



ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2025-0077; FRL-12476-03-OCSP]

Certain New Chemicals or Significant New Uses; Statements of Findings – March 2025

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Toxic Substances Control Act (TSCA) requires EPA to publish in the *Federal Register* a statement of its findings after its review of certain TSCA submissions 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. This document presents statements of findings made by EPA on such submissions during the period from March 1, 2025 to March 31, 2025.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2025-0077, is available online at <https://www.regulations.gov>. Additional information about dockets generally, along with instructions for visiting the docket in-person, is available at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT:

For technical information: Rebecca Edelstein, New Chemical Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-1667 email address: edelstein.rebecca@epa.gov.

For general information: 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. Does this action apply to me?

This action provides information that is directed to the public in general.

B. What action is the Agency taking?

This document lists the statements of findings made by EPA after review of submissions 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 applicable period.

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

TSCA section 5(a)(3) requires EPA to review a submission under TSCA section 5(a) and make specific findings pertaining to whether the substance may present unreasonable risk of injury to health or the environment. Among those potential findings is that the chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment per TSCA Section 5(a)(3)(C).

TSCA section 5(g) requires EPA to publish in the *Federal Register* a statement of its findings after its review of a submission under TSCA section 5(a) 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.

II. Statements of Findings under TSCA Section 5(a)(3)(C)

In this unit, EPA identifies the PMNs, MCANs and SNUNs for which 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. For the findings made during this period, the following list provides the EPA case number assigned to the TSCA section 5(a) submission and the chemical identity (generic name if the specific name is claimed as confidential).

- J-25-0003, Strain of *Escherichia coli* modified with genetically-stable, plasmid-borne DNA for the production of an enzyme (Generic Name).
- P-21-0191, Fatty acids, C18-unsatd., dimers, hydrogenated, polymers with polyethylene glycol, dihexanoates, CASRN: 2641992-22-3.
- P-21-0192, Fatty acids, C18-unsatd., dimers, hydrogenated, polymers with polyethylene glycol, diesters with C8-10 fatty acids, CASRN: 2641992-26-7.

To access 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), lookup the specific case number at <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/chemicals-determined-not-likely>.

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

Dated: May 23, 2025.

Shari Z. Barash,

Director, New Chemicals Division, Office of Pollution Prevention and Toxics.

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