

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2019-0271; FRL-9995-83]

Certain New Chemicals or Significant New Uses; Statements of Findings for May 2019

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Section 5(g) of the Toxic Substances Control Act (TSCA) requires EPA to publish in the **Federal Register** a statement of its findings after its review of TSCA section 5(a) notices when EPA makes a finding that a new chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment. Such statements apply to premanufacture notices (PMNs), microbial commercial activity notices (MCANs), and significant new use notices (SNUNs) submitted to EPA under TSCA section 5. This document presents statements of findings made by EPA on TSCA section 5(a) notices during the period from May 1, 2019 to May 31, 2019.

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Greg Schweer, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; telephone number: 202-564-8469; email address: schweer.greg@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. General Information

A. Does this action apply to me?

This action is directed to the public in general. As such, the Agency has not attempted to describe the specific entities that this action may apply to. Although others may be affected, this action applies directly to the submitters of the PMNs addressed in this action.

B. How can I get copies of this document and other related information?

The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2018-0097, is available at <http://www.regulations.gov> or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket),

Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

II. What action is the Agency taking?

This document lists the statements of findings made by EPA after review of notices submitted under TSCA section 5(a) that certain new chemical substances or significant new uses are not likely to present an unreasonable risk of injury to health or the environment. This document presents statements of findings made by EPA during the period from May 1, 2019 to May 31, 2019.

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

TSCA section 5(a)(3) requires EPA to review a TSCA section 5(a) notice and make one of the following specific findings:

- The chemical substance or significant new use presents an unreasonable risk of injury to health or the environment;
- The information available to EPA is insufficient to permit a reasoned evaluation of the health and environmental effects of the chemical substance or significant new use;
- The information available to EPA is insufficient to permit a reasoned evaluation of the health and environmental effects and the chemical substance or significant new use may present an unreasonable risk of injury to health or the environment;
- The chemical substance is or will be produced in substantial quantities, and such substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance; or
- The chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment.

Unreasonable risk findings must be made without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation

identified as relevant under the conditions of use. The term "conditions of use" is defined in TSCA section 3 to mean "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of."

EPA is required under TSCA section 5(g) to publish in the **Federal Register** a statement of its findings after its review of a TSCA section 5(a) notice when EPA makes a finding that a new chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment. Such statements apply to PMNs, MCANs, and SNUNs submitted to EPA under TSCA section 5.

Anyone who plans to manufacture (which includes import) a new chemical substance for a non-exempt commercial purpose and any manufacturer or processor wishing to engage in a use of a chemical substance designated by EPA as a significant new use must submit a notice to EPA at least 90 days before commencing manufacture of the new chemical substance or before engaging in the significant new use.

The submitter of a notice to EPA for which EPA has made a finding of "not likely to present an unreasonable risk of injury to health or the environment" may commence manufacture of the chemical substance or manufacture or processing for the significant new use notwithstanding any remaining portion of the applicable review period.

IV. Statements of Administrator Findings Under TSCA Section 5(a)(3)(C)

In this unit, EPA provides the following information (to the extent that such information is not claimed as Confidential Business Information (CBI)) on the PMNs, MCANs and SNUNs for which, during this period, EPA has made findings under TSCA section 5(a)(3)(C) that the new chemical substances or significant new uses are not likely to present an unreasonable risk of injury to health or the environment:

- EPA case number assigned to the TSCA section 5(a) notice.
- Chemical identity (generic name, if the specific name is claimed as CBI).
- Website link to EPA's decision document describing the basis of the

“not likely to present an unreasonable risk” finding made by EPA under TSCA section 5(a)(3)(C).

EPA case No.	Chemical identity	Website link
P-18-0282	Fatty acid ester, polyether, diisocyanate polymer (generic name)	https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-section-5a3c-determination-234 .
P-17-0108	Carbonodithioic acid, O-[2-[(dithiocarboxy)amino]-2-methylpropyl] ester, sodium salt (1:2) (CASRN: 1947332-67-3).	https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-section-5a3c-determination-233 .
P-16-0429	Endcapped polysiloxane (generic name)	https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-section-5a3c-determination-232 .
P-16-0225	Isomer mixture of Cyclohexanol, 4-ethylidene-2-propoxy- (CASRN: 1631145-48-6) (35-45%) and Cyclohexanol, 5-ethylidene-2-propoxy- (CASRN: 1631145-49-7).	https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-section-5a3c-determination-231 .
P-16-0470	2,7-Nonadien-4-ol, 4,8-dimethyl- (CASRN: 103983-77-3)	https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-section-5a3c-determination-230 .
P-19-0034	Metal, bis(2,4-pentanedionato-kO2,kO4)-, (T-4)-, (generic name)	https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-section-5a3c-determination-229 .
P-19-0028	Alkyl salicylate, metal salts (generic name)	https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-section-5a3c-determination-228 .
P-19-0004	Aromatic dianhydride, polymer with aromatic diamine and heteroatom bridged aromatic diamine, reaction products with aromatic anhydride (generic name).	https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-section-5a3c-determination-226 .
P-18-0322	Heteromonocycle, 4,6-dimethyl-2-(1-phenylethyl)- (generic name)	https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-section-5a3c-determination-225 .
P-18-0321	Poly(oxy-ethanediyl), (methyl ethanediyl)bis[hydroxy-, (generic name)	https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-section-5a3c-determination-224 .
P-18-0270	Ethanol, 2-butoxy-, 1,1'-ester (generic name)	https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-section-5a3c-determination-223 .
P-18-0234	Alkenoic acid, reaction products with bis substituted alkane and ether polyol (generic name).	https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-section-5a3c-determination-221 .
P-18-0228	Branched alkenyl acid, alkyl ester, homopolymer (generic name)	https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-section-5a3c-determination-220 .
P-18-0091	Vegetable oil, polymers with diethylene glycol- and polyol- and polyethylene glycol-depolymerized poly(ethylene terephthalate) waste plastics and arylcarboxylic acid anhydride (generic name).	https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-section-5a3c-determination-219 .
P-16-0425	Amino-silane (generic name)	https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-section-5a3c-determination-217 .
P-16-0314	Ethanone, 1-(5-propyl-1,3-benzodioxol-2-yl)-	https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-section-5a3c-determination-216 .
J-19-0018	Protein-producing modified microorganism, with chromosomally-borne modifications (generic name).	https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-section-5a3c-determination-215 .
P-18-0339	Alkyl heteromonocycle with heteroatom substituted alkyl cycloalkane and 2-hydroxyethyl heteromonocycle methacrylate-blocked homopolymer (generic name).	https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-section-5a3c-determination-214 .
P-18-0220	Heteromonocycle [(alkylalkylidene)bis (substituted carbomonocycle)]bis-, polymer with alkyl isocyanate, alkenoate (ester) (generic name).	https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-section-5a3c-determination-213 .
P-18-0120	1H-Pyrrole-2,5-dione, 1,1'-C36-alkylenebis- (CASRN: 1911605-95-2)	https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-section-5a3c-determination-212 .
P-19-0057	Alkanamine, [(Alkoxy)alkoxy]alkyl (generic name)	https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-section-5a3c-determination-211 .
P-19-0056, P-19-0060-0061.	(P-19-0056) Aliphatic hydrocarbons, C8-C20-branched and linear, (P-19-0060) Aliphatic hydrocarbons, C8-C18-branched and linear, (P-19-0061) Aliphatic hydrocarbons, C16-20-branched and linear (generic names).	https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-section-5a3c-determination-210 .
P-19-0054	Polyamines, reaction products with succinic anhydride polyalkenyl derivs, metal salts, Polyamines, reaction products with succinic anhydride polyalkenyl derivs, metal salts (generic name).	https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-section-5a3c-determination-209 .
P-18-0188	Alkyl substituted alkenoic acid, alkyl ester, polymer with alkanediol alkyl-alkenoate, reaction products with alkenoic acid, isocyanato-(isocyanatoalkyl)-alkyl substituted carbomonocycle and substituted alkanediol (generic name).	https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-section-5a3c-determination-202 .
P-18-0406	Formaldehyde, polymer with alkyl aryl ketones (generic name)	https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-section-5a3c-determination-201 .

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

Dated: July 3, 2019.

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ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2017-0026; FRL 9993-96]

Statutory Requirements for Substantiation of Confidential Business Information (CBI) Claims Under the Toxic Substances Control Act (TSCA)

AGENCY: Environmental Protection
Agency (EPA).

ACTION: Notice.

SUMMARY: On January 19, 2017, EPA announced an interpretation of section 14 of the Toxic Substances Control Act (TSCA). Under this interpretation, non-exempt confidential business information (CBI) claims must be substantiated at the time the information claimed as CBI is submitted to EPA, and non-exempt CBI claims submitted without a substantiation are considered deficient. To facilitate compliance with the change in interpretation, EPA announced it would undertake a non-statutorily required