



ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2023-0061; FRL-10581-05-OCSPP]

Certain New Chemicals; Receipt and Status Information for May 2023

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 5/1/2023 to 5/31/2023.

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-2023-0061, through the *Federal eRulemaking Portal* at <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting and visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Jim Rahai, Project Management and Operations Division (MC 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 5/01/2023 to 5/31/2023. 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-notices>. This information is updated on a weekly basis.

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

Under the 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:

<https://www.epa.gov/chemicals-under-tsca>.

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 <https://www.epa.gov/dockets/commenting-epa-dockets>.

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” (i.e., 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 05/01/2023 to 05/31/2023

Case No.	Version	Received Date	Manufacturer	Use	Chemical Substance
P-21-0168A	4	05/10/2023	CBI	(G) Colorant	(G) Metal, [heteropolycyclic]-, [[[hydroxyalkyl)amino]sulfonyl]alkyl]sulfonyl(sulfoalkyl)sulfonyl derivs., ammonium

					sodium salts
P-22-0014A	5	05/03/2023	Colonial Chemical, Inc.	(G) Precursor	(G) Sodium bis(chloropropanediol) phosphate
P-22-0053A	4	05/11/2023	CBI	(G) Additive in agricultural formulations	(S) Ethanol, 2-amino-, compds. with polyethylene glycol hydrogen sulfate C10-16-alkyl ether
P-22-0078A	5	05/09/2023	CBI	(S) Dispersing agent for pesticide formulators	(G) Oxirane, 2-methyl-, polymer with oxirane, mono-isoalkyl ethers, phosphates, salt
P-22-0095A	4	05/05/2023	Locus Fermentation Solutions	(G) Surfactant for commercial, industrial, consumer applications	(G) Glycolipids, sophorose-contg., yeast-fermented, from glycerides and carbohydrates
P-22-0096A	4	05/05/2023	Locus Fermentation Solutions	(G) Surfactant for commercial, industrial, consumer applications	(G) Glycolipids, sophorose-contg., yeast-fermented, from glycerides and carbohydrates
P-22-0097A	4	05/05/2023	Locus Fermentation Solutions	(G) Surfactant for commercial, industrial, consumer applications	(G) Glycolipids, sophorose-contg., yeast-fermented, from glycerides and carbohydrates
P-22-0098A	4	05/05/2023	Locus Fermentation Solutions	(G) Surfactant for commercial, industrial, consumer applications	(G) Glycolipids, sophorose-contg., yeast-fermented, from glycerides and carbohydrates
P-22-0099A	4	05/05/2023	Locus Fermentation Solutions	(G) Surfactant for commercial, industrial, consumer applications	(G) Glycolipids, sophorose-contg., yeast-fermented, from glycerides and carbohydrates
P-22-0100A	4	05/05/2023	Locus Fermentation Solutions	(G) Surfactant for commercial, industrial, consumer applications	(G) Glycolipids, sophorose-contg., yeast-fermented, from glycerides and carbohydrates
P-22-0130A	4	05/17/2023	Integrity Bio-chemical, LLC	(S) Surfactant - surface tension reducing agent for use in production enhancement in oil wells (industrial), emulsifier, surface	(S) Maltodextrin, octanoate

				reduction household and industrial detergents, emulsifier, wetting agent personal care, cosmetic, and pet care grooming products, wetting agent - agriculture, surfactants - as raw materials for use in the manufacture of industrial products and consumer and household products	
P-22-0131A	4	05/17/2023	Integrity Bio-chemical, LLC	(S) Surfactant - surface tension reducing agent for use in production enhancement in oil wells (industrial), emulsifier, surface reduction household and industrial detergents, emulsifier, wetting agent personal care, cosmetic, and pet care grooming products, wetting agent - agriculture, surfactants - as raw materials for use in the manufacture of industrial products and consumer and household products	(S) Maltodextrin, hexadecanoate
P-22-0132A	4	05/17/2023	Integrity Bio-chemical, LLC	(S) Surfactant - surface tension reducing agent for use in production enhancement in oil wells (industrial), emulsifier, surface reduction household and industrial detergents, emulsifier, wetting agent personal care, cosmetic, and pet care grooming products, wetting agent - agriculture, surfactants - as raw materials for use in the	(S) Maltodextrin, decanoate

				manufacture of industrial products and consumer and household products	
P-22-0133A	4	05/17/2023	Integrity Bio-chemical, LLC	(S) Surfactant - surface tension reducing agent for use in production enhancement in oil wells (industrial), emulsifier, surface reduction household and industrial detergents, emulsifier, wetting agent personal care, cosmetic, and pet care grooming products, wetting agent - agriculture, surfactants - as raw materials for use in the manufacture of industrial products and consumer and household products	(S) Maltodextrin, octadecanoate
P-22-0134A	4	05/17/2023	Integrity Bio-chemical, LLC	(S) Surfactant - surface tension reducing agent for use in production enhancement in oil wells (industrial), emulsifier, surface reduction household and industrial detergents, emulsifier, wetting agent personal care, cosmetic, and pet care grooming products, wetting agent - agriculture, surfactants - as raw materials for use in the manufacture of industrial products and consumer and household products	(S) Maltodextrin, dodecanoate
P-22-0135A	4	05/17/2023	Integrity Bio-chemical, LLC	(S) Surfactant - surface tension reducing agent for use in production enhancement in oil	(S) Maltodextrin, tetradecanoate

				wells (industrial), emulsifier, surface reduction, household and industrial detergents, emulsifier, wetting agent personal care, cosmetic, and pet care grooming products, wetting agent - agriculture, surfactants - as raw materials for use in the manufacture of industrial products and consumer and household products	
P-22-0151A	5	05/08/2023	CBI	(G) Surfactant for commercial applications	(G) Glycolipids, sophorose-contg., yeast-fermented, from glycerides and carbohydrates
P-23-0070A	3	05/04/2023	CBI	(G) Surfactant for cleaning products, pet shampoo, hand cleansing, laundry, and dishwasher detergent	(S) Fatty Acids, C8-14, methyl-2-sulfoethyl esters, sodium salts
P-23-0079	4	05/09/2023	Lawter	(G) Non-reactive resin to improve ink performance Establishes a good flow and disperse pigment and has lithographic properties	(S) rosin, maleated, polymer with benzoic acid, glycerol, propylene glycol and 3a,4,7,7a-tetrahydro-1,3-isobenzofurandione
P-23-0105A	3	05/02/2023	Heebut Materials, LLC	(G) Plastic and rubber additive	(G) Multi-Walled Carbon Nanotube
P-23-0118	3	04/27/2023	CBI	(G) Reactant	(G) Glycerides from fermentation of genetically modified microorganism, ethoxylated, reaction products with ethanol, polycyclic isocyanate
P-23-0127	2	05/18/2023	CBI	(S) Ingredient in laundry detergent that is used for degradation of stains on fabric	(G) Polysaccharide Lyase
P-23-0128	2	05/17/2023	CBI	(G) Textile softening applications	(S) Fatty acids, C16-18, reaction products with diethanolamine

P-23-0129	3	05/16/2023	Polymer Additives, Inc.	(G) Used as an intermediate and will be consumed internally by Valtris to make the end product which is intended to market to customers	(G) Soy or rapeseed fatty acid, benzyl esters
P-23-0133	1	05/08/2023	CBI	(G) Component in asphalt	(G) Fatty acids reaction products with alcoholamine reaction by-products, salts
P-23-0135	1	05/12/2023	CBI	(G) Destructive use	(G) Alken-1-ol, 1-acetate
P-23-0136	1	05/17/2023	CBI	(G) Component in asphalt	(G) Fatty acids, reaction products with hexamethylenediamine and 12-hydroxyoctadecanoic acid
P-23-0140	2	05/23/2023	CBI	(G) Additive for consumer and commercial products	(G) Polysaccharide, (hydroxytrialkylammonio)alkyl ether, chloride
P-23-0141	1	05/23/2023	Hach Company	(G) Buffer solution for free chlorine determination	(S) 2-Butenedioic acid (2Z)-, potassium salt (1:?)
SN-16-0013A	5	05/08/2023	CBI	(G) Surfactant	(G) Polyfluorinated alkyl quaternary ammonium chloride
SN-20-0003A	10	05/08/2023	CBI	(S) An anionic fluorosurfactant used in firefighting foam concentrates such as AFFF (Aqueous Film Forming Foam) and AR-AFFF (Alcohol Resistant Aqueous Film Forming Foam)	(S) 1-Propanesulfonic acid, 2-methyl-2-[[1-oxo-3-[(3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)thio]propyl]amino]-, sodium salt (1:1)
SN-21-0011A	3	05/11/2023	CBI	(G) Solvent	(S) 2-Propanol, 1-[bis(2-hydroxyethyl)amino]-

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 05/01/2023 to 05/31/2023

Case No.	Received Date	Commencement Date	If Amendment, Type of Amendment	Chemical Substance
P-19-0185	05/11/2023	04/03/2023	N	(S) Benzoic acid, 2-chloro-3-methyl-, sodium salt (1:1)
P-95-0224	05/16/2023	04/28/1995	N	(S) 2-propenoic acid,2-methyl-,2-(dimethylamino)ethyl ester, polymer with 1-ethenylhexahydro-2h-azepin-2-one & vinylpyrrolidone

* 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 05/01/2023 to 05/31/2023

Case No.	Received Date	Type of Test Information	Chemical Substance
P-23-0124	05/24/2023	Acute Oral Toxicity/Pathogenicity (OCSP Test Guideline 885.3050); Bacterial Reverse Mutation Test (OECD Test Guideline 471)	(G) Sulfonium, tricabocyclic-, 2-heteroatom-substituted-(halocarbocyclic)carboxylate (1:1)

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: June 14, 2023.

Pamela Myrick,

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

[FR Doc. 2023-13165 Filed: 6/20/2023 8:45 am; Publication Date: 6/21/2023]