.10691.

**§ 721.10691 [Removed]**

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