

Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 721 and 725

[EPA-HQ-OPPT-2022-0863; FRL-12967-01]

RIN 2070-AB27

Modification of Significant New Use Rules of Certain Chemical Substances (23-1.M)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to amend the significant new use rules (SNURs) for certain chemical substances identified herein, which were the subject of one or more premanufacture notices (PMNs), a Microbial Commercial Activity Notice (MCAN) for one substance, and in some cases significant new use notices (SNUNs). This action would amend the SNURs to (1) allow certain new uses reported in the SNUNs or PMNs without additional notification requirements, (2) modify the significant new use notification requirements based on the actions and determinations for the SNUN or PMN submissions or based on the examination of new test data or other information, and (3) make technical amendments to several SNURs. EPA is proposing these amendments based on our review of new and existing data for the chemical substances.

DATES: Comments must be received on or before November 28, 2025.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2022-0863, online at <https://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. Additional instructions on commenting and visiting the docket, along with more information about dockets generally, is

available at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT:

For technical information: Brianna Godwin, New Chemicals Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; telephone number: (202) 565-0076; email address: godwin.brianna@epa.gov.

For general information on SNURs: William Wysong, New Chemicals Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; telephone number: (202) 564-4163; email address: wysong.william@epa.gov.

For general information on TSCA: The TSCA Assistance Information Service Hotline, Goodwill Vision Enterprises, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (800) 471-7127 or (202) 554-1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. What is the Agency's authority for taking this action?

TSCA section 5(a)(2) (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a "significant new use." EPA must make this determination by rule after considering all relevant factors, including the factors in TSCA section 5(a)(2) (see also the discussion in Unit II.). Procedures and criteria for modifying or revoking SNUR requirements appear at 40 CFR 721.185 or 725.984 (for microorganisms).

B. What action is the Agency taking?

EPA is proposing amendments to the SNURs for certain chemical substances in 40 CFR part 721, subpart E and part 725, subpart M (for microorganisms). A SNUR for a chemical substance designates certain activities as a significant new use. Persons who intend to manufacture or process the chemical substance for the significant new use must notify EPA at least 90 days before commencing that activity. The required notification (*i.e.*, a SNUN) initiates EPA's evaluation of the intended use. Manufacture and processing for the significant new use may not commence until EPA has conducted a review of the notice, made an appropriate

determination on the notice, and taken such actions as are required in association with that determination.

C. Does this action apply to me?

1. General Applicability

This action applies to you if you manufacture, process, or use the chemical substances contained in this proposed 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 one or more subject chemical substances (NAICS codes 325 and 324110), *e.g.*, chemical manufacturing and petroleum refineries.

2. Applicability to Importers and Exporters

This action may also apply to certain entities through pre-existing import certification and export notification requirements under TSCA (<https://www.epa.gov/tsc-import-export-requirements>).

Chemical importers are subject to TSCA section 13 (15 U.S.C. 2612), the requirements in 19 CFR 12.118 through 12.127; see also 19 CFR 127.28. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. Chemical importers must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA, including regulations issued under TSCA sections 5, 6, 7 and Title IV.

Pursuant to 40 CFR 721.20 or 40 CFR 725.920 (for microorganisms), any persons who export or intend to export a chemical substance identified in this document are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)) and must comply with the export notification requirements in 40 CFR part 707, subpart D.

D. What are the incremental economic impacts of this action?

1. Estimated Costs for SNUN Submissions

If a SNUN is submitted, costs are an estimated \$45,000 per SNUN submission for large business submitters and \$14,500 for small business

submitters. These estimates include the cost to prepare and submit the SNUN (including registration for EPA's Central Data Exchange (CDX)), and the payment of a user fee. Businesses that submit a SNUN would be subject to either a \$37,000 user fee required by 40 CFR 700.45(c)(2)(ii) and (d), or, if they are a small business as defined at 13 CFR 121.201, a reduced user fee of \$6,480 (40 CFR 700.45(c)(1)(ii) and (d)) per fiscal year 2022. The costs of submission for SNUNs will not be incurred by any company unless a company decides to pursue a significant new use as defined in these SNURs. Additionally, these estimates reflect the costs and fees as they are known at the time of this rulemaking.

2. Estimated Costs for Export Notifications

EPA has also evaluated the potential costs associated with the export notification requirements under TSCA section 12(b) and the implementing regulations at 40 CFR part 707, subpart D. For persons exporting a substance that is the subject of a SNUR, a one-time notice to EPA must be provided for the first export or intended export to a particular country. The total costs of export notification will vary by chemical, depending on the number of required notifications (*i.e.*, the number of countries to which the chemical is exported). While EPA is unable to make any estimate of the likely number of export notifications for the chemical substances covered by these SNURs, as stated in the accompanying economic analysis, the estimated cost of the export notification requirement on a per unit basis is approximately \$106.

E. What should I consider as I prepare my comments for EPA?

1. Submitting CBI

Do not submit CBI to EPA through email or <https://www.regulations.gov>. If you wish to include CBI in your comment, please follow the applicable instructions at <https://www.epa.gov/dockets/commenting-epa-dockets#rules> and clearly mark the information that you claim to be CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR parts 2 and 703.

2. Tips for Preparing Your Comments

When preparing and submitting your comments, see the commenting tips at <https://www.epa.gov/epa-dockets>.

II. Background

This unit provides general information about SNURs. For additional information about EPA's new

chemical program go to <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca>.

A. Significant New Use Determination Factors

TSCA section 5(a)(2) 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 determining whether and how to modify EPA's identification of significant new uses for the chemical substances that are the subject of these SNURs, EPA considered the four factors specifically identified in TSCA section 5(a)(2) and relevant information about the toxicity of the chemical substances, and potential human exposures and environmental releases that may be associated with the substances.

B. Rationale and Objectives of the SNURs

1. Rationale

Under TSCA, no person may manufacture a new chemical substance or manufacture or process a chemical substance for a significant new use until EPA makes a determination as described in TSCA section 5(a) and takes any required action. The issuance of a SNUR is not a risk determination itself, only a notification requirement for "significant new uses," so that the Agency has the opportunity to review the SNUN for the significant new use and make a TSCA section 5(a)(3) risk determination.

In those instances where EPA is proposing to expand the scope of a significant new use or identify an additional significant new use, the Agency identified concerns, as discussed in Unit III.C, associated with certain potential new uses. EPA considered the factors discussed in Unit II.A, and EPA determined that uses of concern could result in changes in the type or form of exposure to the chemical substance, increased exposures to the chemical substance, and/or changes in the reasonably anticipated manner and

methods of manufacturing, processing, distribution in commerce, and disposal of the chemical substance.

In those instances where EPA is proposing to narrow the scope of a significant new use, EPA has (1) received significant new use or premanufacture notices for some of the activities designated as significant new uses of the substance and, after reviewing such notices, concluded that there is no need to require additional notice from persons who propose to engage in identical or similar activities; or (2) received test data or other information that led the Agency to conclude that certain activities designated as significant new uses are not likely to present an unreasonable risk of injury to health or the environment.

2. Objectives

EPA proposes SNURs because the Agency has determined it is appropriate:

- To have an opportunity to review and evaluate data submitted in a SNUN before the submitter begins manufacturing or processing a listed chemical substance for the described significant new use.
- To be obligated to make a determination under TSCA section 5(a)(3) regarding the use described in the SNUN, under the conditions of use. The Agency will either determine under TSCA section 5(a)(3)(C) that the significant new use is not likely to present an unreasonable risk, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, or make a determination under TSCA section 5(a)(3)(A) or (B) and take the required regulatory action associated with the determination, before manufacture or processing for the significant new use of the chemical substance can occur.

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 at <https://www.epa.gov/tsca-inventory>.

C. Significant New Uses Claimed as CBI

The SNURs that EPA is proposing to modify include certain significant new uses which have been claimed as CBI subject to Agency confidentiality regulations at 40 CFR part 2 and 40 CFR part 720, subpart E or 40 CFR part 725, subpart C (for microorganisms). Absent a final determination or other

disposition of the confidentiality claim under 40 CFR part 2 procedures, EPA is required to keep this information confidential. EPA promulgated a procedure to deal with the situation where a specific significant new use or specific chemical identity is CBI, at 40 CFR 721.11.

Under these procedures a manufacturer or processor may request EPA to identify the confidential significant new use under the rule. The manufacturer or processor must show that it has a *bona fide* intent to manufacture or process the chemical substance. If EPA concludes that the person has shown a *bona fide* intent to manufacture or process the chemical substance, EPA will identify the confidential significant new use to that person. Since some of the specific chemical identities of the chemical substances subject to these SNURs are also CBI, manufacturers and processors may similarly request EPA to determine whether a chemical substance is subject to these SNURs, and can combine the *bona fide* submission for confidential significant new use and specific chemical identity under the procedure in 40 CFR 721.11 into a single step.

D. Applicability of General Provisions

General provisions for SNURs appear in 40 CFR part 721, subpart A and (for microorganisms) 40 CFR part 725, subpart L. These provisions describe persons subject to SNURs, recordkeeping requirements, exemptions to reporting requirements, and applicability of the rule to uses occurring before the effective date of the rule. Pursuant to 40 CFR 721.1(c) or 725.900(b) (for microorganisms), persons subject to SNURs must comply with the same requirements and EPA regulatory procedures as submitters of PMNs (or MCANs) under TSCA section 5(a)(1)(A). In particular, these requirements include the information submission requirements of TSCA sections 5(b) and 5(d)(1), the exemptions authorized by TSCA sections 5(h)(1), 5(h)(2), 5(h)(3), and 5(h)(5) and the regulations at 40 CFR part 720 or part 725 (for microorganisms). In addition, provisions relating to user fees appear at 40 CFR part 700.

Once EPA receives a SNUN, EPA must either determine that the significant new use is not likely to present an unreasonable risk of injury under the conditions of use for the chemical substance or take such regulatory action as is associated with an alternative determination under TSCA section 5 before the manufacture (including import) or processing for the

significant new use can commence. If EPA determines that the significant new use of the chemical substance is not likely to present an unreasonable risk, EPA is required under TSCA section 5(g) to make public, and submit for publication in the **Federal Register**, a statement of EPA's findings.

As discussed in Unit I.C.2., persons who export or intend to export a chemical substance identified in a proposed or final SNUR are subject to the export notification provisions of TSCA section 12(b), and persons who import a chemical substance identified in a final SNUR are subject to the TSCA section 13 import certification requirements. See also <https://www.epa.gov/tsca-import-export-requirements>.

E. Applicability of the Proposed SNURs to Uses Occurring Before the Effective Date of the Final Rule

To establish a significant new use, EPA must determine that the use is not ongoing. For one of the SNURs addressed in this proposed rule, EPA is proposing to designate as a "significant new use" additional uses that are not currently specifically designated as a significant new use under the SNURs, but which would be designated as a significant new use requiring notification if this proposed rule is finalized. EPA solicits comments on whether any of these uses are ongoing. These specific significant new uses are:

- For the SNUR at 40 CFR 721.10471, (1) use without personal protective equipment when workers are dermally exposed to the chemical substance; (2) use without a National Institute for Occupational Safety and Health (NIOSH)-certified respirator with an assigned protection factor (APF) of at least 50 when workers are exposed by inhalation to the chemical substance; (3) manufacture of the chemical substance in any manner that results in inhalation exposure; (4) release of the chemical substance resulting in surface water concentrations that exceed 11 ppb; (5) use of the chemical substance in a consumer product; and (6) use of the chemical substance without establishing a hazard communication program.

EPA will not determine that a use is a "significant new use" if information reasonably available to the Agency, including that received during the period for public comment, establishes that the use is ongoing at the time the proposed rule is published in the **Federal Register**. It is therefore incumbent on any entity who believes they have an ongoing use to inform EPA of that fact during the comment period for a proposed SNUR. If a use that was

not identified during the comment period is subsequently demonstrated to have been ongoing at the time the proposed rule was published, such information should be brought to EPA's attention immediately.

Persons who begin manufacture or processing of the chemical substances for a significant new use identified on or after the designated cutoff date specified in Unit III.A. would have to cease any such activity upon the effective date of the final rule. To resume their activities, these persons would have to first comply with all applicable SNUR notification requirements and EPA would have to take action under TSCA section 5 allowing manufacture or processing to proceed.

F. Important Information About SNUN Submissions

1. SNUN Submissions

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 <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca>.

2. Development and Submission of Information

EPA recognizes that TSCA section 5 does not require development of any particular new information (e.g., generating test data) before submission of a SNUN. There is an exception: If a person is required to submit information for a chemical substance pursuant to a rule, order or consent agreement under TSCA section 4, then TSCA section 5(b)(1)(A) requires such information to be submitted to EPA at the time of submission of the SNUN.

In the absence of a rule, TSCA order, or consent agreement under TSCA section 4 covering the chemical substance, persons are required only to submit information in their possession or control and to describe any other information known to or reasonably ascertainable by them (see 40 CFR 720.50 or 40 CFR 725.160 [for microorganisms]). However, upon review of PMNs and SNUNs, the Agency has the authority to require appropriate testing. To assist with EPA's analysis of the SNUN, submitters are encouraged, but not required, to provide the potentially useful information identified for the chemical substance in Unit III.C.

EPA strongly encourages persons, before performing any testing, to consult

with the Agency pertaining to protocol selection. Furthermore, pursuant to TSCA section 4(h), which pertains to reduction of testing in vertebrate animals, EPA encourages consultation with the Agency on the use of alternative test methods and strategies (also called New Approach Methodologies, or NAMs), if available, to generate the recommended test data. EPA encourages dialog with Agency representatives to help determine how best the submitter can meet both the data needs and the objective of TSCA section 4(h). For more information on alternative test methods and strategies to reduce vertebrate animal testing, visit <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/alternative-test-methods-and-strategies-reduce>.

The potentially useful information described in Unit III. may not be the only means of providing information to evaluate the chemical substance associated with the significant new uses. However, submitting a SNUN without any test data may increase the likelihood that EPA will take action under TSCA sections 5(e) or 5(f). 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 substances.

III. Chemical Substances Subject to These Significant New Use Rule Amendments and Proposed Changes

A. What is the designated cutoff date for determining whether the new use is ongoing for these chemical substances?

EPA designates October 28, 2025 as the cutoff date for determining whether the new use is ongoing. This designation is explained in more detail in Unit II.E.

B. What information is provided for each chemical substance?

For each chemical substance identified in Unit III.C., EPA provides the following information:

- CFR citation for the existing SNUR that EPA is proposing to amend.
- PMN (or MCAN) and SNUN number(s), as applicable.
- Chemical name (generic name, if the specific name is claimed as CBI).
- Chemical Abstracts Service Registry Number (CASRN) (if assigned for non-confidential chemical identities).

- **Federal Register** citation(s) for the previously issued final rule(s).
- Basis for the proposed amendment.

C. Which chemical substances are subject to the proposed amendments?

The substances subject to the proposed amendments presented in this document are as follows:

CFR citation: 40 CFR 721.1725.

PMN and SNUN number(s): P-82-438.

Chemical name: Benzoic acid, 3,3'-methylenebis [6 amino-, di-2-propenyl ester.

CASRN: 61386-02-5.

Final rule FR citation(s): May 6, 1986 (51 FR 16687) (FRL-2926-9).

Basis for the proposed amendment: Certain new chemical SNURs have a significant new use designation that is based on confidential business information (CBI) in a PMN or other TSCA section 5 notice and therefore, not disclosed in the published SNUR. In the **Federal Register** of May 6, 1986 (51 FR 16687), EPA promulgated a procedure at 40 CFR 721.1725(b)(1) under which a manufacturer or processor could request that EPA determine whether a specific use would be a significant new use under the rule. The procedure required a manufacturer or processor to establish a *bona fide* intent to manufacture or process the chemical substance and to identify the specific use for which it intended to manufacture or process the chemical substance. Many subsequent SNURs with confidential significant new uses include a cross-reference to the provisions of 40 CFR 721.1725(b)(1).

In the **Federal Register** of July 5, 2022 (87 FR 39756) (FRL-5605-02-OCSPP), EPA finalized updates to the regulations governing significant new uses of chemical substances under TSCA. This rule modified the existing *bona fide* procedure for CBI chemical identities in 40 CFR 721.11 to apply to all SNURs containing any CBI, including the significant new use. Accordingly, the previous procedure at 40 CFR 721.1725(b)(1) is now obsolete and unnecessary. EPA is proposing to amend this SNUR to replace the *bona fide* procedure at paragraph (b)(1) with a statement directing readers to the updated regulations at 40 CFR 721.11.

Potentially useful information: None.

CFR citation: 40 CFR 721.2076.

PMN and SNUN number(s): P-00-7, SN-5-1, SN-06-4, SN-07-3, SN-07-5.

Chemical name: D-Glucuronic acid, polymer with 6-deoxy-L-mannose and D-glucose, acetate, calcium magnesium potassium sodium salt.

CASRN: 595585-15-2.

Final rule FR citation(s): December 17, 2003 (80 FR 37165) (FRL-9928-93).

Basis for the proposed amendment: The proposed amendment to the SNUR would amend the CASRN of the chemical substance from 125005-87-0 to 595585-15-2. The change was agreed upon between EPA and the PMN submitter in order to incorporate sufficient information to adequately and uniquely identify the polysaccharide gum produced by the fermentation of a particular bacteria.

Potentially useful information: None.

CFR citation: 40 CFR 721.10070.

PMN and SNUN number(s): P-05-309, SN-13-4.

Chemical name: 1,3-Butanediol, 3-methyl-

CASRN: 2568-33-4.

Final rule FR citation(s): September 19, 2007 (72 FR 53483) (FRL-8135-8).

Basis for the proposed amendment: P-05-309 states that the PMN substance will be used as an inkjet ink. Based on test data on the PMN substance and on analogous chemicals, EPA predicted concerns for developmental toxicity, liver toxicity, blood/immune system effects and possibly digestive tract and kidney effects. EPA did not determine that the proposed processing or use of the substance may present an unreasonable risk. EPA did determine, however, that domestic manufacture or use of the substance other than as described in the PMN may cause serious health effects. Based on this information, the PMN substance met the concern criteria at § 721.170(b)(1)(i)(C), (b)(3)(ii), and (b)(4)(ii). On September 19, 2007, EPA issued a SNUR for P-05-309 which included the following significant new uses: domestic manufacture and use other than the use in the PMN.

On January 30, 2013, EPA received SNUN S-13-4 for use as a fixing agent of ink for inkjet printers. EPA determined that the new use will not present an unreasonable risk of injury to human health. The proposed amendment to the SNUR would remove use as a fixing agent of ink for inkjet printers from the scope of the significant new use and would require notification for any uses not listed in the SNUR or PMN.

Potentially useful information: EPA has determined that certain information may be potentially useful if a manufacturer or processor is considering submitting a SNUN for a significant new use designated by this SNUR. EPA has determined that the results of developmental or chronic toxicity testing may be potentially useful to characterize the health effects of the substance.

CFR citation: 40 CFR 721.10471.

PMN and SNUN number(s): P-03-622, SN-17-5, SN-20-7, SN-21-4, SN-23-7.

Chemical name: 2-Propenoic acid, 1,1'-(3-methyl-1,5-pentanediy) ester.
CASRN: 64194-22-5.

Final rule FR citation(s): September 21, 2012 (77 FR 58698) (FRL-9357-2).

Basis for the proposed amendment: P-03-622 states that the generic (non-confidential) use of the substance will be as a component of a UV coating agent. For P-03-622, based on structure activity relationships (SAR) analysis of test data on analogous acrylates, EPA identified concerns for oncogenicity, mutagenicity, sensitization, irritation to membranes, and developmental toxicity. In addition, based on Ecological Structure Activity Relationships (EcoSAR) analysis of test data on analogous acrylates, EPA predicted toxicity to aquatic organisms may occur if releases of the substance to surface waters, from uses other than as described in the PMN, exceed releases from the assessed use described in the PMN. As stated in the PMN, the substance will be imported and not manufactured in the United States. For the use identified in the PMN, significant worker exposures are not expected during processing and use activities and significant environmental releases are not expected. Therefore, EPA did not determine that the proposed processing or use of the substance may present an unreasonable risk. EPA determined, however, that domestic manufacture or use of the substance other than as described in the PMN may cause serious health effects and significant adverse environmental effects. Based on this information, the PMN substance met the concern criteria at § 721.170(b)(1)(i)(C), (b)(3)(ii), and (b)(4)(ii). On September 21, 2012, EPA issued a SNUR for P-03-622 which included the following significant new uses: domestic manufacture and use other than as described in the PMN (generically, use as a component of a UV coating agent). EPA also recommended certain human health and environmental toxicity testing in the SNUR.

On January 27, 2017, EPA received SNUN SN-17-5 for use as a monomer used in production of UV curable coatings and printing inks. After review of SN-17-5, information available to EPA indicated that there is a potential for human or environmental exposure to the SNUN substance, that the SNUN substance may present a risk to workers exposed via the dermal route for irritation, sensitization, and other toxicological endpoints, and the SNUN substance may present a risk to aquatic

organisms if released to water in sufficient quantity. On August 2, 2017, EPA issued an Order for SN-17-5 under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health and the environment. The submitter of SN-17-5 is subject to the following Order requirements:

- Submittal to EPA of certain human health and environmental toxicity testing before manufacturing (including import) a total of 61,000 kilograms of the substance;
- Use of a NIOSH-certified full-facepiece respirator with an APF of at least 50 where there is a potential for inhalation exposure;
- Use of personal protective equipment including impervious gloves where there is a potential for dermal exposure;
- Establishment of a hazard communication program, including human health precautionary, statements on each label and in the SDS;
- No release of the substance, or any waste stream containing the substance, resulting in surface water concentrations that exceed 1 part per billion (ppb);
- Use the substance only as a monomer for use in production of UV curable coatings and printing inks; and
- Manufacture of the substance only by import into the United States (*i.e.*, no domestic manufacture).

On July 21, 2020, EPA received SNUN SN-20-7 for domestic manufacturing and use as a component of UV curable coatings and printing inks. After review of SN-20-7, information available to EPA indicates that there is a potential for human or environmental exposure to the SNUN substance and that the SNUN substance may present a risk to workers exposed via the dermal route for local dermal effects and skin sensitization, may present a risk to workers exposed via the inhalation route for irritation, sensitization and respiratory effects, and may present risk to aquatic organisms from chronic exposure to the environment based on the chronic COC of 12 ppb being during use. Therefore, EPA determined according to TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I) that the new uses may present an unreasonable risk to human health and that an Order was required to protect against those risks. On September 18, 2023, EPA issued an Order for SN-20-7 under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a

reasoned evaluation, the substance may present an unreasonable risk of injury to human health and the environment. The submitter of SN-20-7 and the submitter's two confidential joint submitters are subject to the following Order requirements:

- Use of personal protective equipment where there is a potential for dermal exposure;
- Use of a NIOSH-certified respirator with an APF of at least 50 where there is a potential for inhalation exposure;
- No release of the substance resulting in surface water concentrations that exceed 12 ppb;
- No use of the substance in a consumer product;
- No use of the substance other than as a component of UV curable coatings and printing inks or for the additional confidential use listed in the Order; and
- Establishment of a hazard communication program, including human health precautionary statements, on each label and in the SDS.

The submitter of SN-20-7 and the submitter's two confidential joint submitters are permitted to manufacture the substance domestically in accordance with the requirements listed above.

On March 31, 2021, EPA received SNUN SN-21-4 for the generic use as a monomer. Based on submitted test data on the substance, information provided in the SDS, and comparison to analogous chemical substances, EPA has identified concerns for acute inhalation toxicity; irritation to eyes, skin, and respiratory tract; skin sensitization; systemic effects; and developmental effects. Based on physical/chemical properties of the substance, EPA also identified concerns for aspiration hazard. Based on the bifunctional reactive groups (terminal alkenes) indicating potential for protein crosslinking, EPA has also identified concerns for respiratory sensitization. Based on comparison to analogous acrylates and methacrylates, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 12 ppb. On August 16, 2022, EPA issued an Order for SN-21-4 under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health and the environment. The submitter of SN-21-4 is subject to the following Order requirements:

- Use of personal protective equipment where there is a potential for dermal exposure;

- Use of a NIOSH-certified respirator with an APF of at least 50 where there is a potential for inhalation exposure;
- No release of the substance resulting in surface water concentrations that exceed 12 ppb;
- No use of the substance in a consumer product;
- No use of the substance other than for the confidential use listed in the Order; and
- Establishment of a hazard communication program, including human health precautionary statements, on each label and in the SDS.

On January 9, 2023, EPA received SNUN SN-23-7 for use as a component of UV curable coatings and printing inks, manufacturing additive, adhesives, composites, 3D printing, and coating systems. Based on test data on the substance and information provided in the SDS, EPA has identified concerns for acute inhalation toxicity; irritation to eyes, skin, and respiratory tract; skin sensitization; systemic effects; and developmental effects. Based on analogous data, EPA also identified concerns for respiratory effects. Based on the bifunctional reactive groups, EPA identified concerns for respiratory sensitization. Based on acute and chronic toxicity data on the SNUN substance, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 11 ppb. On July 19, 2024, EPA issued an Order for SN-23-7 under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health and the environment. The submitter of SN-23-7 is subject to the following Order requirements:

- Use of personal protective equipment where there is a potential for dermal exposure;
- Use of a NIOSH-certified respirator with an APF of at least 50 where there is a potential for inhalation exposure;
- No manufacture in any manner that results in inhalation exposure to the substance;
- No release of the substance resulting in surface water concentrations that exceed 11 ppb;
- No use of the substance in a consumer product;
- No use of the substance other than for use as a component of UV curable coatings and printing inks, additive manufacturing, adhesives, composites, 3D printing, and coating systems; and
- Establishment of a hazard communication program, including human health precautionary statements on each label and in the SDS.

The proposed amendment to the SNUR would remove domestic manufacture and use of the substance other than as described in PMN P-03-622 (including a confidential use) from the significant new uses, allowing these conditions of use to occur without notification to EPA. The proposed amendment would instead designate the following activities as significant new uses: (1) use without worker personal protective equipment for dermal protection; (2) use without worker PPE of a NIOSH-certified respirator with an APF of at least 50; (3) use of the chemical substance without establishing a hazard communication program; (4) release of the chemical substance to water resulting in surface water concentrations that exceed 11 ppb; (5) manufacture of the chemical substance in any manner that results in inhalation exposure; (6) use other than as a component of UV curable coatings and printing inks, additive manufacturing, adhesives, composites, 3D printing, and coating systems; and (7) use of the chemical substance in a consumer product. Additionally, the amendment would add an exemption from the SNUR requirements when the substance has been completely reacted or cured.

Potentially useful information: EPA has determined that certain information may be potentially useful if a manufacturer or processor is considering submitting a SNUN for a significant new use designated by this SNUR. EPA has determined that the results of aquatic toxicity testing may be potentially useful to characterize the environmental effects of the SNUN substance.

CFR citation: 40 CFR 721.10966.

PMN and SNUN number(s): P-14-260.

Chemical name: 1-Propene, 2-bromo-3,3,3-trifluoro-.

CASRN: 1514-82-5.

Final rule FR citation(s): September 21, 2017 (82 FR 44093) (FRL-9959-81).

Basis for the proposed amendment: P-14-260 states that the substance will be used as a fire extinguishing agent for: portable extinguishers (onboard aviation and all nonresidential); niche systems (aircraft, normally unoccupied systems, self-contained automatic fire extinguishing systems); and streaming systems for aircraft rescue fire fighting vehicles. Based on test data on the PMN substance, EPA identified concerns for reproductive effects for unprotected workers from repeated inhalation exposures. An Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I), based on a finding that the substance may present an

unreasonable risk of injury to human health and the environment. The submitter of P-14-260 was subject to the following Order requirements:

- Manufacture of the substance only by import into the United States (*i.e.*, no domestic manufacture);
- Use of personal protective equipment including a National Institute for Occupational Safety and Health (NIOSH)-certified respirator with an assigned protection factor (APF) of at least 10 or compliance with a new chemical exposure limit (NCEL) of 1.0 parts per million (ppm) as an 8-hour time-weighted average, when there is a potential for inhalation exposures;
- Establishment and use of a hazard communication program, including human health precautionary statements, on each label and in the Safety Data Sheet (SDS);
- Processing (including filling of hand-held fire extinguishers or fire extinguishing systems) of the PMN substance only in an enclosed process; and
- Use only as either (1) total flooding agent in unoccupied spaces, specifically engine nacelles and auxiliary power units (APUs) in aircraft; or (2) streaming fire extinguishing agent for use only in handheld extinguishers in aircraft.

On September 21, 2017, EPA issued a SNUR designating significant new uses based on and consistent with the Order requirements.

On April 20, 2018, EPA received a request from the PMN submitter to modify the Order to allow two additional uses: streaming in all non-residential uses (except for commercial home office and personal watercraft), and niche flooding application for unoccupied spaces, such as “not normally occupied volumes” up to 500 ft³ (*e.g.*, large data storage rooms). EPA assessed exposures from the proposed new uses and determined that exposures and risk—*i.e.*, acceptable risks, except for filling of canisters, which is controlled under the original Order—from the proposed new uses are the same as for the original uses identified in P-14-260. As a result, EPA modified the Order. Accordingly, the proposed amendment to the SNUR would reduce the scope of the significant new uses to exclude the two additional uses.

Potentially useful information: EPA has determined that certain information may be potentially useful if a manufacturer or processor is considering submitting a SNUN for a significant new use designated by this SNUR. EPA has determined that inhalation monitoring data, collected according to EPA’s draft Inhalation

Monitoring Data Collection Guidelines (available in the docket for this rulemaking), may be potentially useful to characterize the human health effects of the substance.

CFR citation: 40 CFR 721.11180.

PMN and SNUN number(s): P-17-283.

Chemical name: Arenesulfonic acid, alkyl derivatives, metal salts (generic).

CASRN: Not Available.

Final rule FR citation(s): December 5, 2019 (84 FR 66596) (FRL-10001-47).

Basis for the proposed amendment: P-17-283 states that the substance will be used as a lubricating oil additive for automotive engine oils. Based on analysis of test data on the substance, EPA identified a concern for corrosion to skin, eyes, mucous membranes, and lungs. There are also concerns for surfactant effects on the lung based on surfactant properties of the compounds and for acute toxicity, mutagenicity, irritation, and sensitization based on submitted analogue test data. An Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health and the environment. The Order was also issued under TSCA sections 5(a)(3)(B)(ii)(II) and 5(e)(1)(A)(ii)(II), based on a finding that the substance is or will be produced in substantial quantities and that the substance either enters or may reasonably be anticipated to enter the environment in substantial quantities, or there is or may be significant (or substantial) human exposure to the substance. The submitter of P-17-283 is subject to the following Order requirements:

- Submittal to EPA of certain toxicity testing within six months of filing a notice of commencement (NOC) to EPA;
- Use of personal protective equipment where there is a potential for dermal exposure;
- Establishment of a hazard communication program, including human health precautionary statements on each label and in the SDS; and
- No manufacture, processing, or use of the substance in any manner that produces a vapor, mist, spray or aerosol.

The Order also prohibited the company from manufacturing the substance six months after filing a notice of commencement with the EPA unless the company conducts sensitization testing. On December 5, 2019, EPA issued a SNUR designating significant new uses based on and consistent with the Order requirements.

On September 14, 2018, the PMN submitter submitted the results of sensitization testing conducted as required by the Order. EPA concluded, upon review of the test data, that the substance is a sensitizer. On January 23, 2020, EPA received a request from the PMN submitter to revise the SNUR to remove the significant new use requiring notification for manufacture of the substance beyond 6 months because the Local Lymph Node Assay was completed on the PMN substance. The proposed amendment to the SNUR would remove this significant new use.

Potentially useful information: EPA has determined that certain information may be potentially useful if a manufacturer or processor is considering submitting a SNUN for a significant new use designated by this SNUR. EPA has determined that the results of physical-chemical properties and acute and chronic pulmonary toxicity testing may be potentially useful to characterize the health effects of the substance.

CFR citation: 40 CFR 725.1080.

MCAN number: J-19-1.

Chemical name: Trichoderma reesei (generic).

CASRN: Not Available.

Final rule FR citation(s): April 30, 2021 (86 FR 22875) (FRL-10016-30).

Basis for the proposed amendment: EPA included references to 40 CFR part 721 sections 125 and 185 in the SNUR for this microorganism. Equivalent sections exist in the regulations under part 725 which are more appropriate for SNURs for microorganisms. The proposed amendment would modify the SNUR to reference the recordkeeping requirements specified at 725.950(b)(2) through (4) (rather than 721.125(a) through (c)) and the provisions of 725.984 (rather than 721.185). The proposed amendment would also require recordkeeping to document compliance with applicable limitations in paragraph (a)(2) of the SNUR rather than the requirement to keep records as described in 721.125(i).

Potentially useful information: None.

IV. Statutory and Executive Order Reviews

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

A. Executive Order 12866: Regulatory Planning and Review

This action proposes to modify SNURs for chemical substances that were the subject of PMNs or MCANs. The Office of Management and Budget (OMB) has exempted these types of

actions from review under Executive Order 12866 (58 FR 51735, October 4, 1993).

B. Executive Order 14192: Unleashing Prosperity Through Deregulation

Executive Order 14192 (90 FR 9065, February 6, 2025) does not apply because a significant new use rule for a chemical under TSCA section 5 is exempted from review under Executive Order 12866.

C. Paperwork Reduction Act (PRA)

According to the 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.

The information collection requirements related to SNURs have already been approved by OMB pursuant to PRA under OMB control number 2070-0038 (EPA ICR No. 1188). 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 submission. 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.

EPA always welcomes your feedback on the burden estimates. When submitting comments on these proposed SNURs, include comments about the accuracy of the burden estimate, and any suggested methods for improving the collection instruments or instruction or minimizing respondent burden, including through the use of automated collection techniques.

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA (5 U.S.C. 601 *et seq.*). 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, EPA has concluded 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 SNURs covering over 1,000 chemicals, the Agency receives only a small number of notices per year. For example, the number of SNUNs received was 9 in fiscal year FY2022, 23 in FY2023, and 7 in FY2024, and only a fraction of these submissions was from small businesses.

In addition, the Agency currently offers relief to qualifying small businesses by reducing the SNUN submission fee from \$37,000 to \$6,480. This lower fee reduces the total reporting and recordkeeping cost of submitting a SNUN to about \$14,500 per SNUN submission for qualifying small firms. Therefore, the potential economic impacts of complying with these proposed 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 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.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of \$100 million or more (in 1995 dollars) in any one year as described in UMRA, 2 U.S.C. 1531-1538, and does not significantly or uniquely affect small governments. Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by SNURs, and EPA does not have any reasons to believe that any State, local, or Tribal government will be impacted by these SNURs. In addition, the estimated costs of this action to the private sector do not exceed \$183 million or more in any one year (the 1995 dollars are adjusted to 2023 dollars for inflation using the GDP implicit price deflator). The estimated costs for this action are discussed in Unit I.D.

F. Executive Order 13132: Federalism

This action will not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it is not expected to 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. Accordingly, the requirements of Executive Order 13132 do not apply to this action.

G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action will not have Tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000), because it is not expected to have substantial direct effects on Indian Tribes, significantly or uniquely affect the communities of Indian Tribal governments and does not involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of Executive Order 13175 do not apply to this action.

H. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it does not concern an environmental health or safety risk. Since this action does not concern a human health risk, EPA's 2021 Policy on Children's Health also does not apply. Although the establishment of these SNURs do not address an existing children's environmental health concern because the chemical uses involved are not ongoing uses, SNURs require that persons notify EPA at least 90 days before commencing manufacture (defined by statute to include import) or processing of the identified chemical substances for an activity that is designated as a significant new use by the SNUR. This notification allows EPA to assess the intended uses to identify potential risks and take appropriate actions before the activities commence.

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

This action is not a "significant energy action" as defined in Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

J. National Technology Transfer and Advancement Act (NTTAA)

This action does not involve any technical standards subject to NTTAA section 12(d) (15 U.S.C. 272 note).

List of Subjects in 40 CFR Part 721 and 725

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

Dated: October 21, 2025.

Mary Elissa Reaves,

Director, Office of Pollution Prevention and Toxics.

For the reasons stated in the preamble, EPA proposes to amend 40 CFR chapter I as follows:

PART 721—SIGNIFICANT NEW USES OF CHEMICAL SUBSTANCES

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

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

■ 2. Amend § 721.1725 by revising paragraph (b) to read as follows:

§ 721.1725 Benzoic acid, 3,3'-methylenebis [6-amino-, di-2-propenyl ester.

- (a) * * *
- (1) * * *
- (2) * * *
- (b) * * *

(1) *Determining whether a specific use is subject to this rule.* The provisions of § 721.11 apply to paragraph (a)(1) of this section and to chemical substances which are subject to a significant new use rule in subpart E of this part.

- (2) * * *

■ 3. Amend § 721.2076 by revising paragraph (a)(1) to read as follows:

§ 721.2076 D-Glucuronic acid, polymer with 6-deoxy-L-mannose and D-glucose, acetate, calcium magnesium potassium sodium salt.

- (a) * * *

(1) The chemical substance identified as D-glucuronic acid, polymer with 6-deoxy-L-mannose and D-glucose, acetate, calcium magnesium potassium sodium salt (PMN P-00-7; SNUNs S-05-1, S-06-4, S-07-03, and S-07-5; CAS No. 595585-15-2) is subject to reporting under this section for the significant new use described in paragraph (a)(2) of this section.

- (2) * * *
- (i) * * *
- (ii) * * *
- (b) * * *
- (1) * * *
- (2) * * *

■ 4. Amend § 721.10070 by revising paragraphs (a)(1) and (a)(2)(i) to read as follows:

§ 721.10070 1,3-Butanediol, 3-methyl-

(a) * * *

(1) The chemical substance identified as 1,3-butanediol, 3-methyl- (PMN P-05-309; SNUN S-13-4; CAS No. 2568-33-4) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) * * *

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80 (f). It is a significant new use to use the substance other than as inkjet ink or as a fixing agent of ink for inkjet printers.

(ii) * * *

(b) * * *

(1) * * *

(2) * * *

■ 5. Revise and republish § 721.10471 to read as follows:

§ 721.10471 2-Propenoic acid, 1,1'-(3-methyl-1,5-pentanediyl) ester.

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

(1) The chemical substance identified as 2-propenoic acid, 1,1'-(3-methyl-1,5-pentanediyl) ester (PMN P-03-622; SNUNs S-17-5, S-20-7, S-21-4, and S-23-7; CAS No. 64194-22-5) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the chemical substance after they have been completely reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.*

Requirements as specified in § 721.63(a)(1), (3) through (6), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) and (4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 50.

(ii) *Hazard communication.*

Requirements as specified in § 721.72(a) through (d), (f), (g)(1), (3)(iii), and (5). For purposes of § 721.72(g)(1), this substance may cause: acute toxicity (inhalation only), skin irritation, eye

irritation, respiratory sensitization, skin sensitization, specific target organ toxicity, and aspiration hazard. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o). It is a significant new use to manufacture the substance in any manner that results in inhalation exposure to the substance. It is a significant new use to use the substance other than as a component of UV curable coatings and printing inks, additive manufacturing, adhesives, composites, 3D printing, and coating systems.

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where N=11.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) and (k) are applicable to manufacturers (including importers) and processors of this substance.

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

■ 6. Amend § 721.10966 by revising paragraphs (a)(2)(iii) to read as follows:

§ 721.10966 1-Propene, 2-bromo-3,3,3-trifluoro-

(a) * * *

(1) * * *

(2) * * *

(i) * * *

(A) * * *

(1) * * *

(2) * * *

(3) * * *

(4) * * *

(5) * * *

(B) * * *

(ii) * * *

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(c) and (f). It is a significant new use to use the substance other than as a fire extinguishing agent as a total flooding agent in unoccupied spaces, specifically engine nacelles and auxiliary power units (APUs) in aircraft; as a streaming fire extinguishing agent for use only in handheld extinguishers

in aircraft; streaming in all non-residential uses, except for commercial home office and personal watercraft; or niche flooding application for unoccupied spaces, such as “not normally occupied volumes” up to 500 ft³ (e.g., large data storage rooms).

(b) * * *

(1) * * *

(2) * * *

■ 7. Amend § 721.11180 by revising paragraph (a)(2)(iii) to read as follows:

§ 721.11180 Arenesulfonic acid, alkyl derivatives, metal salts (generic).

(a) * * *

(1) * * *

(2) * * *

(i) * * *

(ii) * * *

(iii) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture, process, or use the substance in any manner that results in the generation of a vapor, mist, spray, or aerosol.

(b) * * *

(1) * * *

(2) * * *

PART 725—SIGNIFICANT NEW USES OF MICROORGANISMS

■ 8. The authority citation for part 725 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, 2613, and 2625.

■ 9. Amend § 725.1080 by revising paragraphs (b)(1) and (2) to read as follows:

§ 725.1080 Trichoderma reesei (generic).

(a) * * *

(1) * * *

(2) * * *

(i) * * *

(ii) * * *

(b) * * *

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 725.950(b)(2) through (4) and a requirement to maintain records documenting compliance with limitations in paragraph (a)(2) are applicable to manufacturers and processors of this microorganism.

(2) *Modification or revocation of certain notification requirements.* The provisions of § 725.984 apply to this section.

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