

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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1. Background

The Toxic Substances Control Act (TSCA), as amended in 2016 by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, requires EPA to make determinations on new chemical substance notices received under TSCA section 5. EPA's New Chemicals Division (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.

Mixed metal oxides (MMOs) are a key component in lithium-ion batteries used in automotives, semi-conductors, and renewable energy generation and storage, such as for artificial intelligence (AI) data centers. MMOs are the key material for production of cathode active materials (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, this standardized scientific assessment is limited in its 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).

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.

Based on NCD's experience conducting risk assessments on this chemical class, and as outlined in the "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," memorandum (March 2026) (U.S. EPA, 2026g), this document reflects the standardized assessments for each scientific discipline (fate, human health hazard, environmental hazard, environmental releases and exposure, and human health and environmental risk) for MMO CAMs that are within the scope as described.

2. Fate

NCD's approach to the environmental fate assessment of MMOs is detailed in a 2025 standard operating procedure (SOP) (U.S. EPA, 2025u) and is applicable to all MMOs, including MMO

CAMs as defined by the scope of this document. In addition, the environmental fate has been separately assessed for each constituent metal if NCD fate assessors determine there is potential for their release from the MMO CAM under environmental conditions. This determination considers the water solubility (measured or estimated) of the MMO CAM and any available leaching/dissolution data for the new chemical substance or an analogous substance. In the absence of data for the MMO CAM or a close analogue showing negligible water solubility and leaching, all constituent metals are rated.

MMO CAMs receive persistence (P) and bioaccumulation (B) ratings of P3B*low, indicating that they are very persistent in the environment and have a low potential for bioaccumulation in exposed organisms.¹ MMO CAMs are not expected to undergo biodegradation, hydrolysis, photolysis, or atmospheric oxidation. NCD predicts that MMO CAMs will have a high destruction and removal efficiency (DRE) within a municipal incinerator. Although the MMO CAM is not destroyed within the incinerator, an estimated 99.9% of the substance is effectively captured within the bottom ash of the incinerator, which is subsequently landfilled. NCD assigns MMO CAMs a wastewater treatment removal rating of 90% based on their very strong predicted sorption to sludge. Due to large particle size and very strong sorption to soil and sediment, MMO CAMs are expected to exhibit negligible migration to groundwater.

All constituent metals receive a persistence rating of P3, indicating they are very persistent in the environment. Metals are not expected to undergo biodegradation, and are not rated with respect to hydrolysis, photolysis, or atmospheric oxidation potential. Wastewater treatment removal for constituent metals within the MMO CAM is not estimated because NCD does not anticipate that the metals will dissociate from the parent material in appreciable amounts on a time scale relevant to wastewater treatment (hours to days) (U.S. EPA, 2025u).

Sorption to soil and sediment, groundwater migration, and bioaccumulation ratings are unique to specific metals. The sorption rating and related potential for groundwater migration are based on available scientific literature for each metal. Bioaccumulation potential is assessed according to NCD's weight of evidence approach, which integrates multiple lines of evidence to assign a rating of B*low (low bioaccumulation potential), B*high (high bioaccumulation potential), or BU (bioaccumulation unknown) to each metal (U.S. EPA, 2025t). Individual, metal-specific bioaccumulation assessments are detailed in reports that are attached to MMO fate assessment reports. Through February 2026, the bioaccumulation potential of 22 metals was determined using this framework (U.S. EPA, 2025a-2025q; U.S. EPA, 2026a-2026e). Additional metals are under assessment.

¹ "B*" denotes that the rating is for a chemical that does not bioaccumulate via lipophilic partitioning. The "low" or "high" designation indicates whether the chemical is expected to have low or high potential to bioaccumulate via other mechanisms.

Table 1. Metals Assessed (as of February 2026) under NCD’s Weight of Evidence Approach for Evaluating the Bioaccumulation Potential of Metals (U.S. EPA, 2025a-2025q; U.S. EPA, 2026a-2026e)

| Metal | Bioaccumulation Rating | Metal | Bioaccumulation Rating |
|----------------|------------------------|-------------------|------------------------|
| Cesium (Cs) | B*high | Molybdenum (Mo) | B*low |
| Germanium (Ge) | BU | Nickel (Ni) | |
| Aluminum (Al) | B*low | Palladium (Pd) | |
| Boron (B) | | Praseodymium (Pr) | |
| Cerium (Ce) | | Strontium (Sr) | |
| Chromium (Cr) | | Titanium (Ti) | |
| Cobalt (Co) | | Tungsten (W) | |
| Iron (Fe) | | Vanadium (V) | |
| Lanthanum (La) | | Yttrium (Y) | |
| Lithium (Li) | | Zinc (Zn) | |
| Manganese (Mn) | | Zirconium (Zr) | |

In summary, the environmental fate of MMO CAMs and their constituent metals are rated as shown in Table 2.

Table 2. NCD Environmental Fate Ratings for MMO CAMs and Their Constituent Metals

| Parameters | Ratings for MMO CAMs | Ratings for Constituent Metals |
|-----------------------------------------------|---------------------------|---------------------------------------------------------|
| DRE | 99.9% removal to landfill | Not rated |
| Overall removal in wastewater treatment plant | 90% | Not rated |
| Removal via adsorption | Very strong | Not rated |
| Removal via volatilization | Negligible | Not rated |
| Removal via biodegradation | Negligible | Not rated |
| Aerobic biodegradation half-life | >6 months | >6 months |
| Anaerobic biodegradation half-life | >6 months | >6 months |
| Sorption to soil and sediment | Very strong | Low to very strong, depending on identity of the metal |
| Migration to groundwater | Negligible | Negligible to rapid, depending on identity of the metal |
| Persistence call | P3 | P3 |

| | | |
|----------------------|-------|---------------------------------------------------------|
| Bioaccumulation call | B*low | B*low, B*high, or BU depending on identity of the metal |
|----------------------|-------|---------------------------------------------------------|

3. Human Health Hazard

NCD has developed a standardized approach to assess human health hazards associated with MMO CAMs (U.S. EPA, 2025r). This approach is specific to MMO CAMs and was based on an evaluation of available risk assessments for individual metals and confidential analogue data. The approach was presented in a series of public webinars, and the presentations are available on EPA's web site.² This approach utilizes a decision framework to facilitate hazard identification and point of departure (POD) selection for substances used in battery manufacturing.

The evaluation of MMO CAMs has identified multiple hazards and exposure limits consistent with this subclass of chemicals. To identify hazards for MMO CAMs, EPA applied its integrated approach for MMO CAM new chemicals review (U.S. EPA, 2025r) and synthesized the results from ten completed individual MMO CAM risk assessments. The Globally Harmonized System of Classification and Labelling of Chemical (GHS) hazards identified for MMO CAMs are carcinogenicity, genetic toxicity, reproductive toxicity, and specific target organ toxicity. If the cobalt composition is >3%, dermal and respiratory sensitization have also been identified. Due to the hazards and expected routes of exposure, there are potential dermal, inhalation, and oral risks. Since absorption is expected to be negligible through the skin, no systemic risks are expected via dermal exposures. If the cobalt composition is >3%, the MMO CAM is expected to be a skin sensitizer, and dermal risks are expected for workers if dermal exposure occurs. Cancer hazards are not expected for exposures lasting less than one year (U.S. EPA, 2026h).

NCD has used two approaches to assess inhalation risks. For MMO CAM risk assessments completed through February 2026, NCD used a screening-level inhalation POD from a confidential 90-day Organisation for Economic Cooperation and Development (OECD) 413 guideline study on an analogue substance. A benchmark concentration lower bound (BMCL_{1SD}) based on respiratory effects (i.e., increased lung weight, macroscopic changes in the lung, and histopathological changes in the respiratory tract) was initially calculated in 2023 as 8.4E-3 mg/m³ and, using updated EPA methods, was recalculated in February 2026 to 1.7E-2 mg/m³. Nine PMN assessments³ relied on a BMCL_{1SD} of 8.4E-3 mg/m³; one PMN assessment⁴, following methodological updates, used a BMCL_{1SD} of 1.7E-2 mg/m³. In each instance, the BMCL_{1SD} constituted the most sensitive analogue-derived, screening-level value and was applied to all occupational and general population inhalation scenarios, including lifetime exposures.

² <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/integrated-approach-mixed-metal> (U.S. EPA, 2025r)

³ Case numbers: P-23-0029 (withdrawn), P-23-0120 to P-23-0122, P-23-xxx (redacted), P-24-0179 to P-24-0182

⁴ Case number: P-24-0188

NCD is now using a refined, human-specific no observed adverse effect concentration (NOAEC) of $5.3E-3$ mg/m³ 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, 2026h). 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 points of departure, 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 (ATSDR, 2024). Therefore, human-specific PODs are preferred for cobalt over animal-derived PODs (U.S. EPA, 2026h). NCD now uses the human-specific NOAEC to assess inhalation exposure scenarios lasting less than one year.

The oral POD for the general population is calculated based on cobalt, the most toxic metal component, adjusted for the percent composition. The unadjusted values range from a lowest observed adverse effect level (LOAEL) of 1 mg/kg per day for cobalt based on blood effects (polycythemia [ATSDR, 2024]) to a no observed adverse effect level (NOAEL) of 1.12 mg/kg per day adjusted for the percent of nickel based on developmental effects (perinatal toxicity [NiPERA, 2000; Smith *et al.*, 1993]).

4. Environmental Hazard

In the absence of hazard data on the new chemical substance and/or on analogs, the environmental hazard assessment assumes that the metals that make up the MMO CAM may leach from the MMO CAM as ionized salts and are bioavailable to environmental receptors (e.g., fish). NCD uses the most protective environmental endpoints for each metal contained within the MMO CAM *and* adjusts for the percent composition of the *individual* metal’s toxicity (e.g., 20% nickel) compared to the 100% MMO CAM.

Based on metal toxicity data in the scientific literature, as well as data from ambient water quality criteria studies from EPA’s Office of Water (U.S. EPA, 2025s), NCD uses standard toxicity profiles for some of the common metals (at 100% purity as an inorganic ionized species [e.g., Ni⁺Cl⁻]) to make the molecular weight adjustments. Table 3 provides an example of the nickel standard toxicity profile and the percent molecular weight adjusted hazard values when nickel is 20% of a new chemical MMO CAM.

Table 3. Nickel Toxicity Profile with a Molecular Weight Adjustment Based on a New Chemical Substance with 20% Nickel (Example)

| Taxa and Duration | 100% Nickel Toxicity Endpoint (mg/L) | 20% Molecular Weight Adjusted Nickel Toxicity Endpoint (mg/L) |
|------------------------------------|---------------------------------------------|----------------------------------------------------------------------|
| Fish 96-hr LC ₅₀ | 15.0 | 75.0 |
| Daphnia 48-hr EC ₅₀ | 0.11 | 0.55 |
| Green algae 96-hr IC ₅₀ | 0.23 | 1.15 |
| Fish chronic value (ChV) | 0.44 | 2.17 |
| Daphnia ChV | 0.04 | 0.21 |
| Green Algae ChV | 0.09 | 0.45 |

LC₅₀ = Lethal concentration; concentration resulting in the death of 50% of the test organisms.

EC₅₀ = Effect concentration; concentration resulting in a 50% change in immobilization.

IC₅₀ = Concentration causing 50% inhibition of the response variable (e.g., growth rate, yield).

As indicated in Table 3, NCD commonly uses aquatic toxicity profiles to characterize new chemical environmental hazards for each NCD screening-level risk assessment, including three acute (e.g., fish, aquatic invertebrates, and algae) and three chronic (e.g., fish, aquatic invertebrates, and algae) environmental receptors. The most protective acute and chronic endpoints within the environmental toxicity profile are used to generate acute and chronic concentrations of concern (COCs). Harm to the aquatic environment may occur if the COC is exceeded in the surface water.

Based on NCD's environmental toxicity profiles (U.S. EPA, 2026f) (see Table 3 for nickel example), when lithium, cobalt, nickel, yttrium, or aluminum metals are at or above 70, 20, 20, 10, and 60 percent, respectively, in a MMO CAM new chemical submission, the overall MMO CAM will have a high environmental hazard determination. As an example, nickel is often above 20% in many recent MMO CAM new chemical submissions. Based on previous submissions, the acute COC ranges from 4 to 110 (parts per billion) ppb and the chronic COC ranges from 1 to 5 ppb, resulting in a *high* environmental hazard.

5. Environmental Releases and Exposure

NCD has developed an environmental releases and exposure assessment methodology for chemicals used in electric vehicle (EV) battery applications, drawing on information from MMO CAM new chemical submissions, physical and chemical property data, literature reviews, consultations with subject-matter experts at EPA (e.g., Office of Land and Emergency Management), and site visits. This methodology addresses environmental releases and human

exposures, which are primarily driven by the manufacturing, processing (including recycling activities), and use of MMO CAMs associated with EV battery production. Consequently, the approach is largely consistent across different chemical types—such as MMOs, including CAMs, or carbon nanotubes—used in EV battery applications. For the purposes of this standardized scientific assessment, the focus is on MMO CAMs in battery applications.

The typical life-cycle of a MMO CAM used in these applications includes import or manufacture, processing into forms suitable for battery production, battery manufacturing, recycling of production scrap, and end-of-life (EOL) batteries.

Environmental releases serve as the primary drivers of exposure for the general population and aquatic species. For example, emissions from incineration can result in general population exposure to any remaining fraction of the MMO CAM that is not removed. Similarly, water discharges from industrial operations may result in exposures to aquatic organisms and, through drinking-water ingestion, to the general population. Consumer exposure is not expected because the MMO CAM remains contained within the battery (an article) throughout its useful life.

Table 4 summarizes environmental releases and the resulting exposures (human and ecological) associated with MMO CAMs used in lithium-ion battery applications. The first column identifies the life-cycle stage of the MMO CAM, the second column provides a brief description of the life-cycle stage, and the remaining columns describe the typical release routes and corresponding exposure pathways.

Table 4. Expected MMO CAM Environmental Releases and Human, Ecological Exposures

| Life-Cycle Stage | Operation Description | Release Media ^{1,5} | Worker Exposures ² | General Population and Environmental Exposures |
|---------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------|---------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------|
| Manufacturing ³ | Production of MMO CAM | Water (only one case), Air (stack), Landfill | Dermal Inhalation (miscellaneous processing and handling) | Ingestion (drinking water), Inhalation (stack air), Ecological Receptors |
| Processing and Use ⁴ | Processing MMO CAM into a form suitable to produce battery cells (e.g., making slurry from solid MMO CAM) and subsequent use in battery manufacturing | Air (stack), Landfill | Dermal, Inhalation (unloading solid raw material from transport containers/ miscellaneous process activities) | Ingestion (groundwater), Inhalation (stack air) |

| | | | | |
|-----------|-----------------------------------------------------------------------------------------------------------------|------------------------------------------------|--------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------|
| Recycling | Processing batteries and scrap materials containing MMO CAM from upstream processing and use, to reclaim metals | Water, Air (uncertain), Incineration, Landfill | Dermal, Inhalation (handling black mass ⁶ containing MMO CAM) | Ingestion (drinking water and groundwater), Inhalation (fugitive air and incineration), Ecological Receptors |
|-----------|-----------------------------------------------------------------------------------------------------------------|------------------------------------------------|--------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------|

¹ Release media are derived from five recently completed EV battery cases which had all manufacturing, processing, and use at submitter-controlled sites with specified release media. These are expected to be representative of similar future cases.

² Exposure pathways are derived from five recently completed EV battery cases which had all manufacturing, processing, and use at submitter-controlled sites. There might be exposure from other activities beyond the ones identified here, since NCD typically only assesses potentially highest exposure activity.

³ Releases to and resultant exposures from fugitive air, groundwater, and incineration, are possible from unknown manufacturing sites. In recent cases, releases were sent to Resource Conservation and Recovery Act (RCRA) Subtitle C landfill that eliminated potential exposure from groundwater ingestion.

⁴ Releases to and resultant exposures from fugitive air, surface water (including ecological receptors), and incineration, are possible for unknown processing and use sites.

⁵ Releases to surface water and resultant exposure from drinking water from manufacturing, processing, and use are less common but possible.

⁶ Black mass is a common industry term referring to a granular material made up of shredded cathodes and anodes of the batteries ([https://www.epa.gov/hw/lithium-ion-battery-recycling#:~:text=Black%20mass%20contains%20the%20materials,based%20leaching%20process%20\(hydrometallurgy\).](https://www.epa.gov/hw/lithium-ion-battery-recycling#:~:text=Black%20mass%20contains%20the%20materials,based%20leaching%20process%20(hydrometallurgy).))

6. Human Health and Environmental Risk Characterization

Risk assessment of MMO CAMs across human and environmental exposure scenarios has consistently 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.

Inhalation Risks

NCD has used two approaches to assess inhalation risks (i.e., screening level approach and refined, human-specific approach) (see Section 3).

NCD assessed risks for inhalation scenarios using a screening-level approach. For this approach, risk to human health is indicated where the margin of exposure (MOE) falls below the benchmark MOE of 100.⁵

- The screening-level $BMCL_{1SD}$ of $8.4E-3 \text{ mg/m}^3$ was used as the occupational inhalation POD to quantify cancer and non-cancer respiratory risks (U.S. EPA, 2025r). Across the nine risk assessments for MMO CAMs, risk to workers was identified since MOEs are consistently below the benchmark of 100. Specifically, inhalation risks have been

⁵ EPA applies a total uncertainty factor (UF) of 100 to the $BMCL$: a UF_H of 10 for human variability and a UF_A of 10 for extrapolation from animals to humans.

identified with MOEs ranging from 2E-4 to 1. Using the recalculated $BMCL_{1SD}$ of 1.7E-2 mg/m^3 in one risk assessment, inhalation risks were identified with an MOE of 9E-3.

- Where cobalt is >3%, risk to workers for skin and respiratory sensitization has been identified but not quantified.
- The screening-level $BMCL_{1SD}$ of 8.4E-3 mg/m^3 was used as the general population inhalation POD to quantify cancer and non-cancer respiratory risks. Across the nine risk assessments for MMO CAMs, risk to the general population is identified since MOEs are consistently below the benchmark of 100. Specifically, inhalation risks have been identified for fugitive air releases (MOEs of 9E-3 to 4.9E-1) and for incineration releases (MOE of 7). Using the recalculated $BMCL_{1SD}$ of 1.7E-2 mg/m^3 in one risk assessment, inhalation risks were identified for fugitive air releases (MOE of 5E-2) and for incineration releases (MOE of 7).

NCD also assessed risks for inhalation scenarios using a refined, human-specific value. For this approach, risk to human health is indicated when the estimated exposures exceed the minimal effect level as calculated by EPA (U.S. EPA, 2026h). 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 mg/m^3 , and it is protective against non-cancer respiratory effects for exposures lasting less than one year (U.S. EPA, 2026h). Across the nine⁶ 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 4,000.⁷
- The general population inhalation exposure level with a low probability of adverse health effects for MMO CAMs is 1.3E-4 mg/m^3 for exposures lasting less than one year (U.S. EPA, 2026h). 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).

⁶ EPA did not include one withdrawn case in the refined approach to inhalation risk calculations.

⁷ 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, 2026h), which assumes use of an APF-1000 respirator.

Oral Risks

Risk to human health is indicated where the MOE falls below the benchmark MOE of 100.⁸

- 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 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.

Environmental Risk

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 COCs). 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 observations of potential human health and environmental risk for MMO CAMs within the scope of this assessment are due to three factors:

1. The metal components in MMO CAMs result in high human health and environmental hazard. Although there are few MMO CAM-specific toxicology studies, the toxicology of

⁸ EPA applies a total uncertainty factor (UF) of 100 to the NOAEL: a UF_H of 10 for human variability and a UF_A of 10 for extrapolation from animals to humans.

the metal components is well studied; there are few uncertainties associated with the hazard and potency of the metal components.

2. MMO CAMs used for battery applications are being produced (or expected to be produced) at high production volumes. From 26 EV battery cases⁹ (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. Over time, NCD has refined the screening-level methods used to estimate environmental releases and exposures for MMO CAMs used in EV batteries. Release media and worker exposure estimates are also refined with site-specific information (e.g., for submitter-controlled sites). However, when site-specific information is unavailable—particularly for downstream processing (e.g., unknown recycling) sites—the standard screening approaches and assumptions are utilized. Combined with the high production volumes noted in item 2, this yields 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.

7. Hazard and Risk Summary

Environmental Fate

Environmental fate is the determination of which environmental compartment(s) a chemical moves to, the expected residence time in the environmental compartment(s), and the removal and degradation processes. Environmental fate is an important factor in determining exposure and, thus, in determining whether a chemical may present an unreasonable risk.

Destruction and Removal Efficiency

EPA predicts that the MMO CAM new chemical substance will have a high DRE within a municipal incinerator. Although the MMO CAM new chemical substance is not destroyed within the incinerator, an estimated 99.9% of the substance is effectively captured within the incinerator bottom ash, which is subsequently landfilled.

Wastewater Treatment Removal

EPA predicts the MMO CAM new chemical substance has a wastewater treatment removal rating of 90% based on very strong predicted sorption to sludge. Wastewater treatment removal for constituent metals within the MMO CAM new chemical substance is not estimated because EPA

⁹ Includes one submission which was later withdrawn.

does not anticipate that the metals will dissociate from the MMO CAM new chemical substance in appreciable amounts on a time scale relevant to wastewater treatment (hours to days).

Migration to Groundwater

Due to large particle size and very strong sorption to soil and sediment, the MMO CAM new chemical substance is expected to exhibit negligible migration to groundwater. Sorption to soil and sediment and groundwater migration ratings are unique to specific metals. The sorption rating and related potential for groundwater migration are based on available scientific literature for each metal.

Persistence

Persistence is relevant to whether a MMO CAM new chemical substance is likely to present an unreasonable risk because chemicals that are not degraded in the environment at rates that prevent substantial buildup in the environment, and thus increase potential for exposure, may present a risk if the substance presents a hazard to human health or the environment.

The MMO CAM new chemical substance and all constituent metals are expected to be very persistent. The MMO CAM new chemical substance is not expected to undergo biodegradation, hydrolysis, photolysis, or atmospheric oxidation. The constituent metals are not expected to undergo biodegradation, and are not rated with respect to hydrolysis, photolysis, or atmospheric oxidation potential.

The MMO CAM new chemical substance and all constituent metals received a P rating of P3, indicating that they are very persistent in the environment.

Bioaccumulation¹⁰

Bioaccumulation is relevant to whether a MMO CAM new chemical substance is likely to present an unreasonable risk because substances that bioaccumulate in aquatic and/or terrestrial species pose the potential for elevated exposures to humans and other organisms via food chains.

MMO CAMs are expected to have low bioaccumulation potential based on large molecular volume, which limits bioavailability, and are assigned a B rating of B*low (low bioaccumulation potential). The bioaccumulation potential of each constituent metal is assessed according to NCD's weight of evidence approach, which integrates multiple lines of evidence to assign a rating of B*low, B*high (high bioaccumulation potential), or BU (unknown bioaccumulation

¹⁰ Bioaccumulation: A chemical substance is considered to have a low potential for bioaccumulation if there are bioconcentration factors (BCFs) or bioaccumulation factors (BAFs) of less than 1,000 or if there are equivalent or analogous data. A chemical substance is considered to be bioaccumulative if there are BCFs or BAFs of 1,000 or greater and less than 5,000 or if there are equivalent or analogous data. A chemical substance is considered to be very bioaccumulative if there are BCFs or BAFs of 5,000 or greater or if there are equivalent or analogous data. (64 FR 60194; November 4, 1999)

potential. All constituent metals present in MMO CAMs assessed to date have had a bioaccumulation rating of B*low. Individual, metal-specific bioaccumulation assessments are detailed in reports that are attached to fate assessment reports for the MMO CAM new chemical substance. Any deviation will be identified in the record for the MMO CAM new chemical substance.

Human Health Hazard Summary

Human health hazard is relevant to whether a MMO CAM new chemical substance is likely to present an unreasonable risk because the significance of the risk is dependent upon both the hazard (or toxicity) of the chemical substance and the extent of exposure to the substance.

For in scope MMO CAMs, EPA identified the following hazards: carcinogenicity, genetic toxicity, reproductive toxicity, specific target organ toxicity, and dermal and respiratory sensitization if cobalt is present at >3% by weight in the MMO CAM new chemical substance. Cancer hazards are not expected for exposures lasting less than one year (U.S. EPA, 2026h). EPA identified an inhalation NOAEC from a cross-sectional study on a component (cobalt) of $5.3E-3$ mg/m³ based on respiratory effects (i.e., irritation). This NOAEC is used to characterize all occupational and general population inhalation risk for exposures lasting less than one year since it is the most health protective, human-derived value identified to assess non-cancer inhalation risks.

To characterize risk from potential oral exposures, EPA used oral PODs ranging from a LOAEL of 1 mg/kg-day for cobalt (based on blood effects) to a NOAEL of 1.12 mg/kg-day for nickel (based on developmental effects). Based on these values, the drinking water equivalent level (DWEL) is as low as 129 ppb.

Environmental Hazard Summary

Environmental hazard is relevant to whether a MMO CAM new chemical substance is likely to present unreasonable risk because the significance of the risk is dependent upon both the hazard (or toxicity) of the chemical substance and the extent of exposure to the substance.

The MMO CAM new chemical substance presents a *high* environmental hazard (see Section 6 [Human Health and Environmental Risk Characterization]) due to its toxicity profile and the assumption that the metal components may leach from the MMO CAM new chemical substance as ionized salts and are bioavailable to environmental receptors (e.g., fish). EPA used the most conservative environmental endpoints (e.g., acute fish lethal concentration 50% [LC₅₀] toxicity value). The acute COC for the MMO CAM new chemical substance ranges from 4 to 110 ppb and the chronic COC ranges from 1 to 5 ppb, resulting in a *high* environmental hazard.

Exposure and Risk Summary

EPA considers workers to be a potentially exposed or susceptible subpopulation (PESS) on the basis of greater exposure potential compared to the general population. EPA also considers PESS in conducting general population drinking water exposures by evaluating risks associated with water intake rates for multiple age groups, ranging from infants to adults. EPA considers consumers of specific products to be a PESS on the basis of greater exposure potential compared to the general population who do not use specific products.

For this MMO CAM new chemical substance, EPA expects exposures to workers during manufacturing and processing. EPA also expects environmental releases including fugitive air, landfill, emissions from incineration, stack, and water discharges from industrial operations leading to exposures to the general population and the environment.

Risks to Human Health

Risks to Workers

Risks to workers for cancer and non-cancer respiratory effects from inhalation exposures are expected during manufacture, processing (including recycling), and use of the MMO CAM new chemical substance. Sensitization (dermal and inhalation) is expected only when the cobalt content is >3%.

Risks to the General Population

Risks to the general population for lung effects via inhalation exposure are expected from fugitive and incineration releases, but not from stack releases. Risks to the general population are expected for developmental effects from ingestion of drinking water and groundwater impacted by landfill leachate.

EPA expects the MMO CAM new chemical substance to have low potential to bioaccumulate, so risks via fish ingestion are not expected.

Risks to Consumers

Risks to consumers were not evaluated because consumer exposures were not identified under the intended conditions of use.

Risks to the Environment

Environmental risk is indicated when modeled surface water concentrations exceed environmental concern levels (i.e., acute and/or COC). The ratio of the modeled surface water concentration divided by the COC is the 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.

RQs for acute and chronic exposures are expected to be >1 (with greater than 20 days of exceedance for all chronic scenarios). Therefore, EPA concludes that environmental releases of the MMO CAM new chemical substance are expected to result in acute and chronic environmental risk.

Potentially Useful Information

EPA has determined that results from testing for acute toxicity, biosolubility, carcinogenicity, genetic toxicity, neurotoxicity, pulmonary effects, reproductive and developmental toxicity, specific target organ toxicity, and aquatic toxicity may be useful for characterizing the human health and environmental effects of the MMO CAM new chemical substance. If the substance contains >3% cobalt, skin sensitization testing may also be useful.

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