



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[EPA-HQ-OPPT-2025-2932; FRL-13085-01-OCSPP]

RIN 2070-AB27

Significant New Use Rules on Certain Chemical Substances (26-2)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is issuing significant new use rules (SNURs) under the Toxic Substances Control Act (TSCA) for certain chemical substances that were the subject of premanufacture notices (PMNs) and are also subject to an Order issued by EPA pursuant to TSCA. The SNURs require persons to notify EPA at least 90 days before commencing the manufacture (defined by statute to include import) or processing of any of these chemical substances for an activity that is designated as a significant new use in the SNUR. The required notification initiates EPA's evaluation of the conditions of that use for that chemical substance. In addition, the manufacture or processing for the significant new use may not commence until EPA has conducted a review of the required notification; made an appropriate determination regarding that notification; and taken such actions as required by that determination.

DATES: Comments 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-2025-2932 online 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: James Yan, New Chemicals Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., N.W., Washington, DC 20460-0001; telephone number: (202) 564-2138; email address: yan.james@epa.gov.

For general information on SNURs: William Wysong, New Chemicals Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., N.W., Washington, DC 20460-0001; telephone number: (202) 564-4163; email address: wysong.william@epa.gov.

For general information on TSCA: The TSCA Assistance Information Service Hotline, Goodwill Vision Enterprises, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (800) 471-7127 or (202) 554-1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

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

TSCA section 5(a)(2) (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a “significant new use.” EPA must make this determination by rule after considering all relevant factors, including the factors in TSCA section 5(a)(2) (see also the discussion in Unit II.).

B. What action is the Agency taking?

EPA is proposing SNURs for the chemical substances discussed in Unit III. These SNURs, if finalized as proposed, would require persons who intend to manufacture or process any of these chemical substances for an activity that is designated as a significant new use to notify EPA at least 90 days before commencing that activity.

C. Does this action apply to me?

1. General applicability.

This action applies to you if you manufacture, process, or use the chemical substances contained in this proposed rule. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Manufacturers or processors of one or more subject chemical substances (NAICS codes 325 and 324110), e.g., chemical manufacturing and petroleum refineries.

2. Applicability to importers and exporters.

This action may also apply to certain entities through pre-existing import certification and export notification requirements under TSCA (<https://www.epa.gov/tsca-import-export-requirements>).

Chemical importers are subject to TSCA section 13 (15 U.S.C. 2612), the requirements in 19 CFR 12.118 through 12.127, 19 CFR 127.28, and 40 CFR 707.20. Importers of chemical substances in bulk form, as part of a mixture, or as part of an article (if required by rule) must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA, including regulations issued under TSCA sections 5, 6, 7 and Title IV.

Pursuant to 40 CFR 721.20, any persons who export or intend to export a chemical substance that is the subject of this proposed rule on or after **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** are subject to TSCA section 12(b) (15 U.S.C. 2611(b)) and must comply with the export notification requirements in 40 CFR part 707, subpart D.

D. What are the incremental economic impacts of this action?

EPA has evaluated the potential costs of establishing SNUN reporting requirements for potential manufacturers (including importers) and processors of the chemical substances subject to SNURs, which applies to the chemical substances in this rulemaking. This analysis, which is available in the docket, is briefly summarized here.

1. *Estimated costs for SNUN submissions.*

If a SNUN is submitted, costs are an estimated \$45,496 per SNUN submission for large business submitters and \$14,976 for small business submitters. These estimates include the cost to prepare and submit the SNUN (including registration for EPA's Central Data Exchange (CDX)), and the payment of a user fee. Businesses that submit a SNUN would be subject to either a \$37,000 user fee required by 40 CFR 700.45(c)(2)(ii) and (d), or, if they are a small business as defined at 13 CFR 121.201, a reduced user fee of \$6,480 (40 CFR 700.45(c)(1)(ii) and (d)). The costs of submission for SNUNs will not be incurred by any company unless a company decides to pursue a significant new use as defined in these SNURs. Additionally, these estimates reflect the costs and fees as they are known at the time of this rulemaking.

2. *Estimated costs for export notifications.*

EPA has also evaluated the potential costs associated with the export notification requirements under TSCA section 12(b) and the implementing regulations at 40 CFR part 707, subpart D. For persons exporting a substance that is the subject of a SNUR, a one-time notice to EPA must be provided for the first export or intended export to a particular country. The total costs of export notification will vary by chemical, depending on the number of required notifications (i.e., the number of countries to which the chemical is exported). While EPA is unable to make any estimate of the likely number of export notifications for the chemical substances covered by these SNURs, as stated in the accompanying economic analysis, the estimated cost of the export notification requirement on a per unit basis is approximately \$106.

E. *What should I consider as I prepare my comments for EPA?*

1. *Submitting CBI.*

Do not submit CBI to EPA through email or <https://www.regulations.gov>. If you wish to include CBI in your comment, please follow the applicable instructions at <https://www.epa.gov/dockets/commenting-epa-dockets#rules> and clearly mark the information that you claim to be CBI. Information so marked will not be disclosed except in accordance with procedures set forth

in 40 CFR parts 2 and 703.

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. Background

This unit provides general information about SNURs. For additional information about EPA's new chemical program go to <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca>.

A. Significant New Use Determination Factors

TSCA section 5(a)(2) states that EPA's determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors, including:

- The projected volume of manufacturing and processing of a chemical substance.
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.
- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.
- The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

In determining what would constitute a significant new use for the chemical substances that are the subject of these SNURs, EPA considered relevant information about the toxicity of the chemical substances, and potential human exposures and environmental releases that may be associated with the substances, in the context of the four bulleted TSCA section 5(a)(2) factors listed in this Unit and discussed in Unit III.

These proposed SNURs are based on orders issued to certain companies for substances that were the subject of PMN submissions. Those orders were issued under TSCA section 5(e)(1)(A), as required by the determinations made under TSCA section 5(a)(3)(B). The TSCA

orders require protective measures to limit exposures or otherwise mitigate the potential unreasonable risk. Additional consent orders with similar protective measures are outstanding for other PMNs submitted for the same chemical substances. Those other PMN numbers align with the SNURs in this proposed rule as follows:

- for 40 CFR 721.12219, the additional PMNs are P-23-120, P-25-93, P-25-125, P-25-135, and P-25-145.

- for 40 CFR 721.12220, the additional PMNs are P-23-122, P-24-180, and P-25-144.

The proposed SNURs extend the protective measures from the signed consent orders for P-25-73, P-25-152, P-25-137, and P-25-151 to any person intending to manufacture, process, use, distribute in commerce, or dispose of the same new chemical substances and identify as significant new uses any manufacturing, processing, use, distribution in commerce, or disposal that does not conform to the restrictions imposed by the underlying TSCA orders, consistent with TSCA section 5(f)(4). Any person with an outstanding consent order as of [INSERT DATE OF PUBLICATION] for the same new chemical substance may sign it and manufacture, process, use, distribute in commerce, or dispose of the PMN substance consistent with the terms of that order. Any manufacturing, processing, use, distribution in commerce, or disposal of these new chemical substances that does not conform to a signed consent order or occurs in the absence of the protective measures of this SNUR is a significant new use. A SNUN is required prior to any significant new use.

B. Rationale and Objectives of the SNURs

1. Rationale.

Under TSCA section 5(a)(1)(B), no person may manufacture a new chemical substance or manufacture or process a chemical substance for a significant new use until EPA makes a determination as described in TSCA section 5(a)(3) and takes any required action. The issuance of a SNUR is not a risk determination itself, only a notification requirement for “significant new uses,” so that the Agency has the opportunity to review the SNUN for the significant new use

and make a TSCA section 5(a)(3) risk determination.

During review of the PMNs submitted that identify chemical substances subject to these proposed SNURs, EPA concluded that regulation was warranted under TSCA section 5(e), pending the development of information sufficient to make reasoned evaluations of the health or environmental effects of the chemical substances. Based on the findings outlined in Unit III., TSCA section 5(e) Orders requiring the use of appropriate exposure controls and environmental release restrictions were negotiated with the PMN submitters. As a general matter, EPA believes it is necessary to follow a TSCA order with a SNUR that identifies the absence of those protective measures as significant new uses to ensure that all manufacturers and processors – not just the party subject to a TSCA order – are held to the same standard.

2. Objectives.

EPA is proposing these SNURs because the Agency has determined it is appropriate:

- To identify as significant new uses any manufacturing, processing, use, distribution in commerce, or disposal that does not conform to the restrictions imposed by the underlying TSCA Orders, consistent with TSCA section 5(f)(4).

- To identify as significant new uses any manufacturing, processing, use, distribution in commerce, or disposal that does not conform to the restrictions imposed by the underlying TSCA Orders, consistent with TSCA section 5(f)(4).

- To have an opportunity to review and evaluate data submitted in a SNUN before the submitter begins manufacturing or processing a listed chemical substance for the described significant new use.

- To be obligated to make a determination under TSCA section 5(a)(3) regarding the use described in the SNUN, under the conditions of use. The Agency will either determine under TSCA section 5(a)(3)(C) that the significant new use is not likely to present an unreasonable risk, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, or make a

determination under TSCA section 5(a)(3)(A) or (B) and take the required regulatory action associated with the determination, before manufacture or processing for the significant new use of the chemical substance can occur.

Issuance of a proposed SNUR for a chemical substance does not signify that the chemical substance is listed on the TSCA Chemical Substance Inventory (TSCA Inventory). Guidance on how to determine if a chemical substance is on the TSCA Inventory is available at <https://www.epa.gov/tscainventory>.

C. Significant New Uses Claimed as CBI

EPA is proposing to establish certain significant new uses which have been claimed as CBI subject to Agency confidentiality regulations at 40 CFR parts 2 and 703. Absent a final determination or other disposition of the confidentiality claim under these regulations, EPA is required to keep this information confidential. EPA promulgated a procedure at 40 CFR 721.11 to deal with the situation where a specific significant new use is CBI. Under these procedures, a manufacturer or processor may ask EPA to identify the confidential significant new use subject to the SNUR. The manufacturer or processor must show that it has a *bona fide* intent to manufacture or process the chemical substance. If EPA concludes that the person has shown a *bona fide* intent to manufacture or process the chemical substance, EPA will identify the confidential significant new use to that person. Since most of the chemical identities of the chemical substances subject to these SNURs are also CBI, manufacturers and processors can combine the *bona fide* submission under the procedure in 40 CFR 721.11 into a single step.

D. Applicability of General Provisions

General provisions for SNURs appear in 40 CFR part 721, subpart A. These provisions describe persons subject to SNURs, recordkeeping requirements, exemptions to reporting requirements, and applicability of the rule to uses occurring before the effective date of the rule. Pursuant to 40 CFR 721.1(c), persons subject to SNURs must comply with the same requirements and EPA regulatory procedures as submitters of PMNs under TSCA section

5(a)(1)(A). In particular, these requirements include the information submission requirements of TSCA sections 5(b) and 5(d)(1), the exemptions authorized by TSCA sections 5(h)(1), 5(h)(2), 5(h)(3), and 5(h)(5), and the regulations at 40 CFR part 720. In addition, provisions relating to user fees appear at 40 CFR part 700.

Once EPA receives a SNUN, EPA must either determine that the significant new use is not likely to present an unreasonable risk of injury under the conditions of use for the chemical substance or take such regulatory action as is associated with an alternative determination under TSCA section 5 before the manufacture (including import) or processing for the significant new use can commence. If EPA determines that the significant new use of the chemical substance is not likely to present an unreasonable risk, EPA is required under TSCA section 5(g) to make public, and submit for publication in the *Federal Register*, a statement of EPA's findings.

As discussed in Unit I.C.2., persons who export or intend to export a chemical substance identified in a proposed or final SNUR are subject to the export notification provisions of TSCA section 12(b), and persons who import a chemical substance identified in a final SNUR are subject to the TSCA section 13 import certification requirements. See also <https://www.epa.gov/tsca-import-export-requirements>.

E. Applicability of the Proposed SNURs to Uses Occurring Before the Effective Date of the Final Rule

To establish a significant new use, EPA must determine that the use is not ongoing. The chemical substances subject to this proposed rule have undergone premanufacture review and received determinations under TSCA section 5(a)(3)(C). TSCA Orders have been issued for these chemical substances and the PMN submitters are required by the TSCA Orders to submit a SNUN before undertaking activities that would be designated as significant new uses in these SNURs. Additionally, although several PMNs have been submitted for these same chemical substances, the identities of the chemical substances subject to this proposed rule have been claimed as confidential per 40 CFR 720.85, further reducing the likelihood that another party

would manufacture or process the substances for an activity that would be designated as a significant new use. Based on this, the Agency believes that it is highly unlikely that any of the significant new uses identified in Unit III. are ongoing.

When the chemical substances identified in Unit III. are added to the TSCA Inventory, EPA recognizes that, before the rule is effective, other persons might engage in a use that has been identified as a significant new use. Persons who begin manufacture or processing of the chemical substances for a significant new use identified on or after the designated cutoff date specified in Unit III.A. would have to cease any such activity upon the effective date of the final rule. To resume their activities, these persons would have to first comply with all applicable SNUR notification requirements and EPA would have to take action under TSCA section 5 allowing manufacture or processing to proceed.

F. Important Information About SNUN Submissions

1. SNUN submissions.

SNUNs must be submitted on EPA Form No. 7710-25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in 40 CFR 720.40 and 721.25. E-PMN software is available electronically at <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca>.

2. Development and submission of information.

EPA recognizes that TSCA section 5 does not require development of any particular new information (e.g., generating test data) before submission of a SNUN. There is an exception: If a person is required to submit information for a chemical substance pursuant to a rule, order, or consent agreement under TSCA section 4, then TSCA section 5(b)(1)(A) requires such information to be submitted to EPA at the time of submission of the SNUN.

In the absence of a rule, TSCA order, or consent agreement under TSCA section 4 covering the chemical substance, persons are required only to submit information in their possession or control and to describe any other information known to or reasonably ascertainable

by them (see 40 CFR 720.50). However, upon review of PMNs and SNUNs, the Agency has the authority to require appropriate testing. To assist with EPA's analysis of the SNUN, submitters are encouraged, but not required, to provide the potentially useful information as identified for the chemical substance in Unit III.C.

EPA strongly encourages persons, before performing any testing, to consult with the Agency pertaining to protocol selection. Furthermore, pursuant to TSCA section 4(h), which pertains to reduction of testing in vertebrate animals, EPA encourages consultation with the Agency on the use of alternative test methods and strategies (also called New Approach Methodologies, or NAMs), if available, to generate the recommended test data. EPA encourages dialog with Agency representatives to help determine how best the submitter can meet both the data needs and the objective of TSCA section 4(h). For more information on alternative test methods and strategies to reduce vertebrate animal testing, visit <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/alternative-test-methods-and-strategies-reduce>.

The potentially useful information described in Unit III. may not be the only means of providing information to evaluate the chemical substance associated with the significant new uses. However, submitting a SNUN without any test data may increase the likelihood that EPA will take action under TSCA sections 5(e) or 5(f). EPA recommends that potential SNUN submitters contact EPA early enough so that they will be able to conduct the appropriate tests.

SNUN submitters should be aware that EPA will be better able to evaluate SNUNs that provide detailed information about human exposure and environmental release that may result from the significant new use of the chemical substances.

III. Chemical Substances Subject to these Proposed SNURs

A. What is the designated cutoff date for ongoing uses?

EPA designates [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] as the cutoff date for determining whether the new use is ongoing. This designation is explained in more detail in Unit II.E.

B. What information is provided for each chemical substance?

For each chemical substance identified in Unit III.C., EPA provides the following information:

- PMN number(s) (as well as the proposed CFR citation assigned in the regulatory text section of the proposed rule).
- Chemical name (generic name, if the specific name is claimed as CBI).
- Chemical Abstracts Service Registry Number (CASRN) or Accession Number (if assigned for confidential chemical identities).
- Basis for the SNUR (e.g. effective date of and basis for the corresponding TSCA Order).
- Potentially useful information.

The regulatory text section of the proposed rule specifies the activities designated as significant new uses. Certain new uses, including production volume limits and other uses designated in the proposed rules, may be claimed as CBI.

These proposed SNURs include PMN substances that are subject to orders issued under TSCA section 5(e)(1)(A), as required by the determinations made under TSCA section 5(a)(3)(B). Those TSCA Orders require protective measures to limit exposures or otherwise mitigate the potential unreasonable risk. The proposed SNURs identify as significant new uses any manufacturing, processing, use, distribution in commerce, or disposal that does not conform to the restrictions imposed by the underlying TSCA Orders, consistent with TSCA section 5(f)(4).

C. Which chemical substances are subject to these proposed SNURs?

The substances subject to the proposed SNURs in this document are identified below with the proposed CFR citation. For each chemical substance, EPA has identified PMNs that were submitted for the chemical substance, although the SNUR will apply to the chemical substance regardless of whether or not a PMN was submitted prior to the issuance of this

proposed SNUR.

P-25-73 and P-25-152 (40 CFR 721.12219).

Chemical name: Cobalt lithium manganese nickel oxide, metals-doped (generic).

CASRN: Not available.

Effective date of TSCA Orders: March 16, 2026 (P-25-152) and April 9, 2026 (P-25-73)

Basis for the TSCA Orders: The PMNs state that the generic (non-confidential) use will be in batteries. Multiple PMNs were submitted due to the fact that review of the first PMN received had not yet been completed and the PMN substance was not yet on the inventory. The PMN substance is a type of mixed metal oxide that is covered by the analysis EPA conducted that is detailed in the following documents (which are available on the docket): 1) U.S. EPA.

Standardized Scientific Assessment for Mixed Metal Oxide (MMO) Cathode Active Material (CAM) in Battery Applications for Use in TSCA Section 5 New Chemical Reviews, 2026, 2) U.S. EPA. Policy on Standardized Scientific Assessment for Mixed Metal Oxide (MMO) Cathode Active Material (CAM) in Battery Applications for Use in TSCA Section 5 New Chemical Review, 2026, and 3) U.S. EPA. Policy on Standardized Risk Management for Mixed Metal Oxide (MMO) Cathode Active Material (CAM) in Battery Applications for Use in TSCA Section 5 New Chemical Reviews), 2026. EPA identified concerns for carcinogenicity, reproductive toxicity, specific target organ toxicity, and dermal and respiratory sensitization, and EPA predicts that toxicity to aquatic organisms may occur at concentrations from 1-5 ppb. To protect against these risks, the Orders require:

- No use of the PMN substance other than in the manufacture of batteries;
- No use of the PMN substance without labeling the exterior of batteries or

packaging containing multiple batteries. An example of the label text is as follows: “This battery contains substances that are subject to TSCA restrictions, including for recycling and reclamation activities. For details, contact the battery manufacturer or the EPA TSCA hotline.”;

- No manufacturing, processing (all processing includes recycling or reclaiming

substances from batteries or other items containing the PMN substance) or use of the PMN substance except with the use of dust controls with an overall minimum combined capture and control efficiency of 99%;

- No release of the PMN substance to the air at a single site such that the rolling average concentration over 14 days at the property boundary would be more than a maximum of $1.3E-4$ mg/m³ of the PMN substance individually or in any combination (i.e., in aggregate) with other cobalt containing mixed metal oxide (MMO) chemical substances;

- No manufacture or processing of the PMN substance for more than one year unless there is no air release of the PMN substance or the air release limit is updated;

- No manufacture or processing of the PMN substance for more than one year unless there is no inhalation exposure to the PMN substance or the Respiratory Protection Limits are updated;

- No disposal of the PMN substance, or any waste stream containing the PMN substance, other than by hazardous waste landfill in compliance with the Resource Conservation and Recovery Act Subtitle C or incineration if the incinerator ash is disposed of by hazardous waste landfill in compliance with the Resource Conservation and Recovery Act Subtitle C;

- No release of the PMN substance, or any waste stream containing the PMN substance, to water;

- Prior to worker exposure monitoring - use of a National Institute for Occupational Safety and Health (NIOSH)-certified respirator with an assigned protection factor (APF) of at least 1,000 where there is a potential for inhalation exposure to workers.

- Upon exposure monitoring results – use of a NIOSH-certified respirator with an APF in accordance with the below Respiratory Protection Limits, provided that an APF below 50 is only permitted when the PMN substance contains less than or equal to 3% cobalt by weight. If the 8-Hour Time Weighted Average (TWA) is less than $5.3E-4$ mg/m³, no respiratory protection is required. If the 8-Hour TWA is more than or equal to $5.3E-4$ mg/m³ but less than $5.3E-3$

mg/m³, respiratory protection with a minimum APF of 10 is required. If the 8-Hour TWA is more than or equal to 5.3E-3 mg/m³ but less than 2.7E-2 mg/m³, respiratory protection with a minimum APF of 50 is required. If the 8-Hour TWA is more than or equal to 2.7E-2 mg/m³ but less than 5.3E-1 mg/m³, respiratory protection with a minimum APF of 1000 is required. If the 8-Hour TWA is more than or equal to 5.3E-1 mg/m³ but less than 5.3E+00 mg/m³, respiratory protection with a minimum APF of 10,000 is required. If the 8-Hour TWA exceeds 5.3E+00 mg/m³, then manufacturing, processing, and use must cease;

- Use of personal protective equipment where there is a potential for dermal exposure;
- Use of engineering and administrative control measures to prevent exposure;

and

- Establishment of a hazard communication program, including human health and environmental precautionary statements on each label and in the Safety Data Sheet (SDS).

The proposed SNUR would designate as a “significant new use” any use in the absence of these protective measures.

Potentially useful information: EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of aquatic toxicity testing may be potentially useful to characterize the environmental effects of the PMN substances. Although the Order does not require these tests, the Order’s restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

P-25-137 and P-25-151 (40 CFR 721.12220).

Chemical name: Cobalt lithium manganese nickel oxide, metals-doped (generic).

CASRN: Not available.

Effective date of TSCA Orders: March 16, 2026 (P-25-151) and April 7, 2026 (P-25-137)

Basis for TSCA Orders: The PMNs state that the generic (non-confidential) use will be in

batteries. Multiple PMNs were submitted due to the fact that review of the first PMN received had not yet been completed and the PMN substance was not yet on the inventory. The PMN substance is a type of mixed metal oxide that is covered by the analysis EPA conducted that is detailed in the following documents (which are available on the docket): 1) U.S. EPA. Standardized Scientific Assessment for Mixed Metal Oxide (MMO) Cathode Active Material (CAM) in Battery Applications for Use in TSCA Section 5 New Chemical Reviews, 2026, 2) U.S. EPA. Policy on Standardized Scientific Assessment for Mixed Metal Oxide (MMO) Cathode Active Material (CAM) in Battery Applications for Use in TSCA Section 5 New Chemical Review, 2026, and 3) U.S. EPA. Policy on Standardized Risk Management for Mixed Metal Oxide (MMO) Cathode Active Material (CAM) in Battery Applications for Use in TSCA Section 5 New Chemical Reviews), 2026. EPA identified concerns for carcinogenicity, reproductive toxicity, specific target organ toxicity, and dermal and respiratory sensitization, and EPA predicts that toxicity to aquatic organisms may occur at concentrations from 1-5 ppb. To protect against these risks, the Orders require:

- No use of the PMN substance other than in the manufacture of batteries;
- No use of the PMN substance without labeling the exterior of batteries or packaging containing multiple batteries. An example of the label text is as follows: “This battery contains substances that are subject to TSCA restrictions, including for recycling and reclamation activities. For details, contact the battery manufacturer or the EPA TSCA hotline.”;
- No manufacturing, processing (all processing includes recycling or reclaiming substances from batteries or other items containing the PMN substance) or use of the PMN substance except with the use of dust controls with an overall minimum combined capture and control efficiency of 99%;
- No release of the PMN substance to the air at a single site such that the rolling average concentration over 14 days at the property boundary would be more than a maximum of $1.3E-4$ mg/m³ of the PMN substance individually or in any combination (i.e., in aggregate) with other

cobalt containing mixed metal oxide (MMO) chemical substances;

- No manufacture or processing of the PMN substance for more than one year unless there is no air release of the PMN substance or the air release limit is updated;

- No manufacture or processing of the PMN substance for more than one year unless there is no inhalation exposure to the PMN substance or the Respiratory Protection Limits are updated;

- No disposal of the PMN substance, or any waste stream containing the PMN substance, other than by hazardous waste landfill in compliance with the Resource Conservation and Recovery Act Subtitle C or incineration if the incinerator ash is disposed of by hazardous waste landfill in compliance with the Resource Conservation and Recovery Act Subtitle C;

- No release of the PMN substance, or any waste stream containing the PMN substance, to water;

- Prior to worker exposure monitoring - use of a National Institute for Occupational Safety and Health (NIOSH)-certified respirator with an assigned protection factor (APF) of at least 1,000 where there is a potential for inhalation exposure to workers.

- Upon exposure monitoring results – use of a NIOSH-certified respirator with an APF in accordance with the below Respiratory Protection Limits, provided that an APF below 50 is only permitted when the PMN substance contains less than or equal to 3% cobalt by weight. If the 8-Hour Time Weighted Average (TWA) is less than $5.3E-4$ mg/m³, no respiratory protection is required. If the 8-Hour TWA is more than or equal to $5.3E-4$ mg/m³ but less than $5.3E-3$ mg/m³, respiratory protection with a minimum APF of 10 is required. If the 8-Hour TWA is more than or equal to $5.3E-3$ mg/m³ but less than $2.7E-2$ mg/m³, respiratory protection with a minimum APF of 50 is required. If the 8-Hour TWA is more than or equal to $2.7E-2$ mg/m³ but less than $5.3E-1$ mg/m³, respiratory protection with a minimum APF of 1000 is required. If the 8-Hour TWA is more than or equal to $5.3E-1$ mg/m³ but less than $5.3E+00$ mg/m³, respiratory protection with a minimum APF of 10,000 is required. If the 8-Hour TWA exceeds $5.3E+00$

mg/m³, then manufacturing, processing, and use must cease;

- Use of personal protective equipment where there is a potential for dermal exposure;
- Use of engineering and administrative control measures to prevent exposure; and
- Establishment of a hazard communication program, including human health and

environmental precautionary statements on each label and in the Safety Data Sheet (SDS).

The proposed SNUR would designate as a “significant new use” any use in the absence of these protective measures.

Potentially useful information: EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of aquatic toxicity testing may be potentially useful to characterize the environmental effects of the PMN substances. Although the Order does not require these tests, the Order’s restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

IV. Statutory and Executive Order Reviews

Additional information about these statutes and Executive orders can be found at <https://www.epa.gov/laws-regulations/laws-and-executive-orders>.

A. Executive Order 12866: Regulatory Planning and Review

This action proposes to establish SNURs for new chemical substances that were the subject of PMNs. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866 (58 FR 51735, October 4, 1993).

B. Executive Order 14192: Unleashing Prosperity Through Deregulation

Executive Order 14192 (90 FR 9065, February 6, 2025) does not apply because significant new use rules for new chemicals under TSCA section 5 are exempted from review under Executive Order 12866.

C. Paperwork Reduction Act (PRA)

According to the PRA (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the *Federal Register*, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable.

The information collection requirements related to SNURs have already been approved by OMB pursuant to PRA under OMB control number 2070-0038 (EPA ICR No. 1188). This action does not impose any burden requiring additional OMB approval. If an entity were to submit a SNUN to the Agency, the annual burden is estimated to average between 30 and 170 hours per submission. This burden estimate includes the time needed to review instructions, search existing data sources, gather and maintain the data needed, and complete, review, and submit the required SNUN.

EPA always welcomes feedback on the burden estimates. When submitting comments on these proposed SNURs, include comments about the accuracy of the burden estimate, and any suggested methods for improving the collection instruments or instruction or minimizing respondent burden, including through the use of automated collection techniques.

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA (5 U.S.C. 601 *et seq.*). The requirement to submit a SNUN applies to any person (including small or large entities) who intends to engage in any activity described in the final rule as a "significant new use." Because these uses are "new," based on all information currently available to EPA, EPA has concluded that no small or large entities presently engage in such activities.

A SNUR requires that any person who intends to engage in such activity in the future must first notify EPA by submitting a SNUN. Although some small entities may decide to pursue

a significant new use in the future, EPA cannot presently determine how many, if any, there may be. However, EPA's experience to date is that, in response to the promulgation of SNURs covering over 1,000 chemicals, the Agency receives only a small number of notices per year. For example, the number of SNUNs received was 9 in fiscal year FY2022, 23 in FY2023, and 7 in FY2024, and only a fraction of these submissions were from small businesses.

In addition, the Agency currently offers relief to qualifying small businesses by reducing the SNUN submission fee from \$37,000 to \$6,480. This lower fee reduces the total reporting and recordkeeping cost of submitting a SNUN to about \$14,967 per SNUN submission for qualifying small firms. Therefore, the potential economic impacts of complying with these proposed SNURs are not expected to be significant or adversely impact a substantial number of small entities. In a SNUR that published in the *Federal Register* of June 2, 1997 (62 FR 29684) (FRL-5597-1), the Agency presented its general determination that SNURs are not expected to have a significant economic impact on a substantial number of small entities, which was provided to the Chief Counsel for Advocacy of the Small Business Administration.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of \$100 million or more (in 1995 dollars) in any one year as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by SNURs, and EPA does not have any reasons to believe that any State, local, or Tribal government will be impacted by these SNURs. In addition, the estimated costs of this action to the private sector do not exceed \$183 million or more in any one year (the 1995 dollars are adjusted to 2023 dollars for inflation using the GDP implicit price deflator). The estimated costs for this action are discussed in Unit I.D.

F. Executive Order 13132: Federalism

This action will not have federalism implications as specified in Executive Order 13132

(64 FR 43255, August 10, 1999), because it is not expected to have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the requirements of Executive Order 13132 do not apply to this action.

G. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

This action will not have Tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000), because it is not expected to have substantial direct effects on Indian Tribes, significantly or uniquely affect the communities of Indian Tribal governments and does not involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of Executive Order 13175 do not apply to this action.

H. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it does not concern an environmental health or safety risk. Since this action does not concern a human health risk, EPA's 2026 Policy on Children's Health also does not apply. Although the establishment of these SNURs do not address an existing children's environmental health concern because the chemical uses involved are not ongoing uses, SNURs require that persons notify EPA at least 90 days before commencing manufacture (defined by statute to include import) or processing of the identified chemical substances for an activity that is designated as a significant new use by the SNUR. This notification allows EPA to assess the intended uses to identify potential risks and take appropriate actions before the activities commence.

I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not a "significant energy action" as defined in Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not likely to have a significant adverse effect on the

supply, distribution, or use of energy.

J. National Technology Transfer and Advancement Act (NTTAA)

This action does not involve any technical standards subject to NTTAA section 12(d) (15 U.S.C. 272 note).

List of Subjects in 40 CFR Part 721

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: April 21, 2026.

Mary Elissa Reaves,

Director, Office of Pollution Prevention and Toxics.

For the reasons stated in the preamble, EPA proposes to amend 40 CFR chapter I as follows:

PART 721 – SIGNIFICANT NEW USES OF CHEMICAL SUBSTANCES

1. The authority citation for part 721 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

2. Add §§ 721.12219 through 721.12220 to subpart E to read as follows:

Subpart E – Significant New Uses for Specific Chemical Substances

* * * * *

Sec.

721.12219 Cobalt lithium manganese nickel oxide, metals-doped (generic).

721.12220 Cobalt lithium manganese nickel oxide, metals-doped (generic).

* * * * *

§ 721.12219 Cobalt lithium manganese nickel oxide, metals-doped (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as cobalt lithium manganese nickel oxide, metals-doped (PMNs P-25-73 and P-25-152) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after the substance has been incorporated into an “article” as defined at 40 CFR § 720.3, except as to the battery labeling requirements in the *Industrial, commercial, and consumer use* section. The article exemption applies unless/until the article has been shredded or processed such that dust is generated. Once the article containing the substance is or has been shredded or otherwise handled such that there is potential for exposure to or release of the substance, the article exemption no longer applies.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(3) through (6), and (c). When determining which persons are reasonably likely to be exposed as

required for § 721.63(a)(1) and (4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 1,000 prior to the receipt of exposure monitoring results and in accordance with the following Respiratory Protection Limits once exposure monitoring results are available. An APF below 50 is only permitted if the PMN substance contains less than or equal to 3% cobalt by weight. If the 8-Hour Time Weighted Average (TWA) is less than $5.3E-4$ mg/m³, no respiratory protection is required. If the 8-Hour TWA is more than or equal to $5.3E-4$ mg/m³ but less than $5.3E-3$ mg/m³, respiratory protection with a minimum APF of 10 is required. If the 8-Hour TWA is more than or equal to $5.3E-3$ mg/m³ but less than $2.7E-2$ mg/m³, respiratory protection with a minimum APF of 50 is required. If the 8-Hour TWA is more than or equal to $2.7E-2$ mg/m³ but less than $5.3E-1$ mg/m³, respiratory protection with a minimum APF of 1000 is required. If the 8-Hour TWA is more than or equal to $5.3E-1$ mg/m³ but less than $5.3E+00$ mg/m³, respiratory protection with a minimum APF of 10,000 is required. If the 8-Hour TWA exceeds $5.3E+00$ mg/m³, then manufacturing, processing, and use must cease.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (d), (f), (g)(1), (g)(3)(iii), and (g)(5). For purposes of § 721.72(g)(1), this substance may cause: carcinogenicity, genetic toxicity, skin sensitization, respiratory sensitization, reproductive toxicity, neurotoxicity, and specific target organ toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer use.* It is a significant new use to manufacture or process the substance for more than one year if there is any release of the substance to air or inhalation exposure to workers. It is a significant new use to use the substance other than as a

substance for use in the manufacture of batteries. It is a significant new use to manufacture, process (all processing includes recycling or reclaiming substances from batteries or other items containing the PMN substance), or use the substance, except with the use of dust controls with an overall minimum capture and control efficiency of 99%. It is a significant new use to use the substance without labeling the exterior of batteries or the exterior of packaging containing multiple batteries to indicate that they contain a substance that is subject to restrictions under TSCA, including during recycling, consistent with all of the following conditions:

(A) The battery label shall be placed directly on the visible exterior of the wrappings and packaging in which the battery is placed for sale, shipment, or storage. An example of the text on the battery label is as follows: “This battery contains substances that are subject to TSCA restrictions, including for recycling and reclamation activities. For details, contact the battery manufacturer or the EPA TSCA Hotline.”

(B) Any batteries distributed in commerce without packaging or wrapping must be labeled or tagged directly on the visible exterior surface.

(C) Battery labels must be sufficiently durable to equal or exceed the life of the battery and attached in such a manner that they cannot be removed without defacing or destroying them.

(D) Any battery repackaging must ensure that the battery label remains visible or that a new battery label or tag is placed on the visible exterior.

(iv) *Disposal*. It is a significant new use to dispose of the substance or waste streams containing the substance other than by hazardous waste landfill in compliance with the Resource Conservation and Recovery Act Subtitles C or incineration, where the incinerator ash must be disposed of by hazardous waste landfill in compliance with the Resource Conservation and Recovery Act Subtitle C.

(v) *Release to water*. Requirements as specified in § 721.90(a)(1), (b)(1), and (c)(1).

(vi) *Release to air*. It is a significant new use to release the substance to the air at a single site such that the rolling average concentration over 14 days at the property boundary would

be more than a maximum of 1.3E-4 mg/m³ of the substance individually or in any combination (i.e., in aggregate) with other cobalt containing mixed metal oxide (MMO) chemical substances.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.12220 Metal cobalt lithium manganese nickel oxide, metals-doped (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as metal cobalt lithium manganese nickel oxide, metals-doped (PMNs P-25-137 and P-25-151) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after the substance has been incorporated into an “article” as defined at 40 CFR § 720.3, except as to the battery labeling requirements in the *Industrial, commercial, and consumer use* section. The article exemption applies unless/until the article has been shredded or processed such that dust is generated. Once the article containing the substance is or has been shredded or otherwise handled such that there is potential for exposure to or release of the substance, the article exemption no longer applies.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(3) through (6), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) and (4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(a)(5), respirators must provide a National Institute for

Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 1,000 prior to the receipt of exposure monitoring results and in accordance with the following Respiratory Protection Limits once exposure monitoring results are available. An APF below 50 is only permitted if the PMN substance contains less than or equal to 3% cobalt by weight. If the 8-Hour Time Weighted Average (TWA) is less than $5.3E-4$ mg/m³, no respiratory protection is required. If the 8-Hour TWA is more than or equal to $5.3E-4$ mg/m³ but less than $5.3E-3$ mg/m³, respiratory protection with a minimum APF of 10 is required. If the 8-Hour TWA is more than or equal to $5.3E-3$ mg/m³ but less than $2.7E-2$ mg/m³, respiratory protection with a minimum APF of 50 is required. If the 8-Hour TWA is more than or equal to $2.7E-2$ mg/m³ but less than $5.3E-1$ mg/m³, respiratory protection with a minimum APF of 1000 is required. If the 8-Hour TWA is more than or equal to $5.3E-1$ mg/m³ but less than $5.3E+00$ mg/m³, respiratory protection with a minimum APF of 10,000 is required. If the 8-Hour TWA exceeds $5.3E+00$ mg/m³, then manufacturing, processing, and use must cease.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (d), (f), (g)(1), (g)(3)(iii), and (g)(5). For purposes of § 721.72(g)(1), this substance may cause: carcinogenicity, genetic toxicity, skin sensitization, respiratory sensitization, reproductive toxicity, neurotoxicity, and specific target organ toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer use.* It is a significant new use to manufacture or process the substance for more than one year if there is any release of the substance to air or inhalation exposure to workers. It is a significant new use to use the substance other than as a substance for use in the manufacture of batteries. It is a significant new use to manufacture, process (all processing includes recycling or reclaiming substances from batteries or other items containing the PMN substance), or use the substance, except with the use of dust controls with an overall minimum capture and control efficiency of 99%. It is a significant new use to use

the substance without labeling the exterior of batteries or the exterior of packaging containing multiple batteries to indicate that they contain a substance that is subject to restrictions under TSCA, including during recycling, consistent with all of the following conditions:

(A) The battery label shall be placed directly on the visible exterior of the wrappings and packaging in which the battery is placed for sale, shipment, or storage. An example of the text on the battery label is as follows: “This battery contains substances that are subject to TSCA restrictions, including for recycling and reclamation activities. For details, contact the battery manufacturer or the EPA TSCA Hotline.”

(B) Any batteries distributed in commerce without packaging or wrapping must be labeled or tagged directly on the visible exterior surface.

(C) Battery labels must be sufficiently durable to equal or exceed the life of the battery and attached in such a manner that they cannot be removed without defacing or destroying them.

(D) Any battery repackaging must ensure that the battery label remains visible or that a new battery label or tag is placed on the visible exterior.

(iv) *Disposal*. It is a significant new use to dispose of the substance or waste streams containing the substance other than by hazardous waste landfill in compliance with the Resource Conservation and Recovery Act Subtitles C or incineration, where the incinerator ash must be disposed of by hazardous waste landfill in compliance with the Resource Conservation and Recovery Act Subtitle C.

(v) *Release to water*. Requirements as specified in § 721.90(a)(1), (b)(1), and (c)(1).

(vi) *Release to air*. It is a significant new use to release the substance to the air at a single site such that the rolling average concentration over 14 days at the property boundary would be more than a maximum of $1.3E-4$ mg/m³ of the substance individually or in any combination (i.e., in aggregate) with other cobalt containing mixed metal oxide (MMO) chemical substances.

(b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements*. The provisions of § 721.185 apply to this section.

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