



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

March 13, 2026

**MEMORANDUM**

**SUBJECT:** Policy on Standardized Scientific Assessment for Mixed Metal Oxide (MMO) Cathode Active Materials (CAMs) in Battery Applications for Use in TSCA Section 5 New Chemical Reviews

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**TO:** Staff of the New Chemicals Division  
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The purpose of this memorandum is to describe the policy for the EPA New Chemicals Division's (NCD's) Standardized Scientific Assessment for use in Toxic Substances Control Act (TSCA) section 5 new chemical reviews of mixed metal oxide (MMO) cathode active materials (CAMs) in battery applications.

**Background**

TSCA, as amended in 2016 by the Frank R. Lautenberg Chemical Safety for the 21<sup>st</sup> Century Act, requires EPA to make determinations on new chemical substance notices received under TSCA section 5. EPA's NCD is responsible for conducting human health and environmental risk assessments for new chemicals submitted under TSCA section 5 prior to their entry into U.S. commerce. For new chemical submissions, EPA must make an affirmative finding on whether the new chemical substance will pose any unreasonable risks.

MMOs are a key component in lithium-ion batteries used in automobiles, semi-conductors, and renewable energy generation and storage, such as for artificial intelligence (AI) data centers. MMOs are the key material for production of CAMs used in battery cells, which are subsequently assembled into a battery. MMO CAMs are crystallized metal oxides that typically consist of a combination of lithium, cobalt, nickel, and other additional metal oxide modifiers to enhance their electronic, optical, magnetic, and chemical properties. Because MMOs vary in

composition, it is important to clarify that this policy memorandum is limited in applicability to MMO CAMs that are non-nano-sized, contain cobalt and nickel, and are used in battery applications at high production volumes (e.g., millions kg/year). For the purposes of this policy document, references to MMO CAMs herein refer to MMO CAMs that are within this defined scope, unless otherwise specified.

Like any chemical substance not listed on the TSCA Inventory, MMOs, including CAMs, are subject to TSCA section 5, which requires manufacturers (including importers) of new chemical substances to submit a premanufacture notice (PMN) to EPA before initiating any manufacturing or processing, unless an exemption applies. When EPA receives a PMN, TSCA requires the Agency to assess potential hazards and exposures of the new chemical substance, to determine whether it presents an unreasonable risk to human health or the environment, and to take steps to address any risk before it can be manufactured or processed.

In 2022, NCD developed a standardized approach for MMO CAMs to assist risk assessors with human health hazard assessment of PMN submissions and to increase efficiency and consistency in the review of these innovative new chemicals. From December 2022 to January 2026, NCD received approximately 25 PMNs and significant new use notices (SNUNs) for MMO CAMs and has identified several scientific themes associated with human health and environmental hazard and exposure that are consistent across the many MMO CAMs that have been reviewed. This information is documented in the *Standardized Scientific Assessment for Mixed Metal Oxide (MMO) Cathode Active Materials (CAMs) in Battery Applications for Use in TSCA Section 5 New Chemical Reviews* (“MMO CAM Standardized Scientific Assessment”) (U.S. EPA, 2026d).

Because there are no minimum data requirements for the submission of a PMN, it is not common for NCD to have all the information used to assess MMO CAMs. However, MMO CAMs are generally composed of specific metals for which there is a large body of scientific evidence (e.g., cobalt, nickel). Through experience conducting risk assessments for this chemical class, NCD found several conclusions that are consistent for MMO CAM assessments. These findings are summarized in this policy memorandum. The MMO CAM Standardized Scientific Assessment (U.S. EPA, 2026d) explains the standardized risk assessment approach that NCD has developed to assess MMO CAMs. That document also contains the Agency’s scientific analysis and conclusions on fate, human health hazard, environmental hazard, environmental releases and exposure, and human health and environmental risk that support the findings in this memorandum and the TSCA section 5(a)(3) determination for MMO CAM PMN submissions within the scope of this document.

### **Summary of Human Health and Environmental Risk Characterization Findings**

Using the MMO CAM Standardized Scientific Assessment (U.S. EPA, 2026d) across human and environmental exposure scenarios, NCD has identified potential risks from the manufacture, processing (including recycling), distribution, use, and/or disposal of MMO CAMs to human health and the environment when there are no workplace or release restrictions in place. The human health and environmental risk characterization findings are described in the MMO CAM Standardized Scientific Assessment (U.S. EPA, 2026d) and are summarized in this memorandum.

NCD has used two approaches to assess inhalation risks. For MMO CAM risk assessments completed through February 2026, NCD used a screening-level inhalation point of departure (POD) from a confidential 90-day Organisation for Economic Cooperation and Development (OECD) 413 guideline study on an analogue substance. NCD is now using a refined, human-specific no observed adverse effect concentration (NOAEC) from a cross-sectional study on a component (cobalt), based on respiratory effects (i.e., irritation). This NOAEC is used for all occupational and general population inhalation exposure scenarios lasting less than one year and represents the most health protective, human-specific value identified to assess non-cancer inhalation risks (U.S. EPA, 2026c). As discussed in “Time-Limited Use of a Respirator with an Assigned Protection Factor of 1000 for Industrial Hygiene Monitoring for Mixed Metal Oxides (MMO) in Cathode Active Materials (CAMs) and General Population Exposure Considerations,” memorandum (February 2026), when laboratory animal data are used to derive human PODs, the result is often overly conservative due, in part, to the application of the animal to human extrapolation factor. In addition, there are well-documented differences in the anatomy and physiology between rodents and humans that lead to rodent studies being overly conservative for human exposures for many chemicals. The 2024 health assessment by the Agency for Toxic Substances and Disease Registry (ATSDR) shows this trend is true for cobalt. Therefore, human-specific PODs are preferred for cobalt over animal-derived PODs (U.S. EPA, 2026c). NCD now uses the human-specific NOAEC to assess inhalation exposure scenarios lasting less than one year. This memorandum summarizes the application of the refined, human-specific value for assessing inhalation exposure risks. For further details on the application of the screening-level value for assessing inhalation exposure risks, see the MMO CAM Standardized Scientific Assessment (U.S. EPA, 2026d).

For the approach using a refined, human-specific value to assess risks for inhalation scenarios, risk to human health is indicated when the estimated exposures exceed the minimal effect level as calculated by EPA (U.S. EPA, 2026c). The ratio of the estimated inhalation exposure divided by minimal effect level is the hazard quotient (HQ). When the HQ is  $>1$ , risk is identified for lung effects.

- The occupational inhalation exposure level with a low probability of adverse health effects for MMO CAMs is  $5.3E-04 \text{ mg/m}^3$ , and it is protective against non-cancer respiratory effects for exposures lasting less than one year (U.S. EPA, 2026c). Across the individual risk assessments for MMO CAMs, the HQ is typically  $>1$ . Specifically, in the absence of respiratory protection, inhalation risks have been identified with HQs ranging from 6 to 4,000<sup>1</sup>.
- Where cobalt is  $>3\%$ , risk to workers for skin and respiratory sensitization has been identified but not quantified.

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<sup>1</sup> These values assume no respiratory protection. Values were derived from Table 2 in the “Time-Limited Use of a Respirator with an Assigned Protection Factor of 1000 for Industrial Hygiene Monitoring for Mixed Metal Oxides (MMO) in Cathode Active Materials (CAMs) and General Population Exposure Considerations,” memorandum (February 2026) (U.S. EPA, 2026c), which assumes use of an APF-1000 respirator.

- The general population inhalation exposure level with a low probability of adverse health effects for MMO CAMs is  $1.3E-4$  mg/m<sup>3</sup> for exposures lasting less than one year as derived from the same human-specific study as the worker inhalation exposure (U.S. EPA, 2026c). Risk to the general population for lung effects via inhalation has been identified with HQs as high as 1,060 for fugitive air releases and as high as 3 for incineration releases. Risks were not identified for stack air release scenarios as the HQs are <1 (ranging from  $6.33E-5$  to  $1.89E-2$ ).

For oral exposures, risk to human health is indicated when the margin of exposure (MOE) falls below the benchmark MOE of 100<sup>2</sup>.

- The drinking water exposure level with a low probability of adverse health effects for MMO CAMs is as low as 129 ppb. Risk to the general population for developmental effects (perinatal toxicity [NiPERA, 2000; Smith *et al.*, 1993]) via ingestion has been identified with MOEs ranging from  $6E-4$  to 59 for ingestion of drinking water (adults),  $1E-4$  to 71 for ingestion of drinking water (infants), and 3 to 98 for ingestion of groundwater impacted by landfill leachate.

Under these PODs, EPA identified risk to workers and the general population under the conditions of use.

For aquatic receptors (e.g., fish, algae), environmental risk is indicated when modeled surface water concentrations exceed environmental concern levels (i.e., acute and/or chronic concentrations of concern [COC]). The ratio of the modeled surface water concentration divided by the COC is the risk quotient (RQ). For acute scenarios, when the RQ is >1, acute environmental risk is predicted. For chronic scenarios, when the RQ is >1 for greater than 20 days per year (chronic component), chronic environmental risk is predicted. Since the RQs for acute and chronic exposures were all >1 (with greater than 20 days of exceedance for all chronic scenarios), all modeled MMO CAM scenarios have resulted in acute and chronic environmental risk when there are no workplace or release restrictions in place.

- RQs have ranged from 518 to 1287 for acute exposures (acute environmental risk) and 3 (26 days of exceedance) to 1030 (350 days of exceedance) for chronic exposures (chronic environmental risk, if greater than 20 days).
- Since the RQs for acute and chronic exposures were all >1 (with greater than 20 days of exceedance for all chronic scenarios), all modeled MMO CAM scenarios are expected to result in acute and chronic environmental risk.

The potential for human health and environmental risk for MMO CAMs is due primarily to three factors:

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<sup>2</sup> EPA applies a total uncertainty factor (UF) of 100 to the no observed adverse effect level (NOAEL): a UF<sub>H</sub> of 10 for human variability and a UF<sub>A</sub> of 10 for extrapolation from animals to humans.

1. The environmental toxicology of the metal components in MMO CAMs results in high hazard to environmental receptors (e.g., fish, aquatic invertebrates, aquatic plants) in accordance with “EPA’s Approach for Assessing Environmental Hazard of Cathode Active Material New Chemical Substances using Standard Toxicity Profiles,” memorandum (February 2026) (U.S. EPA, 2026a). Although there are few MMO CAM-specific toxicology studies, the toxicology of the metal components is well studied.
2. MMO CAMs will be produced (or expected to be produced) at high production volumes. From 26 electric vehicle (EV) battery cases<sup>3</sup> (December 2022-January 2026), reported production volumes range from approximately 1 million to 73 million kg/year, with a median of 22 million kg/year.
3. When site-specific information is unavailable—particularly for downstream processing (e.g., recycling) sites—the standard screening approaches, combined with the high production volumes, result in large estimates for releases and exposures. As a result, the actual magnitude of environmental releases and resultant exposures to MMO CAMs under these conditions remains highly uncertain.

### **Policy for Risk Assessment of MMO CAMs**

EPA expects that future PMN and SNUN submissions of MMO CAMs will generally yield the same conclusions with respect to substantial calculated risk to humans and the environment.

EPA has determined that for many MMO CAM PMN and SNUN submissions, it may be unnecessary to conduct individual risk assessments as that work would simply replicate what has been done for the most recent MMO CAM submissions. Moving forward, this document will serve as the policy guidance on the baseline scientific evaluation to support review of MMO CAM PMNs and SNUNs that are non-nano-sized, contain cobalt and nickel, and that are used in battery applications at high production volumes (e.g., millions kg/year).

In cases where the MMO CAM Standardized Scientific Assessment (U.S. EPA, 2026d) can be applied and relied upon to support the review of a specific MMO CAM PMN or SNUN, EPA will document this decision with a case-specific cover sheet (including the persistent, bioaccumulative, and toxic [PBT] score, a list of submitted test data, and reviews for acceptable test data) (see Appendix 1 for an example) and reference to the MMO CAM Standardized Scientific Assessment document (U.S. EPA, 2026d). These submissions will move directly towards issuance of a determination under TSCA section 5 and, where necessary, take action to protect against unreasonable risk.

While EPA does not intend to develop routine case-specific technical reports for hazard and exposure, the chemistry report will continue to be fully completed for each case, as this report will document whether the MMO CAM is within the scope of the policy. Each respective fate, environmental hazard/risk, and human health hazard/risk report will still reference the cover

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<sup>3</sup> Includes one submission which was later withdrawn.

sheet and the MMO CAM Standardized Scientific Assessment document (U.S. EPA, 2026d). The engineering and exposure report will reference the MMO CAM Standardized Scientific Assessment document (U.S. EPA, 2026d) and will summarize the environmental media for releases (e.g., air, water, landfill, and incineration) and the associated exposure pathways. It will also acknowledge substantial data submitted for reviews, such as industrial hygiene (IH) studies. On a case-by-case basis, EPA will consider any additional conditions, uses, and other data submitted that may change the applicability of the baseline assessment. All MMO CAMs to date have been determined to have low bioaccumulation potential. If a future MMO CAM is determined to be PBT, NCD will specify this in the case-specific cover sheet. In general, if additional data is submitted that would change the overall conclusions of this assessment, individual risk assessment reports would be generated as is done for routine NCD risk assessments. NCD may consider applying aspects of the MMO CAM Standardized Scientific Assessment (U.S. EPA, 2026d) to an out-of-scope MMO CAM. If so, NCD will document the applicability of the MMO CAM Standardized Scientific Assessment (U.S. EPA, 2026d) to that chemical in the case-specific cover sheet. If it is not appropriate to rely on the MMO CAM Standardized Scientific Assessment (U.S. EPA, 2026d) for a MMO CAM falling outside the scope, NCD will develop an individual risk assessment and tailored risk management.

This memorandum, the *Standardized Scientific Assessment for Mixed Metal Oxide (MMO) Cathode Active Materials (CAMs) in Battery Applications for Use in TSCA Section 5 New Chemical Reviews* (U.S. EPA, 2026d), and the “Policy on Standardized Risk Management for Mixed Metal Oxide (MMO) Cathode Active Materials (CAMs) in Battery Applications for Use in TSCA Section 5 New Chemical Reviews,” memorandum (March 2026) (U.S. EPA, 2026b), will allow for more consistent science and risk management across new MMO CAM cases and will advance the Agency’s mission to protect human health and the environment while also advancing innovation, efficiency, and investment in domestic manufacturing.

## **Policy Implementation**

Moving forward, when NCD receives a MMO CAM new chemical submission, NCD chemists will determine if the MMO CAM falls within the scope of the MMO CAM Standardized Scientific Assessment (U.S. EPA, 2026d). If the MMO CAM is in-scope, NCD chemists will document that decision in the chemistry report and create the draft cover sheet for the new chemical (see Appendix 1 for an example) including the case number, chemical name, intended use, and statement affirming that the substance is in-scope. For records support, the NCD fate, human health hazard/risk, environmental hazard/risk, engineering, and exposure staff will update and finalize the case-specific new chemical cover sheet. The human health team will upload the new chemical cover sheet and the MMO CAM Standardized Scientific Assessment document (U.S. EPA, 2026d) into the specific new chemical “Documents tab” within NCD’s New Chemical Review (NCR) system. The fate, human health hazard/risk, and environmental hazard/risk teams will document in their NCR reports that the specific new chemical substance falls within the scope of the MMO CAM Standardized Scientific Assessment (U.S. EPA, 2026d) and state that the new chemical cover sheet and the MMO CAM Standardized Scientific Assessment document (U.S. EPA, 2026d) is located in the NCR case-specific “Documents tab.” These reports will not contain a scientific assessment of the MMO CAM since the MMO CAM Standardized Scientific Assessment document (U.S. EPA, 2026d) provides that information.

However, the fate reports will include any relevant metal-specific bioaccumulation reports as attachments. Additionally, engineering and exposure scientists will create and upload a summary of expected environmental releases and human and environmental exposures for the specific new chemical substance to the NCR system, placing it in the Attachments/Comments section of their respective discipline's NCR report. In addition, this same engineering and exposure summary information will also reside in the new chemical cover sheet. If the new chemical substance is outside the scope of the MMO CAM Standardized Scientific Assessment (U.S. EPA, 2026d), NCD will generate individual assessments per standard NCD practice. Following either an individual or standardized MMO CAM risk assessment, EPA will issue a determination under TSCA section 5 and, where necessary, take action to protect against unreasonable risk. NCD reserves the option to deviate from the policy as necessary to address the specifics of any individual case.

If chemical-specific or analog test data on the MMO CAM is submitted, it will be evaluated for acceptability and used, if possible. Under this policy, NCD staff and contractors will not search for analog test data on each MMO CAM new chemical substance. Where data has been submitted, the case-specific cover sheet will also include a statement describing submitted data and a statement describing the outcome of the data review.

There are some MMO CAM new chemical submissions that fall within the scope of this policy, for which NCD has already completed a risk assessment at the time of this policy's implementation. Although the risk calculations have evolved since those risk assessments were completed, the risk conclusions of those completed MMO CAM risk assessments are in line with the MMO CAM Standardized Scientific Assessment (U.S. EPA, 2026d). In those cases, NCD may rely on both the completed assessment and the MMO CAM Standardized Scientific Assessment (U.S. EPA, 2026d) for risk management purposes. For other submissions (including those that were submitted before February 2026 for which individual assessments had not been completed at the time of this policy's implementation) that fall within scope of this policy, NCD will apply the MMO CAM Standardized Scientific Assessment (U.S. EPA, 2026d).

## References

Nickel Producers Environmental Research Association (NiPERA). 2000. A One-Generation Reproduction Range-Finding Study in Rats with Nickel Sulfate Hexahydrate. Final Report. Springborn Laboratories, Inc. (Spencerville, OH), for the Nickel Producers Environmental Research Association (NiPERA). December 2000. Durham, NC. 442pp.

Smith, M.K., George, E.L., Stober, J.A., Feng, H.A., and Kimmel, G.L. 1993. Perinatal Toxicity Associated with Nickel Chloride Exposure. *Environ Res.* 1993 May;61(2):200–211.

U.S. EPA. 2026a. Memorandum. EPA's Approach for Assessing Environmental Hazard of Cathode Active Material New Chemical Substances using Standard Toxicity Profiles. February 2026. Washington D.C. 5pp.

U.S. EPA. 2026b. Memorandum. Policy on Standardized Risk Management for Mixed Metal Oxide (MMO) Cathode Active Materials (CAMs) in Battery Applications for Use in TSCA Section 5 New Chemical Reviews. March 2026. Washington D.C. 8pp.

U.S. EPA. 2026c. Memorandum. Time-Limited Use of a Respirator with an Assigned Protection Factor of 1000 for Industrial Hygiene Monitoring for Mixed Metal Oxides (MMO) in Cathode Active Materials (CAMs) and General Population Exposure Considerations. February 2026. Washington D.C. 9pp.

U.S. EPA. 2026d. Standardized Scientific Assessment for Mixed Metal Oxide (MMO) Cathode Active Materials (CAMs) in Battery Applications for Use in TSCA Section 5 New Chemical Reviews. March 2026. EPA 747/B-26-003. Washington D.C. 19pp.

## Appendix 1. MMO CAM Standardized Scientific Assessment Cover Sheet (Example)

**Premanufacture Notice (PMN) Number:** P-26-0000

**Submission Date:** October 1, 2025

**Chemistry Review:** The New Chemical Substance identified as aluminum- and metal- and metal-doped cobalt metal nickel oxide (CASRN 800-471-7127) and submitted as P-26-0000 is a mixed metal oxide (MMO) that is intended to be used for the production of cathode active materials (CAMs). The New Chemical Substance is a non-nano-sized MMO CAM containing cobalt and nickel and used in battery applications at high production volumes (e.g., millions kg/year).

The molecular weight of the New Chemical Substance is dependent on the particle size and is expected to be >100,000 g/mol. The New Chemical Substance has a variable composition of the following elements: 1-20% Ni, 2-25% Co, 3-38% Al, 4-54% Li, 5-38% O.

The chemical composition and intended use of New Chemical Substance fall within scope of the *Standardized Scientific Assessment for Mixed Metal Oxide (MMO) Cathode Active Materials (CAMs) in Battery Applications for Use in TSCA Section 5 New Chemical Reviews (March 2026)*.

**Submitted Data Review:** The following chemical-specific or analog data was submitted with the PMN for this New Chemical Substance:

- Aquatic Ecotoxicity – Aquatic Invertebrate Acute Toxicity Test
- Aquatic Ecotoxicity – Algal Toxicity Test
- Genetic Toxicity – Bacterial Reverse Mutation
- Genetic Toxicity – In Vivo Micronucleus Test
- Health Toxicity – Acute Oral Dose Toxicity Study
- Physical Chemical Property – Water Solubility

The submitted data was evaluated for acceptability. All submitted data was found to be acceptable, but it was not found to change the human health or environmental hazard endpoints or expected releases and exposures detailed in the *Standardized Scientific Assessment for Mixed Metal Oxide (MMO) Cathode Active Materials (CAMs) in Battery Applications for Use in TSCA Section 5 New Chemical Reviews (March 2026)*. [NOTE: if the data does show some differences, those need to be discussed here or acknowledged here and discussed in a referenced document with rationale of why it is still in-scope.]

**Standardized Assessment Approach:** Based on the chemical composition, intended use, and data submitted for the New Chemical Substance, EPA finds that the Standardized Scientific Assessment for MMO CAMs should be applied (see *Standardized Scientific Assessment for Mixed Metal Oxide [MMO] Cathode Active Materials [CAMs] in Battery Applications for Use in TSCA Section 5 New Chemical Reviews [March 2026]*). [NOTE: if there is other relevant data, that needs to be discussed here or acknowledged here and discussed in a referenced document with rationale of why the standardized scientific assessment is still applicable.]

**PBT Assessment:** The PBT rating of the New Chemical Substance is P2/B\*(low)/T2. The New Chemical Substance is not a PBT.

### **Engineering and Exposure Assessment**

**Submitted Information Reviewed:** The following documents from the PMN submission were reviewed to identify potential releases to the environment and the resultant exposures:

Document Name	Attachment Type	Submission/Date
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**Review of IH Data:** The following studies were reviewed for . . .

**Engineering Review Summary:** The engineering operations are reviewed within the life-cycle of a New Chemical Substance used in battery applications based on information from submission, attachments, physical and chemical property data, and general knowledge from prior same-use submissions. The life-cycle of the New Chemical Substance used in battery application includes . . .

**Exposure Review Summary:** Expected release media, worker exposure routes, and general population and environmental exposures were reviewed and determined to fall within the scope of the *Standardized Scientific Assessment for Mixed Metal Oxide (MMO) Cathode Active Materials (CAMs) in Battery Applications for Use in TSCA Section 5 New Chemical Reviews (March 2026)*.