



BILLING CODE 6560-50-P

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 721**

**[EPA-HQ-OPPT-2017-0575; FRL-10005-89]**

**RIN 2070-AB27**

**Revocation of Significant New Use Rule for a Certain Chemical Substance (P-16-581)**

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

**ACTION:** Proposed rule.

**SUMMARY:** EPA is proposing to revoke the significant new use rule (SNUR) under the Toxic Substances Control Act (TSCA) for the chemical substance identified generically as alpha 1,3-polysaccharide, which was the subject of premanufacture notice (PMN) identified as P-16-581. EPA issued a SNUR based on this PMN which designated certain activities as significant new uses. EPA has received test data for the chemical substance and is proposing to revoke the SNUR based on these new data.

**DATES:** Comments must be received on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE **FEDERAL REGISTER**].

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2017-0575, by one of the following methods:

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

- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics

(OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** *For technical information contact:* Kenneth Moss, Chemical Control Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: 202-564-8974; email 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; 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 40 CFR 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 export notification rules under TSCA. 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 April 5, 2019 (84 FR 13531) (FRL-9991-19), EPA promulgated a SNUR at 40 CFR 721.11193 for the chemical substance identified generically as alpha 1,3-polysaccharide (P-16-581). The SNUR designated certain activities as significant new uses. EPA has received new data on the biosolubility of the chemical substance. Based on its review of these data, EPA now proposes to revoke the SNUR pursuant to 40 CFR 721.185. In this unit, EPA provides a brief description of the chemical substance, including the PMN number, generic chemical name, the Federal Register publication date and reference, the docket number, the basis for revoking the SNUR under 40 CFR 721.185, and the CFR citation of the SNUR.

**PMN Number:** P-16-581.

*Chemical name:* Alpha 1,3-polysaccharide (generic).

*CAS number:* Not available.

*Federal Register publication date and reference:* April 5, 2019 (84 FR 13531).

*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 pose potential human health hazards. Specifically, EPA identified a concern that adverse lung effects (i.e., lung overload) could occur if the chemical substance were manufactured, processed, or used in a manner that generated respirable particles. To address this hazard concern, EPA issued a SNUR under TSCA section 5(a)(2), which identified concerns for lung effects if the following protective measures were not followed: (1) no use of the substance other than the uses described in the PMN; and (2) no manufacture, processing, or use with particle size less than 10 micrometers. EPA also identified pulmonary effects toxicity testing as information potentially

useful to characterize the health effects of the PMN substance. The PMN submitter performed biosolubility testing on the ground PMN substance and provided the test data to EPA on February 14, 2019. EPA initiated an internal review of these data; however, it moved forward with publishing the final SNUR on April 5, 2019 having not yet completed its review. The following are the results and conclusions of the Agency's review.

The biosolubility testing was conducted using a conservative respiratory tract fluid volume of 0.3 mL/kg bw (rounded down to 20 mL for a 70 kg individual). This equated to a loading concentration of 15 mg of the PMN substance per mL of simulated epithelial lung fluid (SELF). The SELF represented the intraluminal volume of respiratory tract fluid, without consideration of the daily turnover volume. The estimated average alveolar fluid volume is approximately 37 mL, nearly double the volume used for the biosolubility testing. In comparison, the normal reference range for extra vascular lung water (EVLW) index in humans is  $7.3 \pm 2.8$  mL/kg bw (n = 534) or 511 mL for a 70 kg individual. EVLW index corresponds to the "sum of interstitial, intracellular, alveolar, and lymphatic fluid, not including pleural effusions." Therefore, the solubility of the PMN substance in SELF represented a worst-case loading concentration for the PMN substance in the intraluminal compartment, assuming an equivalent static volume of 20 mL. Given that humans accumulate respirable, poorly soluble particles in the intra-alveolar, interstitial, subpleural, and broncho-vascular bundle compartments, with a predominance of particles eventually being found in the interstitium, the extrapolated *in vitro* to *in vivo* concentration of the PMN substance would equal a loading concentration of approximately 3 mg/mL of EVLW (i.e., 1,500 mg/(511 mL for EVLW - 37 mL for alveolar volume)) approximately 5 times lower than the loading concentration tested in the biosolubility study.

This information supports EPA's determination that the substance has inherently low toxicity and should not be considered a poorly soluble particle with the associated hazard concern for lung overload. Therefore, EPA proposes that the SNUR for this chemical substance be revoked pursuant to 40 CFR 721.185(a)(1).

*CFR citation:* 40 CFR 721.11193.

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

Upon conclusion of the review for P-16-581, EPA designated certain activities as significant new uses. Under 40 CFR 721.185, EPA may at any time revoke a SNUR for a chemical substance which has been added to subpart E of 40 CFR part 721 if EPA makes one of the determinations set forth in 40 CFR 721.185(a)(1) through (a)(6). Revocation may occur on EPA's initiative or in response to a written request. Under 40 CFR 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.

EPA has determined that the criteria set forth in 40 CFR 721.185(a)(1) have been satisfied for the chemical substance. Therefore, EPA is proposing to revoke the SNUR for this chemical substance. The significant new use notification and the recordkeeping requirements at 40 CFR 721.11193 would terminate when this proposed revocation becomes effective. In addition, export notification under TSCA section 12(b) and 40 CFR part 707, subpart D triggered by the SNUR would no longer be required.

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

Additional information about these statutes and Executive Orders can be found at <https://www.epa.gov/laws-regulations-and-executive-orders>.

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.

*A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulations and Regulatory Review*

The Office of Management and Budget (OMB) has exempted these types of regulatory actions from review under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563, entitled (76 FR 3821, January 21, 2011).

*B. Paperwork Reduction Act (PRA)*

This proposed rule does not contain any information collections subject to approval under the PRA, (44 U.S.C.3501 *et seq.*).

*C. Regulatory Flexibility Act (RFA)*

Pursuant to the RFA section 605(b), 5 U.S.C. 601 *et seq.*, the Agency hereby that this SNUR revocation would not have a significant economic impact on a substantial number of small entities. This proposed rule would eliminate a reporting requirement.

*D. Unfunded Mandates Reform Act (UMRA)*

For the same reasons, this action does not require any action under Title II of UMRA (2 U.S.C. 1531-1538 *et seq.*).

*E. Executive Order 13132: Federalism*

This proposed rule does not have 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 (64 FR 43255, August 10, 1999).

*F. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments*

This proposed rule does not have 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 (65 FR 67249, November 9, 2000).

*G. Executive Order 13045: Protection of Children from Environmental Health and Safety Risks*

This action is not subject to Executive Order 13045 (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.

*H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use*

This proposed rule is not subject to Executive Order 13211 (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: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations*

This action does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898 (59 FR 7629, February 16, 1994).

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

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

Dated: March 5, 2020.

**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).

### **§ 721.11193 [Removed]**

2. Remove § 721.11193.

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