



ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2020-0077; FRL-10018-37]

Certain New Chemicals; Receipt and Status Information for November 2020

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 11/01/2020 to 11/30/2020.

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-2020-0077, 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>.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit <https://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 11/01/2020 to 11/30/2020. 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](http://www.epa.gov/regulations) 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 11/01/2020 to 11/30/2020

Case No.	Version	Received Date	Manufacturer	Use	Chemical Substance
J-20-0005	2	10/16/2020	CBI	(G) Ethanol production	(G) Saccharomyces cerevisiae modified
J-20-0013	3	10/27/2020	Greenlight Biociences, Inc.	(G) Production of enzymes for use in internal manufacturing	(G) Modified strains of Escherichia coli
J-20-0014	3	10/27/2020	Greenlight Biociences, Inc.	(G) Production of enzymes for use in internal manufacturing	(G) Modified strains of Escherichia coli
J-20-0015	3	10/27/2020	Greenlight Biociences, Inc.	(G) Production of enzymes for use in internal manufacturing	(G) Modified strains of Escherichia coli
J-20-0016	3	10/27/2020	Greenlight Biociences, Inc.	(G) Production of enzymes for use in internal manufacturing	(G) Modified strains of Escherichia coli
J-20-0017	3	10/27/2020	Greenlight Biociences, Inc.	(G) Production of enzymes for use in internal manufacturing	(G) Modified strains of Escherichia coli
J-20-0018	3	10/27/2020	Greenlight Biociences, Inc.	(G) Production of enzymes for use in internal manufacturing	(G) Modified strains of Escherichia coli
J-20-0025	3	11/03/2020	CBI	(G) Ethanol production	(G) Biofuel producing Saccharomyces cerevisiae modified, genetically stable
P-18-0057 A	12	11/12/2020	CBI	(S) a drier accelerator that is used for superior drying performance in solvent-borne and waterborne air-dried paints, inks and coatings	(G) Vanadium Carboxylate

P-18-0057 A	13	11/18/2020	CBI	(S) a drier accelerator that is used for superior drying performance in solvent-borne and waterborne air-dried paints, inks and coatings	(G) Vanadium Carboxylate
P-18-0057 A	14	11/23/2020	CBI	(S) a drier accelerator that is used for superior drying performance in solvent-borne and waterborne air-dried paints, inks and coatings	(G) Vanadium Carboxylate
P-18-0084 A	9	11/23/2020	ShayoNano USA, Inc.	(S) Additive for water-based paints and coatings	(S) silicon zinc oxide
P-18-0256 A	7	11/11/2020	CBI	(G) Chemical Intermediate	(S) Undecanol, branched
P-18-0293 A	6	11/17/2020	CBI	(S) Monomer for use in emulsion polymers, formulated industrial coatings, industrial adhesives	(S) Propanedioic acid, 2-methylene-, 1,3-dihexyl ester
P-18-0293 A	7	11/20/2020	CBI	(S) Monomer for use in emulsion polymers, formulated industrial coatings, industrial adhesives	(S) Propanedioic acid, 2-methylene-, 1,3-dihexyl ester
P-18-0294 A	6	11/17/2020	CBI	(S) Monomer for use in emulsion polymers, formulated industrial coatings, industrial adhesives	(S) Propanedioic acid, 2-methylene-, 1,3-dicyclohexyl ester
P-18-0294 A	7	11/20/2020	CBI	(S) Monomer for use in emulsion polymers, formulated industrial coatings, industrial adhesive	(S) Propanedioic acid, 2-methylene-, 1,3-dicyclohexyl ester
P-18-0345 A	3	11/24/2020	Chitec Technology Co., Ltd.	(S) R-gen 990 is a liquid aminoketone-based photoinitiator (PI) intended for use as an ultraviolet (UV) curing agent in highly pigmented inks, photoresists, and masks	(S) 1-Butanone, 2-(dimethylamino)-1-[4-(2-ethyl-2-methyl-3-oxazolidinyl)phenyl]-2-(phenylmethyl)-

P-19-0082 A	5	11/12/2020	Bedoukian Research Inc.	(S) Fragrance uses per FFDC: fine fragrance, creams, lotions, etc., TSCA: scented papers, candles, detergents, cleaners, etc.	(S) Heptanal, 6-hydroxy-2,6-dimethyl-
P-20-0010 A	11	11/04/2020	CBI	(G) Polymerization auxiliary	(G) Carboxylic acid, reaction products with metal hydroxide, inorganic dioxide and metal
P-20-0031 A	5	11/02/2020	CBI	(G) Intermediate	(G) Perfluorinated substituted 1,3-oxathiolane dioxide
P-20-0070 A	2	11/07/2020	Clariant Corporation	(S) Solvent for use in formulated pesticide products.	(S) Nonanamide, <i>N,N</i> -dimethyl-
P-20-0076 A	4	11/04/2020	Cytec Industries Inc.	(G) Mining chemical	(S) Glycine, reaction products with sodium <i>O</i> -iso-Pr carbonodithioate, sodium salts
P-20-0077 A	6	11/23/2020	CBI	(S) UV Curing Agent for use in Inks and Coatings	(G) 1-(dialkyl-diphenylene alkane)-2-alkyl-2-hydrooxazine-1-alkylketone;
P-20-0078 A	2	11/11/2020	Ascend Performance Materials	(G) Stabilizer for industrial applications	(G) Dicarboxylic acid, compd. with aminoalkyl-alkyldiamine alkyldioate alkyldioate (1:2:1:1)
P-20-0079 A	2	11/11/2020	Ascend Performance Materials	(G) Stabilizer for industrial applications	(G) Dicarboxylic acid, compd. with aminoalkyl-alkyldiamine (3:2)
P-20-0080 A	5	11/11/2020	Ascend Performance Materials	(G) Stabilizer for industrial applications	(G) Alkyldiamine, aminoalkyl-, hydrochloride (1:3)
P-20-0081 A	5	11/11/2020	Ascend Performance Materials	(G) A stabilizer for industrial applications	(G) Carboxylic acid, compd. with aminoalkyl-alkyldiamine (3:1)
P-20-0082 A	5	11/11/2020	Ascend Performance Materials	(G) Stabilizer for industrial applications	(G) Alkyldiamine, aminoalkyl-, carboxylate (1:3)
P-20-0094 A	3	11/12/2020	CBI	(S) Formulation component in UV/EB coatings, inks and 3D	(G) Alkanedioic acid, polymer with tri-alkyl-

				printing/stereolithography/additive and adhesive manufacturing	isocyanatocarbomono cycle, dialkylglycols, ester with 2,3-dihydroxypropyl alkyl ester, 2-hydroxyethyl methacrylate-blocked
P-20-0105 A	3	11/25/2020	Sound Agriculture Company	(S) Maltol lactone is a compound that promotes microbial activity in the soil, resulting in increased availability of phosphorus for crops. This substance will be used on commercial farming operations	(S) 4H-Pyran-4-one, 3-[(2,5-dihydro-4-methyl-5-oxo-2-furanyl)oxy]-2-methyl-
P-20-0127 A	4	11/12/2020	Kuraray America, Inc.	(S) Industrial Solvent	(S) 2H-Pyran, tetrahydro-4-methyl-
P-20-0138 A	4	11/20/2020	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. The new substance will be used within an adhesive formulation for use within an industrial setting primarily but not limited to industries such as marine, automotive and wind energy	(G) Alkane diglycidyl ether, polymer with alkyl-cycloalkane diamines
P-20-0146 A	2	11/06/2020	CBI	(G) Insulating material for electrical parts	(G) Alkanoic acid, alkyl, carbopolycyclic alkyl ester;
P-20-0148	2	11/12/2020	Solugen Inc.	(G) Additive for consumer, industrial, and commercial uses	(G) Hydroxyalkanoic acid, salt, oxidized
P-20-0149	2	11/12/2020	Solugen Inc.	(G) Additive for consumer, industrial, and commercial uses	(G) Hydroxyalkanoic acid, salt, oxidized
P-20-0150	2	11/12/2020	Solugen, Inc.	(G) Additive for consumer, industrial,	(G) Hydroxyalkanoic

				and commercial uses	acid, salt, oxidized
P-20-0151	2	11/12/2020	Solugen, Inc.	(G) Additive for consumer, industrial, and commercial uses	(G) Hydroxyalkanoic acid, salt, oxidized
P-20-0153 A	4	11/04/2020	CBI	(G) lubricant additive - dispersant	(G) Polyamines, reaction products with succinic anhydride polyalkenyl derivs., borates
P-20-0154 A	4	11/04/2020	CBI	(G) lubricant additive - dispersant	(G) Polyamines, reaction products with succinic anhydride polyalkenyl derivs., borates
P-20-0161 A	2	11/04/2020	Sirrus, Inc.	(S) Film former or crosslinker additive used in coatings, waterborne emulsions, adhesives	(S) Propanedioic acid, 2-methylene-, 1,3-diethyl ester, polymer with 1,4-butanediol
P-20-0169	3	11/23/2020	CBI	(G) Battery Plastics and coatings applications, Conductive agent for conductive plastic and paint	(S) multiwalled carbon nanotube
P-20-0183 A	2	11/16/2020	CBI	(G) Intermediate	(G) Aryl ether epoxide, homopolymer, ether with alkanolamine
P-21-0003	3	11/04/2020	CBI	(G) Polymeric film former for coatings	(G) 4, 4 methylenebis (2, 6 dimethyl phenol) polymer with 2-(chloromethyl) oxirane, 1,4-benzene diol, 2-methyl-2-propenoic acid, mixed alkyl substituted 2-methyl 2-propenoate, and ethyl 2-propenoate, reaction products with 2-(dimthylamino) ethanol
P-21-0004	3	11/11/2020	CBI	(G) Surfactant	(G) Poly alkyl glycol alkyl ether
P-21-0011	2	11/04/2020	CBI	(S) Crosslinking agent for inks and	(G) Hexane, 1,6-diisocyanato-,

				coatings	homopolymer, alkyl epoxy ether- and polyethylene glycol mono-Me ether-blocked, reaction products with propylenimine
P-21-0012	1	10/28/2020	CBI	(G) The notified substance will be used as a fragrance ingredient	(G) Multialkylbicycloalkenyl substituted propanenitrile
P-21-0013	2	11/24/2020	Takasago	(S) Fragrance in fine fragrance, deodorants and cosmetics, household products such as laundry detergents and air fresheners, Shampoos and Body Washes	(G) methyl phenylethyl cyclopropanemethanol
P-21-0014	2	11/06/2020	CBI	(G) oil and gas extraction	(G) Aliphatic alcohol, bis-tetraalkyl ammonium, chloride salts
P-21-0015	1	10/30/2020	Designer Molecules, Inc.	(S) As a raw material in a Temporary Bonding Adhesive formulation	(S) Amines, C36-alkylenedi-, polymers with 5,5'-[(1-methylethylidene)bis(4,1-phenyleneoxy)]bis[1,3-isobenzofurandione] and 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]bis[2-aminophenol]
P-21-0016	1	11/02/2020	CBI	(G) Paint additive, Additive in coating formulations, Component in cleaning agents	(G) Alkanoic acid, dialkyl ester
P-21-0017	1	11/12/2020	Sumitomo Chemical Advanced Technologies LLC	(S) Substance used to improve physical properties in rubber products	(G) [(Substituted-carbomonocyclic) amino] oxoalkenoic acid, inorganic salt
P-21-0018	1	11/12/2020	Shin-Etsu Microsi	(G) Contained use for microlithography for electronic device manufacturing	(G) Sulfonium, triphenyl-, heterocyclic compound-

					carboxylate (1:1)
P-21-0019	2	11/17/2020	CBI	(G) The notified substance will be used as a fragrance ingredient.	(G) Ethyl 4-alkyl-2-oxocycloalkanecarboxylate
P-21-0022	1	11/20/2020	CBI	(S) Flexographic water-based Ink & coating vehicle	(G) Rosin acid esters
P-21-0023	1	11/23/2020	CBI	(G) Photolithography	(G) Sulfonium, carbocyclic-, salt with 1-(alkyl) 2-[4-[polyhydro-2-carbomonocyclic-5-(polyfluoro-2-sulfoalkyl)-4,7-methano-1,3-benzodioxol-2-yl]carbomonocyclic oxy]acetate (1:1)
P-21-0027	1	11/23/2020	CBI	(G) An ingredient used in the manufacture of photoresist	(G) Heteropolycyclic, trihaloalkyl carbomonocyclic-, hydroxy carbomonocyclic salt
SN-17-0006 A	5	10/29/2020	CBI	(G) Physical characteristics modifier for industrial use in certain solid composite articles	(G) Potassium Titanate

*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 11/01/2020 to 11/30/2020

Case No.	Received Date	Commencement Date	If Amendment, Type of Amendment	Chemical Substance
P-09-0492	10/30/2020	10/29/2020	N	(G) Isocyanate polymer, amine blocked
P-17-0387	11/03/2020	10/22/2020	N	(G) Dicarboxylic acids, polymers with alkanolic acid, alkanediol, substituted-alkylalkanoic acid, substituted alkyl carbomonocycle, alkanedioic acid and alkanediol, alkanolamine blocked, compds. with alkanolamine
P-18-0355	11/19/2020	11/10/2020	N	(G) Alkanediol, substituted alkyl, polymer with carbomonocycle, alkanedioate substituted carbomonocycle, ester with substituted alkanolate
P-19-0038	11/23/2020	11/20/2020	N	(S) Fatty acids, coco, iso-bu esters
P-20-0098	11/20/2020	11/13/2020	N	(G) Calcium cycloalkylcarboxylate
P-20-0160	11/23/2020	11/18/2020	N	(S) Amines, c36-alkylenedi-, polymers with bicyclo[2.2.1]heptanedimethanamine, [5,5'-biisobenzofuran]-1,1',3,3'-tetrone and 3a,4,4a,7a,8,8a-hexahydro-4,8-ethano[1h,3h-benzo[1,2-c:4,5-c']difuran-1,3,5,7-tetrone, maleated

*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 11/01/2020 to 11/30/2020

Case No.	Received Date	Type of Test Information	Chemical Substance
P-20-0066	11/24/2020	Daphnia Magna Reproduction Study (OECD Test Guideline 211)	(G) 2-propenoic acid, 2-hydroxyethyl ester, reaction products with dialkyl hydrogen heterosubstituted phosphate and dimethyl phosphonate

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: January 5, 2021.

Pamela Myrick,

Director, Information Management Division, Office of Pollution Prevention and Toxics.

[FR Doc. 2021-02660 Filed: 2/8/2021 8:45 am; Publication Date: 2/9/2021]