



ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2023-0061; FRL-10581-11-OCSP]

Certain New Chemicals; Receipt and Status Information for November 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 11/01/2023 to 11/30/2023.

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 11/01/2023 to 11/30/2023. 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 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/tscainventory>.

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” (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 11/01/2023 to 11/30/2023.

Case No.	Version	Received Date	Manufacturer	Use	Chemical Substance
J-23-0005A	2	09/26/2023	CBI	(G) Production of an enzyme	(G) Microorganisms transformed to express an enzyme
J-23-0006A	2	09/26/2023	CBI	(G) Production of an enzyme	(G) Microorganisms transformed to express an enzyme

P-22-0113A	5	11/02/2023	SOLUGEN INC	(G) Chemical intermediate, Additive	(S) D-Glucaric acid
P-22-0123A	4	11/13/2023	CBI	(G) Mineral processing aid	(G) Propaneamine, 3-(alkyloxy)-, structural variants
P-22-0140A	4	11/28/2023	Colonial Chemical, Inc.	(G) Corrosion inhibitor	(G) 6-[(alkyl-1-oxohexyl)amino]-hexanoic acid, compd. with cyclohexylamine (1:1)
P-23-0069A	4	11/08/2023	CBI	(S) Encapsulating Shell Polymer for Fragrance; Encapsulates for Industrial or Household Consumer Products such as Detergents and Fabric Softeners	(G) Pisum sativum oil, glycerol, crosspolymer with linear and cyclic aliphatic isocyanates
P-24-0001	1	10/03/2023	Cabot Corporation	(G) Additive used in industrial applications	(G) Carbon Nanostructures, purified
P-24-0005A	8	11/16/2023	CBI	(G) Plastic article production	(G) Polycarbomonocyclic diol reaction products with cycloalkylcarbomonocycle and polysubstituted heteromonocycle
P-24-0007	2	11/08/2023	Kenrich Petrochemicals, Inc.	(S) Use as a dispersant for powders, all forms KR PTOA, CAPOW KR PTOA and CAPS KR PTOA.; Use as an adhesion promoter in adhesives and sealants all forms KR PTOA, CAPOW KR PTOA and CAPS KR PTOA	(S) Titanium, branched and linear C16-18 and C18-unsatd. fatty acids iso-Pr alc. complexes
P-24-0024	1	11/08/2023	Enchem America, LLC	(G) Electrolyte additive	(G) Heteroatom-substituted dihalo acid, methyl substituted-alkyl ester
P-24-0030	1	11/10/2023	Barentz North America, LLC	(S) 2-Ethylhexylal currently has widespread use as a functional fluid in lubricants, greases, and other release products; 2-Ethylhexylal currently has widespread use in laboratories as a non-reactive processing aid with no inclusion into	(S) Heptane, 3,3'-[methylenebis(oxymethylene)]bis-(9CI, ACI)

				or onto the article.; 2-Ethylhexylal is also used in consumer products as a solvent or cosolvent in coating products	
P-24-0032	1	11/15/2023	Equinor Marketing & Trading (US), Inc.	(S) Hydrocarbon value for fuel applications (e.g., use in motor fuel, blending stock for other fuels)	(S) Naphtha (glyceridic), light catalytic cracked

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 11/01/2023 to 11/30/2023.

Case No.	Received Date	Commencement Date	If Amendment, Type of Amendment	Chemical Substance
P-16-0313	11/15/2023	11/02/2023	N	(S) Tar acids (shale oil), C6-9 fraction, alkylphenols, low-boiling
P-18-0158	11/28/2023	11/01/2023	N	(G) Sulfonium, triphenyl-, salt with 2,3-bis(substituted) 5-sulfocarboxypolycyclic-2,3-carboxylate derivative (1:1)
P-20-0054	11/07/2023	10/07/2020	N	(S) Nitrile Hydratase
P-20-0178A	11/29/2023	08/02/2023	Amended Generic Chemical Name	(G) Carbopolycyclic alkenyl, 2-carboxylic acid, 2-[[[[[(isocyanatophenyl)alkyl]carbocycle]-amino]carbonyl]oxy]ethyl ester
P-21-0042	11/28/2023	11/01/2023	N	(G) Sulfonium, tricarbocyclic-, 2-heteroatom-substituted-4-(alkyl)carbomonocyclic carboxylate (1:1)
P-21-0131	11/28/2023	11/01/2023	N	(G) Sulfonium, tricarbocyclic-, 2-(4-alkoxyhalocarbomonocyclic)-alpha, alpha, beta, beta-polyhalopolyhydro-4,7-methano-1,3-heteropolycyclic-5-alkanesulfonate (1:1)
P-22-0018	11/20/2023	11/03/2023	N	(G) Substituted polyalkylenepoly, reaction products with substituted heteromonocycle substituted

				heteromonocycle polyalkylene derivs
P-22-0022	11/14/2023	11/04/2023	N	(G) Aryl-substituted-heterocyclic-polyamine, reaction products with polyethylene glycol alkyl-ether, and nitrogen and alkyl-substituted benzene
P-23-0013	11/17/2023	11/15/2023	N	(S) Phenol, polymer with 4,4'-bis(chloromethyl)-1,1'-biphenyl

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 11/01/2023 to 11/30/2023.

Case No.	Received Date	Type of Test Information	Chemical Substance
L-23-0173	11/22/2023	Algal Toxicity (OECD Test Guideline 201)	(G) Cis-Alkenoic Acid
P-16-0543	11/21/2023	Exposure Monitoring Report	(G) Halogenophosphoric acid metal salt
P-23-0017	11/29/2023	Human Repeated Insult Patch Testing	(G) Hydrolyzed collagen, polymer with aromatic isocyanate, n-triethoxysilyl-alkanamine, pectic polysaccharide and poly alkyl alcohol

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: December 18, 2023.

Pamela Myrick,

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

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