



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[EPA-HQ-OPPT-2024-0359; FRL-12342-01-OCSPP]

RIN 2070-AB27

Significant New Use Rules on Certain Chemical Substances (24-1.F)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing significant new use rules (SNURs) under the Toxic Substances Control Act (TSCA) for certain chemical substances that were the subject of premanufacture notices (PMNs). The chemical substances received “not likely to present an unreasonable risk” determinations pursuant to TSCA. The SNURs require persons who intend to manufacture (defined by statute to include import) or process any of these chemical substances for an activity that is proposed as a significant new use by this rulemaking to notify EPA at least 90 days before commencing that activity. The required notification initiates EPA’s evaluation of that use, under the conditions of use for that chemical substance. In addition, the manufacture or processing for the significant new use may not commence until EPA has conducted a review of the required notification, made an appropriate determination regarding that notification, and taken such actions as required by that determination.

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-2024-0359, 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: Geraldine Hilton, New Chemicals Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-8986; email address: Hilton.Geraldine@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-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (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.).

B. What action is the Agency taking?

EPA is proposing SNURs for chemical substances that were the subject of PMNs as discussed in Unit III. These SNURs, if finalized as proposed, would require persons who intend to manufacture or process any of these chemical substances for an activity that is designated as a significant new use to notify EPA at least 90 days before commencing that activity.

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/tsca-import-export-requirements>).

Chemical importers are subject to TSCA section 13 (15 U.S.C. 2612), the requirements promulgated at 19 CFR 12.118 through 12.127, 19 CFR 127.28, and the EPA policy in support of import certification 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, any persons who export or intend to export a chemical substance that is the subject of this proposed rule on or after **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** are subject to 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?*

EPA has evaluated the potential costs of establishing SNUN reporting requirements for potential manufacturers (including importers) and processors of the chemical substances subject to these proposed SNURs. This analysis, which is available in the docket, is briefly summarized

here.

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/dockets/commenting-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 what would constitute a significant new use for the chemical substances that are the subject of these SNURs, EPA considered relevant information about the toxicity of the chemical substances, and potential human exposures and environmental releases that may be associated with the substances, in the context of the four bulleted TSCA section 5(a)(2) factors listed in this unit and discussed in Unit III.

These proposed SNURs include PMN substances that received a "not likely to present an

unreasonable risk” determination in TSCA section 5(a)(3)(c). During its review of these chemicals, EPA identified certain conditions of use that are not intended by the submitters, but reasonably foreseen to occur. EPA is proposing to designate those conditions of use as significant new uses.

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.

During review of the PMNs submitted for the chemical substances that are the subject of these proposed SNURs and as further discussed in Unit III., EPA identified certain other conditions of use, in addition to those conditions of use intended by the submitter. EPA has determined that the chemical under the conditions of use is not likely to present an unreasonable risk. However, EPA has not assessed risks associated with certain conditions of use. EPA is proposing to designate these other circumstances of use as significant new uses. As a result, those significant new uses cannot occur without going through a separate, subsequent EPA review and determination process associated with a SNUN.

2. Objectives.

EPA is proposing these SNURs because the Agency wants:

- To be able to complete its review and determination on each of the PMN substances, while deferring analysis on the significant new uses proposed in these rules unless and until the Agency receives a SNUN.
- 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 proposed 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.

EPA is proposing to establish 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. 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 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 and must identify the specific use for which it intends 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 most of the chemical identities of the chemical substances subject to these SNURs are also CBI, manufacturers and processors can combine the *bona fide* submission 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. 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), persons subject to SNURs must comply with the same 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 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. 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. The chemical substances subject to this proposed rule have undergone premanufacture review. In cases where EPA has not received a notice of commencement (NOC) and the chemical substance has not been added to the TSCA Inventory, no person may commence such activities without first submitting a PMN. Therefore, for chemical substances for which an NOC has not been submitted EPA concludes that the designated significant new uses are not ongoing. The identities of many of the chemical substances subject to this proposed rule have been claimed as confidential per 40 CFR 720.85 and the PMN submitter did not intend to engage in the other circumstances of use that are designated as significant new uses for the chemical substances subject to this proposed rule. Based on this, the Agency believes that it is highly unlikely that any of the significant new uses identified in Unit III. are ongoing.

When the chemical substances identified are added to the TSCA Inventory, EPA recognizes that, before the rule is effective, other persons might engage in a use that has been identified as a significant new use. 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). 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 Proposed SNURs

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

EPA designates **[INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]** 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:

- PMN number (the proposed CFR citation assigned in the regulatory text section of this document).
- 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).
- Basis for the SNUR.
- Potentially useful information.

The regulatory text section of this document specifies the activities designated as significant new uses. Certain new uses, including production volume limits and other uses designated in the proposed rules, may be claimed as CBI.

The chemical substances have undergone premanufacture review. In addition to those

conditions of use intended by the submitter, EPA has identified certain other circumstances of use. EPA has preliminarily determined that the chemicals under their conditions of use are not likely to present an unreasonable risk. However, EPA has not assessed risks associated with the other circumstances of use for these chemicals. EPA is proposing to designate these other circumstances of use as significant new uses. As a result, those significant new uses cannot occur without first going through a separate, subsequent EPA review and determination process associated with a SNUN.

C. Which chemical substances are subject to this proposed rule?

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

PMN Number (proposed CFR citation): P-20-168 (40 CFR 721.11955).

Chemical Name: Polyolefin polyamine succinimide, carbopolycycle alkoxyated (generic).

CASRN: Not available.

Basis for Action: The PMN states that the use of the PMN substance will be as a lubricating additive for engine oils, transmission and hydraulic fluid, and gear oil applications. Based on comparison to analogous chemical substances and the structural alert for aliphatic amines, EPA has identified concerns for irritation to the eyes, skin, and respiratory tract if the chemical substance is not used following the limitation noted. The conditions of use of the PMN substance as described in the PMN include the following protective measure:

- Use of the PMN substance only as a lubricating additive for engine oils, transmission and hydraulic fluid, and gear oil applications.

The proposed SNUR would designate as a “significant new use” the absence of this protective measure.

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

characterize the health effects of the PMN substance.

PMN Number (proposed CFR citation): P-21-5 (40 CFR 721.11956).

Chemical Name: Carbonmonocyclic alkene polymer with alkyl alkenoate, alkyl alkenoate, alkyl alkenoate and polyalkyldiene alkenoate (generic).

CASRN: Not available.

Basis for Action: The PMN states that the use of the PMN substance will be as a polymeric additive in gear oils. Based on comparison to analogous chemical substances, information provided in the Safety Data Sheet (SDS), and physical/chemical properties, EPA has identified concerns for skin and eye irritation and lung effects (lung overload) if the chemical substance is not used following the limitation noted. The conditions of use of the PMN substance as described in the PMN include the following protective measure:

- No manufacture, processing, or use of the PMN substance in any manner that results in worker inhalation exposure to the PMN substance.

The proposed SNUR would designate as a “significant new use” the absence of this protective measure.

Potentially Useful Information: EPA has determined that certain information may be potentially useful to characterize the health effects of the PMN substance if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of skin irritation, eye irritation, and specific target organ toxicity testing may be potentially useful to characterize the health effects of the PMN substance.

PMN Number (proposed CFR citation): P-21-95 (40 CFR 721.11957).

Chemical Name: 1-tetradecene, homopolymer, hydrogenated, by-products from, C28-42 fraction.

CASRN: 2263959-83-5.

Basis for Action: The PMN states that the use of the PMN substance will be as a base oil for crankcase motor oil, transmission oil, and other industrial applications such as compressor and gear fluids and consumer use as a carrier fluid for additives to motor oils and automatic

transmission fluids. Based on comparison to an analogous chemical substance and on physical/chemical properties, EPA has identified concerns for blood, respiratory tract, and lung effects including aspiration hazard if the chemical substance is not used following the limitation noted. The conditions of use of the PMN substance as described in the PMN include the following protective measure:

- No processing of the PMN substance other than in an enclosed system when heated.

The proposed SNUR would designate as a “significant new use” the absence of this protective measure.

Potentially Useful Information: EPA has determined that certain information may be potentially useful to characterize the health effects of the PMN substance if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of specific target organ toxicity and pulmonary effects testing may be potentially useful to characterize the health effects of the PMN substance.

PMN Number (proposed CFR citation): P-21-174 (40 CFR 721.11958).

Chemical Name: Carbonic acid, ester, polymer with alkanediol (C=4,5) (generic).

CASRN: Not available.

Basis for Action: The PMN states that the generic (non-confidential) use of the PMN substance will be as a raw material for polyurethane. Based on test data submitted on the PMN substance, EPA has identified concerns for aquatic toxicity if the chemical substance is not used following the limitation noted. The condition of use of the PMN substance as described in the PMN includes the following protective measure:

- No release of the PMN substance resulting in surface water concentrations that exceed 200 ppb.

The proposed SNUR would designate as a “significant new use” the absence of this protective measure.

Potentially Useful Information: EPA has determined that certain information may be potentially

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

PMN Number (proposed CFR citation): P-23-17 (40 CFR 721.11959).

Chemical Name: Hydrolyzed collagen, polymer with aromatic isocyanate, N-triethoxysilyl-alkanamine, pectic polysaccharide and poly alkyl alcohol (generic).

CASRN: Not available.

Basis for Action: The PMN states that the use of the PMN substance will be as an encapsulant for time-released delivery of fragrance. Based on potential changes to the molecular weight or composition of the PMN substance, EPA has identified concerns for lung toxicity if the chemical substance is not used following the limitation noted. The conditions of use of the PMN substance as described in the PMN include the following protective measure:

- Use of the PMN substance only as an encapsulant for time-released delivery of fragrance.

The proposed SNUR would designate as a “significant new use” the absence of this protective measure.

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

IV. 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>.

A. *Executive Order 12866: Regulatory Planning and Review and Executive Order 14094:*

Modernizing Regulatory Review

This action proposes to establish SNURs for new chemical substances that were the subject of PMNs. 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), as amended by Executive Order 14094 (88 FR 21879, April 11, 2023).

B. 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. Send any 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.

C. 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 16 in Federal fiscal year (FY) FY2018, five in FY2019, seven in FY2020, 13 in FY2021, 11 in FY2022, and 15 in FY2023, and only a fraction of these submissions were 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.

D. *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.

E. 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.

F. 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.

G. 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 any of these chemical substances for an activity that is

designated as a significant new use by this rulemaking. This notification allows EPA to assess the intended uses to identify potential risks and take appropriate actions before the activities commence.

H. 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.

I. 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).

J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations and Executive Order 14096: Revitalizing Our Nation’s Commitment to Environmental Justice for All

This action does not concern human health or environmental conditions and therefore cannot be evaluated with respect to the potential for disproportionate impacts on non-white and low-income populations in accordance with Executive Order 12898 (59 FR 7629, February 16, 1994) and Executive Order 14096 (88 FR 25251, April 26, 2023). Although this action does not concern human health or environmental conditions, the premanufacture notifications required by these SNURs allows EPA to assess the intended uses to identify potential disproportionate risks and take appropriate actions before the activities commence.

List of Subjects in 40 CFR Part 721

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

Dated: [November 22, 2024](#).

Mary Elissa Reaves,

Director, Office of Pollution Prevention and Toxics.

Therefore, 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. Add §§ 721.11955 through 721.11959 to Subpart E to read as follows:

Subpart E – Significant New Uses for Specific Chemical Substances

Sec.

* * * * *

721.11955 Polyolefin polyamine succinimide, carbopolycycle alkoxyated (generic).

721.11956 Carbonmonocyclic alkene polymer with alkyl alkenoate, alkyl alkenoate, alkyl alkenoate and polyalkyldiene alkenoate (generic).

721.11957 1-Tetradecene, homopolymer, hydrogenated, by-products from, C28-42 fraction.

721.11958 Carbonic acid, ester, polymer with alkanediol (C=4,5) (generic).

721.11959 Hydrolyzed collagen, polymer with aromatic isocyanate, N-triethoxysylil-alkanamine, pectic polysaccharide and poly alkyl alcohol (generic).

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§ 721.11955 Polyolefin polyamine succinimide, carbopolycycle alkoxyated (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as polyolefin polyamine succinimide, carbopolycycle alkoxyated (PMN P-20-168) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* It is a significant new use to use the substance other than as a lubricating additive for engine oils, transmission and hydraulic fluid, and gear oil applications.

(ii) [Reserved]

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

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

§ 721.11956 Carbonmonocyclic alkene polymer with alkyl alkenoate, alkyl alkenoate, alkyl alkenoate and polyalkyldiene alkenoate (generic).

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified generically as carbonmonocyclic alkene polymer with alkyl alkenoate, alkyl alkenoate, alkyl alkenoate and polyalkyldiene alkenoate (PMN P-21-5) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities*. It is a significant new use to manufacture, process, or use the substance in any manner that results in worker inhalation exposure to the substance.

(ii) [Reserved]

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

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

§ 721.11957 1-Tetradecene, homopolymer, hydrogenated, by-products from, C28-42 fraction.

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified as 1-tetradecene, homopolymer, hydrogenated, by-products from, C28-42 fraction (PMN P-21-95; CASRN 2263959-83-5) is subject to reporting under this section for the

significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* It is a significant new use to process the substance other than in an enclosed system when heated.

(ii) [Reserved]

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

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

§ 721.11958 Carbonic acid, ester, polymer with alkanediol (C=4,5) (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as carbonic acid, ester, polymer with alkanediol (C=4,5) (PMN P-21-174) 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) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where N=200.

(ii) [Reserved]

(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 (c), and (k) are applicable to manufacturers, importers, and processors of this substance.

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

§ 721.11959 Hydrolyzed collagen, polymer with aromatic isocyanate, N-triethoxysilyl-alkanamine, pectic polysaccharide and poly alkyl alcohol (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as hydrolyzed collagen, polymer with aromatic isocyanate, N-triethoxysilyl-alkanamine, pectic polysaccharide and poly alkyl alcohol (PMN P-23-17) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) Industrial, commercial, and consumer activities. It is a significant new use to use the substance other than as an encapsulant for time-released delivery of fragrance.

(ii) [Reserved]

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

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

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