



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 721 and 725

[EPA-HQ-OPPT-2024-0074; FRL-11916-02-OCSPP]

RIN 2070-AB27

Significant New Use Rules on Certain Chemical Substances (24-1.5e)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is issuing significant new use rules (SNURs) under the Toxic Substances Control Act (TSCA) for certain chemical substances that were the subject of premanufacture notices (PMNs) and a Microbial Commercial Activity Notice (MCAN) and are also subject to an Order issued by EPA pursuant to TSCA. The SNURs require persons to notify EPA at least 90 days before commencing the 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 in the SNUR. The required notification initiates EPA's evaluation of the conditions of that 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: This rule is effective on **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. For purposes of judicial review, this rule shall be promulgated at 1 p.m. (EST) on **[INSERT DATE 14 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: The docket for this action, identified under docket identification (ID) number EPA-HQ-OPPT-2024-0074, is available online at <https://www.regulations.gov> or in person at the Office of Pollution Prevention and Toxics Docket (OPPT Docket) in the Environmental

Protection Agency Docket Center (EPA/DC). Please review the visitor instructions and additional information about the docket 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., N.W., 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., N.W., 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).

B. What action is the Agency taking?

EPA is finalizing SNURs under TSCA section 5(a)(2) for the chemical substances identified in this document. These chemical substances were the subject of PMNs and a Microbial Commercial Activity Notice (MCAN) and are also subject to an Order issued by EPA pursuant to TSCA section 5(e)(1)(A), as required by the determinations made under TSCA section 5(a)(3)(B). The SNURs identify as significant new uses any manufacturing, processing,

use, distribution in commerce, or disposal that does not conform to the restrictions imposed by the underlying TSCA Orders, consistent with TSCA section 5(f)(4). The SNURs require persons who intend to manufacture or process any of these chemical substances for an activity that is designated as a significant new use in the SNURs to notify EPA at least 90 days before commencing that activity.

Previously, EPA proposed SNURs for these chemical substances in the *Federal Register* of August 20, 2024 (89 FR 67368 (FRL-11916-01-OCSP)). The docket includes information considered by the Agency in developing the proposed and final rules, including public comments and EPA's responses to the comments received as discussed in Unit II.D.

C. Does this action apply to me?

1. General applicability.

This action applies to you if you manufacture, process, or use the chemical substances identified in this document. 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 in 19 CFR 12.118 through 12.127, 19 CFR 127.28, and 40 CFR part 707, Subpart B. Importers of chemical substances in bulk form, as part of a mixture, or as part of an article (if required by rule) 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?

EPA has evaluated the potential costs of establishing SNUN reporting requirements for potential manufacturers and processors of the chemical substances identified in this document. This analysis, which is available in the docket, is briefly summarized here.

1. Estimated costs for SNUN submissions.

A SNUR requires that any person who intends to engage in such activity in the future must first notify EPA by submitting a SNUN. 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)). 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 pre-existing 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.

II. Background

A. General Information about SNURs

Unit II. of the proposed rule provides general information about SNURs, and additional information about EPA's new chemical program is available at <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca>.

B. Applicability of the Significant New Use Designation

To establish a significant new use, EPA must determine that the use is not ongoing. As discussed in Unit II.E. of the proposed rule, EPA concluded that the proposed significant new uses were not ongoing. If EPA subsequently determines that such a use was ongoing as of the date of publication of the proposed rule and did not cease prior to issuance of the final rule, EPA will not designate that use as a significant new use in the final rule. EPA has no information to suggest that any of the significant new uses identified in this rule meet this criterion.

As discussed in the *Federal Register* of April 24, 1990 (55 FR 17376 (FRL-3658-5)), EPA believes that the intent of TSCA section 5(a)(1)(B) is best served by designating a use as a significant new use as of the date of publication of the proposed rule rather than as of the effective date of the final rule. The objective of EPA's approach is to ensure that a person cannot impede finalization of a SNUR by initiating a significant new use after publication of the proposed rule but before the effective date of the final rule. Uses arising after the publication of the proposed rule are distinguished from uses that are identified in the final rule as having been ongoing on the date of publication of the proposed rule. The former would be new uses, the latter ongoing uses, except that uses that are identified as ongoing as of the publication of the proposed rule would not be considered ongoing uses if they have ceased by the date of issuance of a final rule.

In the unlikely event that before a final rule becomes effective a person begins commercial manufacturing (including importing) or processing of the chemical substances for a use that is designated as a significant new use in that final rule, such a person 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 wait until all TSCA prerequisites for the commencement of manufacture or processing have been satisfied.

Issuance of a SNUR for a chemical substance does not signify that the chemical substance is listed on the TSCA Chemical Substance Inventory (TSCA Inventory). Guidance on how to determine if a chemical substance is on the TSCA Inventory is available on the Internet at <https://www.epa.gov/tsca-inventory>.

C. 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 as identified for the chemical substance in Unit III.C. of the proposed rule.

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. of the proposed rule 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 about human exposure and environmental release that may result from the significant new use of the chemical substances.

D. Public Comments on Proposed Rule and EPA Responses

EPA received public comments on the proposed SNURs and prepared a Response to Comment document that provides the Agency responses. The comments and the Response to

Comment document are available in the docket. As described in the Response to Comment document, EPA is finalizing these SNURs with the following changes (listed by PMN Number and proposed 40 CFR citation):

- For P-20-175 (40 CFR 721.11897), P-20-176 (40 CFR 721.11898), and P-20-178 (40 CFR 721.11899), based upon review of submitted data indicating the substances are expected to have low environmental hazard, EPA removed the proposed release to water requirements and also modified the proposed hazard communication requirements by removing the proposed reference to 40 CFR 721.72(g)(3); and,

- For P-22-86 (40 CFR 721.11918), P-22-122 (40 CFR 721.11919), P-22-179 (40 CFR 721.11920), P-22-180 (40 CFR 721.11921), and P-22-129 (40 CFR 721.11923), EPA incorporated the requirements of 40 CFR 721.72(e) to include a *de minimis* provision of 1.0% (for P-22-86, P-22-122, and P-22-0129) or 0.1% (for P-22-179 and P-22-180) for consistency with the underlying Orders for these substances. For P-22-86, P-22-122, P-22-0179, and P-22-180, EPA also corrected the significant new use regarding the manner in which the substance is imported. The significant new use now reads “It is a significant new use to import the substance other than in solution, unless in sealed containers weighing 5 kilograms or less.”

In addition to the changes to respond to comments, EPA identified the need to revise the following proposed SNURs (listed by PMN Number and proposed 40 CFR citation):

- For P-22-13 (40 CFR 721.11913) and P-22-15 (40 CFR 721.11914), EPA made minor edits to the significant new use regarding the use of dust collection in the industrial, commercial, and consumer activities paragraph to be consistent with the Order.

- For P-18-356 (40 CFR 721.11894), P-18-357 (40 CFR 721.11895), P-19-188 (40 CFR 721.11896), P-21-32 (40 CFR 721.11901), P-21-33 (40 CFR 721.11902), P-21-96 (40 CFR 721.11905), P-21-98 (40 CFR 721.11906), P-21-126 (40 CFR 721.11907), P-21-175 (40 CFR 721.11908), P-22-10 (40 CFR 721.11912), P-22-13 (40 CFR 721.11913), P-22-15 (40 CFR 721.11914), P-22-37 (40 CFR 721.11914), P-22-54 (40 CFR 721.11917), and P-22-162 (40 CFR

721.11924), EPA simplified the requirements in the hazard communication paragraph by referencing 40 CFR 721.72(g)(3)(iii) rather than referencing 721.72(g)(3) and writing out the required environmental hazard statement.

- For P-20-178 (40 CFR 721.11899), EPA updated the generic name of the chemical substance. A provisional generic name was used in the proposed rule.

III. Chemical Substances Subject to these SNURs

A. What is the designated cutoff date for ongoing uses?

EPA designates the date of publication of the proposed rule as the cutoff date for determining whether the new use is ongoing, i.e., August 20, 2024 (89 FR 67368 (FRL-11916-01-OCSP)). This designation is explained in more detail in Unit II.B.

B. What information was provided for each chemical substance?

In Unit III.C. of the proposed rule, EPA provided the following information for each chemical substance subject to these SNURs:

- PMN number (the 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) or Accession Number (if assigned for confidential chemical identities).
- Basis for the SNUR (e.g., effective date of and basis for the TSCA Order).
- Potentially useful information.

The regulatory text section of this document specifies the chemical substances and activities designated as significant new uses. Certain new uses, including production volume limits and other uses designated, may be claimed as CBI, as discussed in more detail in Unit II.C. of the proposed rule.

In addition, as discussed in Unit III.B. of the proposed rule, these SNURs include PMN substances that are subject to Orders issued under TSCA section 5(e)(1)(A), as required by the

determinations made under TSCA section 5(a)(3)(B). Those TSCA Orders require protective measures to limit exposures or otherwise mitigate the potential unreasonable risk. As such, the SNURs identify as significant new uses any manufacturing, processing, use, distribution in commerce, or disposal that does not conform to the restrictions imposed by the underlying TSCA Orders, consistent with TSCA section 5(f)(4).

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

This action establishes 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).

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 new chemical under TSCA section 5 is exempt 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.

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 7 in Federal fiscal year (FY) 2020, 9 in FY2021, 9 in FY2022, 23 in FY2023, and 7 in FY2024, 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.

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).

K. Congressional Review Act (CRA)

This action is subject to the CRA (5 U.S.C. 801 *et seq.*), and EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects

40 CFR Part 721

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

40 CFR Part 725

Environmental protection, Administrative practice and procedure, Biologics, Chemicals, Hazardous substances, Imports, Labeling, Occupational safety and health, Reporting and recordkeeping requirements.

Dated: July 24, 2025.

Mary Elissa Reaves,

Director, Office of Pollution Prevention and Toxics.

For the reasons stated in the preamble, 40 CFR chapter I is amended 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 §§ 721.11894 through 721.11924 to subpart E to read as follows:

Subpart E – Significant New Uses for Specific Chemical Substances

§ 721.11894 Sulfonated phenolic resin salt, polymer with acetone-phenol reaction products, formaldehyde and phenol, sodium salt (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as sulfonated phenolic resin salt, polymer with acetone-phenol reaction products, formaldehyde and phenol, sodium salt (PMN P-18-356) 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 substance after they have been completely reacted or cured.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1) and (3), (b), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), 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(b), the concentration is set at 1.0%.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(3)(iii) and (g)(5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), this substance may cause: skin corrosion; serious eye damage; reproductive toxicity; specific target organ toxicity. 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, process, or use the substance in any manner that results in inhalation exposure.

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where N=6.

(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, importers, and processors of this substance.

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

§ 721.11895 Sulfonated phenolic resin salt, polymer with acetone-phenol reaction products, formaldehyde and phenol, potassium salt (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as sulfonated phenolic resin salt, polymer with acetone-phenol reaction products, formaldehyde and phenol, potassium salt (PMN P-18-357) 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 substance after they have been completely reacted or cured.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1) and (3), (b), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), 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(b), the concentration is set at 1.0%.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(3)(iii) and (g)(5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), this substance may cause: skin corrosion; serious eye damage; reproductive toxicity; specific target organ toxicity. 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, process, or use the substance in any manner that results in inhalation exposure.

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where N=6.

(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, importers, and processors of this substance.

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

§ 721.11896 Octadecanamide, N,N-dialkyl, salts (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as octadecanamide, N,N-dialkyl, salts (PMN P-19-188) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1) and (3), (b), and (c). When determining which persons are reasonably likely to be exposed as required for §

721.63(a)(1), 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(b), the concentration is set at 1.0%.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), and (g)(1), (g)(3)(iii) and (g)(5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), this substance may cause: skin irritation; eye irritation; specific target organ toxicity; serious eye damage. 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, process, or use the substance in any manner that results in inhalation exposure.

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where $N=34$.

(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, importers, and processors of this substance.

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

§ 721.11897 Acid N-[4-(4-diarylalkyl)]-, carbopolycyclic alkenyl, methyl ester (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as acid N-[4-(4-diarylalkyl)]-, carbopolycyclic alkenyl, methyl ester (PMN P-20-175) 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 substance after they have been completely reacted or cured.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1) and (3), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), 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.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (d), (f), and (g)(1) and (5). For purposes of § 721.72(g)(1), this substance may cause: skin irritation; eye irritation; respiratory sensitization; skin sensitization; carcinogenicity; specific target organ toxicity. 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, process, or use the substance in any manner that results in inhalation exposure.

(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, importers, and processors of this substance.

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

§ 721.11898 Acid N-(diarylalkyl)-, carbopolycyclic alkenyl, methyl ester (generic).

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

(1) The chemical substance identified generically as acid N-(diarylalkyl)-, carbopolycyclic alkenyl, methyl ester (PMN P-20-176) 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 substance after they have been completely reacted or cured.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1) and (3), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), 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.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (d), (f), and (g)(1) and (5). For purposes of § 721.72(g)(1), this substance may cause: skin irritation; eye irritation; respiratory sensitization; skin sensitization; carcinogenicity; specific target organ toxicity. 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, process, or use the substance in any manner that results in inhalation exposure.

(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, importers, and processors of this substance.

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

§ 721.11899 Carbopolycyclic alkenyl, 2-carboxylic acid, 2-[[[(isocyanatophenyl)alkyl]carbocycle]amino]carbonyloxyethyl ester (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as carbopolycyclic alkenyl, 2-carboxylic acid, 2-

[[[(isocyanatophenyl) alkyl]carbocycle]amino]carbonyl]oxy]ethyl ester (PMN P-20-178) 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 substance after they have been completely reacted or cured.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1) and (3), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), 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.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (d), (f), and (g)(1) and (5). For purposes of § 721.72(g)(1), this substance may cause: skin irritation; eye irritation; respiratory sensitization; skin sensitization; carcinogenicity; specific target organ toxicity. 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, process, or use the substance in any manner that results in inhalation exposure.

(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, importers, and processors of this substance.

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

§ 721.11900 Amines, C36-alkylenedi-, polymers with 5,5'-[(1-methylethylidene)bis(4,1-phenyleneoxy)]bis[1,3-isobenzofurandione] and 4,4'-[2,2,2-trifluoro-1-

(trifluoromethyl)ethylidene]bis[2-aminophenol].

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as amines, C36-alkylenedi-, polymers with 5,5'-[(1-methylethylidene)bis(4,1-phenyleneoxy)]bis[1,3-isobenzofurandione] and 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]bis[2-aminophenol] (PMN P-21-15; CASRN 2419899-87-7) 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 substance after they have been completely reacted (cured).

(2) The significant new uses are:

(i) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), and (g)(1) and (5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), this substance may cause: specific target organ toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(ii) *Industrial, commercial, and consumer activities.* It is a significant new use to use the substance other than as a raw material in a temporary bonding adhesive formulation. The adhesive is used to bond completed semiconductor wafers to a backing substrate to facilitate mechanical grinding of the wafer to reduce its thickness. It is a significant new use to manufacture, process, or use the substance in any manner that results in worker inhalation exposure.

(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 (f) through (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.

§ 721.11901 Poly[oxy(methyl-1,2-ethanediyl)], .alpha.-(3-aminopropyl)-.omega.-(1-methylethoxy)-.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as poly[oxy(methyl-1,2-ethanediyl)], .alpha.-(3-aminopropyl)-.omega.-(1-methylethoxy)- (PMN P-21-32; CASRN 2304726-48-3) 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 substance after they have been completely reacted or destroyed.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1) and (3), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), 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.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (d), (f), (g)(1), (g)(3)(iii), and (g)(5). For purposes of § 721.72(g)(1), this substance may cause: acute toxicity; skin corrosion; serious eye damage; skin sensitization; specific target organ toxicity. 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 process or use the substance in any manner in formulation containing the substance at greater than 4%.

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where N=110. Whenever the substance is released together with poly[oxy(methyl-1,2-ethanediyl)], .alpha.-(3-aminopropyl)-.omega.-butoxy- (PMN P-21-33; CASRN 2304726-50-7), N should be calculated using the combined number of kilograms of both substances released per

site per day.

(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, importers, and processors of this substance.

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

§ 721.11902 Poly[oxy(methyl-1,2-ethanediyl)], .alpha.-(3-aminopropyl)-.omega.-butoxy-.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as poly[oxy(methyl-1,2-ethanediyl)], .alpha.-(3-aminopropyl)-.omega.-butoxy- (PMN P-21-33; CASRN 2304726-50-7) 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 substance after they have been completely reacted or destroyed.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1) and (3), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), 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.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (d), (f), and (g)(1), (g)(3)(iii) and (g)(5). For purposes of § 721.72(g)(1), this substance may cause: acute toxicity; skin corrosion; serious eye damage; skin sensitization; specific target organ toxicity. 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 process or use the substance in any manner in formulation containing the substance at greater than 4%.

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where N=110. Whenever the substance is released together with poly[oxy(methyl-1,2-ethanediyl)], .alpha.-(3-aminopropyl)-.omega.-(1-methylethoxy)- (PMN P-21-32; CASRN 2304726-48-3), N should be calculated using the combined number of kilograms of both substances released per site per day.

(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, importers, and processors of this substance.

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

§ 721.11903 Alkanoic acid, hydroxy-(hydroxyalkyl)-alkyl-, polymer with .alpha.-[(hydroxyalkyl)alkyl]-.omega.-alkoxypoly(oxy-alkanediyl), dialkyl carbonate, alkanediol, alkylene[isocyanato-carbomonocycle] and [oxybis(alkylene)]bis[alkyl-alkanediol] alkenoate, compd. with dialkyalkanamine (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as alkanoic acid, hydroxy-(hydroxyalkyl)-alkyl-, polymer with .alpha.-[(hydroxyalkyl)alkyl]-.omega.-alkoxypoly(oxy-alkanediyl), dialkyl carbonate, alkanediol, alkylene[isocyanato-carbomonocycle] and [oxybis(alkylene)]bis[alkyl-alkanediol] alkenoate, compd. with dialkyalkanamine (PMN P-21-75) 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 substance after they have been completely reacted or cured.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1) and (3) through (5), 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, or 1000 if spray applied.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (d), (f), and (g)(1) and (5). For purposes of § 721.72(g)(1), this substance may cause: acute toxicity; skin corrosion; skin irritation; serious eye damage; eye irritation; respiratory sensitization; reproductive toxicity; specific target organ toxicity. 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).

(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) 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.

§ 721.11904 Alkanedioic acid, polymers with alkanedioic acid-dipentaerythritol reaction products, alkanedioic acid dihydrazide, hydroxy-(hydroxyalkyl)-alkylalkanedioic acid, isocyanato-(isocyanatoalkyl)-alkyl substituted carbomonocycle, dialkylalkanedioic acid and polyalkylene glycol(hydroxyalkyl)alkyl alkyl ether (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as alkanedioic acid, polymers with alkanedioic acid-dipentaerythritol reaction products, alkanedioic acid dihydrazide, hydroxy-(hydroxyalkyl)-alkylalkanoic acid, isocyanato-(isocyanatoalkyl)-alkyl substituted carbomonocycle, dialkylalkanediol and polyalkylene glycol(hydroxyalkyl)alkyl alkyl ether (PMN P-21-80) 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 substance after they have been completely reacted or cured.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1) and (3) through (5), 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, or 1000 if spray applied.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (d), (f), and (g)(1) and (5). For purposes of § 721.72(g)(1), this substance may cause: skin irritation; eye irritation; respiratory sensitization; skin sensitization; specific target organ toxicity. 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).

(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) 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.

§ 721.11905 Phenol, 4,4'-(1-methylethylidene)bis-, polymer with 2,2'-[(1-methylethylidene)bis(4,1-phenyleneoxymethylene)]bis[heteromonocycle], bis(2-methyl-2-propenoate) (generic).

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified generically as phenol, 4,4'-(1-methylethylidene)bis-, polymer with 2,2'-[(1-methylethylidene)bis(4,1-phenyleneoxymethylene)]bis[heteromonocycle], bis(2-methyl-2-propenoate) (PMN P-21-96) 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 substance after they have been completely reacted or cured.

(2) The significant new uses are:

(i) *Protection in the workplace*. Requirements as specified in § 721.63(a)(1) and (3), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), 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.

(ii) *Hazard communication*. Requirements as specified in § 721.72(a) through (d), (f), (g)(1), (g)(3)(iii) and (g)(5). For purposes of § 721.72(g)(1), this substance may cause: skin irritation; eye irritation; respiratory sensitization; skin sensitization; reproductive toxicity; specific target organ toxicity. 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*. It is a significant new use to manufacture, process, or use the substance in any manner that results in inhalation exposure.

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where N=2.

(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, importers, and processors of this substance.

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

§ 721.11906 Poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-[2(or 3)-[[substituted benzoyl]oxy]hydroxypropoxyl]-, .alpha., .alpha.', .alpha."-ether with 2-ethyl-2-(hydroxymethyl)-1,3-propanediol (3:1) (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-[2(or 3)-[[substituted benzoyl]oxy]hydroxypropoxyl]-, .alpha., .alpha.', .alpha."-ether with 2-ethyl-2-(hydroxymethyl)-1,3-propanediol (3:1) (PMN P-21-98) 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 substance after they have been completely reacted or cured.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1) and (3) through (5), 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 10.

(ii) *Hazard communication*. Requirements as specified in § 721.72(a) through (d), (f), (g)(1), (g)(3)(iii) and (g)(5). For purposes of § 721.72(g)(1), this substance may cause: skin irritation; eye irritation; skin sensitization; specific target organ toxicity; reproductive toxicity. 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 or process the substance in any manner or method that results in inhalation exposure. It is a significant new use to use the substance in formulations at concentrations greater than 4%.

(iv) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where N=12.

(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, importers, and processors of this substance.

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

§ 721.11907 Substituted heteromonocycle, polymer with haloalkyl substituted heteromonocycle, dialkyl-alkanediamine, (alkylalkylidene)bis[hydroxy-carbomonocycle] and oxybis[alkanol], reaction products with metal oxide and dialkanolamine (generic).

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified generically as substituted heteromonocycle, polymer with haloalkyl substituted heteromonocycle, dialkyl-alkanediamine, (alkylalkylidene)bis[hydroxy-carbomonocycle] and oxybis[alkanol], reaction products with metal oxide and dialkanolamine (PMN P-21-126) 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 substance after they have been completely destroyed.

(2) The significant new uses are:

(i) *Hazard communication*. Requirements as specified in § 721.72(a) through (f), (g)(3)(iii), and (g)(5). For purposes of § 721.72(e), the concentration is set at 1.0%. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(ii) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where N=230.

(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), (f) through (h), 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.

§ 721.11908 Carbonic acid, diphenyl ester, polymer with 1,4-butanediol and 1,10-decanediol.

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified as carbonic acid, diphenyl ester, polymer with 1,4-butanediol and 1,10-decanediol (PMN P-21-175; CASRN 1615685-41-0) 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 substance after they have been completely destroyed.

(2) The significant new uses are:

(i) *Hazard communication*. Requirements as specified in § 721.72(a) through (f), (g)(3)(iii), and (g)(5). For purposes of § 721.72(e), the concentration is set at 1.0%. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and

OSHA Hazard Communication Standard may be used.

(ii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where N=22.

(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), (f), 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.

§ 721.11909 3,5,8-Trioxa-4-silaalkanoic acid, 4-ethenyl-4-(2-alkoxy-1-alkyl-2-oxoethoxy)-2,6-dialkyl-7-oxo-, alkyl ester (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as 3,5,8-trioxa-4-silaalkanoic acid, 4-ethenyl-4-(2-alkoxy-1-alkyl-2-oxoethoxy)-2,6-dialkyl-7-oxo-, alkyl ester (PMN P-22-7) 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 substance after they have been completely reacted or destroyed.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1) and (3), (b), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), 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(b), the concentration is set at 1.0%.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), and (g)(1) and (5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of §

721.72(g)(1), this substance may cause: eye irritation; reproductive toxicity; specific target organ toxicity. 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.* It is a significant new use to process for use or use the substance other than as a crosslinker in formulating general purpose sealants and adhesives. It is a significant new use to process for use or use the substance in consumer products other than in the form of a paste. It is a significant new use to process for use or use the substance where the concentration of the substance exceeds 6% by weight in consumer products. It is a significant new use to manufacture, process, or use the substance in any manner that results in inhalation exposure.

(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) 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.

§ 721.11910 .beta.-N-Acetylhexosaminidase (expressed in genetically modified *Bacillus licheniformis* strain ATJI0138).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as .beta.-N-acetylhexosaminidase (expressed in genetically modified *Bacillus licheniformis* strain ATJI0138) (PMN P-22-8; CASRN 9012-33-3) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1) and (3), and
(c). When determining which persons are reasonably likely to be exposed as required for §

721.63(a)(1), 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.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (d), (f), and (g)(1) and (5). For purposes of § 721.72(g)(1), this substance may cause: skin irritation; eye irritation; respiratory sensitization; skin sensitization; specific target organ toxicity. 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.* It is a significant new use to manufacture, process, or use the substance in any manner that results in inhalation exposure. It is a significant new use to process the substance to greater than 1% in formulation for use in a consumer product.

(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) 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.

§ 721.11911 Alkanes, C4-9-branched and linear.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as alkanes, C4-9-branched and linear (PMN P-22-9; CASRN 2577172-51-9) 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 substance after they have been incorporated into a fuel or refined or blended into other chemical or fuel formulations.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1) and (3), (b), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), 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(b), the concentration is set at 0.1%.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a).

(iii) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture, process, or use the substance other than as a fuel, a refinery feedstock, a chemical feedstock, or a fuel blending additive or component.

(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 (f), 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.

§ 721.11912 Amino alkanolic acid, N-[3-(trimethoxysilyl)propyl]-, 3-(trimethoxysilyl)propyl ester (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as amino alkanolic acid, N-[3-(trimethoxysilyl)propyl]-, 3-(trimethoxysilyl)propyl ester (PMN P-22-10) 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 substance after they have been completely reacted or cured.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1) and (3), (b),

and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), 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(b), the concentration is set at 1.0%.

(ii) *Hazard communication*. Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(3)(iii) and (g)(5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), this substance may cause: skin irritation; serious eye damage; reproductive toxicity; specific target organ toxicity. 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, process, or use the substance in any manner that generates inhalation exposure.

(iv) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where $N=80$.

(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, importers, and processors of this substance.

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

§ 721.11913 2-Pyridinecarboxylic acid, 3-halo-4-nitrogen-substituted-5-halo-6-halo, aryl ester (generic).

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified generically as 2-pyridinecarboxylic acid, 3-halo-4-nitrogen-substituted-5-

halo-6-halo, aryl ester (PMN P-22-13) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1) and (3) through (5), 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), (g)(3)(iii) and (g)(5). For purposes of § 721.72(g)(1), this substance may cause: eye irritation; skin sensitization; specific target organ toxicity. 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(g). It is a significant new use to manufacture, process, or use the substance in solid form without using a dust collection system with a combined capture and control efficiency of at least 32%.

(iv) *Release to water.* Requirements as specified in § 721.90(a)(1), (b)(1), and (c)(1).

(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, importers, and processors of this substance.

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

**§ 721.11914 2-Pyridinecarboxylic acid, 3-halo-4-nitrogen-substituted-5-halo-6-halo-
(generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as 2-pyridinecarboxylic acid, 3-halo-4-nitrogen-substituted-5-halo-6-halo- (PMN P-22-15) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1) and (3) through (5), (b), 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. For purposes of § 721.63(b), the concentration is set at 1.0%.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(3)(iii) and (g)(5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), this substance may cause: eye irritation; specific target organ toxicity. 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(g). It is a significant new use to manufacture, process, or use the substance in solid form without using a dust collection system with a combined capture and control efficiency of at least 32%.

(iv) *Release to water.* Requirements as specified in § 721.90(a)(1), (b)(1), and (c)(1).

(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, importers, and processors of this substance.

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

§ 721.11915 Polyphosphoric acids, esters with heteromonocycle homopolymer (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as polyphosphoric acids, esters with heteromonocycle homopolymer (PMN P-22-37) 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 substance after they have been completely reacted or cured.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1) and (3) through (5), (b), 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. For purposes of § 721.63(b), the concentration is set at 1.0%.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(3)(iii) and (g)(5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), this substance may cause: skin corrosion; skin irritation; serious eye damage; eye irritation; specific target organ toxicity. 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 process the substance to greater than 1% in formulation. It is a significant new use to use the substance in a formulation containing the substance at a concentration greater than 1%.

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where N=2.

(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, importers, and processors of this substance.

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

§ 721.11916 Silica gel, reaction products with alkyl metal salt (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as silica gel, reaction products with alkyl metal salt (PMN P-22-44) 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 substance after they have been completely destroyed.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1) and (3) through (5), (b), 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. For

purposes of § 721.63(b), the concentration is set at 1.0%.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), and (g)(1) and (5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), this substance may cause: eye irritation; skin irritation; specific target organ toxicity. 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(a) through (c).

(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) 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.

§ 721.11917 Graphene nanoplatelets (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as graphene nanoplatelets (PMN P-22-54) 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 substance after they have been:

(i) Completely reacted or cured; or

(ii) Embedded into a permanent solid polymer form that is not intended to undergo further processing, except mechanical processing or physical blending.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1) and (3) through (5), (b), 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. For purposes of § 721.63(b), the concentration is set at 1.0%.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(3)(iii) and (g)(5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), this substance may cause: specific target organ toxicity. 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(k), (v)(3), and (x)(3). It is a significant new use to manufacture the substance other than by import into the United States in the form of a solution (i.e., no domestic manufacture). It is a significant new use to process the substance in any manner that generates inhalation exposure. It is a significant new use to use the substance in an application method where the concentration of the substance in the formulation exceeds the confidential concentration listed in the Order.

(iv) *Release to water.* Requirements as specified in § 721.90(a)(1), (b)(1), and (c)(1).

(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, importers, and processors of this substance.

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

§ 721.11918 Phenoxathiinium, 10-phenyl-, 5-alkyl-2-alkyl-4-(2,4,6-substituted tri-carbopolycycle, hetero-acid)benzenesulfonate (1:1) (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical

substance identified generically as phenoxathiinium, 10-phenyl-, 5-alkyl-2-alkyl-4-(2,4,6-substituted tri-carbopolycycle, hetero-acid)benzenesulfonate (1:1) (PMN P-22-86) 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 substance after they have been completely reacted or adhered (during photolithographic processes) onto a semiconductor wafer surface or similar manufactured article used in the production of semiconductor technologies.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i) and (iii), (a)(3), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), 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.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(2)(i) through (iii) and (v), (g)(3)(i) and (ii), and (g)(5). For purposes of § 721.72(e) the concentration is set at 1.0%. For purposes of § 721.72(g)(1), this substance may cause: acute toxicity; skin irritation; serious eye damage; skin sensitization; genetic toxicity; specific target organ toxicity. 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(f), (k), and (t). It is a significant new use to import the substance other than in solution, unless in sealed containers weighing 5 kilograms or less. It is a significant new use to process the substance in any way that generates a vapor, dust, mist, or aerosol in a non-enclosed process. It is a significant new use to manufacture the substance longer than 9 months.

(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) 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.

§ 721.11919 Heterotrisubstituted-bile acid, 1-(difluorosulfomethyl)-2,2,2-trifluoroethyl ester, ion(1-), (5)-, 5-phenyldibenzothiophenium (1:1) (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as heterotrisubstituted-bile acid, 1-(difluorosulfomethyl)-2,2,2-trifluoroethyl ester, ion(1-), (5)-, 5-phenyldibenzothiophenium (1:1) (PMN P-22-122) 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 substance after they have been completely reacted or adhered (during photolithographic processes) onto a semiconductor wafer surface or similar manufactured article used in the production of semiconductor technologies.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i) and (iii), (a)(3), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), 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.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(2)(i) through (iii) and (v), (g)(3)(i) and (ii), and (g)(5). For purposes of § 721.72(e) the concentration is set at 1.0%. For purposes of § 721.72(g)(1), this substance may cause: acute toxicity; skin irritation; serious eye damage; skin sensitization; genetic toxicity; specific target

organ toxicity. 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(f), (k), and (t). It is a significant new use to import the substance other than in solution, unless in sealed containers weighing 5 kilograms or less. It is a significant new use to process the substance in any way that generates a vapor, dust, mist, or aerosol in a non-enclosed process. It is a significant new use to manufacture the substance longer than 9 months.

(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) 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.

§ 721.11920 Sulfonium, (alkylsubstitutedphenyl)diphenyl-, salt with 1-(heterosubstitutedalkyl)-2,2,2-triheterosubstitutedalkyl trisubstitutedbenzoate (1:1) (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as sulfonium, (alkylsubstitutedphenyl)diphenyl-, salt with 1-(heterosubstitutedalkyl)-2,2,2-triheterosubstitutedalkyl trisubstitutedbenzoate (1:1) (PMN P-22-179) 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 substance after they have been completely reacted or adhered (during photolithographic processes) onto a semiconductor wafer surface or similar manufactured article used in the production of semiconductor technologies.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i) and

(iii), (a)(3), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), 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.

(ii) *Hazard communication*. Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(2)(i) through (iii) and (v), (g)(3)(i) and (ii), and (g)(5). For purposes of § 721.72(e) the concentration is set at 0.1%. For purposes of § 721.72(g)(1), this substance may cause: acute toxicity; skin irritation; serious eye damage; skin sensitization; genetic toxicity; carcinogenicity; specific target organ toxicity. 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(f), (k), and (t). It is a significant new use to import the substance other than in solution, unless in sealed containers weighing 5 kilograms or less. It is a significant new use to process the substance in any way that generates a vapor, dust, mist, or aerosol in a non-enclosed process. It is a significant new use to manufacture the substance longer than 9 months.

(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) 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.

§ 721.11921 Dibenzothiophenium, 5-phenyl-, 4-[1-(heterosubstitutedalkyl)-2,2,2-triheterosubstitutedalkoxy]-4-oxoalkyl trisubstitutedbenzoate (1:1) (generic).

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified generically as dibenzothiophenium, 5-phenyl-, 4-[1-(heterosubstitutedalkyl)-

2,2,2-triheterosubstitutedalkoxy]-4-oxoalkyl trisubstitutedbenzoate (1:1) (PMN P-22-180) 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 substance after they have been completely reacted or adhered (during photolithographic processes) onto a semiconductor wafer surface or similar manufactured article used in the production of semiconductor technologies.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i) and (iii), (a)(3), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), 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.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(2)(i) through (iii) and (v), (g)(3)(i) and (ii), and (g)(5). For purposes of § 721.72(e) the concentration is set at 0.1%. For purposes of § 721.72(g)(1), this substance may cause: acute toxicity; skin irritation; serious eye damage; skin sensitization; genetic toxicity; carcinogenicity; specific target organ toxicity. 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(f), (k), and (t). It is a significant new use to import the substance other than in solution, unless in sealed containers weighing 5 kilograms or less. It is a significant new use to process the substance in any way that generates a vapor, dust, mist, or aerosol in a non-enclosed process. It is a significant new use to manufacture the substance longer than 9 months.

(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) 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.

§ 721.11922 .beta.-cyclodextrin, polymer with 2,3,5,6-tetrafluoro-1,4-benzenedicarbonitrile, hydrolyzed, 2-(trimethylammonio)ethyl ethers, chlorides.

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified as .beta.-cyclodextrin, polymer with 2,3,5,6-tetrafluoro-1,4-benzenedicarbonitrile, hydrolyzed, 2-(trimethylammonio)ethyl ethers, chlorides (PMN P-22-115; CASRN 2683011-63-2) 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 substance after they have been incorporated into an article.

(2) The significant new uses are:

(i) *Protection in the workplace*. Requirements as specified in § 721.63(a)(1) and (3) through (5), (b), 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 10. For purposes of § 721.63(b), the concentration is set at 1.0%.

(ii) *Hazard communication*. Requirements as specified in § 721.72(a) through (f), and (g)(1) and (5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), this substance may cause: skin irritation; eye irritation; specific target organ toxicity. 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.* It is a significant new use to manufacture, process, or use the substance with particle size less than 20 microns. It is a significant new use to process for use or use the substance in consumer products except when incorporated into an article.

(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) 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.

§ 721.11923 Substituted heterocyclic onium compound, salt with heteropolysubstitutedalkyl substitutedtricycloalkane carboxylate (1:1), polymer with 1-alkenyl-4-[(alkylcycloalkyl)oxy]carbomonocycle, 5-ethyloctahydro-4,7-methano-1H-inden-5-yl 2-methyl-2-propenoate, hexahydro-5-oxo-2,6-methanofuro[3,2-b]furan-3-yl 2-methyl-2-propenoate and 4-hydroxyphenyl 2-methyl-2-propenoate (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as substituted heterocyclic onium compound, salt with heteropolysubstitutedalkyl substitutedtricycloalkane carboxylate (1:1), polymer with 1-alkenyl-4-[(alkylcycloalkyl)oxy]carbomonocycle, 5-ethyloctahydro-4,7-methano-1H-inden-5-yl 2-methyl-2-propenoate, hexahydro-5-oxo-2,6-methanofuro[3,2-b]furan-3-yl 2-methyl-2-propenoate and 4-hydroxyphenyl 2-methyl-2-propenoate (PMN P-22-129) 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 substance after they have been completely reacted or adhered (during photolithographic processes) onto a semiconductor wafer surface or similar manufactured article used in the production of semiconductor technologies.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i) and (iii), (a)(3), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), 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.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(2)(i) through (iii) and (v), (g)(3)(i) and (ii), and (g)(5). For purposes of § 721.72(e) the concentration is set at 1.0%. For purposes of § 721.72(g)(1), this substance may cause: acute toxicity; skin irritation; serious eye damage; skin sensitization; genetic toxicity; specific target organ toxicity. 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(f), (k), and (t). It is a significant new use to import the substance other than in solution, unless in sealed containers weighing 5 kilograms or less. It is a significant new use to process the substance in any way that generates dust, mist, or aerosol in a non-enclosed process. It is a significant new use to manufacture the substance longer than 18 months.

(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) 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.

§ 721.11924 Haloalkylfurancarboxaldehyde (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as haloalkylfurancarboxaldehyde (PMN P-22-162) 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 substance after they have been completely reacted (destroyed).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1) and (3), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), 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.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (d), (f), and (g)(1), (g)(3)(iii) and (g)(5). For purposes of § 721.72(g)(1), this substance may cause: acute toxicity; skin irritation; serious eye damage; skin sensitization; genetic toxicity; reproductive toxicity; specific target organ toxicity. 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(a) through (c), and (o). It is a significant new use to manufacture, process, or use the substance in any manner that results in inhalation exposure.

(iv) *Disposal.* It is a significant new use to dispose of the substance, or any waste streams containing the substance, other than by hazardous waste incineration achieving at least 99.99% destruction of the substance.

(v) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where $N=540$.

(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 (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.

PART 725 – REPORTING REQUIREMENTS AND REVIEW PROCESSES FOR MICROORGANISMS

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

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

4. Add §§ 725.1082 to subpart M to read as follows:

Subpart M – Significant New Uses for Specific Microorganisms

§ 725.1082 Microorganism expressing enzymes (generic).

(a) *Microorganism and significant new uses subject to reporting.* (1) The genetically-modified microorganism identified generically as microorganism expressing enzymes (MCAN J-23-3) 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) It is a significant new use to manufacture, process, or use the microorganism other than in a fermentation system that meets all of the following conditions:

(A) Enzyme production occurs by submerged fermentation (i.e., for enzyme production, growth of the microorganism occurs beneath the surface of the liquid growth medium); and

(B) Any fermentation of solid plant material or insoluble substrate to which the microorganism fermentation broth is added after the standard industrial fermentation is completed is initiated only after the inactivation of the microorganism as delineated in § 725.422(d).

(ii) [Reserved]

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

(1) *Recordkeeping*. Recordkeeping requirements as specified in § 725.950(b)(2) through (4) 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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