



ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2021-0068; FRL-10024-18]

Certain New Chemicals; Receipt and Status Information for April 2021

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is required under the Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, to make information publicly available and to publish information in the *Federal Register* pertaining to submissions under TSCA Section 5, including notice of receipt of a Premanufacture notice (PMN), Significant New Use Notice (SNUN) or Microbial Commercial Activity Notice (MCAN), including an amended notice or test information; an exemption application (Biotech exemption); an application for a test marketing exemption (TME), both pending and/or concluded; a notice of commencement (NOC) of manufacture (including import) for new chemical substances; and a periodic status report on new chemical substances that are currently under EPA review or have recently concluded review. This document covers the period from 04/01/2021 to 04/30/2021.

DATES: Comments identified by the specific case number provided in this document 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-2021-0068, and the specific case number for the chemical substance related to your comment, 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:* Jim Rahai, Project Management and Operations Division (7407M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-8593; email address: rahai.jim@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. Executive Summary

A. What action is the Agency taking?

This document provides the receipt and status reports for the period from 04/01/2021 to 04/30/2021. The Agency is providing notice of receipt of PMNs, SNUNs and MCANs (including amended notices and test information); an exemption application under 40 CFR part 725 (Biotech exemption); TMEs, both pending and/or concluded; NOCs to manufacture a new chemical substance; and a periodic status report on new

chemical substances that are currently under EPA review or have recently concluded review.

EPA is also providing information on its web site about cases reviewed under the amended TSCA, including the section 5 PMN/SNUN/MCAN and exemption notices received, the date of receipt, the final EPA determination on the notice, and the effective date of EPA's determination for PMN/SNUN/MCAN notices on its web site at:

<https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/status-pre-manufacture-notice>. This information is updated on a weekly basis.

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

Under the Toxic Substances Control Act (TSCA), 15 U.S.C. 2601 *et seq.*, a chemical substance may be either an "existing" chemical substance or a "new" chemical substance. Any chemical substance that is not on EPA's TSCA Inventory of Chemical Substances (TSCA Inventory) is classified as a "new chemical substance," while a chemical substance that is listed on the TSCA Inventory is classified as an "existing chemical substance." (See TSCA section 3(11).) For more information about the TSCA Inventory please go to: *<https://www.epa.gov/tsca-inventory>*.

Any person who intends to manufacture (including import) a new chemical substance for a non-exempt commercial purpose, or to manufacture or process a chemical substance in a non-exempt manner for a use that EPA has determined is a significant new use, is required by TSCA section 5 to provide EPA with a PMN, MCAN or SNUN, as appropriate, before initiating the activity. EPA will review the notice, make a risk determination on the chemical substance or significant new use, and take appropriate action as described in TSCA section 5(a)(3).

TSCA section 5(h)(1) authorizes EPA to allow persons, upon application and under appropriate restrictions, to manufacture or process a new chemical substance, or a chemical substance subject to a significant new use rule (SNUR) issued under TSCA

section 5(a)(2), for “test marketing” purposes, upon a showing that the manufacture, processing, distribution in commerce, use, and disposal of the chemical will not present an unreasonable risk of injury to health or the environment. This is referred to as a test marketing exemption, or TME. For more information about the requirements applicable to a new chemical go to: <http://www.epa.gov/oppt/newchems>.

Under TSCA sections 5 and 8 and EPA regulations, EPA is required to publish in the *Federal Register* certain information, including notice of receipt of a PMN/SNUN/MCAN (including amended notices and test information); an exemption application under 40 CFR part 725 (biotech exemption); an application for a TME, both pending and concluded; NOCs to manufacture a new chemical substance; and a periodic status report on the new chemical substances that are currently under EPA review or have recently concluded review.

C. Does this action apply to me?

This action provides information that is directed to the public in general.

D. Does this action have any incremental economic impacts or paperwork burdens?

No.

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

1. *Submitting confidential business information (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. Status Reports

In the past, EPA has published individual notices reflecting the status of TSCA section 5 filings received, pending or concluded. In 1995, the Agency modified its approach and streamlined the information published in the *Federal Register* after providing notice of such changes to the public and an opportunity to comment (see the *Federal Register* of May 12, 1995 (60 FR 25798) (FRL-4942-7). Since the passage of the Lautenberg amendments to TSCA in 2016, public interest in information on the status of section 5 cases under EPA review and, in particular, the final determination of such cases, has increased. In an effort to be responsive to the regulated community, the users of this information, and the general public, to comply with the requirements of TSCA, to conserve EPA resources and to streamline the process and make it more timely, EPA is providing information on its web site about cases reviewed under the amended TSCA, including the section 5 PMN/SNUN/MCAN and exemption notices received, the date of receipt, the final EPA determination on the notice, and the effective date of EPA's determination for PMN/SNUN/MCAN notices on its web site at:

<https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/status-pre-manufacture-notices>. This information is updated on a weekly basis.

III. Receipt Reports

For the PMN/SNUN/MCANs that have passed an initial screening by EPA during this period, Table I provides the following information (to the extent that such information is not subject to a CBI claim) on the notices screened by EPA during this period: The EPA case number assigned to the notice that indicates whether the submission is an initial submission, or an amendment, a notation of which version was received, the date the notice was received by EPA, the submitting manufacturer (i.e.,

domestic producer or importer), the potential uses identified by the manufacturer in the notice, and the chemical substance identity.

As used in each of the tables in this unit, (S) indicates that the information in the table is the specific information provided by the submitter, and (G) indicates that this information in the table is generic information because the specific information provided by the submitter was claimed as CBI. Submissions which are initial submissions will not have a letter following the case number. Submissions which are amendments to previous submissions will have a case number followed by the letter “A” (e.g. P-18-1234A). The version column designates submissions in sequence as “1”, “2”, “3”, etc. Note that in some cases, an initial submission is not numbered as version 1; this is because earlier version(s) were rejected as incomplete or invalid submissions. Note also that future versions of the following tables may adjust slightly as the Agency works to automate population of the data in the tables.

Table I. – PMN/SNUN/MCANs Approved* from 04/01/2021 to 04/30/2021

Case No.	Version	Received Date	Manufacturer	Use	Chemical Substance
J-21-0012	1	03/31/2021	Vestaron corporation	(G) Production of an agricultural product	(G) Yeast that has been stably modified for the production of an agricultural product
J-21-0013	1	04/02/2021	Vestaron corporation	(G) Production of an agricultural product	(G) Yeast that has been stably modified for the production of an agricultural product

P-18-0293A	10	04/12/2021	Sirrus, Inc.	(S) Intermediate: Monomer used as a chemical intermediate in the manufacture of polymers substance, industrial coatings (e.g., protective floor coatings) is not used in spray applications., adhesives (e.g., reactive, industrial structural adhesives or lamination) applied from a liquid form (not aerosol or spray) as a bead or film and are applied via static mixer, roller, brush, roll coater, or squeegee	(S) Propanedioic acid, 2-methylene-, 1,3-dihexyl ester
P-18-0294A	10	04/12/2021	Sirrus, Inc.	(S) Monomer used as a chemical intermediate in the manufacture of polymers. The PMN substance is loaded into the polymerization equipment and is consumed during the polymerization process -- no inhalation exposure is expected during transfer and polymerization. After incorporation into the polymer, there is no worker exposure to the PMN substance	(S) Propanedioic acid, 2-methylene-, 1,3-dicyclohexyl ester
P-18-0353A	3	04/13/2021	CBI	(G) Adhesive	(G) Phenolic resin, alkali, polymer with acetone-phenol reaction products, formaldehyde and phenol, sodium salts

P-18-0354A	3	04/13/2021	CBI	(G) Adhesive	(G) Phenolic resin, alkali, polymer with acetone-phenol reaction products, formaldehyde and phenol, potassium salts
P-20-0001A	7	04/05/2021	Santolubes Manufacturing, LLC	(S) Synthetic engine, gear & lubricating oils & greases	(S) Poly(oxy-1,4-butanediyl), alpha-(1-oxononyl)-omega-[(1-oxononyl)oxy]-
P-20-0050	4	04/07/2021	CBI	(G) Additive in consumer products	(S) Benzenepentanol, alpha, gamma-dimethyl-
P-20-0093A	4	04/06/2021	Ashland, Inc.	(G) Coating	(G) Alkanoic acid, 3-heteroatom substituted-2-(heteroatom-substituted alkyl)-2-alkyl-, polymer with 1,2-alkanediamine, alpha-hydro-omega-heteroatom-substituted poly(oxy-1,4-alkanediyl) and 5-hetero-atom substituted- 1- (heteroatom-substituted alkyl)-1, 3, 3-trialkylcycloalkane
P-20-0109A	3	04/13/2021	Huntsman Corporation	(S) Exhaust dyeing of cotton and cotton blends	(G) Acetamide, N-[3-alkyl(carbomonocyclic) substituted]carbomonocycle]-, coupled with diazotized 2- substituted-3-halo-5-nitrobenzonitrile
P-20-0138A	5	04/16/2021	Gurit (USA), Inc.	(S) The substance is part of a mixture with other amines to act as a curative for a 2-part epoxy adhesive formulation but not limited to industries such as marine, automotive and wind energy. The adhesive is “cured” at either ambient conditions or using heat and a chemical reaction occurs forming a solid composite structure	(G) Alkane diglycidyl ether, polymer with alkyl-cycloalkane diamines

P-20-0138A	6	04/22/2021	Gurit (USA), Inc.	(S) The substance is part of a mixture with other amines to act as a curative for a 2-part epoxy adhesive formulation but not limited to industries such as marine, automotive and wind energy. The adhesive is “cured” at either ambient conditions or using heat and a chemical reaction occurs forming a solid composite structure	(G) Alkane diglycidyl ether, polymer with alkyl-cycloalkane diamines
P-20-0174A	6	04/13/2021	P2 Science, Inc.	(S) For use in consumer products, as well as direct addition to consumer products. Specific functions would be as solubilizer, rheology modifier and fragrance oil	(S) 6-Octen-1-ol, 3,7-dimethyl-, homopolymer, monoacetate
P-20-0184A	4	04/13/2021	P2 Science, Inc.	(S) For use in fragrances for consumer products, as well as direct addition to consumer products. Specific functions would be as solubilizer, rheology modifier and fragrance oil	(S) 6-Octen-1-ol, 3,7-dimethyl-, homopolymer
P-21-0014A	3	04/19/2021	CBI	(G) oil and gas extraction	(G) Aliphatic alcohol, bis-tetra-alkyl ammonium, chloride salts
P-21-0048	3	04/20/2021	CBI	(G) Photolithography	(G) Sulfonium, tricyclic-, polyfluoropolyhydro-2,2-dicyclic -4,7-methano-1,3-benzodioxole-5-alkanesulfonate (1:1)

P-21-0087	3	04/06/2021	CBI	(G) Detergent additive	(G) Syrups, hydrolyzed starch, dehydrated, polymers with methacrylic acid and alkenenylbenzene
P-21-0091A	4	04/02/2021	CBI	(G) Laundry detergent additive/emulsifier., emulsifier - water treatment, Industrial fluid, Coatings and Plastics	(G) Fatty acid esters polymer with Dicarboxylic Acid
P-21-0102	3	04/07/2021	CBI	(G) Raw material for industrial Additive Manufacturing, UV-curable inks, coatings and adhesives	(G) heteromonocycle, polymer, [2-[(1-oxo-2-propen-1-yl)oxy]alkyl]ester
P-21-0104	2	04/07/2021	CBI	(G) Lubricant	(G) Alkanedioic acid, di branched alkyl esters
P-21-0104A	3	04/19/2021	CBI	(G) Lubricant	(G) Alkanedioic acid, di branched alkyl esters
P-21-0105	2	04/07/2021	CBI	(G) Lubricant	(G) Alkanedioic acid, di C11-14 isoalkyl esters
P-21-0105A	3	04/19/2021	CBI	(G) Lubricant	(G) Alkanedioic acid, di C11-14 isoalkyl esters
P-21-0106	2	04/14/2021	Eastman Chemical Company, Inc	(S) Chemical additive for production of tire and non-tire rubber products	(G) Distillates (petroleum), polymers with branched alkene
P-21-0107	2	04/14/2021	Eastman Chemical Company, Inc	(S) Chemical additive for production of tire and non-tire rubber products	(G) Distillates (petroleum), polymers with branched alkene, hydrogenated
P-21-0108	1	04/14/2021	Enchem America, LLC.	(S) Additive for use in battery electrolyte formulations	(G) Oxathiole, oxide
P-21-0109	2	04/21/2021	Chevron El Segundo Refinery	(G) Component in fuels	(G) Hydrocarbons linear and branched, light alkylate
P-21-0110	2	04/21/2021	Chevron El Segundo Refinery	(G) Component in fuels	(G) Hydrocarbons linear and branched, light catalytic cracked
P-21-0111	2	04/21/2021	Chevron El Segundo Refinery	(G) Component in fuels	(G) Hydrocarbons linear and branched, heavy catalytic cracked

P-21-0112	2	04/21/2021	Chevron El Segundo Refinery	(G) Component in fuels	(G) Hydrocarbons linear and branched, light hydrocracked
P-21-0113	2	04/21/2021	Chevron El Segundo Refinery	(G) Component in fuels	(G) Hydrocarbons linear and branched, isomerization
P-21-0114	2	04/21/2021	Chevron El Segundo Refinery	(G) Component in fuels	(G) Hydrocarbons linear and branched, heavy catalytic reformed
P-21-0115	2	04/21/2021	CBI	(G) Raw material for industrial Additive Manufacturing, UV-curable inks, coatings and adhesives for industrial adhesives, inks and coatings	(G) heteromonocycle, polymer, substituted aliphatic carbamate, [2-[(1-oxo-2-propen-1-yl)oxy]alkyl]ester
P-21-0116	2	04/21/2021	Chevron El Segundo Refinery	(G) Component in fuels	(G) Hydrocarbons linear and branched, hydrotreated light
P-21-0117	2	04/21/2021	Chevron El Segundo Refinery	(G) Component in fuels	(G) Hydrocarbons linear and branched, hydrotreated light paraffinic
P-21-0118	2	04/21/2021	Chevron El Segundo Refinery	(S) Chemical Intermediate	(G) Hydrocarbons linear and branched, light catalytic cracked
P-21-0119	2	04/21/2021	Chevron El Segundo Refinery	(S) Chemical intermediate	(G) Hydrocarbons linear and branched, heavy hydrocracked
P-21-0122	1	04/26/2021	Chevron El Segundo Refinery	(S) Chemical Intermediate	(G) Hydrocarbons linear and branched, heavy hydrocracked
P-21-0123	1	04/26/2021	Chevron El Segundo Refinery	(G) Component in fuels	(G) Hydrocarbons linear and branched, light hydrocracked
P-21-0124	1	04/26/2021	CBI	(G) Photolithography	(G) Sulfonium, triphenyl-, salt with fluoroalkyl 5-sulfobicyclo[2.2.1]heptane carboxylate (1:1)
SN-21-0004	1	03/31/2021	CBI	(G) Monomer	(S) 2-Propenoic acid, 1,1'-(3-methyl-1,5-pentanediyloxy) diester

*The term 'Approved' indicates that a submission has passed a quick initial screen ensuring all required information and documents have been provided with the submission prior to the start of the 90 day review period, and in no way reflects the final status of a complete submission review.

In Table II of this unit, EPA provides the following information (to the extent that such information is not claimed as CBI) on the NOCs that have passed an initial screening by EPA during this period: The EPA case number assigned to the NOC including whether the submission was an initial or amended submission, the date the NOC was received by EPA, the date of commencement provided by the submitter in the NOC, a notation of the type of amendment (e.g., amendment to generic name, specific name, technical contact information, etc.) and chemical substance identity.

Table II. – NOCs Approved* From 04/01/2021 to 04/30/2021

Case No.	Received Date	Commencement Date	If Amendment, Type of Amendment	Chemical Substance
J-20-0021	04/12/2021	04/12/2021	N	(G) Modified saccharomyces cerevisiae
J-20-0023	04/12/2021	04/12/2021	N	(G) Modified saccharomyces cerevisiae
P-13-0365	03/31/2021	03/23/2021	N	(G) Mdi modified polyalkene glycols
P-16-0307	04/19/2021	04/14/2021	N	(G) Heteropolycycliccarboxylic acid, 1,3-dihydro-disubstituted-, polymer with 1,1'-methylenebis[4-isocyanatobenzene], reaction products with silica
P-17-0152A	04/05/2021	06/04/2019	CBI Substantiation provided	(G) Poly(alkyl-oxo-2-propen-1-yl)ester with alkaneaminium trialkyl chloride and alkoxy-poly(oxy-alkanediyl)
P-18-0345	04/22/2021	04/19/2021	N	(S) 1-butanone, 2-(dimethylamino)-1-[4-(2-ethyl-2-methyl-3-oxazolidinyl)phenyl]-2-(phenylmethyl)-
P-18-0384	04/27/2021	04/25/2021	N	(S) Lithium 6
P-19-0122	04/12/2021	04/01/2021	N	(G) 2-propenoic acid, 2-(hydrogenated animal-based nitrogen-substituted)ethyl ester
P-19-0131	04/08/2021	03/28/2021	N	(G) Isoalkylaminium, n-isoalkyl,-n, n-dimethyl chloride,
P-19-0131A	04/13/2021	03/28/2021	CBI Substantiation provided	(G) Isoalkylaminium, n-isoalkyl,-n, n-dimethyl chloride,
P-20-0025	04/22/2021	04/15/2021	N	(G) Bt4

P-20-0027	04/08/2021	03/18/2021	N	(G) Glycols, alpha, omega-, c2-6, polymers with adipic acid, dodecanedioic acid, hydracrylic acid polyester, isophthalic acid, 1,1'-methylenebis[4-isocyanatobenzene], neopentyl glycol and terephthalic acid
P-20-0028	04/08/2021	03/18/2021	N	(G) Glycols, alpha, omega-, c2-6, polymers with adipic acid, aromatic polyester, dodecanedioic acid, hydracrylic acid polyester, isophthalic acid, 1,1'-methylenebis[4-isocyanatobenzene], neopentyl glycol and terephthalic acid
P-20-0083	04/12/2021	04/01/2021	N	(G) 2-propenoic acid, nitrogen-substituted alkyl, n-c16-18-acyl derivs
P-20-0132	04/02/2021	03/25/2021	N	(S) 1h-pyrrole-2,5-dione, 3-methyl-, 1,1'-c36-alkylenebis-
P-21-0006	03/31/2021	03/25/2021	N	(G) Naphthalene derivative

*The term 'Approved' indicates that a submission has passed a quick initial screen ensuring all required information and documents have been provided with the submission

In Table III of this unit, EPA provides the following information (to the extent such information is not subject to a CBI claim) on the test information that has been received during this time period: The EPA case number assigned to the test information; the date the test information was received by EPA, the type of test information submitted, and chemical substance identity.

Table III. – Test Information Received from 04/01/2021 to 04/30/2021

Case No.	Received Date	Type of Test Information	Chemical Substance
P-14-0712	04/21/2021	Quarterly PCDD/F Test of PMN Substance using EPA Test Method 8290A	(G) Plastics, wastes, pyrolyzed, bulk pyrolysate
P-16-0543	04/14/2021	Exposure Monitoring Report March 2021	(G) Halogenophosphoric acid metal salt

P-19-0036	04/26/2021	Daphnia sp., Acute Immobilization Test (Test Guideline OECD 202); Fish, Acute Toxicity Test (Test Guideline OECD 203); Freshwater Alga and Cyanobacteria, Growth Inhibition Test (Test Guideline OECD 201)	(S) 1,4-benzenedicarboxylic acid, 1,4-bis(2-phenoxyethyl) ester
P-21-0022	04/27/2021	Bacterial Reverse Mutation Test (Test Guideline OECD 471)	(G) Rosin acid esters
P-21-0027	04/26/2021	Photodegradation of onium cations of photoacid generators (PAGs) exposed to irradiation at 254 nm in liquid medium	(G) Heteropolycyclic, trihaloalkyl carbomonocycle-, hydroxy carbomonocyclic salt

If you are interested in information that is not included in these tables, you may contact EPA's technical information contact or general information contact as described under **FOR FURTHER INFORMATION CONTACT** to access additional non-CBI information that may be available.

Authority: 15 U.S.C. 2601 *et seq.*

Dated: May 13, 2021.

Pamela Myrick,

*Director, Project Management and Operations Division,
Office of Pollution Prevention and Toxics.*

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