



## ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2023-0061; FRL-10581-09-OCSP]

### Certain New Chemicals; Receipt and Status Information for September 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 9/1/2023 to 9/30/2023.

**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](mailto: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](mailto: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 9/01/2023 to 9/30/2023. 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-tsc>.

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 09/01/2023 to 09/30/2023**

Case No.	Version	Received Date	Manufacturer	Use	Chemical Substance
J-23-0005	1	08/30/2023	CBI	(G) Production of an enzyme	(G) Microorganisms transformed to express and enzyme
J-23-0006	1	08/30/2023	CBI	(G) Production of an	(G) Microorganisms

				enzyme	transformed to express and enzyme
P-21-0143A	4	09/25/2023	CBI	(G) Coating and adhesive ingredient	(G) Aliphatic Diisocyanate, homopolymer, aliphatic alcohol blocked
P-21-0215A	2	09/01/2023	Coventya, Inc.	(S) The PMN substance is used in a primarily aqueous alkaline electroplating solution that produces a nominal zinc (Zn) nickel (Ni) alloy deposit on iron bearing substrates	(S) Pyridinium, 3-carboxy-1-methyl-, inner salt
P-22-0011A	5	08/24/2023	Lord Corporation	(G) Functionalized rubber in resin side of two component epoxy modified acrylic adhesive	(G) Alkadiene, homopolymer, hydroxy-terminated, bis[N-[2-[(1-oxo-2-propen-1-yl)oxyethyl]carbamates]
P-22-0024A	3	09/25/2023	CBI	(G) Ingredient in Industrial Coating	(G) Amino salt, polymer with 1,6-diisocyanatohexane, oxime- and glycol ether-blocked
P-22-0043A	3	09/13/2023	CBI	(G) Intermediate	(G) Fatty acids, hydroxyethoxy ethyl esters
P-22-0151A	7	08/28/2023	CBI	(G) Surfactant for commercial applications	(G) Glycolipids, sophorose-contg., yeast-fermented, from glycerides and carbohydrates
P-22-0157A	2	09/01/2023	Evonik Corporation	(S) Polyurethane catalyst	(S) 1,2-Ethanediamine, N1,N2-dimethyl-N1-(1-methylethyl)-N2-[2-[methyl(1-methylethyl)amino]ethyl]-
P-22-0157A	3	09/07/2023	Evonik Corporation	(S) Polyurethane catalyst	(S) 1,2-Ethanediamine, N1,N2-dimethyl-N1-(1-methylethyl)-N2-[2-[methyl(1-methylethyl)amino]ethyl]-
P-22-0168	2	09/11/2023	Colonial	(S) The product is	(G) Amides, alkyl, N-

			Chemical, Inc.	used as a reaction intermediate to make surfactant end-products. It is not sold commercially or used outside of our manufacturing facility	[3-(dimethylamino)propyl]
P-22-0168A	3	09/25/2023	Colonial Chemical, Inc.	(S) The product is used as a reaction intermediate to make surfactant end-products. It is not sold commercially or used outside of our manufacturing facility	(G) Amides, alkyl, N-[3-(dimethylamino)propyl]
P-22-0175A	3	09/06/2023	Wacker Chemical Corporation	(S) Polymer Resin Binder for composite stone (Engineered Stone)	(G) Modified Silsesquioxane, alkoxy-terminated
P-23-0022A	2	09/08/2023	Cabot Corporation	(G) Additive used in industrial applications	(G) Multi-walled carbon nanotubes
P-23-0023A	2	09/08/2023	Cabot Corporation	(G) Additive used in industrial applications	(G) Multi-walled carbon nanotubes
P-23-0024A	2	09/08/2023	Cabot Corporation	(G) Additive used in industrial applications	(G) Multi-walled carbon nanotubes
P-23-0033A	2	09/08/2023	Cabot Corporation	(G) Additive used in industrial applications	(G) Multi-walled carbon nanotubes
P-23-0077A	3	08/31/2023	CBI	(G) Additive for industrial applications	(G) Alkanepolyoxy acid, alkyl substituted
P-23-0077A	4	09/01/2023	CBI	(G) Additive for industrial applications	(G) Alkanepolyoxy acid, alkyl substituted
P-23-0154A	3	09/20/2023	RWDC Industries	(G) The primary application areas for PHA are for food packaging and other uses where its biodegradable properties provide nontraditional end-of-use options	(G) Vegetable oils, genetically modified Cupriavidus-fermented, polyhydroxyalkanoate copolymer
P-23-0163	2	09/06/2023	CBI	(G) Surface coating	(S) 1,2-Ethanediamine, N1-[3-(trimethoxysilyl)propyl]-, hydrolysis products with 3-(trimethoxysilyl)-N-[3-(trimethoxysilyl)propyl]-1-propanamine, nitrates (salts)
P-23-0171	2	09/06/2023	Interplastic	(G) Polyester Resin	(S) 1,2,3-

			Corporation	Additive	Propanetricarboxylic acid, 2-hydroxy-, octyl ester
P-23-0172A	2	09/13/2023	CBI	(G) Photolithography	(G) Sulfonium, tricarboxylic-, alkylcarbomocyclic-polyfluoro-heteropolycyclic-alkyl sulfonate (1:1), polymer with alkylaryl and carbomonocyclic alkyl alkanoate, di-Me 2,2'-(1,2-diazenediyl)bis[2-alkylalkanoate]-initiated
P-23-0175	2	09/27/2023	CBI	(G) rinse material for photolithography	(G) Bis(fluoroalkylsubstituted) sulfonyl sulfonamide
P-23-0176	1	09/06/2023	CBI	(G) An ingredient used in the manufacture of photoresist	(G) Sulfonium, bis(dihalo carbomonocycle)carbomonocycle-, salt with dihalo-sulfoalkyl trisubstituted benzoate
P-23-0177	2	09/19/2023	Colonial Chemical, Inc.	(G) Corrosion inhibitor	(G) fatty acids, vegetable oil, reaction products with diethylenetriamine
P-23-0178	1	09/07/2023	CBI	(S) Lens resins for photoelectric conversion adapters	(S) Benzenamine, 4,4'-(9H-fluoren-9-ylidene)bis-
P-23-0179	1	09/08/2023	CBI	(G) An ingredient used in the manufacture of photoresist	(G) Sulfonium, bis(dihalocarbomonocycle)carbomonocycle-, salt with substituted-dihalobenzoate
P-23-0181	1	09/13/2023	CBI	(G) Used as adhesive	(G) Alkanedioic acid, polymer with mixed alkanediol, polyalkyl glycol, carbomonocycle carbomonocycle, alkane carbopolycycle diisocyanate
P-23-0182	1	09/15/2023	CBI	(G) Base oils in lubricants	(G) Cyclic ether, polymer with 2-methyloxirane and oxirane, monobutyl ether

P-23-0183	2	09/22/2023	CBI	(G) Additive in paints, coatings and inks, paint removal formulations, wire coatings	(G) Ethyl Modified Lactam
P-23-0184	2	09/25/2023	CBI	(G) Intermediate	(G) Perfluorosulfonyl fluoride polymer, with perfluorodioxolane
P-23-0185	2	09/25/2023	CBI	(G) Intermediate	(G) Perfluorosulfonic acid polymer, salt, with perfluorodioxolane
P-23-0186	2	09/25/2023	CBI	(G) Dispersive Use	(G) Perfluorosulfonic acid polymer, with perfluorodioxolane
P-23-0187	1	09/21/2023	CBI	(S) Polymer for use in powder and tablet laundry detergent formulations	(G) Substituted benzenedicarboxylic acid, sodium salt, polymer with benzenedicarboxylic acids and 1,2-ethanediol
P-23-0188	2	09/27/2023	CBI	(G) Destructive Use	(G) Alkenoic acid, 3-methyl-, 1,1-dimethyl-2-propen-1-yl ester; Alkenoic acid, 3-methyl-, 1,1-dimethyl-2-propen-1-yl ester;
P-23-0189	1	09/25/2023	CBI	(G) Component in polymers	(G) Dimethanocarbopolycycle, alkyl-polyhydro-
P-23-0191	1	09/25/2023	CBI	(G) Photolithography	(G) Sulfonium, tricyclic-, heteroatom-substituted-(halocarbocyclic)carboxylate (1:1)

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 09/01/2023 to 09/30/2023**

Case No.	Received Date	Commencement Date	If Amendment, Type of Amendment	Chemical Substance
J-22-0023	09/28/2023	09/15/2023	N	(G) Microorganisms stably transformed to manufacture PHA
J-22-0024	09/29/2023	09/20/2023	N	(G) Microorganisms stably transformed to manufacture PHA
J-22-0025	09/29/2023	09/29/2023	N	(G) Microorganisms stably transformed to manufacture PHA
J-23-0004	09/18/2023	09/11/2023	N	(G) Genetically modified microorganism
P-21-0073	09/25/2023	09/07/2023	N	(S) 4-cyclohexanedicarboxylic acid, 1,4-dinonyl ester, branched and linear
P-21-0175	09/29/2023	09/22/2023	N	(G) Polycarbonate diol / benebiol nldb grade
P-97-0954A	09/21/2023	10/23/2020	Amended generic chemical name	(G) Isocyanic acid, polymethylenepolyphenylene ester, polymer with .alpha.,.alpha.'-[(1-methylethylidene)di-4,1-phenylene]bis[.omega.-hydroxypoly(oxyalkanediyl)] and 1,2-alkanediol, 2-alkoxyethanol-blocked

\*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 09/01/2023 to 09/30/2023**

Case	Received	Type of Test Information	Chemical Substance
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No.	Date		
P-16-0543	09/01/2023	Exposure Monitoring Report	(G) Halogenophosphoric acid metal salt
P-16-0543	09/01/2023	Exposure Monitoring Report	(G) Halogenophosphoric acid metal salt
P-18-0304	09/06/2023	Partition Coefficient (n-octanol/water), Shake Flask Method (OECD Test Guideline 107); Partition Coefficient (n-octanol/water), Estimation by Liquid Chromatography (OECD Test Guideline 117)	(G) Sulfonium, bis(dihalocarbomonocycle) carbomonocycle, salt with substituted heteropolycycle dihalo sulfoalkanoate (1:1)
P-22-0046	09/01/2023	Published Studies on Allergenicity	(S) Fibroins
P-22-0128	09/20/2023	Mass Spectrometry, IR Spectrometry, NMR Testing Data	(G) Alkyl cycloalkane, polyfluoro-

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:** October 18, 2023.

**Pamela Myrick,**

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

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