



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 721 and 725

[EPA-HQ-OPPT-2018-0777; FRL-9994-62]

RIN 2070-AB27

Significant New Use Rules on Certain Chemical Substances (19-1.F)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing significant new use rules (SNURs) under the Toxic Substances Control Act (TSCA) for 31 chemical substances, 30 of which were the subject of premanufacture notices (PMNs) and 1 (a microorganism) that was the subject of a Microbial Commercial Activity Notice (MCAN). 17 of these chemical substances are subject to Orders issued by EPA pursuant to the TSCA. This action would require persons who intend to manufacture (defined by statute to include import) or process any of these 31 chemical substances for an activity that is proposed as a significant new use to notify EPA at least 90 days before commencing that activity. The required notification initiates EPA's evaluation of the use, under the conditions of use for that chemical substance, within the applicable review period. Persons may not commence manufacture or processing for the significant new use until EPA has conducted a review of the notice, made an appropriate determination on the notice, and has taken such actions as are required by that determination.

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

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-

HQ-OPPT-2018-0777, by one of the following methods:

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

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

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

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

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Kenneth Moss, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-9232; email address: moss.kenneth@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you manufacture, process, or use the

chemical substances contained in this proposed rule. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Manufacturers or processors of one or more subject chemical substances (NAICS codes 325 and 324110), e.g., chemical manufacturing and petroleum refineries.

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Chemical importers are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements promulgated at 19 CFR 12.118 through 12.127 and 19 CFR 127.28. Chemical importers must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA. Importers of chemicals subject to final SNURs must certify their compliance with the SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export a chemical substance that is the subject of this proposed rule on or after **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]** are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)) (see 40 CFR 721.20 or § 725.920), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

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

1. *Submitting CBI.* Do not submit this information to EPA through *regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific

information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

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

II. Background

A. What Action is the Agency Taking?

EPA is proposing these SNURs under TSCA section 5(a)(2) for chemical substances that were the subject of PMNs and an MCAN. These proposed SNURs would require persons to notify EPA at least 90 days before commencing the manufacture or processing of a chemical substance for any activity proposed as a significant new use. Receipt of such notices would allow EPA to assess risks and, if appropriate, to regulate the significant new use before it may occur. Additional background regarding SNURs is more fully set out in the preamble to EPA's first direct final SNUR published in the **Federal Register** issue of April 24, 1990 (55 FR 17376). Consult that preamble for further general information on the objectives, rationale, and procedures for SNURs and on the basis for significant new use designations, including provisions for developing test data.

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

Section 5(a)(2) of TSCA (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 four bulleted TSCA section 5(a)(2) factors listed in Unit III. Once EPA determines that a use of a chemical substance is a significant new

use, TSCA section 5(a)(1)(B) requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture or process the chemical substance for that use (15 U.S.C. 2604(a)(1)(B)(i)). TSCA furthermore prohibits such manufacturing or processing from commencing until EPA has conducted a review of the notice, made an appropriate determination on the notice, and taken such actions as are required in association with that determination (15 U.S.C. 2604(a)(1)(B)(ii)).

C. Applicability of General Provisions

General provisions for SNURs appear in 40 CFR part 721, subpart A and (for microorganisms) 40 CFR part 725, subpart L. These provisions describe persons subject to the proposed rule, recordkeeping requirements, and exemptions to reporting requirements, and applicability of the rule to uses occurring before the effective date of the rule. Provisions relating to user fees appear at 40 CFR part 700. Pursuant to § 721.1(c), persons subject to SNURs must comply with the same SNUN requirements and EPA regulatory procedures as submitters of PMNs under TSCA section 5(a)(1)(A) (15 U.S.C. 2604(a)(1)(A)). In particular, these requirements include the information submission requirements of TSCA section 5(b) and 5(d)(1) (15 U.S.C. 2604(b) and 2604(d)(1)), the exemptions authorized by TSCA section 5(h)(1), (h)(2), (h)(3), and (h)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUN, EPA must either determine that the use is not likely to present an unreasonable risk of injury under the conditions of use for the chemical substance or take such regulatory action as is associated with an alternative determination before the manufacture or processing for the significant new use can commence. In the case of a determination other than not likely to present unreasonable risk, the applicable review period must also expire before manufacturing or processing for the new use may commence. If EPA determines that the use is not likely to present an unreasonable risk,

EPA is required under TSCA section 5(g) to make public, and submit for publication in the **Federal Register**, a statement of EPA's findings.

III. Significant New Use Determination

Section 5(a)(2) of TSCA states that EPA's determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors, including:

- The projected volume of manufacturing and processing of a chemical substance.
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.
- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.
- The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

In determining significant new uses for the 31 chemical substances that are the subject of these SNURs, EPA considered relevant information about the toxicity of the chemical substances and potential human exposures and environmental releases that may be associated with the conditions of use for the substances, in addition to the factors in TSCA section 5(a)(2). Note that when the Agency issues an order under TSCA section 5(e), section 5(f)(4) requires that the Agency consider whether to promulgate a SNUR for any use not conforming to the restrictions of the Order or publish a statement describing the reasons for not initiating the rulemaking.

IV. Substances Subject to this Proposed Rule

EPA is proposing significant new use and recordkeeping requirements for 30 chemical substances in 40 CFR part 721, subpart E and 1 chemical substance that is a microorganism

described in MCAN J-18-41 in 40 CFR part 725. In this unit, EPA provides the following information for each chemical substance:

- PMN or MCAN number.
- Chemical name (generic name, if the specific name is claimed as CBI).
- Chemical Abstracts Service (CAS) Registry number (if assigned for non-confidential chemical identities).
- Basis for the SNUR or basis for the TSCA 5(e) Order.
- Information identified by EPA that would help characterize the potential health and/or environmental effects of the chemical substance in support of a request by the PMN/MCAN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use designated by the SNUR. This information may include testing required in a TSCA section 5(e) Order to be conducted by the PMN/MCAN submitter, as well as testing not required to be conducted but which would also help characterize the potential health and/or environmental effects of the PMN/MCAN substance. Any recommendation for information identified by EPA was made based on EPA's consideration of available screening-level data, if any, as well as other available information on appropriate testing for the chemical substance. Further, any such testing identified by EPA that includes testing on vertebrates was made after consideration of available toxicity information, computational toxicology and bioinformatics, and high-throughput screening methods and their prediction models. EPA also recognizes that whether testing/further information is needed will depend on the specific exposure and use scenario in the SNUN. EPA encourages all SNUN submitters to contact EPA to discuss any potential future testing. See Unit VII. for more information.
- CFR citation assigned in the regulatory text section of the proposed rule. The regulatory

text section of each proposed rule specifies the activities that would be designated as significant new uses. Certain new uses, including exceedance of production volume limits (i.e., limits on manufacture volume) and other uses designated in this proposed rule, may be claimed as CBI.

These proposed rules include 17 PMN substances that are subject to Orders issued under TSCA section 5(e)(1)(A), as required by the determinations made under section 5(a)(3)(B).

Those Orders require protective measures to limit exposures or otherwise mitigate the potential unreasonable risk. The proposed SNURs would 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 Orders, consistent with TSCA section 5(f)(4).

Where EPA determined that the PMN substance may present an unreasonable risk of injury to human health via inhalation exposure, the underlying TSCA section 5(e) Order usually requires, among other things, that potentially exposed employees wear specified respirators unless actual measurements of the workplace air show that air-borne concentrations of the PMN substance are below a New Chemical Exposure Limit (NCEL) that is established by EPA to provide adequate protection to human health. In addition to the actual NCEL concentration, the comprehensive NCELs provisions in TSCA section 5(e) Orders, which are modeled after Occupational Safety and Health Administration (OSHA) Permissible Exposure Limits (PELs) provisions, include requirements addressing performance criteria for sampling and analytical methods, periodic monitoring, respiratory protection, and recordkeeping. However, no comparable NCEL provisions currently exist in 40 CFR part 721, subpart B, for SNURs. Therefore, for these cases, the individual SNURs in 40 CFR part 721, subpart E, will state that persons subject to the SNUR who wish to pursue NCELs as an alternative to the § 721.63 respirator requirements may request to do so under § 721.30. EPA expects that persons whose §

721.30 requests to use the NCELS approach for SNURs that are approved by EPA will be required to comply with NCELS provisions that are comparable to those contained in the corresponding TSCA section 5(e) Order for the same chemical substance.

These proposed rules also include 13 PMN substances and 1 MCAN substance that received “not likely to present an unreasonable risk” determination in TSCA section 5(a)(3)(C). However, during the course of these reviews, EPA identified concerns for certain health and/or environmental risks if the chemicals were not used following the limitations identified by the submitters in the notices, but the section 5(a)(3)(C) determinations did not deem those uses as reasonably foreseen. The proposed SNURs would identify as significant new uses any manufacturing, processing, use, distribution in commerce, or disposal that does not conform to those same protection measures.

The chemicals subject to these proposed SNURs are as follows:

PMN Number: P-17-157

Chemical name: Silane amine carbonate (generic).

CAS number: Not available.

Effective date of TSCA section 5(e) Order: October 15, 2018.

Basis for TSCA section 5(e) Order: The PMN states that the generic (non-confidential) use of the substance will be for an open, non-dispersive use. Based on the physical/chemical properties of the PMN substance and Structure Analysis Relationships (SAR) analysis of test data on analogous substances, EPA has identified concerns for lung toxicity and irritation, if the chemical substance is not used following the limitations noted. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an

unreasonable risk to human health and the environment. To protect against these risks, the Order requires:

1. Use of personal protective equipment to prevent dermal exposure where there is a potential for dermal exposure;
2. Use of a National Institute of Occupational Safety and Health (NIOSH)-certified respirator with an Assigned Protection Factor (APF) of at least 1,000 where there is a potential for inhalation exposure; and
3. Establishment and use of a hazard communication program, including precautionary statements on each label and in the Safety Data Sheet (SDS).

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

Potentially useful information: EPA has determined that certain information may be potentially useful to characterize the health effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this SNUR. EPA has determined that the results of irritation and pulmonary effects testing would help characterize the potential health effects of the PMN substance. Although the Order does not require this test, the Order’s restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

CFR citation: 40 CFR 721.11267.

PMN Number: P-17-295

Chemical Name: Hydrochlorofluorolefin (generic).

CAS Number: Not Available.

Effective date of TSCA section 5(e) Order: November 7, 2018.

Basis for TSCA section 5(e) Order: The PMN states that the generic use of the PMN substance will be as a refrigerant used in closed systems for chillers (commercial comfort air conditioners) and industrial process refrigeration. EPA identified concerns for death, suppression of food consumption, lower weights of the thymus and epididymides in males, and histological changes in the lungs, testes, liver, and kidney based on an inhalation toxicity study conducted on the PMN substance. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to the health or environment. To protect against these risks, the Order requires:

1. Use of personal protective equipment to prevent dermal exposure where there is a potential for dermal exposure;
2. Use of NIOSH certified respirators with an APF of at least 10 where there is a potential for inhalation exposure, or compliance with a NCEL of 23.6 mg/m³ as an 8-hour time-weighted average, to prevent inhalation exposure;
3. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS;
4. No domestic manufacture of the PMN substance (import only);
5. No consumer use; and
6. Use only as a refrigerant used in closed systems for chillers (commercial comfort air conditioners) and industrial process refrigeration.

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

Potentially useful information: EPA has determined that certain information about potential exposure to the PMN substance may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this SNUR. EPA has determined that information that demonstrates adequate control of emissions using engineering controls other than those described in the PMN would be useful in determining the exposure to the PMN substance. Although the Order does not require this information, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

CFR citation: 40 CFR 721.11268.

PMN Numbers: P-17-306 and P-17-307

Chemical names: Fatty acid modified aromatic polyester polyols (generic).

CAS numbers: Not available.

Effective date of TSCA section 5(e) Order: December 27, 2018.

Basis for TSCA section 5(e) Order: The PMNs state that the generic (non-confidential) use of the substances will be as components in foam insulation. Based on data on primary metabolites, EPA identified concern for ocular toxicity, bladder effects, and kidney effects. EPA also identified concern for lung effects, irritation to eyes, mucous membranes and lung, and anesthetization of the eye based on surfactant properties. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, that the substances may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

1. Use of personal protective equipment involving impervious gloves where there is a potential for dermal exposure;

2. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS; and

3. Refraining from use of the PMN substances involving any application method that generates a vapor, mist, aerosol or dust to which workers may be exposed.

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

Potentially useful information: EPA has determined that certain information about the health effects of the PMN substances may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this SNUR. A specific target organ toxicity test would help EPA determine the potential effects of the PMN substances. Although the Order does not require this test, the Order’s restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

CFR citation: 40 CFR 721.11269 (P-17-306 and P-17-307).

PMN Number: P-17-320

Chemical Name: Dodecanedioic acid and 1,6-hexanediol polymer with 3-hydroxy-2,2-dimethylpropyl 2,2-dimethylhydracrylate, neopentylglycol, 1,2 ethanediol, adipic acid, Isophthalic acid, terephthalic acid, 2-Oxooxopane, BayFlex 2002H and 1,1'-methylenebis(isocyanatobenzene) (generic).

CAS Number: Not available.

Effective date of TSCA section 5(e) Order: December 28, 2018.

Basis for TSCA section 5(e) Order: The PMN states that the generic use of the PMN substance will be as an industrial adhesive. EPA identified concerns for dermal and respiratory sensitization, lung and mucous membrane irritation and mutagenicity based on isocyanate moiety for the low molecular weight fractions. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation the substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

1. Use of personal protective equipment to prevent dermal exposure where there is a potential for dermal exposure;
2. Use of a NIOSH-certified respirator with an APF of at least 50 where there is a potential for inhalation exposure;
3. Refraining from using the PMN substance involving any application method that generates a vapor, mist, aerosol, or dust;
4. Refraining from manufacturing the PMN substance with greater than 1% residual isocyanate by weight;
5. Refraining from using the PMN substance for consumer or commercial use; and
6. Establishment and use of a hazard communication program, including human health precautionary statements on each label and the SDS.

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

Potentially useful information: EPA has determined that certain information about the health effects of the PMN substance may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a

SNUN for a significant new use that would be designated by this SNUR. EPA has also determined that sensitization and mutagenicity effects testing of the PMN substance would be useful in determining the health effects of the PMN substance. Although the Order does not require this information, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

CFR citation: 40 CFR 721.11270.

PMN Number: P-17-329

Chemical name: Ethanone, 1-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]-

CAS number: 1417782-28-5

Effective date of TSCA section 5(e) Order: August 30, 2018.

Basis for TSCA section 5(e) Order: The PMN states that the generic (non-confidential) use of the substance will be as an intermediate used in synthesis. EPA has identified concerns for sensitization, liver, blood, spleen, reproductive, and aquatic toxicity at concentrations that exceed 7 ppb based on hazard data submitted for the PMN. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health or the environment. The Order was also issued under TSCA sections 5(a)(3)(B)(ii)(II) and 5(e)(1)(A)(ii)(II), based on a finding that the substance is or will be produced in substantial quantities and that the substance either enters or may reasonably be anticipated to enter the environment in substantial quantities, or there is or may be significant (or substantial) human exposure to the substance. To protect against these risks, the Order requires:

1. Use of the PMN substance only for the confidential use specified in the Order;
2. No release of the PMN substance to surface waters exceeding 7 parts per billion (ppb);

3. Use of personal protective equipment to its workers to prevent dermal exposure where there is potential for dermal exposure;

4. Use of NIOSH-certified respirators with an APF of at least 50 where there is potential for inhalation exposure; and

5. Establishment and use of a hazard communication program, including human health precautionary statements on each label and the SDS.

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

Potentially useful information: EPA has determined that certain information about the environmental effects of the PMN substance may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this SNUR. A chronic aquatic toxicity test would help EPA determine the potential environmental effects of the PMN substance. Although the Order does not require this information, the Order’s restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

CFR citation: 40 CFR 721.11271.

PMN Numbers: P-17-367, P-17-368, P-17-369, P-17-370, P-17-371, P-17-372

Chemical names: Vegetable oil, polymer with alkanedioic acid, alkali lignin, diethylene glycol- and polyol-depolymd. poly(ethylene terephthalate) waste plastics and arylcarboxylic acid anhydride (generic) (P-17-367); Vegetable oil, polymer with alkanedioic acid, alkali lignin, diethylene glycol- and polyol-depolymd. poly(ethylene terephthalate) waste plastics (generic) (P-17-368); Waste plastics, poly(ethylene terephthalate), depolymd. with diethylene glycol,

polymers with alkanedioic acid, alkali lignin and arylcarboxylic acid anhydride (generic) (P-17-369); Waste plastics, poly(ethylene terephthalate), depolymd. with diethylene glycol and polyol, polymers with alkanedioic acid, alkali lignin and arylcarboxylic acid anhydride (generic) (P-17-370); Vegetable oil, polymer with alkanedioic acid, alkali lignin, diethylene glycol- and polyol-depolymd. poly(ethylene terephthalate) waste plastics and arylcarboxylic acid anhydride (generic) (P-17-371); Vegetable oil, polymer with alkanedioic acid, alkali lignin, diethylene glycol-depolymd. poly(ethylene terephthalate) waste plastics and arylcarboxylic acid anhydride (generic) (P-17-372).

CAS numbers: Not available.

Effective date of TSCA section 5(e) Order: November 2, 2018.

Basis for TSCA section 5(e) Order: The PMNs state that the use of the substances will be as intermediates for use in the manufacture of polymers. EPA has estimated low human health hazard of the PMN substances based on their estimated physical properties, and by comparing them to structurally analogous chemical substances. If the PMN substances are manufactured differently as polymers under the same Chemical Abstracts Service Registry Number (CAS RN) (i.e., changes in the proportion of repeating units, the average molecular weight, percentage of low molecular weight components, and/or proportion of surface active monomers), hazard concerns may result based on changes in water solubility, dispensability, absorption, etc. Concerns may also result from ester moieties if the PMN substances are not manufactured as described in the PMN submissions. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substances may present an unreasonable risk of injury to human health and the environment. The Order was also issued under TSCA sections 5(a)(3)(B)(ii)(II) and

5(e)(1)(A)(ii)(II), based on a finding that the substances are or will be produced in substantial quantities and that the substances either enter or may reasonably be anticipated to enter the environment in substantial quantities, or there is or may be significant (or substantial) human exposure to the substances. To protect against these risks, the Order requires:

1. Manufacture of the PMN substances with less than or equal to the confidential percentages of low molecular weight components and not less than the confidential average molecular weight specified in the Order; and

2. Hazard communication requirements if new information identifies potential injury to human health or the environment.

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

Potentially useful information: EPA has determined that certain information about the physical-chemical properties and environmental effects of the PMN substances may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this SNUR. Physical-chemical property and aquatic toxicity testing would help EPA determine the potential effects of the PMN substances. Although the Order does not require this information, the Order’s restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

CFR citations: 40 CFR 721.11272 (P-17-367); 40 CFR 721.11273 (P-17-368); 40 CFR 721.11274 (P-17-369); 40 CFR 721.11275 (P-17-370); 40 CFR 721.11276 (P-17-371); and 40 CFR 721.11277 (P-17-372).

PMN Number: P-17-382

Chemical name: Amides, tallow, N,N-bis(2-hydroxypropyl).

CAS number: 1454803-04-3.

Basis for action: The PMN states that the use of the substance will be as a friction modifier for automotive lubricants. Based on the physical/chemical properties of the PMN substance and Structure Analysis Relationships (SAR) analysis of test data on analogous substances, EPA has identified concerns for sensitization, specific organ toxicity, lung toxicity, and aquatic toxicity at concentrations that exceed 11 ppb if the chemicals are not used following the limitations noted. The intended conditions of use of the PMN substance described in the PMN include the following protective measures:

1. No processing resulting in an end use product containing greater than 3% by weight of the PMN substance;
2. No manufacture, processing or use that results in inhalation exposures; and
3. No release of the PMN substance to surface waters exceeding 11 ppb.

Potentially useful information: EPA has determined that certain information may be potentially useful to characterize the health and environmental effects of the PMN substance if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of sensitization, pulmonary effects, specific organ toxicity, and aquatic toxicity testing would help characterize the potential health and environmental effects of the PMN substance.

CFR citation: 40 CFR 721.11278.

PMN Number: P-17-394

Chemical Name: Substituted propanoic acid, polymer with alkylisocyanate-substituted carbomonocycle, dialkyl carbonate, hydroxyl alkyl substituted alkanediol, alkanediol, isocyanato

substituted carbomonocycle, alkanol substituted amines-blocked, compds. with (alkylamino)alkanol, (generic).

CAS Number: Not available.

Effective date of TSCA section 5(e) Order: April 12, 2018.

Basis for TSCA section 5(e) Order: The PMN states that the use of the PMN substance will be as a coating to improve chemical resistance. EPA identified concerns for nasal and ocular irritation and lung toxicity. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation the substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

1. Refraining from manufacture of the PMN substance in the United States (import only);
2. No use of the PMN substance other than as a coating to improve chemical resistance;
3. Import of the PMN substance with an average molecular weight greater than 1,000 daltons;
4. Import of the PMN substance to contain no more than 0.1% residual isocyanate by weight; and
5. Import of the PMN substance to contain no more than 4% of a confidential component identified in the Order by weight.

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

Potentially useful information: EPA has determined that certain information about the human health and environmental effects of the PMN substance may be potentially useful to characterize the effects of the PMN substance, in support of a request by the PMN submitter to modify the

Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of reproductive/developmental and aquatic toxicity testing would help characterize the potential health and environmental effects of the PMN substance. Although the Order does not require this information, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

CFR citation: 40 CFR 721.11279.

PMN Numbers: P-18-23 and P-18-24

Chemical Names: Propanediol phosphate (generic) (P-18-23) and substituted cashew, nutshell liquid, polymer with epichlorohydrin, phosphate (generic) (P-18-24).

CAS Numbers: Not Available.

Effective date of TSCA section 5(e) Order: December 19, 2018.

Basis for TSCA section 5(e) Order: The PMN states that the use of the PMN substances will be as epoxy hardener/curatives. EPA identified concerns for lung effects and irritation to the eyes, lungs, and mucous membranes based on surfactant activity. EPA also identified concern for corrosion to all tissues based on the low pH of the PMN substances. There are also concern for liver and systemic toxicity (P-18-23) and sensitization due to the presence of cashew nutshell liquid (P-18-24). Based on analysis of test data on analogous chemicals, EPA predicts toxicity to aquatic organisms may occur at concentrations greater than 3 ppb for P-18-23. Based on SAR predictions for anionic surfactants, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb for P-18-24. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation the substance may present an unreasonable risk of

injury to human health and the environment. To protect against these risks, the Order requires:

1. No manufacture, processing, or use of the PMN substances involving an application method that generates a vapor, mist, or aerosol;
2. No use of the PMN substances in a consumer product;
3. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS; and
4. No release of the PMN substances into the waters of the United States.

The SNUR designates as a “significant new use” the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the health and environmental effects of the PMN substances may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of specific target organ toxicity, skin irritation/corrosion, sensitization, and aquatic toxicity testing would help characterize the potential health and environmental effects of the PMN substance. Although the Order does not require this information, the Order’s restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

CFR citations: 40 CFR 721.11280 (P-18-23) and 40 CFR 721.11281 (P-18-24).

PMN Number: P-18-41

Chemical name: 2,5-Furandione, polymer with 2-ethyl-2-(hydroxymethyl)-1,3-propanediol, 3a,4,5,6,7,7a-hexahydro-4,7-methano-1H-inden-5(or 6)-yl ester, ester with 2,3-dihydroxypropyl neodecanoate.

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as an intermediate polyol for further reaction. Based on SAR analysis of test data on 2-ethylhexanoic acid, EPA identified concerns for developmental toxicity for the branched acid low molecular weight components and metabolic degradation products of the terminal ester group of the PMN substance if the chemicals are not used following the limitations noted. The intended conditions of use of the PMN substance described in the PMN include the following protective measures:

1. No manufacture (including import) of the PMN substance with the number average molecular weight of less than 1000 daltons; and
2. No use of the PMN substance for other than as a chemical intermediate.

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

Potentially useful information: EPA has determined that certain information about the health effects of the PMN substance may be potentially useful if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of physical chemical properties, absorption, distribution, metabolism, and elimination (ADME), developmental toxicity testing would help characterize the potential health effects of the PMN substance.

CFR Citation: 40 CFR 721.11282.

PMN Number: P-18-70

Chemical name: Waste plastics, polyester, depolymd. with glycols, polymers with dicarboxylic acids (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as an intermediate for the polyurethane industry. Based on data for a metabolite of a component of the PMN substance EPA identified concerns for blood, bladder and developmental toxicity if the chemicals are not used following the limitations noted. The intended conditions of use of the PMN substance described in the PMN include the following protective measure:

1. No use the PMN substance other than the confidential uses stated in the PMN submission.

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

Potentially useful information: EPA has determined that certain information about the health effects of the PMN substance may be potentially useful to characterize the health effects of the PMN substance if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of specific target organ and developmental/reproductive toxicity testing would help characterize the potential health effects of the PMN substance.

CFR Citation: 40 CFR 721.11283.

PMN Number: P-18-88

Chemical Name: Di(substituted-1,3-trialkylammonium) dialkylammonium salt (generic).

CAS Number: Not available.

Effective date of TSCA section 5(e) Order: December 17, 2018.

Basis for TSCA section 5(e) Order: The PMN states that the generic use of the PMN substance will be in oil and gas production. EPA identified concerns for lung effects based on physical-

chemical properties. There are also concerns for neurotoxicity, hepatotoxicity and eye irritation based on data for analogous chemical substances. EPA has also identified concern for aquatic toxicity due to cationic (quarternary ammonium) surfactants. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health and the environment. The Order was also issued under TSCA sections 5(a)(3)(B)(ii)(II) and 5(e)(1)(A)(ii)(II), based on a finding that the substance is or will be produced in substantial quantities and that the substance either enters or may reasonably be anticipated to enter the environment in substantial quantities, or there is or may be significant (or substantial) human exposure to the substance. To protect against these risks, the Order requires:

1. Refraining from using the PMN substance other than for the confidential uses identified in the Order;
2. Refraining from manufacturing, processing, or use of the PMN substance that would result in the generation of vapor, mist, particulate, or aerosol;
3. No release of the PMN substance to surface water that exceed 1000 ppb; and
4. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.

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

Potentially useful information: EPA has determined that certain information about health effects of the PMN substance may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has also determined

that specific eye irritation, specific target organ toxicity, and pulmonary effects testing of the PMN substance would be useful in determining the effects of the PMN substance. Although the Order does not require this information, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

CFR citation: 40 CFR 721.11284.

PMN Numbers: P-18-100 and P-18-102

Chemical names: Substituted alkanolic acid polymer with alkylcarbonate, alkanediols and isocyanate substituted carbomonocycles, sodium salt, alkenoic acidsubstituted polyol reaction products-blocked (generic) (P-18-100) and alkenoic acid, ester with [oxybis(alkylene)]bis[alkyl-substituted alkanediol], polymer with alkylcarbonate, alkanediols, substituted alkanolic acid and isocyanate and alkyl substituted carbomonocycle, sodium salt (generic) (P-18-102).

CAS numbers: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substances will be as UV curable coating resins. Based on analogy to structurally similar substances, EPA has identified concerns for irritation, sensitization, developmental toxicity, and liver toxicity if the chemicals are not used following the limitations noted. The intended conditions of use of the PMN substances described in the PMNs include the following protective measures:

1. No domestic manufacture in the United States (i.e., import only); and
 2. No use of the PMN substances other than the confidential use described in the PMNs;
- and
3. No use in a consumer product.

The proposed SNUR would designate as a "significant new use" the absence of these

protective measures.

Potentially useful information: EPA has determined that certain information about the health effects of the PMN substances may be potentially useful if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of specific organ toxicity, reproductive/developmental toxicity, and sensitization would help characterize the potential health effects of the PMN substances.

CFR Citation: 40 CFR 721.11285 (P-18-100) and 40 CFR 721.11286 (P-18-102).

PMN Number: P-18-116

Chemical name: Castor oil, reaction products with soybean oil.

CAS number: 1186514-12-4.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as an intermediate for industrial chemicals. Based on the physical/chemical properties of the PMN substance and Structure Analysis Relationships (SAR) analysis of test data on analogous substances, EPA has identified concerns for sensitization, and aquatic toxicity at surface water concentrations exceeding 4 parts per billion (ppb), if the chemical substance is not used following the limitations noted. The intended conditions of use of the PMN substance described in the PMN include the following protective measures:

1. No manufacture (excluding import) of the PMN substance in the United States;
2. Not exceeding the confidential annual production volume stated in the PMN submission;
3. No use of the PMN substance other than for the confidential use stated in the PMN submission; and

4. No processing or use of the PMN substance resulting in inhalation exposures to aerosols or mists.

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

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

CFR citation: 40 CFR 721.11287.

PMN Number: P-18-134

Chemical Name: Benzene, 1-(chloromethyl)-3-methyl-.

CAS Number: 620-19-9.

Effective date of TSCA section 5(e) Order: November 1, 2018.

Basis for TSCA section 5(e) Order: The PMN states that the generic (non-confidential) use of the PMN substance will be as a chemical intermediate. EPA identified concerns for severe skin burns and eye damage, serious eye irritation, respiratory irritation, skin irritation, and oral toxicity based on structural alerts and information in the submitted SDS. Based on test data submitted with the PMN, there are also concerns for skin irritation and sensitization.

Mutagenicity, carcinogenicity, neurotoxicity, developmental toxicity, and respiratory and dermal sensitization are of concern based on analysis of test data on an analog. Risks for lung toxicity and carcinogenicity via inhalation cancer via dermal exposure were identified to workers based

on analysis of test data on an analogue substance. Based on QSAR predictions for analogous chemicals, EPA also predicts toxicity to aquatic organisms. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(I)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation the substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

1. Use of personal protective equipment to prevent dermal exposure where there is a potential for dermal exposure;
2. Use of a NIOSH-certified respirator with an APF of at least 1000 to prevent inhalation exposure where there is potential for inhalation exposure;
3. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS;
4. Refrain from varying the process or use methods described in the PMN such that occupational exposure is increased;
5. Refrain from using the PMN substance other than for the confidential use allowed in the Order; and
6. No release of the PMN substance into the waters of the United States.

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

Potentially useful information: EPA has determined that certain information about the health and environmental effects of the PMN substance may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has also determined that the results or specific target organ toxicity,

reproductive/developmental toxicity testing, aquatic toxicity testing, and carcinogenicity testing would help characterize the potential human and environmental effects of the PMN substance. Although the Order does not require this information, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

CFR citation: 40 CFR 721.11288.

PMN Number: P-18-136

Chemical name: 1-Butanaminium,N,N,N-tributyl-,2(or5)- [[benzoyldihydrodioxo[(sulfohenyl) amino]heteropolycycle[oxy]-5(or2)-(1,1-dimethylpropyl)benzenesulfonate (2:1) (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as a coloring agent. Based on the physical/chemical properties of the PMN substance and Structure Analysis Relationships (SAR) analysis of test data on analogous substances, EPA has identified concerns for systemic toxicity, and aquatic toxicity at surface water concentrations exceeding 19 parts per billion (ppb), if the chemical substance is not used following the limitations noted. The intended conditions of use of the PMN substance described in the PMN include the following protective measures:

1. No manufacture, processing, or use of the PMN substance if it results in inhalation exposure; and

2. No release of the PMN substance to surface water that exceed 19 ppb.

The proposed SNUR would designate as a "significant new use" the absence of these protective measures.

Potentially useful information: EPA has determined that certain information may be potentially

useful to characterize the health and environmental effects of the PMN substance if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of specific target organ toxicity, and aquatic toxicity testing would help characterize the potential health and environmental effects of the PMN substance.

CFR citation: 40 CFR 721.11289.

PMN Number: P-18-137

Chemical name: Alkylsilsequioxane, ethoxy-terminated (generic).

CAS number: Not available.

Basis for action: The PMN states that the use of the substance will be as a water repellent for fiber-reinforced cement products in construction materials, like fiber-cement board. Based on the physical/chemical properties of the PMN substance, data on the PMN substance, and Structure Analysis Relationships (SAR) analysis of test data on analogous substances, EPA has identified concerns for liver toxicity, lung toxicity by waterproofing of lung membranes, irritation, developmental toxicity, and aquatic toxicity at surface water concentrations exceeding 58 parts per billion (ppb), if the chemical substance is not used following the limitations noted. The intended conditions of use of the PMN substance described in the PMN include the following protective measures:

1. No release of the PMN substance to surface waters that exceed 58 ppb; and
2. No processing or use of the PMN substance in any manner that results in inhalation exposures.

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

Potentially useful information: EPA has determined that certain information may be potentially useful to characterize the health and environmental effects of the PMN substance if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of physical-chemical property testing, absorption, distribution, metabolism, elimination (ADME) testing, pulmonary effects, and specific target organ and aquatic toxicity testing would help characterize the potential health and environmental effects of the PMN substance.

CFR citation: 40 CFR 721.11290.

PMN Number: P-18-219

Chemical name: Polythioether, short chain diol polymer terminated with aliphatic diisocyanate (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as an intermediate for topcoat. Based on test data on the PMN substance and on test data on analogous chemical substances, EPA has identified concerns for irritation, sensitization and lung effect if the chemical is not used following the limitations noted. The intended conditions of use of the PMN substance described in the PMN include the following protective measures:

1. No manufacture (including import) the PMN substance with molecular weight greater than 10,000 daltons; and
2. No manufacture (including import) the PMN substance with free isocyanate residuals greater than 0.01% by weight.

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

Potentially useful information: EPA has determined that certain information about the PMN substance may be potentially useful to characterize the health effects of the PMN substance if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of absorption, specific target organ toxicity, irritation and sensitization testing would help characterize the potential health effects of the PMN substance.

CFR citation: 40 CFR 721.11291.

PMN Numbers: P-18-224 and P-18-225

Chemical names: Alkenoic acid, polymer with alkenylcarbomonocycle, [alkanediylbis(substituted alkylene)] bis[heteromonocycle] and (alkylalkenyl) aromatic, salt (generic) (P-18-224) and Alkenoic acid, polymer with substituted alkyloxirane, alkenylcarbomonocycle, alkyl substituted alkyl alkanediol and (alkylalkenyl) aromatic salt (generic) (P-18-225).

CAS numbers: Not available.

Basis for action: The PMNs state that the generic (non-confidential) use of the substances will be as a component of ink. Based on analogy to structurally similar substances, EPA has identified concerns for carcinogenicity, neurotoxicity and developmental toxicity and lung effects if the chemicals are not used following the limitations noted. The intended conditions of use of the PMN substances described in the PMNs include the following protective measures:

1. No manufacture, processing or use of the PMN substances that results in inhalation exposures; and

2. Manufacture of the PMN substances with acid content no greater than 20% by weight.

The proposed SNUR would designate as a “significant new use” the absence of these

protective measures.

Potentially useful information: EPA has determined that certain information may be potentially useful to characterize the health effects of the PMN substances if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of absorption, neurotoxicity and pulmonary effects testing of the PMN substances may be potentially useful in characterizing the health effects of the PMN substances.

CFR citation: 40 CFR 721.11292 (P-18-224) and 40 CFR 721.11293 (P-18-225).

PMN Number: P-18-233

Chemical name: Alkyl alkenoic acid, alkyl ester, telomer with alkylthiol, substituted carbomonocycle, substituted alkyl alkyl alkenoate and hydroxyalkyl alkenoate, tertbutyl alkyl peroxyate-initiated, (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as a coating agent. Based on data for analogous compounds, EPA has identified concerns for systemic, reproductive and developmental, and lung toxicity if the chemical is not used following the limitations noted. The intended conditions of use of the PMN substance described in the PMN include the following protective measure:

1. No manufacturing (including import) in a solid form.

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

Potentially useful information: EPA has determined that certain information may be potentially useful to characterize the health effects of the PMN substance if a manufacturer or processor is

considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of absorption and metabolism, systemic, reproductive, and developmental toxicity testing would help characterize the potential health effects of the PMN substance.

CFR citations: 40 CFR 721.11294.

PMN Number: P-18-279

Chemical name: Substituted heteromonocycle, polymer with substituted alkanediol and diisocyanate substituted carbomonocycle, alkylene glycol acrylate-blocked (generic).

CAS number: Not available.

Basis for action: The PMN states that the use of the substance will be as a UV curable coating resin. Based on the physical/chemical properties of the PMN substance and test data on structurally similar substances, EPA has identified concerns for sensitization and irritation if the chemical is not used following the limitations noted. The intended conditions of use of the PMN substance described in the PMN include the following protective measure:

1. Use of NIOSH-certified respirator with an APF of 1000 when there is inhalation exposure from spray application.

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

Potentially useful information: EPA has determined that certain information about the health effects of the PMN substance may be potentially useful to characterize the effects of the PMN substance if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of corrosion/irritation and sensitization testing would help characterize the potential health effects

of the PMN substance.

CFR citation: 40 CFR 721.11295.

MCAN Number: J-18-41

Chemical name: Arsenic detecting strain of *E. coli* with extra-chromosomal elements, including an intergeneric screening marker (generic).

CAS number: Not available.

Basis for action: The MCAN states that the use of the substance will be to detect arsenic in small water samples. Based on the inclusion of antibiotic resistance genes in the MCAN microorganism, conferring resistance to clinically important antibiotics, EPA has identified concerns for loss of therapeutic value of these antibiotics if the resistance gene were to be horizontally transferred to a pathogen in the environment and if infections caused by those pathogens are treated with these antibiotics. There is low potential for gene transfer, and due to the low expected releases, the risks from this MCAN microorganism are low under the intended conditions of use. The intended conditions of use of the MCAN microorganism described in the MCAN include the following protective measures:

1. No domestic manufacture within the United States (i.e., import only); and
2. No use of the MCAN microorganism other than to detect arsenic in small water samples.

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

Potentially useful information: EPA has determined that certain information about the environmental fate and transfer of the antibiotic resistance gene in the MCAN microorganism may be potentially useful to characterize the health and environmental effects of the MCAN

microorganism if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of a study of transformation of intergeneric DNA (*bla*_{TEM-1}) from the MCAN microorganism (either living or inactivated) into microbes in the environment would help characterize the potential health and environmental effects of the MCAN microorganism.

CFR citation: 40 CFR 725.1079.

V. Rationale and Objectives of the Proposed Rule

A. Rationale

During review of the PMNs submitted for the chemical substances that are subject to these proposed SNURs, EPA concluded that for 17 chemical substances regulation was warranted under TSCA section 5(e), pending the development of information sufficient to make reasoned evaluations of the health or environmental effects of the chemical substances. The basis for such findings is outlined in Unit IV. Based on these findings, TSCA section 5(e) Orders requiring the use of appropriate exposure controls were negotiated with the PMN/MCAN submitters. The SNURs would 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 Orders, consistent with TSCA section 5(f)(4).

During review of the other 14 chemical substances that are the subject of these SNURs and as further discussed in Unit IV, EPA identified circumstances different from the intended conditions of use identified in the PMNs that raised potential risk concerns. EPA determined that deviations from the protective measures identified in the submissions could result in changes in the type or form of exposure to the chemical substances and/or increased exposures to the chemical substances and/or changes in the reasonably anticipated manner and methods of

manufacturing, processing, distribution in commerce, and disposal of the chemical substances, and therefore warranted SNURs. The SNURs would identify as significant new uses any manufacturing, processing, use, distribution in commerce, or disposal that does not conform to the protection measures in the submission.

B. Objectives

EPA is proposing these SNURs for specific chemical substances which have undergone premanufacture review because the Agency wants to achieve the following objectives with respect to the significant new uses that would be designated in this proposed rule:

- EPA would receive notice of any person's intent to manufacture or process a listed chemical substance for the described significant new use before that activity begins.
- EPA would be required to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing or processing a listed chemical substance for the described significant new use.
- EPA would be required to either determine that the prospective manufacture or processing is not likely to present an unreasonable risk, or to take necessary regulatory action associated with any other determination, before the described significant new use of the chemical substance occurs.

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

<http://www.epa.gov/opptintr/existingchemicals/pubs/tscainventory/index.html>.

VI. Applicability of the Proposed Significant New Use Designation

To establish a significant new use, EPA must determine that the use is not ongoing. The

chemical substances subject to this proposed rule have undergone premanufacture review. In cases where EPA has not received a notice of commencement (NOC) and the chemical substance has not been added to the TSCA Inventory, no person may commence such activities without first submitting a PMN. Therefore, for chemical substances for which an NOC has not been submitted EPA concludes that the designated significant new uses are not ongoing.

When chemical substances identified in this proposed rule are added to the TSCA Inventory, EPA recognizes that, before the rule is effective, other persons might engage in a use that has been identified as a significant new use. However, TSCA section 5(e) Orders have been issued for 17 of the 31 chemical substances, and the PMN submitters are prohibited by the TSCA section 5(e) Orders from undertaking activities which would be designated as significant new uses. The identities of 27 of the 31 chemical substances subject to this proposed rule have been claimed as confidential (per §§ 720.85 and 725.85) for a chemical substance covered by this action. Based on this, the Agency believes that it is highly unlikely that any of the significant new uses described in the regulatory text of this proposed rule are ongoing.

Therefore, EPA designates **[INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]** as the cutoff date for determining whether the new use is ongoing. The objective of EPA's approach is to ensure that a person cannot defeat a SNUR by initiating a significant new use before the effective date of the final rule.

Persons who begin commercial manufacture or processing of the chemical substances for a significant new use identified as of that date 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 EPA has conducted a review of the notice, made an appropriate determination on the notice, and has taken such actions

as are required with that determination.

VII. Development and Submission of Information

EPA recognizes that TSCA section 5 does not require developing any particular new information (e.g., generating test data) before submission of a SNUN. There is an exception: development of test data is required where the chemical substance subject to the SNUR is also subject to a rule, order or consent agreement under TSCA section 4 (see TSCA section 5(b)(1)).

In the absence of a TSCA section 4 test rule 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 and 725.155). However, upon review of PMNs and SNUNs, the Agency has the authority to require appropriate testing. Unit IV. lists potentially useful information identified by EPA that would help characterize the potential health and/or environmental effects of the PMN/SNUN substance for all of the listed SNURs. EPA recognizes that the 2016 Lautenberg Amendments have led to modifications in our approach to testing requirements, including an increased consideration of alternatives to vertebrate testing. Descriptions of tests/information needs are provided for informational purposes only and EPA strongly encourages persons, before performing any testing, to consult with the Agency pertaining to protocol selection. 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 potentially useful information. EPA encourages dialogue with Agency representatives to help determine how best the submitter can meet both the data needs and the objective of TSCA section 4(h). To access the OCSPP test guidelines referenced in this document electronically, please go to <http://www.epa.gov/ocspp> and

select “Test Methods and Guidelines.” The Organisation for Economic Co-operation and Development test guidelines are available from the OECD Bookshop at <http://www.oecdbookshop.org> or SourceOECD at <http://www.sourceoecd.org>.

The potentially useful information listed in Unit IV. may not be the only means of addressing the potential risks of the chemical substance. EPA recommends that potential SNUN submitters contact EPA early enough so that they will be able to conduct the appropriate tests.

SNUN submitters should be aware that EPA will be better able to evaluate SNUNs which provide detailed information on the following:

- Human exposure and environmental release that may result from the significant new use of the chemical substances.

VIII. SNUN Submissions

According to 40 CFR 721.1(c), persons submitting a SNUN must comply with the same notification requirements and EPA regulatory procedures as persons submitting a PMN or MCAN, including submission of test data on health and environmental effects as described in 40 CFR 720.50 or § 725.160. 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 (or 40 CFR 725.25 and § 725.27). E-PMN software is available electronically at <http://www.epa.gov/opptintr/newchems>.

IX. Economic Analysis

EPA has evaluated the potential costs of establishing SNUN requirements for potential manufacturers and processors of the chemical substances subject to this proposed rule. EPA's complete economic analysis is available in the docket under docket ID number EPA-HQ-OPPT-2018-0777.

X. Statutory and Executive Order Reviews

A. Executive Order 12866

This proposed rule would establish SNURs for several new chemical substances that were the subject of PMNs, an MCAN, and TSCA section 5(e) Orders. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993).

B. Paperwork Reduction Act (PRA)

According to 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 this proposed rule have already been approved by OMB pursuant to PRA under OMB control number 2070-0012 (EPA ICR No. 574). 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 response. 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.

Send any comments about the accuracy of the burden estimate, and any suggested methods for minimizing respondent burden, including through the use of automated collection

techniques, to the Director, Regulatory Support Division, Office of Mission Support (2822T), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. Please remember to include the OMB control number in any correspondence, but do not submit any completed forms to this address.

C. Regulatory Flexibility Act (RFA)

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency hereby certifies that promulgation of this proposed SNUR would not have a significant adverse economic impact on a substantial number of small entities. 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, it appears 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 seven in Federal fiscal year (FY) 2013, 13 in FY2014, six in FY2015, 10 in FY2016, 14 in FY2017, and 18 in FY2018 and only a fraction of these were from small businesses. In addition, the Agency currently offers relief to qualifying small businesses by reducing the SNUN submission fee from \$16,000 to \$2,800. This lower fee reduces the total reporting and recordkeeping of cost of submitting a SNUN to about \$10,116 for qualifying small firms. Therefore, the potential economic impacts of complying with this proposed SNUR 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 final SNURs are not expected to have a significant economic impact on a substantial number of small entities, which was provided to the Chief Counsel for Advocacy of the Small Business Administration.

D. Unfunded Mandates Reform Act (UMRA)

Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reasons to believe that any State, local, or Tribal government will be impacted by this action. As such, EPA has determined that this proposed rule would not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the requirements of UMRA sections 202, 203, 204, or 205 (2 U.S.C. 1501 *et seq.*).

E. Executive Order 11632

This proposed rule would not 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, as specified in Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999).

F. Executive Order 13175

This proposed rule would not have Tribal implications because it is not expected to have substantial direct effects on Indian Tribes. This proposed rule would not significantly nor uniquely affect the communities of Indian Tribal governments, nor would it involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249,

November 9, 2000), do not apply to this action.

G. Executive Order 13045

This proposed rule is not subject to Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997), because this is not an economically significant regulatory action as defined by Executive Order 12866, and this action does not address environmental health or safety risks disproportionately affecting children.

H. Executive Order 13211

This proposed rule is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001), because this proposed rule is not expected to affect energy supply, distribution, or use and because this proposed rule is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

In addition, since this proposed rule would not involve any technical standards, NTTAA section 12(d) (15 U.S.C. 272 note), does not apply to this action.

J. Executive Order 12898

This proposed rule does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

List of Subjects

40 CFR Parts 721 and 725

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

Dated: June 24, 2019.

Tala Henry,

Deputy Director, Office of Pollution Prevention and Toxics.

Therefore, it is proposed that 40 CFR chapter I be 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, 2613, and 2625(c).

2. Add §§ 721.11267 through 721.11295 to subpart E to read as follows:

Subpart E--Significant New Uses for Specific Chemical Substances

* * * * *

Sec.

721.11267 Silane amine carbonate (generic).

721.11268 Hydrochlorofluorolefin (generic).

721.11269 Fatty acid modified aromatic polyester polyols (generic).

721.11270 Dodecanedioic acid and 1,6-hexanediol polymer with 3-hydroxy-2,2-dimethylpropyl 2,2-dimethylhydracrylate, neopentylglycol, 1,2 ethanediol, adipic acid, Isophthalic acid, terephthalic acid, 2-Oxooxopane, BayFlex 2002H and 1,1'-methylenebis(isocyanatobenzene) (generic).

721.11271 Ethanone, 1-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl].

721.11272 Vegetable oil, polymer with alkanedioic acid, alkali lignin, diethylene glycol- and polyol-depolymd. poly(ethylene terephthalate) waste plastics and arylcarboxylic acid anhydride (generic).

721.11273 Vegetable oil, polymer with alkanedioic acid, alkali lignin, diethylene glycol- and polyol-depolymd. poly(ethylene terephthalate) waste plastics (generic).

721.11274 Waste plastics, poly(ethylene terephthalate), depolymd. with diethylene glycol, polymers with alkanedioic acid, alkali lignin and arylcarboxylic acid anhydride (generic).

721.11275 Waste plastics, poly(ethylene terephthalate), depolymd. with diethylene glycol and polyol, polymers with alkanedioic acid, alkali lignin and arylcarboxylic acid anhydride (generic).

721.11276 Vegetable oil, polymer with alkanedioic acid, alkali lignin, diethylene glycol- and polyol-depolymd. poly(ethylene terephthalate) waste plastics and arylcarboxylic acid anhydride (generic).

721.11277 Vegetable oil, polymer with alkanedioic acid, alkali lignin, diethylene glycol-depolymd. poly(ethylene terephthalate) waste plastics and arylcarboxylic acid anhydride (generic).

721.11278 Amides, tallow, N,N-bis(2-hydroxypropyl).

721.11279 Substituted propanoic acid, polymer with alkylisocyanate-substituted carbomonocycle, dialkyl carbonate, hydroxyl alkyl substituted alkanediol, alkanediol, isocyanato substituted carbomonocycle, alkanol substituted amines-blocked, compds. with (alkylamino)alkanol (generic).

721.11280 Propanediol phosphate (generic).

721.11281 Substituted cashew, nutshell liquid, polymer with epichlorohydrin, phosphate (generic).

721.11282 2,5-Furandione, polymer with 2-ethyl-2-(hydroxymethyl)-1,3-propanediol, 3a,4,5,6,7,7a-hexahydro-4,7-methano-1H-inden-5(or 6)-yl ester, ester with 2,3-dihydroxypropyl neodecanoate.

721.11283 Waste plastics, polyester, depolymd. with glycols, polymers with dicarboxylic acids (generic).

721.11284 Di(substituted-1,3-trialkylammonium) dialkylammonium salt (generic).

721.11285 Substituted alkanolic acid polymer with alkylcarbonate, alkanediols and isocyanate substituted carbomonocycles, sodium salt, alkenoic acidsubstituted

polyol reaction products-blocked (generic).

721.11286 Alkenoic acid, ester with [oxybis(alkylene)]bis[alkyl-substituted alkanediol], polymer with alkylcarbonate, alkanediols, substituted alkanic acid and isocyanate and alkyl substituted carbomonocycle, sodium salt (generic).

721.11287 Castor oil, reaction products with soybean oil.

721.11288 Benzene, 1-(chloromethyl)-3-methyl-.

721.11289 1-Butanaminium,N,N,N-tributyl-,2(or 5)- [[benzoyldihydrodioxo [(sulfohenyl) amino]heteropolycycle]oxy]-5(or2)-(1,1-dimethylpropyl)benzenesulfonate (2:1) (generic).

721.11290 Alkylsilsesquioxane, ethoxy-terminated (generic).

721.11291 Polythioether, short chain diol polymer terminated with aliphatic diisocyanate (generic).

721.11292 Alkenoic acid, polymer with alkenylcarbomonocycle, [alkanediylbis(substituted alkylene)] bis[heteromonocycle] and (alkylalkenyl) aromatic, salt (generic).

721.11293 Alkenoic acid, polymer with substituted alkyloxirane, alkenylcarbomonocycle, alkyl substituted alkyl alkanediol and (alkylalkenyl) aromatic salt (generic).

721.11294 Alkyl alkenoic acid, alkyl ester, telomer with alkylthiol, substituted carbomonocycle, substituted alkyl alkyl alkenoate and hydroxyalkyl alkenoate, tertbutyl alkyl peroxyoate-initiated, (generic).

721.11295 Substituted heteromonocycle, polymer with substituted alkanediol and diisocyanate substituted carbomonocycle, alkylene glycol acrylate-blocked (generic).

§721.11267 Silane amine carbonate (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as silane amine carbonate (PMN P-17-157) 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), (3), (4), and (5) (respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 1,000. 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), (a)(6)(v), (vi), and (b) (concentrations set at 1.0%).

(ii) Requirements, as specified in §721.72(a) through (d), (e) (concentrations set at 1.0%), (f), (g)(1)(i) and (ii), (g)(2)(i) through (v), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(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 (h), are applicable to manufacturers and processors of this substance.

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

§721.11268 Hydrochlorofluorolefin (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as hydrochlorofluoroolefin (PMN P-17-295) 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) through (5) (respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 10). 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, (a)(6)(v) and (vi), and (b) (concentrations set at 1.0%).

(A) As an alternative to the respirator requirements in this paragraph (a)(2)(i), a manufacturer or processor may choose to follow the new chemical exposure limit (NCEL) provision listed in the TSCA section 5(e) Order for this substance. The NCEL is 23.6 mg/m³ (3.9 ppm) as an 8-hour time weighted average. Persons who wish to pursue NCELS as an alternative to §721.63 respirator requirements may request to do so under §721.30. Persons whose §721.30 requests to use the NCELS approach are approved by EPA will be required to follow NCELS provisions comparable to those contained in the corresponding TSCA section 5(e) Order.

(ii) Requirements, as specified in §721.72(a) through (d), (e) (concentrations set at 1.0%), (f), (g)(1)(iv) and (vi), (fatality), (g)(2)(i) through (iv) (use respiratory protection or maintain workplace airborne concentrations at or below an 8-hour time-weighted average of 23.6 mg/m³ (3.9 ppm), and (v)

(i) *Industrial, commercial, and consumer activities.* Requirements, as specified in §721.80(f), (k) (a refrigerant used in closed systems for chillers (commercial comfort air

conditioners) and industrial process refrigeration), and (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 and processors of this substance.

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

§ 721.11269 Fatty acid modified aromatic polyester polyols (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substances generically identified as fatty acid modified aromatic polyester polyols (PMN P-17-306 and PMN P-17-307) are 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), (a)(2)(i), (iii), (a)(3), 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, (b)(concentration set at 1.0%), and (c).

(ii) *Hazard communication.* Requirements, as specified in § 721.72(a) through (e) (concentration set at 1.0%), (f), (g)(1)(iv), (ocular effects), (g)(2)(i), (v), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System (GHS) and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* It is a significant new use for any application method that generates a vapor, mist, aerosol or dust to which workers may be exposed.

(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 and processors of this substance.

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

§ 721.11270 Dodecanedioic acid and 1,6-hexanediol polymer with 3-hydroxy-2,2-dimethylpropyl 2,2-dimethylhydracrylate, neopentylglycol, 1,2 ethanediol, adipic acid, Isophthalic acid, terephthalic acid, 2-Oxooxopane, BayFlex 2002H and 1,1'-methylenebis(isocyanatobenzene) (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as Dodecanedioic acid and 1,6-hexanediol polymer with 3-hydroxy-2,2-dimethylpropyl 2,2-dimethylhydracrylate, neopentylglycol, 1,2 ethanediol, adipic acid, Isophthalic acid, terephthalic acid, 2-Oxooxopane, BayFlex 2002H and 1,1'-methylenebis(isocyanatobenzene) (PMN P-17-320) 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) through (4), 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, (5) (respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 50), (a)(6)(v) and (vi), (particulate), and (c).

(ii) *Hazard communication.* Requirements, as specified in §721.72(a) through (d), (f), (g)(1)(i) and (ii), (mutagenicity), (g)(2)(i), (ii), (iv), (v), and (g)(5). 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) and (y)(1) and (2). It is a significant new use to manufacture the substance containing more than 1% residual isocyanate by weight,

(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 and processors of this substance.

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

§ 721.11271 Ethanone, 1-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl].

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as ethanone, 1-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]- (PMN P-17-329, CAS No. 1417782-28-5) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements, as specified in § 721.63(a)(1), (a)(2)(i) through (iv), (a)(3) and (4), when determining which persons are reasonably likely to be exposed as required for §721.63(a)(1), (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, (5) (respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 50), (a)(6)(v) and (vi), (particulate), and (c).

(ii) *Hazard communication.* Requirements, as specified in § 721.72(a) through (d), (f), (g)(1)(ii), (iv), (vi), (sensitization), (g)(2)(i), (ii), (iv), and (v), (g)(3)(i) and (ii), (g)(4) (do not release to water at concentrations that exceed 7 parts per billion), and (5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System (GHS) and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements, as specified in § 721.80(k).

(iv) *Release to water.* Requirements, as specified in § 721.90(a)(4), (b)(4), and (c)(4) where $N=7$.

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

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

(2) *Limitations or revocation of certain notification requirements.* The provisions of

§721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of §721.1725(b)(1) apply to paragraph (a)(2)(iii) of this section.

§ 721.11272 Vegetable oil, polymer with alkanedioic acid, alkali lignin, diethylene glycol- and polyol-depolymd. poly(ethylene terephthalate) waste plastics and arylcarboxylic acid anhydride (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as vegetable oil, polymer with alkanedioic acid, alkali lignin, diethylene glycol- and polyol-depolymd. poly(ethylene terephthalate) waste plastics and arylcarboxylic acid anhydride (P-17-367) 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) *Hazard communication program.* A significant new use of these substances is any manner or method of manufacture, import, or processing associated with any use of these substances without providing risk notification as follows:

(A) If as a result of the test data required under the Order for the substance, the employer becomes aware that the substance may present a risk of injury to human health or the environment, the employer must incorporate this new information, and any information on methods for protecting against such risk, into an SDS as described in § 721.72 (c) within 90 days from the time the employer becomes aware of the new information. If the substance is not being manufactured, processed, or used in the employer's workplace, the employer must add the new information to an SDS before the substance is reintroduced into the workplace.

(B) The employer must ensure that persons who will receive the PMN substance from the

employer, or who have received the PMN substance from the employer within 5 years from the date the employer becomes aware of the new information described in paragraph (a)(2)(i)(A) of this section, are provided an SDS containing the information required under paragraph (a)(2)(i)(A) of this section within 90 days from the time the employer becomes aware of the new information.

(ii) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture, process, or use the substance with greater than the confidential percentages of low molecular weight components and less than the confidential average molecular weight specified in the Order.

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

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

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

§ 721.11273 Vegetable oil, polymer with alkanedioic acid, alkali lignin, diethylene glycol- and polyol-depolymd. poly(ethylene terephthalate) waste plastics (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substances generically identified as vegetable oil, polymer with alkanedioic acid, alkali lignin, diethylene glycol- and polyol-depolymd. poly(ethylene terephthalate) waste plastics (P-17-368) 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) *Hazard communication program.* A significant new use of these substances is any manner or method of manufacture, import, or processing associated with any use of these substances without providing risk notification as follows:

(A) If as a result of the test data required under the Order for the substance, the employer becomes aware that the substances may present a risk of injury to human health or the environment, the employer must incorporate this new information, and any information on methods for protecting against such risk, into an SDS as described in § 721.72(c) within 90 days from the time the employer becomes aware of the new information. If the substance is not being manufactured, processed, or used in the employer's workplace, the employer must add the new information to an SDS before the substance is reintroduced into the workplace.

(B) The employer must ensure that persons who will receive the PMN substance from the employer, or who have received the PMN substance from the employer within 5 years from the date the employer becomes aware of the new information described in paragraph (a)(2)(i)(A) of this section, are provided an SDS containing the information required under paragraph (a)(2)(i)(A) of this section within 90 days from the time the employer becomes aware of the new information.

(ii) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture, process, or use the substance with greater than the confidential percentages of low molecular weight components and less than the confidential average molecular weight specified in the Order.

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

(1) *Recordkeeping.* Recordkeeping requirements, as specified in § 721.125(a) through (c)

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

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

§ 721.11274 Waste plastics, poly(ethylene terephthalate), depolymd. with diethylene glycol, polymers with alkanedioic acid, alkali lignin and arylcarboxylic acid anhydride (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substances generically identified as waste plastics, poly(ethylene terephthalate), depolymd. with diethylene glycol, polymers with alkanedioic acid, alkali lignin and arylcarboxylic acid anhydride (P-17-369) 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) *Hazard communication program.* A significant new use of these substances is any manner or method of manufacture, import, or processing associated with any use of these substances without providing risk notification as follows:

(A) If as a result of the test data required under the Order for the substance, the employer becomes aware that the substance may present a risk of injury to human health or the environment, the employer must incorporate this new information, and any information on methods for protecting against such risk, into an SDS as described in § 721.72(c) within 90 days from the time the employer becomes aware of the new information. If the substance is not being manufactured, processed, or used in the employer's workplace, the employer must add the new information to an SDS before the substance is reintroduced into the workplace.

(B) The employer must ensure that persons who will receive the PMN substance from the employer, or who have received the PMN substance from the employer within 5 years from the

date the employer becomes aware of the new information described in paragraph (a)(2)(i)(A) of this section, are provided an SDS containing the information required under paragraph (a)(2)(i)(A) of this section within 90 days from the time the employer becomes aware of the new information.

(ii) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture, process, or use the substance with greater than the confidential percentages of low molecular weight components and less than the confidential average molecular weight specified in the Order.

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

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

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

§ 721.11275 Waste plastics, poly(ethylene terephthalate), depolymd. with diethylene glycol and polyol, polymers with alkanedioic acid, alkali lignin and arylcarboxylic acid anhydride (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substances generically identified as waste plastics, poly(ethylene terephthalate), depolymd. with diethylene glycol and polyol, polymers with alkanedioic acid, alkali lignin and arylcarboxylic acid anhydride (P-17-370) 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) *Hazard communication program.* A significant new use of these substances is any manner or method of manufacture, import, or processing associated with any use of these substances without providing risk notification as follows:

(A) If as a result of the test data required under the Order for the substance, the employer becomes aware that the substance may present a risk of injury to human health or the environment, the employer must incorporate this new information, and any information on methods for protecting against such risk, into an SDS as described in § 721.72(c) within 90 days from the time the employer becomes aware of the new information. If the substance is not being manufactured, processed, or used in the employer's workplace, the employer must add the new information to an SDS before the substance is reintroduced into the workplace.

(B) The employer must ensure that persons who will receive the PMN substance from the employer, or who have received the PMN substance from the employer within 5 years from the date the employer becomes aware of the new information described in paragraph (a)(2)(i)(A) of this section, are provided an SDS containing the information required under paragraph (a)(2)(i)(A) of this section within 90 days from the time the employer becomes aware of the new information.

(ii) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture, process, or use the substance with greater than the confidential percentages of low molecular weight components and less than the confidential average molecular weight specified in the Order.

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

(1) *Recordkeeping.* Recordkeeping requirements, as specified in § 721.125(a) through (c)

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

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

§ 721.11276 Vegetable oil, polymer with alkanedioic acid, alkali lignin, diethylene glycol- and polyol-depolymd. poly(ethylene terephthalate) waste plastics and arylcarboxylic acid anhydride (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substances generically identified as vegetable oil, polymer with alkanedioic acid, alkali lignin, diethylene glycol- and polyol-depolymd. poly(ethylene terephthalate) waste plastics and arylcarboxylic acid anhydride (P-17-371) 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) *Hazard communication program.* A significant new use of these substances is any manner or method of manufacture, import, or processing associated with any use of these substances without providing risk notification as follows:

(A) If as a result of the test data required under the Order for the substance, the employer becomes aware that the substance may present a risk of injury to human health or the environment, the employer must incorporate this new information, and any information on methods for protecting against such risk, into an SDS, as described in § 721.72(c), within 90 days from the time the employer becomes aware of the new information. If the substance is not being manufactured, processed, or used in the employer's workplace, the employer must add the new information to an SDS before the substance is reintroduced into the workplace.

(B) The employer must ensure that persons who will receive the PMN substance from the

employer, or who have received the PMN substance from the employer within 5 years from the date the employer becomes aware of the new information described in paragraph (a)(2)(i)(A) of this section, are provided an SDS containing the information required under paragraph (a)(2)(i)(A) of this section within 90 days from the time the employer becomes aware of the new information.

(ii) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture, process, or use the substance with greater than the confidential percentages of low molecular weight components and less than the confidential average molecular weight specified in the Order.

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

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

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

§ 721.11277 Vegetable oil, polymer with alkanedioic acid, alkali lignin, diethylene glycol-depolymd. poly(ethylene terephthalate) waste plastics and arylcarboxylic acid anhydride (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substances generically identified as vegetable oil, polymer with alkanedioic acid, alkali lignin, diethylene glycol-depolymd. poly(ethylene terephthalate) waste plastics and arylcarboxylic acid anhydride (P-17-372) 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) *Hazard communication program.* A significant new use of these substances is any manner or method of manufacture, import, or processing associated with any use of these substances without providing risk notification as follows:

(A) If as a result of the test data required under the Order for the substance, the employer becomes aware that the substance may present a risk of injury to human health or the environment, the employer must incorporate this new information, and any information on methods for protecting against such risk, into an SDS, as described in § 721.72(c), within 90 days from the time the employer becomes aware of the new information. If the substance is not being manufactured, processed, or used in the employer's workplace, the employer must add the new information to an SDS before the substance is reintroduced into the workplace.

(B) The employer must ensure that persons who will receive the PMN substance from the employer, or who have received the PMN substance from the employer within 5 years from the date the employer becomes aware of the new information described in paragraph (a)(2)(i)(A) of this section, are provided an SDS containing the information required under paragraph (a)(2)(i)(A) of this section within 90 days from the time the employer becomes aware of the new information.

(ii) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture, process, or use the substance with greater than the confidential percentages of low molecular weight components and less than the confidential average molecular weight specified in the Order.

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

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

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

§ 721.11278 Amides, tallow, N,N-bis(2-hydroxypropyl).

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified as amides, tallow, N, N-bis (2-hydroxypropyl) (PMN P-17-382; CAS No. 1454803-04-3) 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) *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 exposures. It is a significant new use to process the substance resulting in an end use product containing greater than 3% by weight of the substance.

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

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

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

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

§ 721.11279 Substituted propanoic acid, polymer with alkylisocyanate-substituted

carbomonocycle, dialkyl carbonate, hydroxyl alkyl substituted alkanediol, alkanediol, isocyanato substituted carbomonocycle, alkanol substituted amines-blocked, compds. with (alkylamino)alkanol (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as substituted propanoic acid, polymer with alkylisocyanate-substituted carbomonocycle, dialkyl carbonate, hydroxyl alkyl substituted alkanediol, alkanediol, isocyanato substituted carbomonocycle, alkanol substituted amines-blocked, compds. with (alkylamino)alkanol (PMN P-17-394) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements, as specified in §721.80(f). It is a significant new use to use the substance for any use other than as a coating to improve chemical resistance. It is a significant new use to import the substance with average molecular weight greater than 1,000 daltons, containing greater than 0.1% residual isocyanate by weight, or with greater than 4% of the confidential chemical component specified in the Order.

(ii) [Reserved]

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

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

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

(3) *Determining whether a specific use is subject to this section.* The provisions of

§721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.

§ 721.11280 Propanediol phosphate (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as propanediol phosphate (PMN P-18-23) 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 reacted (cured).

(2) The significant new uses are:

(i) *Hazard communication.* Requirements, as specified in §721.72(a) through (d), (f), (g)(1)(i), (ii), and (iv), (eye irritation), (g)(2)(i), (ii), and (v), (use eye protection), (avoid eye contact), (g)(3)(i) and (ii), (g)(4)(iii), and (g)(5). 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.* 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 a vapor, spray, mist, or aerosol.

(iii) *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 (c), (f) through (i), and (k), are applicable to manufacturers and processors of this substance.

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

§ 721.11281 Substituted cashew, nutshell liquid, polymer with epichlorohydrin, phosphate (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as substituted cashew, nutshell liquid, polymer with epichlorohydrin, phosphate (generic) (PMN P-18-24) 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 reacted (cured).

(2) The significant new uses are:

(i) *Hazard communication.* Requirements, as specified in §721.72(a) through (d), (f), (g)(1)(i) and (ii), (eye irritation), (g)(2)(i), (ii), and (v), (use eye protection), (avoid eye contact), (g)(3)(i) and (ii), (g)(4)(iii), and (g)(5). 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.* 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 a vapor, spray, mist, or aerosol.

(iii) *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 §721.125 125(a) through (c), (f) through (i), and (k), are applicable to manufacturers and processors of this substance.

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

§ 721.11282 2,5-Furandione, polymer with 2-ethyl-2-(hydroxymethyl)-1,3-propanediol, 3a,4,5,6,7,7a-hexahydro-4,7-methano-1H-inden-5(or 6)-yl ester, ester with 2,3-dihydroxypropyl neodecanoate.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 2,5-furandione, polymer with 2-ethyl-2-(hydroxymethyl)-1,3-propanediol, 3a,4,5,6,7,7a-hexahydro-4,7-methano-1H-inden-5(or 6)-yl ester, ester with 2,3-dihydroxypropyl neodecanoate (PMN P-18-41) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements, as specified in § 721.80(g). It is a significant new use to manufacture (including import) the substance with the number average molecular weight of less than 1000 daltons.

(ii) [Reserved]

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

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

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

§ 721.11283 Waste plastics, polyester, depolymd. with glycols, polymers with dicarboxylic acids (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as waste plastics, polyester, depolymd. with glycols, polymers

with dicarboxylic acids (PMN P-18-70) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements, as specified in § 721.80(j).

(ii) [Reserved]

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

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

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

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(ii) of this section

§ 721.11284 Di(substituted-1,3-trialkylammonium) dialkylammonium salt (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as di(substituted-1,3-trialkylammonium) dialkylammonium salt (PMN P-18-88) 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 reacted (cured).

(2) The significant new uses are:

(i) *Hazard communication.* Requirements, as specified in §721.72(a) through (d), (e) (concentration set at 1.0%), (f), (g)(1)(ii), (iii), and (iv), (g)(2)(i), (ii), (iii), and (v), and (g)(5).

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.* Requirements, as specified in §721.80(k). It is a significant new use to manufacture, process, or use the substance in any manner that results in the generation of a vapor, mist, particulate, or aerosol.

(iii) *Release to water.* Requirements, as specified in §721.90(a)(4), (b)(4), and (c)(4) where N=1000.

(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), (b), (c), (f), (g), (h), (i), and (k), are applicable to manufacturers and processors of this substance.

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

(3) *Determining whether a specific use is subject to this section.* The provisions of §721.1725(b)(1) apply to paragraph (a)(2)(iii) of this section.

§ 721.11285 Substituted alkanolic acid polymer with alkylcarbonate, alkanediols and isocyanate substituted carbomonocycles, sodium salt, alkenoic acidsubstituted polyol reaction products-blocked (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as substituted alkanolic acid polymer with alkylcarbonate, alkanediols and isocyanate substituted carbomonocycles, sodium salt, alkenoic acidsubstituted polyol reaction products-blocked (PMN P-18-100) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements, as specified in § 721.80(f), (j), and (o).

(ii) [Reserved]

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

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

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

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(ii) of this section

§ 721.11286 Alkenoic acid, ester with [oxybis(alkylene)]bis[alkyl-substituted alkanediol], polymer with alkylcarbonate, alkanediols, substituted alkenoic acid and isocyanate and alkyl substituted carbomonocycle, sodium salt (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as alkenoic acid, ester with [oxybis(alkylene)]bis[alkyl-substituted alkanedio], polymer with alkylcarbonate, alkanediols, substituted alkenoic acid and isocyanate and alkyl substituted carbomonocycle, sodium salt (PMN P-18-102) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements, as specified in §

721.80(f), (j), and (o).

(ii) [Reserved]

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

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

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

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(ii) of this section

§ 721.11287 Castor oil, reaction products with soybean oil.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as castor oil, reaction products with soybean oil (PMN P-18-116) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements, as specified in § 721.80(f) and (j). It is a significant new use to process or use the substance that generates an aerosol or mist. It is a significant new use to exceed the confidential annual production volume stated in the PMN.

(ii) [Reserved]

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

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

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

(3) *Determining whether a specific use is subject to this section*. The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(ii) of this section

§ 721.11288 Benzene, 1-(chloromethyl)-3-methyl-

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified as benzene, 1-(chloromethyl)-3-methyl- (P-18-134, CAS No. 620-19-9) 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), (a)(2)(i) and (iii), and (a)(3) through (5) (respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 1000), 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, (a)(6)(v) and (vi), (particulate), (combination gas/vapor and particulate), (b)(concentration set at 0.1%), and (c).

(ii) *Hazard communication*. Requirements, as specified in §721.72(a) through (d), (e) (concentration set at 0.1%), (f), (g)(1)(i), (iii), (vi), (vii), and (ix), (respiratory irritation), (severe skin burns and eye damage), (sensitization (respiratory and dermal)), (serious eye irritation),

(g)(2)(i), (ii), (iii), (iv), and (v), (g)(3) and (ii), (g)(4)(iii), and (g)(5). 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). It is a significant new use to vary the process or use methods described in the PMN such that occupational exposure is increased; and

(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 and processors of this substance.

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

(3) *Determining whether a specific use is subject to this section.* The provisions of §721.1725(b)(1) apply to paragraph (a)(2)(iii) of this section.

§ 721.11289 1-Butanaminium,N,N,N-tributyl-,2(or 5)- [[benzoyldihydrodioxo [(sulfophenyl) amino]heteropolycycle]oxy]-5(or2)-(1,1-dimethylpropyl)benzenesulfonate (2:1) (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as 1-butanaminium,N,N,N-tributyl-,2(or 5)- [[benzoyldihydrodioxo [(sulfophenyl) amino]heteropolycycle]oxy]-5(or2)-(1,1-dimethylpropyl)benzenesulfonate (2:1) (PMN P-18-136) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

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

(ii) *Release to water.* Requirements, as specified in § 721.90(a)(4), (b)(4), and (c)(4) where N = 19.

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

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

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

§ 721.11290 Alkylsilsesquioxane, ethoxy-terminated (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as alkylsilsesquioxane, ethoxy-terminated (PMN P-18-137) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

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

(ii) *Release to water.* Requirements, as specified in § 721.90(a)(4), (b)(4), and (c)(4) where N = 58.

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

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

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

§ 721.11291 Polythioether, short chain diol polymer terminated with aliphatic diisocyanate (generic).

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified generically as polythioether, short chain diol polymer terminated with aliphatic diisocyanate (PMN P-18-219) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities*. It is a significant new use to manufacture the PMN substance with molecular weight greater than 10,000 daltons. It is a significant new use to manufacture the PMN substance with, free isocyanate residuals greater than 0.01% by weight.

(ii) [Reserved]

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

(1) *Recordkeeping*. Recordkeeping requirements, as specified in § 721.125(a) though (c) and (i), are applicable to manufacturers and processors of this substance.

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

§ 721.11292 Alkenoic acid, polymer with alkenylcarbomonocycle,

[alkanediylbis(substituted alkylene)] bis[heteromonocycle] and (alkylalkenyl) aromatic, salt (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as alkenoic acid, polymer with alkenylcarbomonocycle, [alkanediylbis (substituted alkylene)] bis[heteromonocycle] and (alkylalkenyl) aromatic, salt (PMN P-18-224) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture, process or use the substance in any manner resulting in inhalation exposures. It is a significant new use to manufacture the substance to contain an acid content greater than 20% by weight.

(ii) [Reserved]

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

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

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

§ 721.11293 Alkenoic acid, polymer with substituted alkyloxirane, alkenylcarbomonocycle, alkyl substituted alkyl alkanediol and (alkylalkenyl) aromatic salt (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as alkenoic acid, polymer with substituted alkyloxirane,

alkenylcarbomonocycle, alkyl substituted alkyl alkanediol and (alkylalkenyl) aromatic salt (PMN P-18-225) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements, as specified in §721.80. It is a significant new use to manufacture, process or use the substance in any manner resulting in inhalation exposures. It is a significant new use to manufacture the substance to contain an acid content greater than 20% by weight.

(ii) [Reserved]

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

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

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

§ 721.11294 Alkyl alkenoic acid, alkyl ester, telomer with alkylthiol, substituted carbomonocycle, substituted alkyl alkyl alkenoate and hydroxyalkyl alkenoate, tertbutyl alkyl peroxyate-initiated, (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as alkyl alkenoic acid, alkyl ester, telomer with alkylthiol, substituted carbomonocycle, substituted alkyl alkyl alkenoate and hydroxyalkyl alkenoate, tertbutyl alkyl peroxyate-initiated (PMN P-18-233) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements, as specified in § 721.80(w)(2).

(ii) [Reserved]

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

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

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

§ 721.11295 Substituted heteromonocycle, polymer with substituted alkanediol and diisocyanate substituted carbomonocycle, alkylene glycol acrylate-blocked (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as substituted heteromonocycle, polymer with substituted alkanediol and diisocyanate substituted carbomonocycle, alkylene glycol acrylate-blocked (PMN P-18-279) 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)(only persons subject to inhalation exposure from spray application are subject to these requirements), (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, and (5) (respirator

must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 1,000).

(ii) [Reserved]

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

(1) *Recordkeeping.* Recordkeeping requirements, as specified in § 721.125(a) through (d), are applicable to manufacturers and processors of this substance.

(2) *Limitations 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(c).

4. Add § 725.1079 to subpart M to read as follows:

§ 725.1079 Arsenic detecting strain of *E. coli* with extra-chromosomal elements, including an intergeneric screening marker (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as Arsenic detecting strain of *E. coli* with extra-chromosomal elements, including an intergeneric screening marker (MCAN J-18-41) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements, as specified in § 721.80(f). It is a significant new use to use the microorganism other than to detect arsenic in small water samples.

(ii) [Reserved]

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

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

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

[FR Doc. 2019-13989 Filed: 7/30/2019 8:45 am; Publication Date: 7/31/2019]